'Bringing the healthcare system to account: lessons learned from Mid Staffs'

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Introductory and Outline of Talk

1. The Mid Staffs public inquiry was a very substantial, and timely review of the operation of the healthcare system and the regulatory framework that is supposed to govern it. The public inquiry's remit was:

   "To examine the operation of the commissioning, supervisory and regulatory organisations and other agencies, including the culture and systems of those organisations in relation to their monitoring role at Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009 and to examine why problems at the Trust were not identified sooner, and appropriate action taken. This includes, but is not limited to, examining, the actions of the Department of Health, the local strategic health authority, the local primary care trusts, the Independent Regulator of NHS Foundation Trusts (Monitor), the Care Quality Commission, the Health and Safety Executive, local scrutiny and public engagement bodies and the local Coroner"

2. The executive summary was 125 pages, and concluded with 290 recommendations. The full report is over 1,700 pages long. The report contains a very substantial body of evidence, and a thoughtful and careful analysis of the key themes which emerged from the Inquiry.

3. The recommendations covered those themes which were broadly as follows:

   (i) Fundamental standards
   (ii) Openness, transparency and candour
   (iii) Nursing standards
   (iv) Patient-centred leadership
   (v) Information.

4. It is those themes which I will take as my subject matter today in order to pose, and I hope to some extent at least try to answer, the question, whether, and if so what, lessons have been learned from the Mid Staffs inquiry?

5. Before seeking to do so, I think it helpful to give the Inquiry some legal and factual context, including how it came about and why. After a high profile campaign by Cure the NHS, a group of patients and relatives who banded together to seek to bring to the attention of the authorities what they perceived as serious shortfalls in care at their local hospital, and Indpendent Inquiry was set up to investigate and report on their concerns. That Independent Inquiry led Robert Francis in 2010 heard a large amount of evidence from patients, relatives and staff at the Trust. Its conclusions were damning. There were a wide range of failings across the Trust including a board too focussed on finance at the expense of the quality of care being delivered to patients, understaffing and a culture of poor practice and neglect that staff felt powerless to change. That might have been all. But because of concerns about the excess mortality a the Trust and the possibility that over the relevant period somewhere between 400 and 1200 excess deaths might have been caused, Cure the NHS continued to push for a public inquiry.

6. The then Labour Government refused to hold a public inquiry, saying that the Independent Inquiry was sufficient, (particularly as there had already been an investigation by the Healthcare Commission) lessons had already been learnt, and there were in place plans of action that might overcome what was essentially a local problem in the management of Trust.

7. Judicial review proceedings were threatened basing the argument for holding a public inquiry squarely on human rights grounds. Thus the pre-action letter on behalf of Julie Bailey, from Cure the NHS read as follows:-

> *"It is currently unclear how many patients died as a direct result of the Trust's systemic failures, but the Commission found that mortality rates in emergency care were between 27 per cent and 45 per cent higher than would be expected, equating to between 400 and 1,200 "excess" deaths. We consider the State has an investigative obligation under Article 2 ECHR to investigate deaths which may have been caused by systemic failures of the type which appear to have occurred here.*

On the basis of the Healthcare Commission report, some relatives appear to be claiming that their relatives had been left, sometimes for hours, in wet or soiled sheets putting them at increased risk of infection and pressure sores. This, and certain other serious deficiencies identified by the report may amount to a violation of Article 3. A similar investigative obligation arises in respect of such potential Article 3 violations.
We consider that the state's investigative obligations under Article 2 and Article 3 are engaged and require the State (e.g. the Government) to provide or to institute an effective official and public investigation, the purposes of which are clear, and which should ensure that culpable and discreditable conduct is exposed and brought to public notice; that suspicion of deliberate wrongdoing (if justified) is allayed; that dangerous practices and procedures are rectified; and that those who have lost their relatives may at least have the satisfaction of knowing that lessons learned from his/her death may save the lives of others –see by analogy, R (Amin) v. Home Secretary)."

Pre-action Letter Leigh Day to Secretary of State

8. That challenge was never ruled upon, but as the general election approached, the concerns about Mid Staffs, and the questions it raised about the wider healthcare system were seized upon as a sufficiently important issue by the Conservative party to become a manifesto commitment of Conservative party to an Inquiry.

9. I mention this because I think it is helpful to put Mid Staffordshire, and its inquiry into the system failures (including the regulatory and other systems) into some sort of legal context. Human Rights legislation, rather than the NHS Act 2006 is, or was the nearest black letter law comes to spelling out a clear duty to deliver an effective system of healthcare. As Lord Rodger observed in *Savage* [2008] UKHL 74:-

> 68. *In terms of article 2, health authorities are under an over-arching obligation to protect the lives of patients in their hospitals. In order to fulfil that obligation, and depending on the circumstances, they may require to fulfil a number of complementary obligations.*
> 69. *In the first place, the duty to protect the lives of patients requires health authorities to ensure that the hospitals for which they are responsible employ competent staff and that they are trained to a high professional standard. In addition, the authorities must ensure that the hospitals adopt systems of work which will protect the lives of patients. Failure to perform these general obligations may result in a violation of article 2. If, for example, a health authority fails to ensure that a hospital puts in place a proper system for supervising mentally ill patients and, as a result, a*

patient is able to commit suicide, the health authority will have violated the patient's right to life under article 2.....

72. *....Finally, article 2 imposes a further "operational" obligation on health authorities and their hospital staff. This obligation is distinct from, and additional to, the authorities' more general obligations. The operational obligation arises only if members of staff know or ought to know that a particular patient presents a "real and immediate" risk of suicide. In these circumstances article 2 requires them to do all that can reasonably be expected to prevent the patient from committing suicide. If they fail to do this, not only will they and the health authorities be liable in negligence, but there will also be a violation of the operational obligation under article 2 to protect the patient's life.*

10. System failure is also dealt with in the important case of *Regina (Takoushis) v Inner North London Coroner and another* [2006] 1 WLR 461, which was a judicial review of a Coroner's decision as to the scope of an Inquest, and in particular whether it was Article 2 by reason of system failure. The facts are helpfully explained in the judgment:-

11. *The trust had a system in place for assessing the needs of patients who present themselves at the A&E department. This was based on a document called Emergency Triage which was produced by the Manchester Triage Group. It involves the clinical prioritisation of patients including those with mental health problems and includes a flowchart, which identifies five categories of priority with differing target times for the patient to be seen. The times vary from immediate to 240 minutes. Category two provides for the patient to be seen by a doctor or appropriate person within 10 minutes. This is the most urgent category possible for a patient, including a psychiatric patient, unless he or she has in addition sustained life-threatening physical trauma, requiring, for example, immediate resuscitation.*

12. *Nurse Blake recorded that Mr Takoushis was at "high risk of self harm. Nurse Blake took Mr Takoushis' temperature at 1315. Her evidence was that she was with him until about 1330, when she wrote up the notes in which she summarised the position thus:*

"Brought in by LAS. Summoned by Police. Patient seen standing on Tower Bridge intending to jump. Police involved with negotiation for 45 mins. O/A patient very calm, complained of slight frontal headache. Says he went to bridge to do "silly thing". Says has been having problem with his wife, who is accusing him of having affairs. Good eye contact. Limited English."

14. *At about 1335 Nurse Blake handed over to a colleague, Staff Nurse Brown, and played no further part in Mr Takoushis' case. There was no evidence from Nurse Brown but it appears that Mr Takoushis was then left alone in his cubicle until 1355, when he was offered an analgesic, which he refused. At 1400 a Dr Fritz attended to see Mr Takoushis but he was nowhere to be found.*

Unfortunately this was almost an hour after the patient's arrival and well beyond the 10 minutes envisaged by the system. Just before 1500, an office worker at St Katherine's Way called Anne Matthews saw a man jump into the Thames at St Katherine's Dock. Her description of the man fitted that of Mr Takoushis. His body was recovered from the River Thames at Wapping some five weeks later, on 14 February

In considering the Coroner was wrong to conclude no arguable systemic failure arose the Court observed:-

> *"It might have emerged that there was some error on their part or on the part of someone else at the hospital or it might have emerged that there was other pressing work which one or more of them had to do before Mr Takoushis could be seen. It might, for example, have emerged that pressure was often so great at the A&E Department that, notwithstanding that the system provided in principle for a person assessed as a category 2 patient to be seen within about 10 minutes, it was not always possible for the system to be operated in that way because of the demands of other patients. In that event the question would have arisen whether the system was satisfactory (or indeed reasonable) or whether other steps should have been taken, and in particular safeguards put in place, in order to improve the system, so as for example to keeping a watch on a patient like Mr Takoushis, who had very recently attempted suicide, by seeking at least to persuade him not to leave the hospital before he could be seen. The question would also have arisen whether safeguards were in place for the future, since, so far as we can see on the evidence, the coroner was not aware of the remedial steps taken by the hospital before the inquest began"*

11. The reason I refer to these cases is to demonstrate that the common law, and through the Human Rights Act, there is an enforceable legal obligation against the state to operate systems of public healthcare in a way which does expose individuals to individual risk of harm. If those systems are patently inadequate, or fail to respond to risks appropriately, then the NHS is exposed to liability not just in tort for individual failings, but under human rights legislation for systemic failings. For those who say: "*it should never happen again*", enforceable rights in the hands of the patient against the NHS, at least where there are serious systemic failures which cause proven harm, are part of the safeguard against recurrence. Such an ability to bring proceedings – where justified, also responds to a commonly understood desire to bring persons responsible for what are alleged to be serious or gross system failures to account.

12. It is of note therefore that Mid Staffs has had its casualties in that sense. The then Chief Executive of Mid Staffs left his post for ill health reasons never to return. The

then CQC chief Cynthia Bower, (after some pressure) resigned, and Sir David Nicholson (after some delay) likewise. But it was by no means all one way. Julie Bailey, who founded Cure the NHS as a group to seek to improve the health standards of her local hospital, was herself hounded out of Stafford. The Support Stafford Hospital Facebook page accused her of "wrecking health services in the town" and one post said her award of CBE was a "*complete insult*" to hospital staff.

13. In terms of accountability at law, however, the very real problem was, or is the limited scope for a claim under the HRA (essentially against the state, or state actors e.g. institutions) and the limited remedy available (declarations of violation rather than damages as a primary remedy) was that such claims are expensive to bring and difficult to prove and may yield little or nothing in terms of damages.

14. It will be seen from what follows that the new Regulations to be laid before Parliament, now look to confer enforceable (in criminal law at least) duties on NHS professionals and institutions in respect of fundamental standards of care. This (as will be detailed later on) is a fundamental and important change to the legislative powers that exist to regulate and enforce, what for want of a better word may be called healthcare system failure.

15. Turning then to the key themes of the Inquiry and how they have been dealt with.

(1) Fundamental Standards

15. Virtually all of the recommendations in the Francis Report were accepted by the Department of Health. The government published an initial response to the Report in March 2013: *Patients First and Foremost*. A longer response: *Hard Truths: the journey to putting patients first,* was published in November 2012.

16. In terms of fundamental standards the key recommendations concerned the reporting and publishing of standards information and encouraging staff to contribute to the improvement of standards within hospitals. As was explained in the Executive Summary to the Report at 1.118-20:-

"...there needs to be a relentless focus on the patient's interests and the obligation to keep patients safe and protected from substandard care. This means that the patient must be first in everything that is done: there must be no tolerance of substandard care; frontline staff must be empowered with responsibility and freedom to act in this way under strong and stable leadership in stable organisations.
1.119 To achieve this does not require radical reorganisation but re-emphasis of what is truly important:
- Emphasis on and commitment to common values throughout the system by all within it;
- Readily accessible fundamental standards and means of compliance;
- No tolerance of non-compliance and the rigorous policing of fundamental standards;
- Openness, transparency and candour in all the system's business;
- Strong leadership in nursing and other professional values;
- Strong support for leadership roles;
- A level playing field for accountability;
- Information accessible and useable by all allowing effective comparison of performance by individuals, services and organisation.

1.120 By bringing all this together, all who work to provide patient care, from porters and cleaners to the Secretary of State, will be working effectively in partnership in a common and positive culture."

(2) Openness transparency and candour

17. In the Government's second volume of response (which runs to some 248 pages) the government set out a commitment to introduce significant changes to the way in which the healthcare system operates including a proposal to legislate to create a duty of candour for providers and the development of a criminal charge of wilful neglect.

18. A consultation was conducted and draft regulations are to be approved and come into force in October. It is worth looking at those regulations in some detail because in terms of learning lessons and accountability, it perhaps a marker for what to expect in terms of enforceability. They go much further than simply dealing with the duty of candour –although the fact that they deal with it at all has been a very significant victory for those who have argued that patients need such a duty to be written into contractual terms of employment, and capable of enforcement at least by the Regulator.

19. Of particular note is Regulation 5 which lays down a new fit and proper person requirement that must be met by directors of an NHS trust, an NHS foundation trust or

a Special Health Authority that carries on a regulated activity. This responds to the concern raised throughout the Independent and Public Inquiry, that there was no effective enforcement or regulation of the managers of NHS Trusts and NHS Foundation Trusts. The requirement lays down criteria to be met by such directors, including that they are of good character and that none of the grounds of unfitness specified in Part 1 of Schedule 4 apply. A person must not perform the relevant role if they fail the fit and proper person requirement. A health service body that fails to comply with this requirement could have a condition imposed on its registration with the Care Quality Commission, requiring it to comply with the requirement, under section 12(5)(b) of the Act.

20. Fundamental standards are then dealt with at Regulations 8-19. Regulation 20 lays down a further fundamental standard to be met by health service bodies. The fundamental standards provide that:

    (a) care and treatment must be appropriate and reflect service users needs and preferences (regulation 9);

    (b) service users must be treated with dignity and respect (regulation 10);

    (c) care and treatment must only be provided with consent (regulation 11)

    (d) care and treatment must be provided in a safe way (regulation 12);

    (e) service users must be protected from abuse and improper treatment (regulation 13);

    (f) service users' nutritional and hydration needs must be met (regulation 14);

    (g) all premises and equipment used must be clean, secure, suitable and used properly (regulation 15);

21. These are very far reaching and novel provisions. They criminalise activity which might not (because it does not result in provable personal injury) be actionable in civil proceedings, because the essence of any action in negligence is damage, and in personal injury claims, under the CPR, personal injuries means, any physical or mental *impairment*. Absent provable injury or impairment no action in tort will lie. Although potentially an HRA claim is possible in such cases, such litigation is expensive, and not (or at least not obviously) covered by Qualified One Way Costs Shifting, and is unlikely to yield any, or any significant quantum of damages thus rendering it unviable.

22. Regulation 21 requires registered persons to take into account guidance issued by CQC and the Code of Practice issued by the Secretary of State under s.21 of the Act with regard to the prevention or control of health care associated infections.

23. Regulation 22 creates offences in relation to the breaches of requirements in regulation 11 (need for consent); 12, 13(1)-(4), 14, 16(3), 17(3) or 20(2)(a) and (3) and also includes a due diligence offence. It is worth setting that out in full:-

> ***Offences***
> *22.—(1) It is an offence for a registered person to fail to comply with any of the requirements in*
> *the following regulations, as read with regulation 8—*
> *(a) regulation 11,*
> *(b) regulation 16(3), or*
> *(c) regulation 17(3).*
> *(2) A registered person commits an offence if the registered person fails to comply with a requirement of regulation 12, 13(1) to (4) or 14, as read with regulation 8, and such failure results in—*
> ***(a) avoidable harm (whether of a physical or psychological nature) to a service user,***
> ***(b) a service user being exposed to a significant risk of such harm occurring, or***
> *(c) in a case of theft, misuse or misappropriation of money or property, any loss by a service user of the money or property concerned.*
> *(3) It is an offence for a health service body to fail to comply with regulation 20(2)(a) and (3).*
> *(4) But it is a defence for a registered person, or (in the case of regulation 20(2)(a) and (3)) a health service body, to prove that they took* ***all reasonable steps and exercised all due diligence to prevent the breach of any of those regulations that has occurred.*** *"*
>
> ***Offences: penalties***
> *23.—(1) Paragraph (2) applies if section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012(a) is in force on the day these Regulations are made.*

(2) A person guilty of an offence under regulation 22(1) for breach of regulation 11 or an offence under regulation 22(2) is liable on summary conviction to a fine.

(3) Paragraph (4) applies if section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 is not in force on the day these Regulations are made.

(4) A person guilty of an offence under regulation 22(1) for breach of regulation 11 or an offence under regulation 22(2) is liable on summary conviction to a fine not exceeding £50,000.

(5) A person guilty of an offence under regulation 22(1) for breach of regulation 16(3) or 17(3) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.

(6) A health service body guilty of an offence under regulation 22(3) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale

24. The duty of candour is dealt with in the Regulations as follows:-

Duty of candour

20. (1) A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—

(a)notify the relevant person that the incident has occurred in accordance with paragraph (3), and

(b)provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—

(a)be given in person by one or more representatives of the health service body,

(b)provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,

(c)advise the relevant person what further enquiries into the incident the health service body believes are appropriate,

(d)include an apology, and

(e)be recorded in a written record which is kept securely by the health service body.

(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—

(a)the information provided under paragraph (3)(b),

(b)details of any enquiries to be undertaken in accordance with paragraph (3)(c),

(c)the results of any further enquiries into the incident, and

(d)an apology.

(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body—

(a)paragraphs (2) to (4) are not to apply, and

(b)a written record is to be kept of attempts to contact or to speak to the relevant person.

(6) The health service body must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

"apology" means an expression of sorrow or regret in respect of a notifiable safety incident;

"moderate harm" means—

(a) harm that requires a moderate increase in treatment, and
(b) significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

"notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
(b) severe harm, moderate harm or prolonged psychological harm to the service user;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

(a) on the death of the service user,
(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
(c) where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter;
"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain

damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

25. It may be seen from the above summary that the Regulations are quite far reaching and create criminal offences. They are not it seems intended to create civil liability at the suit of a private individual, and there is no suggestion in the Regulations that they do so. There is also, unlike say, the provisions in relation to statutory nuisance, no apparent ability for the private individual to bring criminal proceedings relying on the Regulations. Rather the power to take proceedings under the Regulations is given to the CQC under its enforcement powers.

26. The Government's consultation response on the draft regulations makes clear that the Duty of Candour will be introduced for NHS bodies only in October 2014, (along with the fit and proper persons requirement). Fundamental standards will be introduced for all providers by April 2015.

27. That response also explains the four-fold reasons for the introduction of the Regulations:-

(i) To introduce fundamental standards
(ii) To make regulations more effective and improve enforcement against them
(iii) To be outcome focused
(iv) To reduce the burden on business

28. Thus it is now (or will soon be the case) that enforceable fundamental standards will apply. It is worth recapping on those standards:

29. The fundamental standards are:

- care and treatment must be appropriate and reflect people's needs and preferences
- people must be treated with dignity and respect
- care and treatment must only be provided with consent
- care and treatment must be provided in a safe way
- people must be protected from abuse

- people's nutritional and hydration needs must be met
- all premises and equipment used must be clean, secure, suitable and be used properly
- complaints must be appropriately investigated and appropriate action taken in response
- systems and processes must be established to ensure compliance with the fundamental standards
- sufficient numbers of suitably qualified, competent, skilled and experienced staff must be deployed
- persons employed must be of good character, have the necessary qualifications, skills and experience, and be able to perform the work for which they are employed
- Providers must be open and transparent with people about their care and treatment (the Duty of Candour)

30. In many ways this is a landmark achievement and the culmination not just the Mid Staffs Inquiry but other key reports including :
    (i) Transforming Care: A national response to Winterbourne View
    (ii) A promise to learn – a commitment to act: Improving the safety of patients in England (the Berwick review); and
    (iii)Healthy Living and Social Care theme of the Red Tape Challenge. (Government further response to Mid Staffs).

31. Obviously there will be practical challenges ahead, and these Regulations will require a little working out in practice. It remains to be seen how easy (or difficult) they are to enforce, and the appetite which the CQC has for enforcement against either individuals or health bodies. But it is difficult to deny that in terms of lessons learnt, the "stick" of enforcement (much in the same way as Health and Safety, and Environmental Prosecutions are used to maintain standards, is capable of being an effective means of ensuring the key lessons from Mid Staffs are learned in the future.

(3) Nursing standards

32. As may be seen from the above, the Regulations include fundamental standards as to: sufficient numbers of suitably qualified, competent , skilled and experienced persons being deployed to meet the requirements of the Regulations.

33. The Francis report fell short of recommending minimum staffing numbers or skill:mix ratios in respect of nursing. The recommendation instead was that NICE develop evidence-based tools for establishing the staffing needs of each service.

34. The problem of Mid-Staffs, or at least one of the key problems was the need to deliver cost savings at the same time as delivering an appropriate standard of care.

35. In the relatively recent Nuffield Study: *The Francis Report: One year on* Sir Robert Francis QC (as he now is) explained that this problem (or the NHS's response to it) does not appear to have gone away:-

> "*Perhaps of most concern are the reports suggesting a persistence of somewhat oppressive reactions to reports of problems in the meeting financial and other corporate requirements. It is vital that national bodies exemplify in their own practice the change of cultural values which all seem to agree is needed in the health service. This may mean a reconsideration of the expression of priorities, behaviour and language, and the reaction to the inevitable tension between finance and quality that will arise in some trusts.*
>
> *If it is impossible, even with good practice, to provide the service required within the resources allocated then it is incumbent on leaders to communicate that openly to those responsible for commissioning and funding services. That then needs to lead to a frank discussion about what needs to be provided within the available resources and what cannot. It is unacceptable to pretend that all can be provided to an acceptable standard when that is not true.*"

36. This point goes wider than nursing, and applies across the board. It has to do with a willingness to be candid and frank, both by hospital staff and managers, but also by local and central government, and CCGs. As the Nuffield Study explains, the NHS Budget has been frozen in real terms since 2010/11 and no significant increases will

occur before 2015. The NHS has identified that it needs to deliver savings equivalent to £20 billion between 2011/2012 and 2014/2015. Staff wages may be frozen, and reductions in the tariff paid for hospital procedures may make some inroads into this figure, but it is very difficult to believe that the full commitment to the standards in the Regulations can be met at the same time as delivering such savings. Something has got to give.

(4) Patient centred leadership

37. Again this topic is dealt with at least up to a degree by the inclusion of fit and proper person test in the governance of NHS institutions. But another aspect of the concern in Mid Staffs was the inability (or seeming inability) of the local population through the Links organisations to have any real effectiveness as a watchdog or protector of the best interests of patients. The duty under 14Z(2) of the NHS Act 2006 requires a large degree of public involvement at every stage of the commissioning cycle. But that duty was in existence at the time of Mid Staffs (old s.242 of the Act). What has changed? My provisional conclusion is regrettably, not much. Absent clear enforcement rights, if a Links was ineffective before, it is difficult to see why Healthwatch should be more effective.

38. Another aspect in which the organisation of the healthcare system has been brought closer to the patient and away from the 'managers' is by the creation of the CCGs in place of the PCTs. The jury is probably out on whether this has been a helpful innovation. There was a sense at the Mid Staffs Inquiry, that PCTs were only just reaching maturity as an organisation and understanding properly their roles and responsibilities. It was at this very point that they were being disbanded and replaced by CCGs, putting the commissioning power back in the hands of doctors. But old hands in the NHS at the Inquiry felt they had seen it before and indeed that the in some sense the NHS not evolving, but revolving, as old methods or approaches are recycled and repackaged as the latest new idea. If there was one message which came out clearly from many of the health bodies it was a strong resistance to fundamental or radical change, and it is a tribute to the sense, and care with which Robert Francis Q.C. fashioned his recommendations that he avoided radical change and sought rather to

change attitudes, culture, and standards by remphasising certain key fundamentals, and ensuring there was a means of enforcement for them.

(5) Information

39. Finally the last domain of the recommendations was information. One has to be very cautious about this because there is the well known risk that too much information may mean that the really important messages may be drowned out or buried in a mass of irrelevant data. Sir Brian Jarman, who, at the Inquiry was the eminence grise of the mortality statistics data and the person who alerted (although their response was too late) the relevant regulatory bodies and Mid Staffs itself to the excess mortality at that hospital was inclined to the view that fewer better information and reporting systems were likely to be more effective. But whatever view one has, availability of information, - whether it be publication of staffing numbers on a ward, or candour as to untoward incidents in the complaints and reporting process, is essential.

Overall

40. Overall, in terms of lesson learned, the proof may well be in the Regulations and how they come to be enforced (or not) by the CQC. Those Regulations embody the fundamental standards which Robert Francis QC recommended.

41. It cannot be said that the Government have not listened, or acted, they plainly have, but the wider challenges, in particular the 'culture' of the NHS, its willingness to be frank and open, and the extent to which it can be honest when dealing with the challenge of delivering financial savings at the same time as acceptable standards of care, remains to be seen. It is perhaps encouraging that the Nuffield Study felt that some Trusts felt empowered by the Francis report to champion quality over finances, and felt it gave them a basis on which to fight against unrealistic financial pressures from those who commission and organise healthcare.

42. It is hoped that the enforceable standards in the Regulations combined with a duty to speak up and out, about mistakes and errors will, over time, deliver the cultural change to the NHS which the Francis Report identified as being critical to its long-term success, and ultimately, survival.

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