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Working Paper

The Mid Staffordshire NHS Foundation Trust Public Inquiry Report. What it is likely to say and the Government's likely response: a risk assessment.

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Key words

Accountability, bullying, NHS, quality, regulation, safety, whistleblowing.

Please note. The numbered paragraph quotes throughout the text are taken from the closing summary of conclusions within the final submission by Counsel to the Inquiry Tom Kark QC, in which he sets out the main areas of concern that the Tribunal Chair is likely to address in his Inquiry Report.

Abstract

This Working Paper explores the likely impact on the safety and quality of NHS provision in the light of the likely Government response to the issues the Inquiry has indicated it will be making recommendations on. The Inquiry Report will be handed to Secretary of State Jeremy Hunt in early January 2013 and he will then respond, though it is unclear when. The Inquiry Chair has made clear the issues he is likely to make recommendations on, and the closing written and verbal submissions from the lead counsel to the Inquiry, Tom Kark QC, give a good steer on what those recommendations are likely to include.

The Inquiry Report is widely regarded as being the most important such Report for a decade and comes amid unprecedented turmoil in the NHS The recommendations and the Government response to them are likely to significantly define important policy issues, political disagreements and discussion about the future role of the providing, commissioning, supervisory and regulatory bodies.

This paper provides a "Risk rating" of the main areas of the likely Inquiry recommendations based on an assessment of the impact that the likely government response will have on care quality and patient safety.

Red indicates serious adverse consequences

Amber indicates moderate adverse consequences

Green indicates no adverse consequences

This Paper concludes that there will remain serious risks for many of the issues likely to be highlighted by the Inquiry Report if Government response is as may be reasonably forecast.

The paper has three sections.

The introduction sets the Inquiry report in context.

The main section considers the central issues that the Inquiry is likely to make recommendations about.

The final section considers concerns not directly considered by the Inquiry but which are regarded as impacting on the implementation of its recommendations.

The Mid Staffordshire NHS Foundation Trust Public Inquiry Report. What it is likely to say and the Government's likely response: a risk assessment.

Introduction

On 9 June 2010, Andrew Lansley MP, then Secretary of State for Health, announced a public inquiry into the role of the commissioning, supervisory and regulatory bodies in the monitoring of Mid Staffordshire Foundation NHS Trust. In January 2013 its chair, Robert Francis QC, is due to hand over his report to the Minister.

This second inquiry follows the earlier independent inquiry (also chaired by Robert Francis QC) into the care provided by Mid Staffordshire NHS Foundation Trust.[1] (Robert Francis, 2010)

The second report may well propose fundamental changes to the commissioning, supervisory and regulatory arrangements in an attempt to ensure that all reasonable and necessary steps are taken to ensure such failings do not happen again. This Working Paper explores, ahead of this second and final report being published:

- what those recommendations are likely to be,
- what the Government response is likely to be, and
- whether, as a result, all reasonable and necessary steps will actually be taken to ensure such failings do not happen again.

Context and significance

The scale of harm caused by the failings in Mid Staffordshire Foundation NHS Trust was stunning. Between 400 and 1200 people died who need not have done. Repeatedly negligent care and systematic breaches of patient dignity took place between 2005 and 2009. Every single agency, or group of staff, whose responsibility it was to raise

concerns, identify poor care and harm, and act to prevent it either failed to do so entirely, or did so ineffectively.[2] (Robert Francis, 2010) The Inquiry Chair concluded by saying:

> As I have remarked at some of the seminars, there seems to me to be a tide of public anger about what has happened. I think this can only be assuaged by identification and implementation of measures which patients and the public are satisfied have a good chance of achieving this.

The NHS has a budget of £100bn, employs 1.3 million people in 59 specialties and makes contact with one million patients every 36 hours. Such a massive undertaking is bound to make mistakes from time to time. The tragedy of Mid Staffordshire Hospital was the scale of the mistakes made, over an extended period, without anyone raising concerns and taking action.

In 2009, an inquiry by the Healthcare Commission highlighted three major shortcomings at Mid Staffordshire Hospitals NHS Foundation Trust. It identified a lack of transparency, a tolerance of poor practice and a systematic denial of its problems alongside poor nursing leadership, insufficient skilled staff, poor risk assessments and serious defects in board level governance. The first Francis Inquiry report came to similar conclusions but linked it directly to its obsession with attaining Trust status. It described a systematic failure of good care.[3] (Healthcare Commission, March 2009.)

This Working Paper will consider many of the issues the Inquiry Chair says he will consider in his recommendations, cognisant that several of those recommendations may well be ones that Ministers might be deeply unhappy about.

Indeed NHS chief executive Sir David Nicholson has already expressed his concerns that

> Recommendations from the Mid Staffordshire Foundation Trust public inquiry run a "very real" risk of conflicting with government policy.[4] (Sarah Calkin. 29 May 2012).

The list of topics upon which the Inquiry Chair stated he was likely to make recommendations (Fig 1) gives a sense of the scale of failure.[5] (Public Inquiry.9th December 2011).

Fig. 1.The main issues likely to be addressed in the Final Report

1. Recruitment, standards, training and regulation of healthcare support workers.
2. The recruitment, standards and training of registered nurses.
3. The training and qualification of those charged with caring for the elderly.
4. The recruitment, training, support and regulation of senior managers of NHS organisations.
5. The standards applicable to healthcare generally.
6. The exercise of the fitness to practise functions of professional regulatory bodies.
7. The engagement of healthcare generally in the leadership and management of their organisations.
8. The nature of standards set for the safety and quality of care, and which organisation or organisations should have the responsibility for setting and enforcing them.
9. The relevance of staffing levels and skill mix to those standards.
10. The interface between the regulation of governance, finance, and quality and safety standards.
11. The use of commissioning to require and monitor safety and quality standards or provision.
12. Methods of monitoring and enforcing those standards.
13. The potential adverse consequence of structural reorganisations and the requirements for addressing these.
14. The role of foundation trust governors and members, and other local public, patient and staff representatives.
15. The nature, scope and definition of a duty of candour and methods of enforcing it.
16. The involvement of external agencies in the complaints process and the use of information from it.
17. The obligations of disclosure to and obtaining of evidence by coroners.
18. The means of embedding the patient voice throughout the system.
19. The development, collection, use and sharing of information and data, including safety alerts, mortality data and performance indicators.
20. And the protection of whistle-blowers.

A central issue: was Mid Staffordshire's failing a unique event?

Central to the evidence provided by some witnesses from the DH and NHS West Midlands had been the assertion that what happened in Mid Staffordshire was a unique event and not a systemic failure. DH officials disagreed on whether there had been a "whole system failure". On 27th September Sir Hugh Taylor, former permanent secretary said he thought it was, whereas the day before Una O'Brien, the current permanent secretary, told the inquiry it wasn't. [6] (Public Inquiry.26th and 27th September 2011)

Counsel to the Inquiry, Tom Kark QC, described the latter suggestion as "dangerous" and responded by saying "frankly [that] is a naive assumption and one which places reliance on a regulatory system which has been demonstrated to have failed in a significant way." He went on:

> 290. ….reports produced in 2008 for the purposes of Lord Darzi's review demonstrate that key features of the Trust's failure (to implement the principles of clinical governance) were replicated to a significant degree more broadly across the NHS….The tendency within the DH to view Mid Staffs as an isolated example is a dangerous one.

In his concluding remarks Robert Francis QC stated

> While we have sat here, serious concerns have surfaced elsewhere in various reports to which I have been referred. Many of them have disturbing echoes of what happened here……To the extent that it was ever thought to be the case, I do not think anyone now maintains that at least some of the appalling experiences of which I have heard are unique to Stafford.[7] (Public Inquiry. 28th November 2011)

Many NHS Trust Chief Executives seem to share his view:

> Nearly half of hospital chief executives believe regulators and the NHS governance system would miss a Mid Staffordshire-style care scandal if it occurred today.[8] (Ben Clover 25 July, 2012).

Indeed whilst the Inquiry was taking evidence, similar (though on a smaller scale) fundamental organisation-wide failures were reported at Morecombe Bay NHS Trust[9] (CQC. 2012) and Winterbourne View[10] (Margaret Flynn. 2012) with many similar characteristics. Mid Staffordshire's failings closely followed those **at** Maidstone and Tunbridge Wells NHS Trust where up to 90 patients died between April 2004 and September 2006 following a major infectious outbreak of Clostridium.[11] (Healthcare Commission. January 2009).

It is worth noting that whilst the focus of the Inquiry has been on failings at acute hospitals, almost everything it is likely to say applies equally to mental health and primary care and, indeed, to much of social care.

Anthony Sumara, the Chief Executive sent into Mid Staffordshire to replace the disgraced former chief executive Martin Yeates told fellow managers:

> In many ways this summer has been a warning that we must not let the outcomes of this Inquiry suffer the fate of so many others that are shelved and never implemented. Too much is at stake. Even at the NHS Confederation conference this year, from a straw poll of over 150 senior NHS managers, two thirds admitted they have not read the original Francis report. (This is despite a letter from David Nicholson to every organisation in the NHS instructing them to read and act on its recommendations).[12] (Antony Sumara, 5 September 2011).

The scale of the challenge facing the NHS was suggested when, despite the strenuous efforts made to change the culture and governance of Mid Staffordshire, just one year after this speech a peer review of breast cancer surgery services at Mid Staffordshire Foundation Trust uncovered a catalogue of concerns and safety fears, despite the trust assessing them as being largely compliant with national standards. While the Trust's self-assessment said the services were almost 94 per cent compliant with standards drawn up by the National Cancer Action Team peer review programme, the team's peer review said they were just 9.7 per cent compliant.[13] (Shaun Lintern. (11 September 2012).

On the basis of the Inquiry hearings it seems unlikely that this Inquiry will repeat the failings of the Clothier Inquiry established following the Beverley Allitt scandal in which it was widely held that, though the inquiry was thorough, it failed to address wider policy concerns, in particular the extent to which that scandal was a unique event driven by circumstances particular to one hospital rather than symptomatic of wider systemic failings.[14] (Nick Davies. February 1994).

It is eleven years since Professor Ian Kennedy completed his landmark Inquiry Report into the deaths of children at Bristol Royal Infirmary[15] (Professor Ian Kennedy. July 2001). The Mid Staffordshire Hospitals NHS Foundation Trust Inquiry Final report is likely to conclude that crucial measures recommended then but not acted upon effectively must be taken:

"In particular, it (the NHS) must promote openness and the preparedness to acknowledge errors and to learn lessons. Healthcare professionals should have a duty of candour to patients. Clinical negligence litigation, as a barrier to openness, should be abolished. Safe care should be promoted and led by a non-executive member of every trust board………To give effect to the following (amongst others):

o   The patient must be at the centre of everything which the NHS does.

o   The commitment and the dedication of staff in the NHS must be valued and acknowledged: those caring for patients must themselves be supported and cared for.

o   There must be openness and transparency in everything which the NHS does.

o   The impact of the way in which services are organised on the quality of care which patients receive must be recognised: the quality of care depends on systems and on facilities, as well as on individual healthcare professionals.

o   The safety of patients must be the foundation of the NHS's commitment to the quality of its services.

o   Sentinel events, that is, errors, other adverse events, and near misses, which occur during the care of patients, must be seen as opportunities to learn, not just as reasons to blame.

o   There must be clear and understood systems of responsibility and accountability: a culture of blame is no substitute for such systems.

o   The quality of healthcare must be guided by agreed standards, compliance with which is regularly monitored."

No healthcare system can rely on human perfection. Errors are inevitable. The challenge is to balance a no blame approach to clinical errors with the need for individual, managerial and organisational accountability.

It is important to distinguish between the human error, at risk behaviour and reckless behaviour. Approaches such as the NPSA Incident Decision Tree seek to distinguish between human errors and more systematic or deep rooted causes, an approach now widely adopted.[16] (NPSA. February 2004).

When patient safety breaks down it is usually caused by clinical systems and processes rather than individuals…..the leader's job is (to help) create an

environment in which people are given the right tools for doing their jobs and are so comfortable with their role in the organisation that they hold themselves accountable." [17](Robert Wachter. 2012).

The promotion of good care and prevention of serious failures of quality depends on:

- frontline professional staff who have a duty of care towards those they care for
- boards and senior managers within health care providers who have a duty of care towards their staff and patients
- the external systems for assuring the public about the quality of care provided
- government who provide the policy framework and funding within which care is provided

It is unclear to what extent the Inquiry Report will address the latter issue. Failure to do so could fundamentally undermine it.

A flurry of initiatives followed the First Inquiry report, some of which were set out in the NHS Chief Executive's letter to all Trust Chief Executives of 24 February 2010[18] (Sir David Nicholson. 24 February 2010) in which he reminded recipients that "both the Government and the Trust have accepted all of the recommendations from Robert Francis. " and listed various initiatives including:

- a requirement to publish Quality Accounts

- accepting the recommendations of or a report recommending a new system of professional accreditation for senior managers

- revised guidance on board governance

- a working group involving key parties and leading academics and they have committed to develop a single hospital standardised mortality ratio (HSMR) for the NHS. He has also asked the NHS Confederation to develop a practical guide to the use and interpretation of HSMRs for the NHS

- publishing a report[19] (National Quality Board. 2010) into early warning systems, which sought to set out very clearly what the respective roles and responsibilities of each and every NHS organisation were in preventing failure.

He concluded by stating:

This is particularly important as we enter a period of tougher economic circumstances and it is why I have stressed that our approach to increasing productivity must be driven by the desire to improve quality.

However, we now know (see above) from Anthony Sumara that two thirds of Trust Chief Executives did not even read the First Inquiry Report.

The main issues the Inquiry Report is likely to make recommendations about

1. Recruitment, standards, training and regulation of healthcare support workers.

Both the Nursing and Midwifery Council and the Royal College of Nursing strongly support the regulation of healthcare support workers considering this necessary for the protection of the public. The Inquiry seems well disposed to the idea, with its Counsel, Tom Kark QC, stating:

> 311. The Inquiry should consider the case for the regulation of healthcare support workers. It appears to be a surprising and potentially dangerous lacuna that there is a complete lack of regulation of a sizeable number of those who work in the health service and have direct contact with the sick and vulnerable. There is at present an unjustifiable distinction between the lack of regulation applied to such individuals and the full regulatory regime applied to nurses.

The DH are opposed to such regulation, referring to its size and complexity.When it was put to Sir David Nicholson that the Royal College of Nursing chief executive Peter Carter and Nursing and Midwifery Council boss Dickon Weir-Hughes believed HCAs should be regulated, he replied "the nursing profession would say that wouldn't they".

When asked by Robert Francis QC how much time he therefore thought should be given to ensure that the people generally "charged with feeding and providing basic care to our most vulnerable patients are fit and proper people to do that?" Sir David Nicholson responded by referring to the need for proper supervision but was unable to think of anything the DH was doing nationally to improve the situation.[20] (Public Inquiry. 8th Sept 2011).

The same day, Dame Christine Beasley agreed, arguing the cost and effort was not "proportionate" to any benefits. When pressed by inquiry chairman Robert Francis QC if she had changed her mind since she recommended regulation for HCAs as a member of the Prime Minister's Commission into Nursing, she stated there might be a case for regulating a higher level of HCA but not the whole workforce.[21] (Public Inquiry. 8th Sept 2011)

Ministers made clear their view clear in deciding to reject the Commons' Health Select Committee recommendation to introduce compulsory regulation for healthcare assistants just weeks before the Inquiry Report was due [22] (DH. September 2012). Ministers argued that "(the) case has not yet been made for imposing further statutory [HCA] regulation", but have produced no evidence to counter that heard at both the Select Committee and the Inquiry

By contrast, Hilary Jones, dean of Staffordshire University's Faculty of Health, told the Inquiry that some senior trust managers appeared happy to replace skilled caregivers with a largely untrained workforce, believing that this would have no effect on care and that "codes of practice, professional values and ethical standards were all sacrificed". She said there was a danger that opting for untrained workers turned nursing into a set of tasks undertaken by rule-following operatives, creating a culture of mediocrity.[23] (Public Inquiry, 2 November. 2011).

Government policy towards the regulation of health care assistants is probably best understood in the context of the Government zeal for deregulation as set out in Equity and excellence: Liberating the NHS[24] (DH, 2010) and by reflecting on DH policy towards the regulation of social care support workers. This latter group had previously expected regulation but this was then dropped[25] (CHRE. September 2009). More recently, the White Paper 'Building the National Care Service' [26] (DH, 2010) has been accompanied by a Health Professions Council proposal[27] (Health Professions Council, 18 September 2012) to consider piloting the "licensing" of social care workers and healthcare support workers. The White Paper says that the pilot of a licensing scheme for social care workers will also include licensing for healthcare support workers but it is unclear what this means and it will certainly be the lightest of "light touch" regulation.

The DH resistance to any robust regulation of healthcare assistants is unevidenced. It complements their opposition to the setting of mandatory skill ratios (or higher staffing levels) – see section 8 below.

Risk rating Red

2. The recruitment, standards and training of registered nurses.

RCN general secretary Peter Carter expressed concern about the selection and training of student nurses and the absence of good-quality mentoring within clinical placements.[28] (Public Inquiry. 2 November 2011).

Chief Nursing Officer for England, Dame Christine Beasley, claimed nursing "lost its way" because there was not enough focus on the "values" of new nursing entrants.[29] (Public Inquiry. 2 November 2011).

Hilary Jones dean of Staffordshire University's Faculty of Health gave a different emphasis. She told the inquiry that nursing departments had had resources cut whilst qualified nurses were unable to attend training days due to staff shortages in clinical areas. She suggested that the NMC Code and nursing ethics were sacrificed by some nurse managers.

The inquiry heard that some hospital placements were barely fit for purpose, the requirements for the accreditation of wards were unclear, the ratio of trained to untrained staff was not set out and competencies of supervisors were rarely assessed. Even when 140 staff were sacked so that Mid Staffordshire could attain Foundation Trust status, students were still allocated to areas with appalling care. Mr Robert Francis QC later echoed that claim in stating

> 'The failure of students to complain suggests that they were being socialised to accept a culture of indifference where poor standards were the norm"[30] (Public Inquiry. (2 November 2011).

Helene Donnelly, one of the few nurses who did repeatedly raise concerns, told the inquiry that she had worked as a staff nurse in accident and emergency at Mid Staffs hospital between 2004 and 2008. The atmosphere was one of fear with a chronic shortage of staff and basic equipment. Two senior ward sisters bullied staff using physical threats and verbal abuse. She described how she witnessed "unimaginable" suffering with patients left "sobbing and humiliated" by staff. Ms Donnelly refused to falsify records and waiting times, and as a result she was threatened and her workload increased considerably.[31] (Public Inquiry. (2 November 2011).

Robert Francis' First Report[32] (Robert Francis QC, 2010) made several recommendations regarding nurses including:

- The board must prioritise ensuring that any member of staff raising a concern is supported and protected
- Clinical audit must be improved, with staff required to take part in audit processes
- Staff involvement in the complaints process must be from investigation to outcomes
- The board must review the management and leadership of nursing
- The management structure must be reviewed to ensure that the views of clinical staff are fully represented at every level of the trust
- All nursing staff should have training in the diagnosis and management of acute confusion

The DH evidence to the Inquiry focussed on the absence of the appropriate "values" demonstrated by nurses. That theme may well have some resonance but it avoids more fundamental issues of leadership, management culture, staffing levels, skill mix and the failure of the nursing regulator to make clear to both nurses and their nurse managers that they must uphold their duty of care and Code of Conduct whatever the pressures to not raise concerns. The inquiry is likely to make robust recommendations on the role of the NMC in this respect.

However the Damascene conversion of NHS leaders to distributed leadership and an open management culture[33] (Kings Fund, 2012) has yet to change what happens in many Trusts as suggested a 2011 survey of nurses reported that "that the overwhelming majority (84%) said they would be concerned about victimisation, personal reprisals or a negative effect on their career if they were to report concerns to their employers."[34] (RCN, 5 December 2011).

The current funding pressures on higher education are likely to mean that resources to monitor and support nurses and ensure they have appropriate placements may continue to be limited.

Risk Rating Amber

3. The training and qualification of those charged with caring for the elderly.

In evidence to the Inquiry, NHS Medical Director Sir Liam Donaldson said he had been "shocked" that the poor care of the elderly had happened when the National Service Framework for older people was such a prominent policy. His view was that

> I think there are two things going on. One was that regulatory systems have not been able to detect those aspects of care because it's a softer and less easily measurable aspect of care than other technical ways, but it could also be to do with society's view of older people and the extent to which that's reflected in one of our national institutions.[35] (Public Inquiry, 19th September 2011).

Numerous recent reports have highlighted shortcomings in the care of the elderly. The Care Quality Commission report[36] (CQC, October 2011). inspected 100 NHS hospitals focussing on dignity and nutrition, and revealing serious failings in hospital care of elderly patients. Les than half of the 100 hospitals inspected (forty five) were fully compliant in both dignity and nutrition whilst 35 complied in one or the other area. Twenty per cent did not comply in either areas. The Equality and Human Rights Commission report' Close to home: older people and human rights in home care' [37] (Equality and Human Rights Commission, 2011) painted an equally depressing picture of the extent to which public authorities promote and protect the human rights of older people (aged 65 and over) with regards to home based care and support. It mirrored the warning from the Commission on Dignity in Care for Older People that commissioners must have robust systems to ensure dignified care is being provided, including feedback from patients, families and independent advocates.[38] (NHS Confederation, 2012)

Anna Dixon and colleagues (Dixon, A, Foot, C, Harrison. 2012) suggest that "serious issues have been well documented in the care of people with dementia across care settings, but the regulatory response to this has arguably not been adequate."[39]

The Commission on Dignity in Care for Older People[40] (2012) identified the top-down culture as a prime cause of poor care, concluding:

> 'If senior managers impose a command and control culture that demoralises staff and robs them of the authority to make decisions, poor care will follow'.

The King's Fund summit on the care of frail older people similarly concluded that:

team leaders in hospital wards and the community should have a higher status in their organisations, with enhanced opportunities for personal development and remuneration that reflects the value, complexity and importance of the role. This enhanced role should extend to playing a major part in recruiting their own team, controlling resources such as equipment and setting the quality of food. All care staff, especially team leaders, should see it as their responsibility to speak up if rules and working practices are undermining care.[41] (Cornwall, J. 2012).

This move away from nurses administering budgets to controlling them would be a step forward but it avoids the crucial issues of the wider management culture, resources (notably staffing levels) and a skill mix which relies on up to half of front line ward staff being unregistered, poorly paid, health care assistants. Moreover the treatment of staff necessarily bears on the quality of care provided and the success of partnership working between patients and staff. The focus of government policy is best indicated by Ministers using the adult care White Paper to emphasise carrot rather than stick when deciding, for example, to rely on "spreading good practice rather than banning ….. the practice of councils contracting for home care "by the minute" or in short-time slots" .bid to end home care contracting by the minute.[42] (Mithran Samuel. 12 July 2012).

Risk rating: Red

4. The recruitment, training, support and regulation of senior managers of NHS organisations.

Counsel to the Inquiry's closing written submission stated:

> 205. Further consideration should be given to the way in which the GMC deals with doctors who are in senior management positions and whose fitness to practice is called into question by reason of their having presided over significant or systemic failings in patient care.

He pointed out that:

> 209. Notwithstanding the duty to raise concerns about patients safety outlined in Good Medical Practice no doctors at the Trust approached the GMC or any other body with their concerns about the standards of patient care generally or to report that a colleague may present a risk of harm to patients.

In his closing verbal submission, Tom Kark QC, counsel to the Inquiry stressed:

> Para 236. The NMC should continue to emphasise that its fitness to practice procedures apply equally to those fulfilling a management function as to those providing frontline care. The NMC should be proactive in pursuing referrals where it is indicated that a registrant fulfilling a management function has presided over a significant failure in quality of care.

Sir David Nicholson told the inquiry that the current situation was "not sustainable" and suggested it was an "anomaly" that whilst the board nurse, doctor and accountant could all be struck off by their respective professional bodies, the chief executive could not.

Tom Kark's closing submission concluded that:

> 312. There is also a strong case for the regulation of senior healthcare managers….Public confidence in the NHS requires that managers should not be rewarded for failure and that those whose continued work in the NHS poses an unacceptable risk to patient should be prevented from doing so.

The DH consultation on *Standards for members of NHS boards and governing bodies in England.*[43] (CHRE, 2012) should be seen as an early response to the Inquiry.

The draft says such senior leaders must demonstrate business skills, such as "being open about the evidence, reasoning and reasons behind decisions about budget and resource allocation, and contract allocation in particular" and "taking appropriate action

to raise concerns if I perceive that my organisation or my colleagues are engaging in any harmful behaviour or misconduct".

The result of the consultation is not known over five months after it closed. Nor is it clear whether the standards will be become a code of conduct, written into contracts of employment or a more modern version of the NHS Managers Code of Conduct which the Inquiry was told had apparently not resulted in a single example of a manager being investigated for breaching the Code since its introduction in 2002[44] (Sarah Calkin, 27 October, 2011). Whether these new principles will be given teeth by the DH is, in any case, open to question. The omens are not good. David Flory, who as Deputy Chief Executive of the NHS sought to block the Mid Staffordshire Inquiry ever being established and who tried to find Martin Yeates, disgraced Mid Staffordshire Chief Executive, another job in the NHS, is to lead the NHS Trust Development Authority.[45] (Public Inquiry, 15 September 2012). The Authority's nursing director is to be Peter Blythin, director of nursing at NHS West Midlands from 2006, who was criticised for having "apparently failed to inject any urgency" into a critical review of nursing levels at Mid Staffs.[46] (Ben Clover, 25 July 2012)

Without teeth, it is unclear what the point of a new Code will be.

Risk rating: Amber

5. The exercise of the fitness to practise functions of professional regulatory bodies.

In his closing submission Tom Kark QC was scathing about the failure of those charged with regulating professionals:

> 204. The GMC's fitness to practice procedures remain focused on the practice of individual doctors. The chairman may wish to consider whether it would be desirable for the GMC to adopt a more proactive approach where through fitness to practice hearings more systematic failings are identified within organisations.

> 209. Notwithstanding the duty to raise concerns about patients safety outlined in Good Medical Practice no doctors at the Trust approached the GMC or any other body with their concerns about the standards of patient care generally or to report that a colleague may present a risk of harm to patients.

> 215. The university's (Keele Medical School) internal quality assurance processes did not identify any of the quality of care issues at the Trust identify in the Healthcare Commission report or the Independent Inquiry report.

> 218. Further, the Chairman may wish to consider whether the communication between the University and GMC is indicative of the GMC being offered a platitude rather than being engaged collaboratively.

> 233. In spite of the fact that the NMC Code of Conduct places a duty on all nurses to raise concerns about patient safety there were a very limited number of examples of such concerns having been raised at or about the trust

> 234. In the past the NMC has exercised its Fitness to Practice function only where a referral has been made

> 236 The NMC should continue to emphasise that its fitness to practice procedures apply equally to those fulfilling a management function as to those providing front line care. The NMC should be proactive in pursuing referrals where it is indicated that a registrant fulfilling a management function has presided over a significant failure in quality of care.

The DH response to concerns about regulators has been to encourage the CHRE to step in when regulators appear to be in crisis whether it be the GSCC[47] (CHRE, September 2009) or the NMC[48] (CHRE, 2012) but in each case the focus appears to have primarily been on improving administrative procedures and management rather than ensuring

professional regulators are proactive in holding to account practitioners and their managers, and in giving robust support to those who, in complying with their Code of Conduct raise concerns about standards of care and conduct within their employer. Though regulators have been more proactive recently in encouraging registrants to raise concerns[49] (NMC. 2012) it remains to be seen whether such activity is sustained and encouraged by the DH.

Risk rating: Amber/Red

6. The engagement of healthcare generally in the leadership and management of their organisations.

Tom Kark's closing submissions on the leadership and management of Mid Staffordshire Trust were damning:

> 88. The Trust failed to place patient safety and quality of care at the heart of everything it did. It lost sight of its key purpose.
>
> 89. The trust did not embrace complaints, adverse incident reporting or whistleblowing as valuable sources of learning and improvement
>
> 90. The Board relied upon the assessments of outside organisations and measures to be satisfied about the standards of care it provided, rather than using effective internal measures and scrutinising information such as complaints and adverse incidents that was available to it to hear what those delivering and experiencing care at the trust were saying.
>
> 102. Effective clinical governance…… should seek to gain valuable data on performance through a variety of key sources including selected quality measures, clinical audit, complaints adverse incidents patient and staff feedback and whistleblowers. Lessons learnt must be implemented and staff held to account where they are not. There is merit in the idea of greater guidance and standardisation of clinical governance procedures in the NHS

The Mid Staffordshire Hospital NHS Foundation Trust management culture was almost a parody of that which research evidence suggests delivers best performance for patients. Research demonstrates that in organisations that value their staff:

- patient experience improves, inspection scores are higher and infection and mortality rates are lower[50] (West M, Dawson J 2012).
- staff are significantly less likely to make mistakes[51] (Prins JT et al, 2010)
- staff provide safer patient care[52] (Laschinger HKS, Leiter MP. 2006)
- there is lower absenteeism and lower levels of turnover[53]. (West M, Dawson J 2011).

Research suggests a strong link between poor treatment of staff and poor Trust performance.[54] (Dawson J. 2009). The Boorman Review of the NHS staff mental health[55] (Dr Steven Boorman, 2009) found a strong link between stress and poor trust performance. Healthcare Commission surveys repeatedly demonstrated that where staff

rated the quality of leadership higher the trust performance was higher, as were scores for clinical governance whilst there were less patient complaints[56] (Healthcare Commission. 2009).

Unfortunately, despite the increasing volume and robustness of such evidence, the management culture of the last two decades was instead characterised by highly hierarchical and often bullying leadership models which might conceivably have been effective for managing a budget, hitting performance targets and rationalising unpopular decisions, but are unlikely to develop staff engagement.

Just eight months ago, a detailed assessment of around 900 participants in the NHS Top Leaders programme concluded:

> they are "high on over-confidence" and suffer from "an absence of attention to detail and completion of tasks"….They are "not necessarily understanding their own limitations" and do not tend to listen to others.[57](Charlotte Santry. 12 January, 2012).

The work of Beverly Alimo-Metcalfe[58] (Alimo-Metcalfe B, Alban-Metcalfe J 2008) and the work on leadership from the Kings Fund[59] (Kings Fund 2012) is becoming increasingly influential but exhortations from Sir David Nicholson for openness and transparency within Trusts[60] (Charlotte Santry. 23 May 2008) sit uneasily with evidence to the Inquiry about the DH culture prior to his arrival and since.

Despite two independent reports to the inquiry and several witness statements, Sir David Nicholson and other DH officials denied there was a "shame and blame culture" within the DH. Sir Hugh Taylor former permanent secretary denied he led a culture of fear in the DH referring instead to "robust management style." The Darzi Review into quality in the NHS[61] (Lord Darzi. 2008) commissioned a review which interviewed more than 50 stakeholders and concluded that a "pervasive culture of fear" existed throughout the NHS and in parts of the DH, with fear among chief executives of public humiliation or losing their jobs as a prime driver for quality improvement. Sir Hugh Taylor denied there was such a widespread culture though the Inquiry then drew his attention to other reports which had reached similar conclusions and he accepted that "at times a level of stridency would have entered the way this programme was taken forward."[62] (Public Inquiry. 26 September 2011).

Notwithstanding such assurances, the NHS Confederation, representing employers, reported in 2009 that

"Several of our interviewees identified a problem of a perceived or real toxicity in the wider system inhabited by chief executives, describing the environment as "brutal", "arbitrary", "prone to favouritism" and intolerant of risk-taking that isn't successful. This has been a recurring theme of any discussion about NHS leadership for a long time. Whether apparent or real, people at director level and below believe that these behaviours are prevalent.

"They may be a significant factor in deterring them from seeking chief executive roles and are likely to have an especially off-putting effect on clinicians. This culture of blame may also shape the behaviour of those already in leadership posts – breeding the passivity and risk aversion we refer to earlier in this paper – and was also a strong theme in 2007 when we investigated this issue."[63] (NHS Confederation. 2009).

Those concerns were shared by Sir Ian Kennedy:

A bullying culture in the NHS is "permeating the delivery of care", Healthcare Commission chair Sir Ian Kennedy has told *HSJ*.

He said: "One thing that worries me more than anything else in the NHS is bullying…..We're talking about something that is permeating the delivery of care in the NHS."

The problem was caused by the NHS's "hierarchical" culture and occurred across all staff groups, he said.

A "strong strand" running through the Bristol Inquiry into children's heart surgery at the Bristol Royal Infirmary, which Sir Ian led, was that its chief nurse had been "bullying everybody", he said.[64] (Charlotte Santry 1 April, 2009)

Chris Hart [65] (Chris Hart. 2003) attributes the rapid increase of a culture of fear to the rise of Self Governing Trusts and general management which led to employers seek to ensure staff were loyal to their employer and were supposed to raise issues internally not through the media as had been common in the 1980s.

DH leaders and various influential think tanks are currently exhorting management to create an open transparent culture in which staff feel confident about raising concerns. Staff may be entitled to be a little sceptical about this emphasis not least because

exactly four years ago in 2008, at the same time as the Darzi Review revealed widespread bullying in the NHS, the very same NHS chief executive David Nicholson told Trust chief executives they must "create an environment where staff can report safety incidents instead of being 'hung up to dry'" He said the fact that only 40 per cent of staff feel able to report incidents "simply isn't good enough",

> "One of the things that really worried me about Maidstone and Tunbridge Wells is that the staff didn't feel they could put their hands up and say there was something wrong. This is a deeply dangerous place for an organisation to be. We need to create an environment where people feel there's a just system and they won't be hung up to dry when they raise safety issues."[66] (Charlotte Santry. 23 May, 2008)

Yet, despite this, only half of Trust Chief executives had read the recently published Report into the Maidstone and Tonbridge Wells scandal and there was no mention at all of improving health and safety in the NHS Operating Plan for that year bar mention of cleanliness and infection control.

The strategic direction for the NHS likely to be set by the NHS Commissioning Board[67] *(DH.* 2012) gives little confidence that practical "teeth" and support will be given to make the leadership culture changes that are needed.

The immense funding pressures, radical restructuring and competition pressures are likely to act as serious obstacles to a more effective engaged leadership culture.

Risk rating: red

7. The nature of standards set for the safety and quality of care, and which organisation or organisations should have the responsibility for setting and enforcing them.

The Inquiry repeatedly heard evidence of systemic shortcomings in the nature of standards and how they were set and enforced by the Strategic Health Authority, Monitor, and CQC. Tom Kark's written closing submission to the Inquiry says of the West Midlands SHA that:

133………. (their) monitoring of the Trust was limited to little more than an assessment of compliance with financial and activity targets.

Of Monitor, he concluded that:

106. Monitor's assessment of the trust placed little emphasis on quality of care. It relied on compliance activity targets and the trust's self declaration against the Core Standards.

Such weaknesses apply to the CQC:

There are concerns also about the quality of care that is offered both within residential care homes and in people's own homes. Regulation by the Care Quality Commission provides some safeguards against poor quality, but doubts remain about the ability of regulators to prevent well-publicised failures in the care of older people in residential settings, in part fuelled by concerns about a shift towards greater self-assessment by providers and fewer formal inspections.[68] (Chris Ham et al. 2012).

In August 2010, when Monitor reported on its response to the care quality scandal at Mid Staffordshire Hospital NHS Foundation Trust, the regulator said it would introduce a detailed "quality governance" assessment for applicants, to ensure they were identifying and managing care quality risks, and taking action on substandard performance.

But Monitor's failings at Mid Staffordshire were then repeated at University Hospitals of Morecambe Bay which it admitted had "deep-seated problems" at the time granted the trust foundation status.

The CQC's failures extended to their own governance. Tom Kark QC asked, in the light of the Inquiry hearing evidence from three internal whistleblowers from the CQC including Board member Kay Sheldon[69] (Public Inquiry. 28 November 2011):

175. Is the leadership of the CQC sufficiently open to internal criticism from which the organisation might learn to improve its systems and behaviour?

Equally damning, the Inquiry heard from CQC inspector Amanda Pollard that the CQC would not necessarily "spot another Mid Staffordshire" and who described an unmanageable workload, a culture focused on targets, and "every incentive not to issue a warning notice" and give a less labour intensive compliance action instead.[70] (Public Inquiry. 28 November (2011). Subsequently both the CQC Chair and Chief Executive have resigned but whilst this is likely to improve the internal culture, a serious lack of resources appears to be leading to a potentially problematic inspection model.[71] (CQC. 2012)

The Health and Safety Executive's role was also questioned:

188. Despite a theoretically broad ranging power to investigate and prosecute in cases of patient harm, the HSE's policy has had the effect in general of limiting its role to investigations of fault equipment and facilities rather than inadequate systems of clinical governance or insufficient quality of care

189. The meant that the HSE was in no position to detect poor care at the trust. Neither its reporting processes under RIDDOR nor its investigative decision making processes were set up to fulfil its role.

He asked (Para 179) whether "urgent action (should be) taken to ensure clear lines of responsibility are created between the CQC and the HSE.

However, the fundamental problem for the HSE is that its funding, staffing and expertise has been critically weakened in recent years undermining its a proactive role. The 2012 Budget statement promised to "scrap or improve 84 per cent of health and safety regulation" but this appears to be an evidence-free policy.

The United States government published research[72] (Paul Schulte et al, 2012) that put the cost of occupational injury and illness in the USA at $250 billion a year. In the UK HSE published research concluded:

"existing evidence suggests that legal regulations and their enforcement constitute a key, and perhaps the most important, driver of director actions in respect of health and safety at work."[73] (James,P. Wright,F. 2006)

The academic literature is dominated by studies showing three factors are key to making work safer: decent regulations; a meaningful threat of enforcement backed up by

punitive penalties; and genuine worker involvement. Yet the numbers of HSE safety inspectors and inspections, already cut repeatedly over the last decade, were further slashed by a third. Most firms were at a stroke removed from any threat of unannounced preventive official safety inspections as "light touch" regulation crept in.[74] (Hazards Magazine. 2010)

Yet research suggests a surprise visit from an official safety inspector is good for both jobs and the bottom line.[75] (Harvard Business School. May 17 2012). Commenting on the study in the, Toffel and co-author David I Levine note:

> "Randomly inspected establishments improve worker safety and reduce employers' premiums for workers' compensation insurance. And we found no evidence that these establishments suffer any of the competitiveness problems suggested by political rhetoric - like disruptions leading to lost sales or solvency concerns, or any effects on wages - compared to our control group. The differences are small but telling: (inspections) offer substantial value to workers, companies, and society."[76] (David I. Levine and Michael W. Toffel May 30, 2012).)

Relatives of those killed at Mid Staffordshire have pressed for a corporate manslaughter prosecution.[77] (Aislinn Laing. (March 1 2010**).**

The impact of any convictions would be both financial (defence of a Corporate Manslaughter Act prosecution will not be indemnified by the NHS Litigation Authority as it is a criminal matter) and reputational, particularly in respect of the Publicity Order.

Whilst the Inquiry is likely (arguably regrettably) to remain silent on that specific issue it acknowledged the more general concern:

> Prosecutions in respect of individual cases of clinical error (save for gross negligence) may not benefit the system or patients but prosecutions of healthcare organisation in respect of systemic failing have the capacity to encourage better care 197.

The Inquiry heard that the HSE was reluctant to undertake just such a prosecution after it was called in by police investigating the death of 66 year old Gillian Astbury in 2007. An inquest into Ms Astbury's death had ruled she died as a result of "shortcomings" in management and staffing levels. The Crown Prosecution Service subsequently they would not seek a conviction for manslaughter by gross negligence. Ms Astbury's partner Ron Street told the inquiry he had met the HSE's principal inspector of factories, to discuss a prosecution in relation to her death and said

"He… informed me that Gillian's case represented possibly one of the most difficult prosecution decisions that he'd faced in his career, because if a successful prosecution was mounted in Gill's case, the HSE was under-resourced [to] cope with the anticipated demands from other families which might ensue."[78] (Public Inquiry. (8 December 2010).

Tom Kark QC noted that

185. There is currently no duty on providers to report near misses to the CQC. The inquiry may wish to give consideration s to whether such a duty should be created.

and suggested

261. It might be thought advisable to make the NPSA's guidance on incident reporting procedure mandatory for trusts….There would seem to be no reason why it should not be mandatory.

More generally, the Inquiry Counsel questioned a more fundamental part of the current regulatory framework, self certification:

171. Any system which employs self certification as part of its model must ensure that the questions are directed to identifying the quality of outcomes for patients and not the quality of processes except insofar as those processes are demonstrated to be effective in promoting positive outcomes.

The Inquiry noted how internal reporting systems failed at Mid Staffordshire, thus obstructing learning from patient safety[79] (Public Inquiry. 8 December 2010) whilst Professor Brian Jarman's evidence went further to suggest that deliberate fabrication of data took place by senior staff, some of whom are presumably still in post[80] (Professor Sir Brian Jarman. 26 May 2011).

Those conclusions parallel those of the Winterbourne View Serious Case Review (SCR) which concluded that institutions such as Winterbourne View were "ill-suited" to the "light-touch" regulatory model employed by the CQC, which was "over-reliant on self-assessment". The SCR said "closed establishments" such as Winterbourne should have a more prescriptive approach, specifying best practice for inputs and processes, such as staffing and models of care, as well as for outcomes.[81] (Margaret Flynn. 2012)

The Inquiry's conclusion that Mid Staffordshire problems were not unique were corroborated by an anonymous posting in Health Service Journal after the Inquiry closed

As a management consultancy we offered an independent, expert review of quality at a Hospital with concerns on mortality rates. We found unreported iatrogenic deaths from a small sample of deceased patients notes, high levels of mortality amongst low incidence surgical procedures, lack of transparency in the reporting of mortality figures meaning that unjustified improvements were being presented as true; lack of follow up to issues involved in clinical audit; lack of follow through on accident and incident reports; lack of full implementation of safety notices; concerns on the hydration and feeding of patients etc, etc. Needless to say we were not invited back. Or have been able to interest other hospitals. Unfortunately many Chief executives and Medical directors see their job as keeping their hospital out of the newspapers. Their best tactic seems to be cover up, wilful blindness and solicitors.[82] (Anonymous comment on Ben Clover. 25th July 2012).

That experience suggests that the reluctance to acknowledge and engage with real problems is still widespread. That "denial" was perhaps encouraged by the fact that in 2008 at the height of the Mid Staffs scandal there was nothing on health and safety in the NHS operating plan beyond infection control and cleanliness.[83] (DH. 2007). Similar concerns about "quality accounts" were raised by NHS Medical Director Sir Bruce Keogh who agreed they would be "self certified spin" if a board wasn't performing effectively[84] (Public Inquiry. 21 September 2012).

Another theme which concerned the Inquiry was the confusion regarding the roles, responsibilities and methodologies of the various regulatory organisations and professional bodies responsible for quality notably the lack of communication, between the CQC's predecessor (the Healthcare Commission) the HSE and Monitor.

The political pressures on the CQC were highlighted in evidence by its then Chair Baroness Young who told the Inquiry that she was often subjected to political pressure to keep bad news out of the media and when CQC reports were found to be unfavourable, she was "leant on" to alter or "tone down" her reports so that they were less critical of the NHS. "Political interference was rife," she said.[85] (Public Inquiry. 21 September 2012).

Yet another concern is how quality governance will be assured outside of foundation trusts – in primary care, private companies and the voluntary sector. The National Quality Board guidance on quality for Boards[86] (National Quality Board (2011) does not make this clear. Contrary to the government "localism" and deregulation agenda, on

these, as on other matters the Inquiry is clearly considering a range of recommendations around the standardisation and mandating of reporting systems:

> 181. Should the production of guidelines for a model of clinical governance (be) made a priority for the CQC?

> 184. A single body is given the responsibility of ensuring all Trusts comply with Patient Safety Alerts and their successors.

The Care Quality Commission is currently consulting on its strategy for 2013-16[87] (CQC. (2012) which suggests it moves away from regular inspections of all regulated organisations and revert towards a more risk-based model, a complete change from which it decided to do a year ago under public pressure. The new strategy appears to be driven as much by its limited resources as any evidence such an approach is more.

Risk rating: Red

8. The relevance of staffing levels and skill mix to those standards.

Particularly controversial in any recommendations will be the issues of staffing levels and skill mix (and the linked matter of healthcare assistant regulation).

Tom Kark QC is clear:

> 182. Consideration should be given to the production of model staffing guidelines for certain types of wards and departments against which the CQC should assess the acceptability of staffing in the providers for which they have regulatory responsibility.

That view was influenced by repeated evidence about staffing shortages:

> 225. The evidence from the College (of Emergency Medicine) indicated that nationally numbers of consultants in Accident and emergency medicine are woefully inadequate…..This is a matter of grave concern.

> 257. A lesson from Mid Staffordshire and elsewhere is that staffing levels are a clear risk factor in acute trusts. Accepting that it would be beyond the remit of a CNST (Clinical Negligence Scheme for Trusts) assessor to scrutinise actual staffing levels it might be thought advisable for the assessment to at least examine how a trust manages the risks arising in this area. A standard or criterion that that required a trust to demonstrate, for example, that it took regular account of the staffing indicators listed in the Royal College of Nursing's policy document RCN *policy position: evidence based nurse staffing levels* or a similar set of agreed indicators might be desirable.

> 297 The DH should consider providing or endorsing guidance on minimum nurse staffing levels…..the Inquiry may well conclude that without some form of centrally approved guidance on staffing levels, an unacceptable risk is created that the pleas of nursing directors may be overborne by management seeking to make cost savings or o9therwise interfere with fundamental levels of care.

Dame Christine Beasley from DH rejected calls for statutory guidance on staff numbers and skill mix. Instead she suggested the CQC as part of its licensing process could look at what processes organisations had in place for determining and monitoring staffing levels. She agreed that a 60:40 registered to unregistered was as low as you should go in an acute hospital ward but claimed minimum staffing levels would become a ceiling not a floor.[88] (Sarah Calkin. 8 September, 2011).

In what looked like an attempt to pre-empt any recommendation on minimum staffing levels the chief executive of the Council for Healthcare Regulatory Excellence claimed:

> "minimum staffing levels are an example of inflexible regulation which distracts staff from time which they should be devoting to patient care. Lack of staff is often an excuse for poor care. But is care better where there are more staff and worse where there are fewer? Will minimum staffing levels secure quality? I doubt it. There is no direct correlation between number of staff and good or bad care, so mandated staffing levels cannot be necessary. But would mandated staffing levels raise the standard of those that are failing? Research suggests not.[89] (Harry Cayton. 15 March 2012).

This is simply not true, as was swiftly pointed out:

> Harry Cayton …. asserts: "There is no direct correlation between number of staff and good or bad care." But more than a decade of published research challenges this perspective.

> A previous UK study found that proportionally fewer patients die in hospitals with better nurse to patient ratios (Rafferty et al, *International Journal of Nursing Studies* 2007). And more recently, research from across Europe published last week in the BMJ demonstrates two key points: staffing varies hugely, even on wards of the same specialty; and differences in patient to nurse ratios are associated with differences in both patient and nurse outcomes (Aiken et al 2012).[90] (Anne Marie Rafferty and Jane Ball. 29 March 2012)

As I responded at the time,

> minimum staffing ratios are being seriously considered by the Mid Staffordshire Foundation Trust inquiry precisely because the current regulatory regime and management culture between them failed dismally to ensure both minimum staffing levels and appropriate staffing ratios between skilled and less skilled staff. ……It is correct that higher staffing levels do not ensure better quality of care if the management and staff culture is wrong. It is equally true however that lower staffing levels make it less likely that quality care will be provided.[91] (Roger Kline.29 March 2012).

In his evidence to the Inquiry, Professor Jarman appeared to take a similar view:

274. Dr Jarman comments (that) lower HSMRs (Hospital Standardised Mortality Rates) are significantly associated with more doctors per bed and fewer managers per bed (although the latter variable is only just significant).....this may be thought to lend weight to the inference of a correlation between high HSMRs and poor staff and patient surveys which relate to poor staff presence and poor communication with patients, In other words, poor staff ratios are directly linked to links.

A similar debate amongst social workers was prompted by an Audit Commission report[92] (Audit Commission. August 2012) which drew robust criticism[93] (Mithran Samuel. August 23, 2012).

Mid Staffordshire was not alone in having inadequate staffing numbers. A survey just three months ago concluded the research found:

the average proportion of registered nursing staff – compared to unregistered healthcare assistants – on day shifts was 56%. Dame Christine Beasley, the previous chief nursing officer for England, has previously said the ratio of nurses to assistants should not fall below 60:40.

The research found the proportion of registered nurses to assistants varied from 43% to 68% between trusts.

Nurses were also asked about patient safety on their ward. Where they said it was "excellent", there was an average of seven patients per registered nurse, compared to more than nine where patient safety was "poor" or "failing.[94] (Jo Stephenson. 24 July 2012)

Tom Kark's view was unequivocal:

25. Healthcare assistants should be regulated

An indication of the likely robust response to any calls by the Inquiry for mandated staffing levels of skill mix rations is given by the DH response to the Commons' Health Select Committee proposals on staffing levels and skill mix The DH maintained its position that local providers were "best placed" to decide these issues. "Health service managers, clinicians and employers…must be free to manage their own workforce and clinical teams to meet the health service needs of their community," it said"[95](DH. September 2012).

Immense funding pressures are likely to continue to exert downward pressures on both staffing levels and skill mix.

Risk rating: red.

9. The interface between the regulation of governance, finance, and quality and safety standards.

The Inquiry QC's closing submission was clear:

> 106. Monitor's assessment of the trust placed little emphasis on quality of care. It relied on compliance activity targets and the trust's self declaration against the Core Standards.

> 17. West Midlands SHA ………. monitoring of the Trust was limited to little more than an assessment of compliance with financial and activity targets.

> 161. In the light of the failures of communication between the quality regulator and the financial regulator and the limited role envisaged for Monitor in the future, the Chairman may wish to consider whether it would be appropriate to make any recommendations as to whether or not there should continue to be a separation between the economic and quality regulators….

> 310. The Inquiry should consider whether a single regulator should have responsibility for quality and finance in the NHS. It is a lesson of the Inquiry that the two are inextricably linked and that focussing on one aspect at the expense of the other can have catastrophic results. A trust's clinical plan and its business plan should have the same priorities.

Sir Liam Donaldson said he "wasn't sure that in their heart of hearts everybody [in the NHS] was convinced that we could run a service which met the financial and productivity targets but also delivered quality".[96] (Public Inquiry. (19th September 2011).

The Draft Mandate to the NHS Commissioning Board[97] (DH (2012) confidently asserts as "Objective 22" that it will:

> "ensure the delivery of efficiency savings in a sustainable manner to maintain or improve quality in the current Spending Review period and beyond."

This might reasonably appear to be a victory of aspiration over reality as was perhaps recognised by the newly appointed CQC chief executive's admission that he was concerned quality would suffer amid public spending constraints. He warned the health and social care system not to be "naïve" about it.

> "As the financial challenges continue I think there is a real risk that quality could begin to be impacted," he said. "We have got a role, not just on quality for

individuals and at individual service level but we need to comment on quality at the national level."[98] (Sarah Calkin. 7 September, 2012).

Further complexity in the balance between finance and quality arises from Ministers' determination that competition must increase. Monitor can reasonably expect to struggle to match its new responsibilities for competition law enforcement with the need for integrated patient care, which requires close co-operation between providers along the pathway.[99] (Bruce Kilpatrick. 23 August 2012).

Healthcare providers and healthcare professionals, faced with reduced resources and rising demand must always ensure that the care that they do provide is safe. To do so may require that, in the absence of improved working methods, what they provide is reduced. There will be immense political pressures to avoid doing so, but organisations that fail to understand the interface between their own duty of care, that of their staff and the available resources are at serious risk.

Risk rating: Red

10. The use of commissioning to require and monitor safety and quality standards or provision.

GPs work largely as small businesses. They will play a dominant role in the NHS following the Health and Social Care Act. Little consideration, beyond assertion, of whether their greatly increased role will improve the accountability of the NHS to patients, or improve quality or lessen harm, appears to have played any part in discussions around their new role. The Inquiry will not comment directly on the implications of the new legislation, but its conclusions (and those of others) are clear. The closing submission from Tom Kark reminds us that:

> 124. The use of contracts and financial incentives to promote quality improvements and to ensure a flow of performance data, patient feedback and safety information to commissioners is vital

> 127. Commissioners must have the skill, ability and resources to monitor and evaluate the information they receive….GPs will require very significant administrative support to enable them to take on this task

However, he shares the wider concerns that:

> 30. The evidence from the GPs did not in general provide grounds for optimism or for making positive recommendations

> 34. The patient experience ought to become embedded in the commissioning process which has clearly not happened to date

The Act will increase competition within the NHS with likely adverse implications for the collaboration and integration essential for good health care and to reduce the risk of harm. UK and EU competition law will apply so:

- Monitor will have a duty to eliminate "anti-competitive" behaviour
- Clinical Commissioning Groups will have major procurement responsibilities without obviously having the capacity or governance to deliver these CCGs may (and many will) outsource commissioning work to private companies
- The courts are likely to regard NHS services as falling within the scope of UK and EU competition law.

Far from increasing transparency (and thus accountability) the new commissioning and provider environment is likely to make any presumption of openness unless there is a need for confidentiality extremely unlikely as providers and commissioners behave likely commercial organisations.

Private health providers who have more expertise and legal capacity than public bodies are likely to turn to time-consuming and costly litigation against commissioners who may well not have the procurement expertise to control a complex procurement process and avoid legal action from private healthcare providers. It is not surprising that Tom Kark concludes:

> 117. The commercial nature of the relationship between the trust and its commissioner, and the inevitable imbalance of clinical expertise may well mean that expecting full disclosure of problems …. is unrealistic

The former acting director general of commissioning at DH told the inquiry

"A number of the changes we made to commissioning over the last ten years have taken longer than they should have done which has unsettled people in the system and taken people's eyes of the ball from their day to day job… There are times when we should have spent longer… working through some of the implications of some changes. Politically commissioning is a longer term solution and the things in health care are often immediate priorities and so maybe commissioning was pushed back because of that."[100] (Public Inquiry. 21st September 2012).

The serious case review into the Winterbourne View scandal agreed that Castlebeck's published policies, procedures, operational practices and clinical governance were good. However there was a huge gap between those paper policies and how patients were actually assessed and cared for. Commissioners had clearly been misled (successfully) and it is far from clear that lessons about monitoring services and feedback have been learnt elsewhere to prevent a recurrence, especially with self assessed quality so prevalent.[101] (Margaret Flynn. (2012).

Concern about the capacity of commissioners is widespread:

> Quality assurance must not stop at the identification of problems or risks – it must ensure that they are dealt with swiftly and effectively. There is evidence that investigation and inquiry reports are insufficiently acted on or followed up. In the immediate future, clinical commissioning groups will find it hard, particularly in view of their limited resources, to carry out these tasks. So, there is a risk that this gap in the current system will be perpetuated.[102] (Dixon, A. Foot, C Harrison, T. (2011).

Risk rating: red/amber

11. The potential adverse consequence of structural reorganisations and the requirements for addressing these.

The Inquiry was provided with evidence confirming "the importance of a systematic handover at times of organisational upheaval"[103] (Public Inquiry. December 1st 2011) and its closing submission heard that:

> 318. The DH should consider wherever possible how it can promote organisational stability within the healthcare system…all those is setting the direction of the NHS must give proper consideration to the detrimental effects of reorganisation on the capacity of those working in the NHS to do their jobs well.

Those fears are underlined by the fearful complexity of the new NHS arrangements. There are:

- five organisations to safeguard patients' interests,
- nine organisations to support care providers and
- three organisations whose role will be 'empowering patients and local communities'.
- Public Health England and local authorities whose role will be to promote public health
- some two hundred clinical commissioning groups
- more than a dozen bodies with a direct role in quality.

These bodies, whose roles will inevitably overlap, will work alongside:

- Around 200 acute and mental health trusts,
- Some 8,300 general practices
- Up to 18,000 care homes
- A growing number of private companies and voluntary sector providers.

Evidence from former Department of Health permanent secretary Sir Hugh Taylor stated that reorganisation of the NHS in 2006 was a major factor in problems at Mid Staffordshire Foundation Trust and that with any restructure that there would be a loss of corporate memory.[104] (Public Inquiry. 26th September).

One aspect of the current radical restructuring has been "a tripling of turnover among the NHS managers, nurses and doctors responsible for monitoring hospital care quality".[105] (Dave West. 9 May, 2012) and those losses complement the existing high rate of turnover of NHS chief executives whose average time in post is allegedly just 700 days'[106] (*The King's Fund Commission on NHS Leadership and Management.* 2011). Anna

Dixon and colleagues (Dixon, A. Foot, C Harrison, and T. 2011) highlight some of the direct consequences for quality of care.

A review of early warning systems was commissioned[108] (National Quality Board (February 2010) in response to an earlier review by the Healthcare Commission into Mid Staffordshire NHS Foundation Trust[109] (Healthcare Commission (March 2009). That report provided a comprehensive overview of the structures and processes in place at the time to assure quality and to ensure early signs of quality failures were identified and addressed. It made a series of recommendations for further steps that could be taken to enhance the mechanisms for safeguarding the quality of care. However, as a result of the Health and Social Care Act 2012, many of the organisations who played a key role in that system of assurance are being abolished and new organisations with different responsibilities are being created.

Importantly, learning and dynamic systems can best develop when there is a basic level of organisational stability, so that organisations and the staff within them can build experience and expertise. Regulation in the health sector has been much more prone to reorganisations than other sectors. The loss of some organisations (such as the National Patient Safety Agency) and the frequent reorganisation of system regulators such as the Care Quality Commission and its predecessors have weakened the system's ability to learn and improve.

Chris Ham, Anna Dixon, and Beatrice Brooke[110] (2012) argue that:

> Constant restructuring of the health and social care system focused on organisational changes not only misses the point that improvements in services are what matters, but also make it difficult for those working in the system to deliver high-quality care in line with their training and values.

There must be a real risk that the impact of the current immense restructuring causes disruption, organisational memory loss and a diversion of attention on at least the scale of previous restructures.

Risk rating: Red

12. The role of foundation trust governors and members, and other local public, patient and staff representatives (and complaints processes and embedding the patient voice).

Foundation Trust governors

There is no shortage of detailed regulation and advice regarding Foundation Trust governors[111] (Monitor. 2009). One authority[111] (Alimo-Metcalfe B. 2012) suggests Trust boards should pay particularly close attention to the results of the NHS staff survey, especially those relating to whether staff would recommend their organisation as a place to work and be treated.

However the extent to which such Governors are themselves really accountable to their nominal constituency is debateable. Their over-riding obligation is to the interests of the Trust. Substantial numbers of Trusts even needed persuading that their Boards should meet in public. Trust Network chief executive Sue Slipman, when questioned whether board meetings should be in public, pointed out that

> Currently around half of the 137 authorised foundation trusts have their board meetings in public. The Foundation Trust Network was not in favour of forcing all FTs to have open board meetings because simply having open meetings does not solve complex issues of governance and accountability.

> A private company's shareholders would not expect to be invited into the boardroom to witness debate and strategy setting.

> In future, all providers of NHS services will be independent organisations. If the argument is that all organisations in receipt of public money should have open board meetings, the rules should apply equally. If open meetings apply only to FTs, government needs to explain why they are different from other independent providers of NHS services.[113] (Sue Slipman. 4 August, 2011).

Apparently those who lead many such Trusts have yet to be convinced that openness and transparency in all matters is necessary. Yet without such openness in all matters, not least the publication of relevant data to make informed comment and decision making, and a genuine commitment to meaningful consultation, the tendency towards denial and a closing of ranks will continue. Following the First Inquiry Report, the DH published comprehensive advice to Boards[114] (Angus Ramsay and Naomi Fulop. February 2011) but recent CQC reports suggest that this is far from being universally followed.

The guidance stressed the importance of internal monitoring and governance rather than reliance on external inspection.

In doing so it referred approvingly to Healthcare Commission research[115] (Healthcare Commission. 2008) and asserted that:

> Research suggests better Board oversight of quality information is associated with superior performance on such indicators as mortality, morbidity and complications

> Research in the healthcare domain suggests that, in such a culture, staff are more likely to engage with incident reporting systems, with better reporting and learning from errors.

Other local public, patient and staff representatives

The role of the statutory complaints procedures and patients advocates was heavily criticised by the Inquiry. The evidence of Malcolm Alexander, as chair of the National Association of LINKs members, however, was compelling in three respects. He expressed deep concern about likely future funding of HealthWatch and about the independence of HealthWatch within its new CQC "home" and made the case for the reintegration of complaints advocacy services, patient and public involvement and local scrutiny of service variation, a view regarded as having some force by the Inquiry Counsel.[116] (Malcolm Alexander. 30 March 2011).

Other organisations with a consultative or scrutiny role came off no better.

> 48. There is good evidence that the (Borough Overview and Scrutiny Committee) (OSC) had lost sight of its duty to scrutinise the Trust's services as well as take an overview of them

> 51. Patient relatives felt that the committee's bureaucratic approach hampered public participation. It might be argued that there should be a clear presumption in favour of structured public participation in the proceedings of such bodies.

As public health functions transfer to local authority it will become even more important that such processes are well known, well understood, and have a presumption of disclosure and involvement.

The OSC must currently be consulted where there is substantial variation or development of services and in some cases there is a duty to consult before the decision is made. It is worth noting that because the Government is removing the Secretary of State's duty to ensure the NHS delivers an appropriate service, appeals from locally elected council bodies and health watchdogs will no longer be decided by the Secretary of State

MPs fared little better:

> 74. MPs do not appear to have played an effective role in the protections of the local population

Complaints processes

The closing submission from the Inquiry Counsel reflected evidence about the shortcomings of the complaints procedures and systems for patient advocacy. Central to the Inquiry recommendation are likely to be an insistence that services must be patient centred with patients concerns and views being a crucial element in identifying poor quality care and improving it. Tom Kark QC states:

> 14. Patients and the public must be informed of how to raise concerns outside their hospitals own structure….There must be more stability and continuity of organisational structures

"Strengthening the patient voice" has been de rigour for DH policies in the last few years yet a combination of defensiveness and secrecy on the one hand, and instability in patient advocacy arrangements on the other, have meant the benefits of effective patient input have not been realised

> 315. The NHS has failed consistently to harness the power of the patient and public voice in monitoring the quality of services PPIFs and LINKs were unsuccessful. In future members of the public should be embedded within hospital governance structures in order to ensure that those delivering care are held to account.

> 19. Meaningful and understandable data on quality and safety must be placed in the public arena in order to facilitate open and honest consideration and learning when things are going wrong.

Tom Kark QC said dealing with complaints must be viewed as:

9. (a) a fundamental part of the hospital's function in caring for patients and respect for their loved ones, and

(b) an opportunity to improve performance and prevent future harm.

However, the complaints process failed at Mid Staffordshire.

3. The complaints process….failed to value and utilise complaints and to treat complainants with the respect they deserved….. When they went to the PALS service they found an office that was chaotic, understaffed and unable to cope with concerns or escalate serious concerns effectively.

6. The Trust showed a defensive attitude towards complaints in keeping with its general reluctance to admit to poor quality care.

There already exists under-used national guidance and standards on complaints handling (The Local Authority Social Services and National Health Service Complaints (England) Regulations 2009) and Tom Kark suggests adherence to such standards "could become part of the key outcomes operated by the CQC" 24.

Ironically, just one month before the inquiry reports, –the National Association of LINk Members (NALM) "condemned" proposals to strip Local Healthwatch of its statutory body status and establish it as a non-statutory 'corporate body' - claiming the proposal will "massively undermine the power and influence of Local Healthwatch." Malcolm Alexander, Chair of NALM said

If the statutory status of Local Healthwatch is removed, it will lose significant influence and power. A high percentage of LINks will simply disappear in the complexity of the transitional arrangements. By removing the statutory status from Local Healthwatch the Government are in practice abolishing LINks and reneging on their promise of an "evolution" to Healthwatch. We are also dismayed that the status, power and influence of LHW will be reduced and undermined if it loses the statutory component – even if retaining some 'statutory duties'. For an organisation populated by local volunteers and the public, expected to influence professional bodies such as commissioners and providers of services, that statutory label is pivotal to gaining meaningful access and exert real and genuine influence on the NHS and social care services."[117] (NALM. February 1st 2012.)

Governments of both complexions over the last decade have fragmented and under-resourced complaints advocacy services, and patient and public involvement in health

services. It appears the obstacles to creating them as integrated, properly resourced and become independent powerful advocates may be as large as ever.

Risk rating: red

13.   The nature, scope and definition of a duty of candour and methods of enforcing it.

In order to encourage or require openness and transparency patients groups have been campaigned for a "duty of candour". The need for more robust means of preventing a climate of denial and bullying was raised at numerous points during the Inquiry.

The Inquiry Counsel agreed:

> 97. It should be made clear to all that a Trust's "best interests" require full disclosure when things go wrong.

> 26. A duty of candour should apply not only to clinicians but to organisations

> 314. Health care providers and those working within them should be subject to a duty of candour.

The idea of a legal "duty of candour" was first suggested by chief medical officer Sir Liam Donaldson in a review of the clinical negligence scheme in 2003. He told the inquiry he supported a duty of candour but said it had to be handled in "a way that's as positive as possible".[118] (Public Inquiry. 20th September 2011).

The DH proposes that all organisations providing services to the NHS will be contractually obliged to inform patients and relatives if a mistake has been made under proposals set out by the government. A 'duty of candour' would be written into the NHS Standard Contracts requiring organisations to be open about where a mistake has caused moderate or severe harm or death. The DH prefers a "contractual mechanism" for introducing such a duty on the basis that the alternative statutory duty would require a national mechanism for enforcing compliance where the only realistic candidate for the role is the CQC which has stated it would be unable routinely to monitor and enforce the duty. It is unclear how a contractual mechanism will result in robust enforcement.[119] (Action against Medical Accidents. September 2012)

Those with experience of aviation, where incident reporting is highly developed, stress that such a duty should **not** result in disciplinary action when the practitioner commits an inadvertent human error and reports it to their employer, and argue that only "reckless or grossly negligent behaviour that organisational norms or situational stress are unable to explain alone" should trigger potential disciplinary action.[120] (Clinical Human Factors Group. November 5th 2011)

Arguably, such a duty of candour will only be effective if health service providers transform their management culture internally rather than simply relying on external

inspection or professional regulators. However if there were to be no effective external inspection and professional regulators fail to hold senior managers to account and support those who comply with their Code of Conduct by raising concerns, then a duty of candour risks being another process for employers to try to sidestep their safety duties.

Risk rating: amber/red

14. The development, collection, use and sharing of information and data, including safety alerts, mortality data and performance indicators.

More than a decade ago, the Institute of Medicine's landmark report *To Err Is Human*[121] (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson. 2000) claimed between 44, 000 and 98,000 Americans die in hospitals each year due to medical errors. In the UK more than 20 per cent of patients suffer avoidable harm during their care at some trusts. The NHS Safety Thermometer "reveals that nine per cent of all NHS patients have suffered an avoidable harm. This means major improvements are required if the NHS is to meet the Department of Health's target to deliver "harm-free care" to 95 per cent of patients "by 2012"."[122] (David Williams. 30 August, 2012). Leading US authorities explained

> "No one wants a single person to be harmed by medical care. Eliminating patient injuries is difficult, even with the best of intentions. Solutions such as 'wash your hands', 'give the antibiotic on time' and 'use the checklist' seem so simple that many ask, 'How could they not do that?' In fact putting these solutions into action is elusive, requiring culture changes, new forms of teamwork, uncomfortable […] transparency, disclosure, dialogue, changes in patterns of workflow, and constant vigilance at all levels."[123] (Joseph McCannon, AB; Donald M. Berwick, MD. (2011)).

The Inquiry heard there is substantial evidence that the use of standard procedures, especially where the organisation itself enthusiastically monitors, prevents harm and improves quality, improve safe care, and so is likely to recommend that

> 17. There is a need for far greater standardisation of operating (or quality) standards in the NHS with close monitoring of compliance**.**

> 317. The publication and transparency of date is a profoundly important factor in driving performance and exposing poor quality care

The use of NICE to create Quality Standards for the use of providers, commissioners and regulators in assessing and promoting safe and high quality care has been welcomed. There is growing evidence that systematic recording allied to checklists improves performance and safety.[124] (Hales BM, Pronovost PJ, 2006)

Numerous shortcomings in the existing data arrangements were highlighted during the inquiry which heard that the National Reporting and Learning System was delayed for

several years after it was first recommended, whilst Sir Liam Donaldson said the reporting of patient safety incidents mandatory was not made mandatory after he said he had been "warned" that doctors would not report.[125] (Public Inquiry. 19th September 2011). Professor Brian Jarman warned that Trusts may try to deceive regulators and gave as a possible example the way in which patients with diabetes and rheumatoid arthritis were coded as being under palliative care to reduce published death rates.[126] (Public Inquiry. 13 June 2011).

Sir Bruce Keogh told the Inquiry that the National Patient Safety Agency's National Reporting and Learning System, which will become the responsibility of the NHS Commissioning Board when the Agency is abolished, is likely to be outsourced to an "NHS trust with an academic interest".[127] (Trust Public Inquiry. 20 September 2011). It is unclear what evidence that such changes would improve health care underpinned this decision.

It is unclear how powerful the Care Quality Commission's new "quality risk profiles, which bring together information about health and social care providers from a range of sources, will be.[128] (Public Inquiry. 28 September 2011).

Tom Kark QC's closing submission reminded the Inquiry that:

> 151. What is also striking about the 2006 report is that it was the product of a single day's visit by volunteers, and yet provided a very clear account of the risks posed by the trust's A and E department which otherwise seems to have escaped effective scrutiny until 2008.
>
> 166. It is critical in our submission that the regular has sufficient access about complaints to allow them to identify trends which may indicate poor standards

There is some evidence that public reporting of data on quality (when benchmarked) can have a powerful effect on the reputation of organisations and individuals [129] (The Health Foundation. 2009). Anna Dixon, Catherine Foot, Tony Harrison (2011) point out[130]:

> High performing organisations find that one 'habit' they have in common is measurement and oversight. While for many organisations measurement is driven by external audiences such as regulators and payers, among these high-performing organisations measurement is for purposes such as internal accountability and performance management. Those organisations go beyond the measures required for external reporting.

Risk rating: Amber

15.   The protection of whistle-blowers.

There is widespread concern that whistleblowers, an essential catalyst for creating safe care, are tolerated at best and victimised at worst in too many NHS organisations.[131] (Roger Kline. 13 December 2011) This is not for want of instruction, guidance and rhetoric from the DH and others.

Speak up for a healthy NHS

The Health Service Circular 1999/198[132] (DH 1999) required every NHS trust and health authority to have in place policies and procedures which comply with the PIDA set out employers' obligations and staff rights**.** Speak up for a Healthy NHS[133] (DH and NHS Social Partnership Forum. 2010) urged employers to have good policies and practice in place. NHS Employers, together with regulators and trade unions issued an updated version of this (The Speaking Up Charter) but it remains to be seen whether this has greater effect than previous declarations of good intent. [134] (NHS Employers. 2012). Guidance for GPs was issued following the Shipman Inquiry report[135]. (Public Concern at Work. 2003) The then Secretary of State for Health, Andrew Lansley, published an updated NHS Constitution in March 2012 stressing the responsibility of staff to report concerns and of employers to act on them, but did not introduce any additional statutory obligations on employers.[136] (DH. March 2012).

The changes include:

- an expectation that staff should raise concerns at the earliest opportunity
- a pledge that NHS organisations should support staff when raising concerns by ensuring their concerns are fully investigated and that there is someone independent, outside of their team, to speak to
- clarity around the existing legal right for staff to raise concerns about safety,
- malpractice or other wrong doing without suffering any detriment

Following all this guidance, the 2010 NHS staff survey found that staff are more aware of their organisation's policies and process for reporting concerns, and that they understand how to raise concerns about risks to patient safety, with 80% saying their "trust encourages us to report errors, near misses, or incidents". Despite this, only a minority (41%) of staff say their trusts "treats staff who are involved in an error, near miss, or incident fairly." [137] (DH. 2011).

Another survey reported that:

More than a third of nurses (34%) said they have been discouraged or told directly not to report their concerns about quality of care. Some 73% said managers had told them not to speak up, while 24% said work colleagues had said it was a bad.[138] (Nursing Times. 5 December 2011).

The draft *Standards for members of NHS boards and governing bodies in England*[139] (2012, CHRE) says Board members must demonstrate business skills, such as "being open about the evidence, reasoning and reasons behind decisions about budget and resource allocation, and contract allocation in particular" and "taking appropriate action to raise concerns if I perceive that my organisation or my colleagues are engaging in any harmful behaviour or misconduct".

The Inquiry Chair has stated he regards protection for whistleblowers as a priority in his forthcoming report and will expect employers and regulators to act accordingly. However the Government's recent refusal to endorse detailed proposals to improve PIDA from Public Interest at Work, and the NHS Confederation's decision to exclude whistleblowing organisations from their recent summit on the subject does not bode well. Despite the DH and Ministerial assurances of the importance of whistleblowing, when recently given the opportunity to improve the Public Interest Disclosure Act, Ministers headed for the hills. In June 2012 Ministers sought to amend the Enterprise and Regulatory Reform Bill to tighten Section 14 so that disclosures would not be protected unless believed to be made in the public interest, a move widely regarded as placing a further obstacle in the way of whistleblowers. There was no public consultation into this proposed amendment so the views of trade unions, UK business and other interested groups were not taken into account when the Government drafted their amendment. This also represents a missed opportunity to take a wider look at the legislation's success and failures which could in turn lead to further reforms that would improve the legislation. This led to Katy Clark MP putting forward an Early Day Motion EDM (359) calling for a public consultation as follows:

"That this House believes greater protection should be provided to whistleblowers in the workplace; is alarmed at the Court of Appeal's decision in NHS Manchester v Fecitt & Ors which indicates that employees are no longer protected from harassment of co-workers; believes that this is just one of a number of issues, including the implementation of the Shipman Inquiry's recommendations to remove the good faith test, and the use of gagging clauses which requires serious debate; believes that the changes put forward in the Enterprise and Regulatory Reform Bill will make it more difficult for individuals to rely on the Public Interest Disclosure Act and calls on the Government to hold a wider consultation on

possible reforms to ensure a meaningful strengthening of the protection of whistleblowers."[140] (Public Concern at Work. 26 July 2012).

Risk rating: red

Additional concerns likely to affect implementation of recommendations

There are significant issues are not listed in the topics Robert Francis QC has said he is likely to consider - notably the implications of the Health and Social Care Act, the likely decisive increase in private sector NHS provision, the role of trade unions and the role of Government, all briefly considered here.

The implications of the Health and Social Care Act

The Faculty of Public Health's risk assessment of the Act[141] (Faculty of Public Health 2012) warned of:

- Loss of a comprehensive Health service,
- Increased costs,
- Reduced quality of care,
- Widening health inequalities

The Faculty of Public Health risk register claims that increased competition, a more overt focus on anti-competitive behaviour and a multiplicity of service providers and commissioners may result not only in a range of increased costs but in reduced quality of care

- "Supplier induced demand - danger of over treatment and harm to patients of unnecessary invasive procedures as demonstrated by research in the US.
- Currently the national tariff covers less than 60% of NHS services. Services not covered by a national tariff will be open to competition on price. Competition on price will encourage a 'race to the bottom' in terms of the quality of care.
- tendering processes service specifications will need to be 'water tight' in terms of quality standards – CCGs lack the expertise and resources to develop contracts that will ensure quality standards are maintained or enhanced. There are also difficulties in measuring quality and setting standards that do not generate perverse incentives.
- Co-ordination of care may be seen as anti-competitive unless it can be clearly demonstrated that providers collaborating to provide services is in the best interests of the patient.
- Medical negligence QC John Whitting claims negligence claims may soar as a result of competitive commissioning. Competition and commercial interests

lead to fewer clinical staff working longer hours, and create an environment in which mistakes are most likely to happen.

- Quality of patient care will be compromised if competing providers are unwilling to share information such as test results, medications etc and co-ordinate services."

Those risks are compounded by widespread concerns about the capacity of Clinical Commissioning Groups to effectively commission quality services more general concerns about accountability in the new system. Jo Maybin and colleagues[142] warn (2011).

> Overall, we think the proposed reforms signal a shift to an over-reliance on weak and unproven accountability relationships given the extent of the government's proposed reforms; this is a significant cause for concern.

Privatisation

The implications of a likely exponential growth in private sector provision was not addressed by the Inquiry, presumably because it was not an issue at Mid Staffordshire itself and because the Inquiry report preceded the implementation of the Health and Social Care Act. Nevertheless, the increased role of the private sector in healthcare may well have fundamental implications for implementation of many of his recommendations.

Not only is there no evidence that hospital competition, at the heart of the Act, saves lives,[143] (Cooper Z, Gibbons S, Jones S, McGuire A. 2011) but it is unclear how co-operation and the integration of care sit alongside competition between providers.

The Inquiry chair in closing the Inquiry said he hoped his recommendations would help those "charged with planning and managing the ever-shifting" NHS but stressed it was not intended to halt any reforms or changes currently underway.[144] (Public Inquiry. Closing submission. December 2011).

The NHS is regarded as one of the fairest and most cost-effective healthcare systems in the world with half the per capita costs of the US health system[145] (Randeep Ramesh. August 7th 2011). At a time of sharp "efficiency savings" and rising demand, funding will inevitably be a central issue in improving patient safety and promoting good care. There is a real risk that, just as Cecil Clothier produced a thorough report following the Beverley Allitt Inquiry[146] (Sir Cecil Clothier. February 1994) but one which did not challenge the overall framework and funding within which deaths occurred, there is a

real risk that if the Inquiry does not seek fundamental changes to the framework of health care provision and delivery that the Health and Social Care Act introduced (which it will not) then its best intentions will be frustrated.

Allyson Pollock[147] (Allyson Pollock. August 27th 2012) suggests one challenge to commissioners and regulators is that "Fraudulent billing and embezzlement will become endemic". She highlights fraud and mischarging convictions against HCA International and Unitedhealth and writes:

> As for public accountability, there is none. Commercial contracts are redacted so that crucial financial information is not in the public domain. Government departments and companies refuse to release the necessary information on the grounds of commercial confidentiality and allows companies to sequester their profits in offshore tax havens

Despite the Secretary of State claiming "I do not think that we will see a big expansion in the number of private sector providers" arising from the Health and Social Care Act,[148] (Hansard. 16 Mar 2011) there will surely need to be an increase in the budgets of those organisations expected to monitor and ensure the safety of such providers. The CQC's £164m annual budget was 30 per cent below the combined funding of the bodies it replaced in 2009, though its duties were greater. It even had to ask the Department of Health for an extra £15m to deal with a rise in whistle-blowing calls following the Panorama programme on abuse at Winterbourne View.[149] (Health Select Committee. 28 June 2011).

Trade Unions

Some individual trade union members, and at least one local representative, acted with real credit in Mid Staffordshire. However trade unions as organisations do not emerge well from the Inquiry proceedings:

> 75. The evidence of Adrian Legan (RCN full time officer) suggests that the Royal College of Nursing may have been out of touch with its membership and the Trusts poor incident reporting culture.

> 78. The unions were effective at representing their members particularly when protecting rights guaranteed by employment legislation. They were less effective in representing their members' interest in ensuring patient safety and a high quality of care.

79. There was some evidence that in protecting their members employment rights the unions assumed they were protecting patients e.g. Mr. Legan's evidence that as there were no compulsory redundancies he was reassured that the workforce reduction had not made patients less safe.

84. The RCN's chief executive did not engage with the presence of the quality regulator (the Healthcare Commission) at the Trust and did not communicate with it. This led to the public receiving potentially confusing messages about the standard of care at the trust.

85. A leading official of Unison gave wrong and confused evidence about whistleblowing in the NHS, suggesting its relative unimportance to that union at a national level. The Chairman will no doubt wish to consider recommendations designed to embed in healthcare unions a culture of raising concerns about unsafe and poor quality care.

86. The brief evidence from the BMA suggested that doctors are even less likely than nurses to raise concerns about unsafe and poor quality care.

The Inquiry heard that at the height of the Trust failures the leader of the biggest nursing union wrote to Mid Staffordshire's director of nursing Helen Moss in May 2008 stating:

> "I was very impressed with the standard of nursing care. As you know, I have visited trusts throughout the UK and I have seldom been as impressed with the quality of care as I witnessed at the Stafford Hospital ……. It was useful to have the opportunity to speak with patients and their relations, all of whom could not have been more fulsome in their praise of the standard of care."[150] (Public Inquiry. 7 March 2012).

The Inquiry's concerns about the inability of trade unions to be effective advocates for staff on patient safety issues at Mid Staffordshire ought to prompt serious reflection amongst members and leaders alike. In reflecting on the Inquiry, trade unions might want to take into account that, in this author's own experience, there exists a more general challenge of developing ways of ensuring trade unions are effective guardians of the public interest and their members' duty of care at local level across all sectors of industry. Trade union members are also patients, relatives and carers. The continuing fall in membership and the "hollowing out" of local representative structures make such reflection imperative if the concluding paragraph of the Inquiry's closing submission from Tom Kark is to be addressed:

99. Unions such as Unison and the Royal College of Nursing failed to detect or communicate failings of care at the Trust despite being in a particularly strong position to pick up on the experiences of their members. Unions should raise such concerns when they become apparent; they must be central to the quality of their members working environment. The unions must support those who speak out.

Government policy

The helpful Kings Fund Review, Preparing for the Francis report: How to assure quality in the NHS[150] (Dixon, A. Foot, C Harrison, and T. 2011), sets out the external systems which the Francis report will need to address:

- the registration and regulation of both providers of services and many groups of staff
- the setting of standards for specific services or professional staff
- monitoring and inspection of care provision and professional staff
- closing down unsafe services or impose sanctions on professional staff
- management of contracts and performance by commissioners and bodies such as Monitor
- financial incentives to providers (most notably GPs)
- patient complaints and legal claims, local authority scrutiny committees and the CQC may hold providers and commissioners to account

However, if the Francis Inquiry report is to make a sustained difference to the likelihood of any repeat of the Mid Staffordshire disaster then its recommendations on these issues will need to be robust. But by stating in advance that its Report will not challenge the enormous reorganisation and market focus of the Health and Social Care Act 2012, it risks its recommendations being seriously undermined.

The Kings Fund Review[151] (Dixon, A. Foot, C Harrison, T. (2011) does not, however, consider the fourth factor essential to the promotion of good care and prevention of serious failures of quality i.e. the role of government in establishing and maintaining a framework to underpin and enable those goals, and the provision of sufficient funding to enable staff to realistically deliver those goals. The widespread concerns that the Health and Social Care Act will undermine that fourth factor, and the Government's insistence on finding a staggering 4 per cent efficiency savings per year for the next four years,

threaten to fatally undermine the Francis Report even if the other three factors were effectively addressed.

Such concerns will have been underlined by Sir David Nicholson whose recent speech. Almost valedictory in nature, welcomed his Secretary of State as follows:

> The head of the NHS has laid bare his fears that the government's controversial reforms of the health service could end in "misery and failure".
>
> Sir David Nicholson, chief executive of the NHS, said high-profile, politically driven changes almost always end in disaster. He warned against "carpet bombing" the NHS with competition but said that competition was best used like a "rifle shot" to fix problems.[152] (Daniel Boffey 13 October 2012*)

Conclusion

It is hard to be optimistic about the difference the Francis Report will make even if its recommendations are as robust as they are likely to be.

The risk rating identified for each of the fifteen key areas of likely recommendations this Paper has considered are summarised in Fig 2.

Fig 2. Summary risk ratings

Risk rating	Number of areas of likely recommendations
Red indicates serious adverse consequences	9
Amber/Red indicates moderate/serious adverse consequences	3
Amber indicates moderate/adverse consequences	3
Green indicates no adverse consequences	0

These are no more than the most approximate indicators of risk, but they suggest that overall, the impact of Ministerial response to the Inquiry Report, is problematic. Ministers and the DH are unlikely to openly resist most recommendations, but certain key

recommendations can expect to be "kicked into the long grass" or diluted to such an extent that their impact is limited, whilst the impact of the Health and Social Care Act appears to not be a factor in the Inquiry recommendations. The report has already been delayed since its first suggested publication date and it is unclear whether the Government response will demonstrate the urgency, let alone the policy response, required.[153] (HC Deb, 8 October 2012). If either (or both) happen then the potential risks identified will become real ones and a repetition of the systemic failings identified at Mid Staffordshire NHS Foundation Trust will remain a continuing possibility, the more likely because of the financial, policy and structural turmoil now underway.

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