

**A NEW ERA OF ENFORCEMENT OF HEALTH AND SAFETY LAW IN HOSPITAL CARE?
THE ROLES OF THE HSE AND CQC POST-STAFFORD**

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1. In February 2013, the Francis Report² into the scandal of appalling care in Mid Staffordshire called for a bold new application of health and safety-style offences to the healthcare sector. In its detailed response to the Report, the Government on 19th November 2013 endorsed the Report's recommendations, pledging new measures to punish failures in care using the criminal law. But who will police the new frontier, and how will the changes alter the roles of the Health and Safety Executive and the Care Quality Commission?
2. This article seeks to explain the impetus for the Public Inquiry's recommendations, and how the Government's new reforms may affect the place of the HSE and the specialist regulator, the CQC, in the future. It makes clear that there we are entering a new era of criminal enforcement of basic standards of care, but that questions remain as to whether the HSE will retain a significant role for itself in policing clinical standards and quality.
3. The scandal of Mid Staffordshire was one involving not just harrowing stories of individual patients forced to endure shocking conditions, but of the comprehensive failure of systems of clinical care which often lay beneath those accounts of suffering.
4. The Public Inquiry into these events highlighted, for example, an Emergency Department operating without some of the basic requirements of modern hospital care, such as clear local protocols for the treatment of patients or systems of clinical audit to monitor results. It discovered a dysfunctional surgical division where clinicians refused to speak to one another. It shone a light on woefully inadequate staffing levels and appalling standards of

¹ www.qebholliswhiteman.co.uk

² Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, published February 2013.

cleanliness. It exposed a systemic failure to learn from incidents of patient harm to prevent repetition in the future.³

5. Those working in industries outside the healthcare sector might well have anticipated vigorous investigation and indeed prosecution by the Health and Safety Executive if they operated such substandard systems for preventing harm to the public. However, that has not generally been the story at hospital trusts like Mid Staffs. Why?
6. The answer may be apparent from the response of the HSE to the tragic death of Gillian Astbury at Stafford Hospital in 2007, which exposed the HSE's reluctance to enter the healthcare fray.
7. Mrs Astbury, a confused insulin-dependant diabetic patient, was admitted to the hospital with a fractured leg and pelvis in early April of that year. Her medical records contained numerous references to the need to monitor her blood sugar levels and to administer insulin. However, following a transfer between wards, the nursing shift coming on duty to care for Mrs Astbury appears to have missed entirely the need to conduct the necessary observations or administer her medication.
8. Three days after her transfer to Ward 8, she died. She was aged 66. Professor Tattersall, the forensic pathologist engaged by the police in the wake of her death, gave the cause of death as diabetic ketoacidosis. The clear implication was that Mrs Astbury had died as a result of a failure to monitor and control her diabetes.⁴
9. The Trust's own internal investigation into the death identified a plethora of serious failings in standards and systems of care, including a failure to administer prescribed drugs, a failure to undertake nursing handovers properly or at all, a failure to conduct ward rounds properly and a failure effectively to make and record care plans.⁵
10. The jury at the inquest into Mrs Astbury's death in 2010 stated in a damning narrative verdict, "The failure to give insulin and measure blood sugar levels on 10 April 2007 was clearly a gross failure to provide basic care."
11. The HSE was aware of these failings from an early stage. In 2008, the Principal Inspector for the HSE with responsibility for the Trust stated in an email to the police, "My conclusion is that there appears to be systemic clinical management and individual(s) failure in respect of Gillian Astbury."⁶

³ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Executive Summary, page 41-.

⁴ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 1, page 103-106.

⁵ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 1, paragraph 1.186, page 104; Public Inquiry document reference WS0000001358.

⁶ Public Inquiry exhibit CB/43, WS0000051679.

12. Until 2013, however, the HSE refused to launch a prosecution - only doing so after the conclusion of the Public Inquiry and increased public pressure to bring accountability to the Trust.
13. To many, this refusal simply reflected a long-established reluctance to become involved in cases relating to inadequate clinical care or poor standards of care quality.
14. It is a reluctance established not by law, but by the HSE's own policies. Indeed, the breadth of section 3 of the Health and Safety at Work Act 1974 means that it is perfectly possible for the HSE to prosecute a hospital trust for exposing patients to risks to their health or safety.⁷ There is no derogation for healthcare.
15. Nonetheless, the HSE's policy has for years operated to limit severely its operation in the healthcare environment. Its published 'priorities' for the enforcement of section 3 state, "HSE does not, in general, investigate matters of clinical judgment or matters related to the quality of care. HSE deal with the major non-clinical risks to patients such as trips and falls, scalding, electrical safety etc; and with some aspects of risks that apply to both staff and patients alike, such as manual handling..."
16. The 'priorities' reflect a more general policy that where an area of work was subject to its own specialist regulator (such as the Healthcare Commission, latterly the Care Quality Commission), the HSE would not treat that area as a priority for its own involvement.
17. The effect of this policy, as the HSE's principal inspector told the Public Inquiry, was to establish that "the primary duty of the HSE is to ensure the health and safety of employed persons in the healthcare sector" - in other words, not to ensure the health and safety of patients.⁸
18. Here then, is the explanation for the principal inspector's ultimate message to the police in 2008, after he had conceded the existence of systemic clinical management failures in the case of Mrs Astbury. In the email highlighted above, he went on to say, "I have therefore to advise you that as no equipment or structural condition has been identified as a causal factor...I am sorry to say that I am unable to assist you in my opinion."⁹
19. Over the following years, pressure on the HSE for a formal investigation and prosecution from Mrs Astbury's family and friends grew. This pressure led the HSE to acknowledge that it had the power to take action in cases like Mrs Astbury's, but to explain that whether it actually would do so involved consideration of a raft of competing factors, not least whether the public

⁷ Section 3, Health and Safety at Work Act 1974.

⁸ Witness statement of Clive Brookes to the Public Inquiry, paragraph 19.

⁹ Public Inquiry exhibit CB/43, WS0000051679.

interest lay in the prosecution of a hospital trust that had already been the subject, by 2008/9, of extensive intervention from outside bodies.

20. The HSE even postponed its final decision on whether to take formal action against the Trust until after the Public Inquiry had reported. From one perspective, this allowed the HSE to gauge the public interest in the light of the fullest information. However, to some this delay appeared simply to demonstrate the HSE's traditional reluctance to interfere in matters of clinical care.
21. Of vital importance to the critics of the HSE's inaction was the fact that there appeared to be no other regulator which would or could pursue a criminal prosecution for the Trust's failings in respect of cases like Mrs Astbury's. This was because, whilst the HSE justified its own limited role in healthcare by pointing to the existence of a specialist regulator in the field, that regulator (the Healthcare Commission until 2009, then the CQC) never prosecuted organisations for such individual incidents of poor care.
22. The result was what Robert Francis QC described in the Public Inquiry report as a clear "regulatory gap."¹⁰
23. He explained, "Whatever is decided about the Mrs Gillian Astbury case, the regulatory gap needs to be closed as a matter of urgency. It should be recognised that there are cases that are so serious that criminal sanction is required, even where the facts fall short of establishing a charge of individual or corporate manslaughter. There will be cases, even where they involve clinical judgment, that expose serious system failings, and grossly incompetent management and procedures, not confined to issues of defective equipment."¹¹
24. Francis' proposal was, however, that it was the CQC (rather than the HSE) that should be responsible for policing health and safety law in the sphere of healthcare provision. It was the CQC that had the specialist knowledge and access to information about standards of care in hospitals to regulate this area most effectively.
25. His Recommendation 87 suggested: "The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the Care Quality Commission should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the Care Quality Commission has power to launch a prosecution."¹²

¹⁰ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, paragraph 13.154.

¹¹ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, paragraph 13.154.

¹² Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Executive Summary, Recommendation 87.

26. In its published response to the Public Inquiry recommendations, the HSE endorsed Recommendation 87 as presenting “the best regulatory solution,” whilst emphasising that it would continue to prosecute cases involving harm to those who work in the healthcare sector.¹³
27. Whilst the HSE made clear that it would re-examine the merits of taking formal action in the case of Gillian Astbury in light of the Public Inquiry’s findings, it was plainly the HSE’s preference that the CQC should be the body responsible for policing standards of care in hospitals.
28. Perhaps one could then be forgiven for thinking there had been a shift in the HSE’s approach when the decision was finally made in August 2013 to prosecute the Trust in respect Mrs Astbury’s death. But such suggestions were vehemently denied by the HSE.
29. Responding to an article in The Guardian on 29th August,¹⁴ the HSE’s Acting Chief Executive Kevin Myers said, “Your article implies HSE’s prosecution of Mid Staffordshire NHS Foundation Trust is a change in its regulatory role in the health service. This is not the case. HSE has previously prosecuted NHS providers, including trusts, in relation to similar incidents.”
30. However, the response also conceded that where safety management failings in the past had been deemed to be clinical or professional failures, “other regulators have been considered better placed to lead.” And it will still appear to many that the decision to prosecute the Trust was a departure from the HSE’s traditional approach in the wake of the Francis Report’s clear call for the more rigorous application of health and safety law in this environment.
31. Furthermore, the Trust’s guilty plea in October 2013 to failing to ensure the safety of Mrs Astbury appears to be a victory not just for her friends and family, but also for the principle of more rigorous enforcement of basic standards of care through criminal proceedings.
32. But is there any prospect that the principle will be applied more widely by the HSE in the future, or is the Astbury case an anomaly? For that, one must look to the Government’s lead.
33. The desire for a new era of enforcement and accountability through the criminal law that was so central to the Francis Report has now been endorsed in the Government’s detailed response to the Public Inquiry. The Government has accepted the Report’s Recommendation 87 in principle. It proposes that trusts should be held to account through criminal prosecution, without the need for any advance warning notice, where

¹³ Health and Safety Executive Board Paper 2013/69261, 27th February 2013.

¹⁴ *Mid Staffs NHS Trust to be prosecuted over death of diabetic patient*, The Guardian, 29th August 2013.

patients have been harmed because of unsafe care in breach of fundamental standards. This advance is clearly intended to fill the “regulatory gap” identified by Robert Francis by introducing criminal offences comparable to those in the Health and Safety at Work Act 1974 to healthcare.¹⁵

34. One must also note other new criminal laws proposed by the Government, in particular the creation of the offence of wilful or reckless neglect or mistreatment of patients, upon which the Government will consult with a view to legislation as soon as possible.¹⁶
35. It seems fair to conclude that the Francis Report may have ushered in a new era of criminal enforcement in the healthcare sector. Those charged with managing provider organisations will need to be mindful of the new risks of prosecution and, as Robert Francis clearly intended, ensure that their systems of clinical and quality governance function effectively.
36. However, the place of the HSE in the new order remains unclear.
37. It is true that the Government agreed with the Francis Report when it stated in its response, “The Care Quality Commission is the right organisation to focus on healthcare, investigate and act where patients have been seriously harmed because of unsafe or poor care.” It is telling that, rather than extend the application of the Health and Safety at Work Act 1974 to all aspects of healthcare, the new offence of causing harm through a breach of fundamental standards of care has been proposed, and that it is to be policed by the CQC rather than the HSE.¹⁷
38. However, almost in the same breath, the Government’s response states, “The Department [of Health] is also working with the Care Quality Commission and the Health and Safety Executive to ensure that the Health and Safety at Work Act 1974 and its relevant statutory provisions will continue to be used by the Health and Safety Executive where it provides for the most specific breaches. Given the Health and Safety Executive’s more limited role for patient safety, the Care Quality Commission and the Health and Safety Executive will together develop and agree criteria and handling arrangements for the matters that the Health and Safety Executive will investigate.”¹⁸

¹⁵ *Hard Truths: The Journey to Putting Patients First*, the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 2 page 79.

¹⁶ *Hard Truths: The Journey to Putting Patients First*, the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 1 page 19.

¹⁷ *Hard Truths: The Journey to Putting Patients First*, the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 2 page 79.

¹⁸ *Hard Truths: The Journey to Putting Patients First*, the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 2 page 80.

39. It also proposes that, “The Health and Safety Executive will support the Care Quality Commission in developing its role in investigating and prosecuting in cases of unacceptable care.”¹⁹
40. In addition, it remains to be seen which organisation will be put forward to enforce the new criminal neglect or mistreatment offence. Will this be a matter for the police, for the specialist regulator, or the HSE?
41. In short, the HSE is far from out of the healthcare sector. It will continue to have a role in investigations and will retain its powers of criminal prosecution in this arena. It will continue to have to make difficult decisions about when it will take action and when it will not.
42. It remains to be seen what the reference to the HSE continuing to prosecute “the most specific breaches” means. Does it mean, for example, cases like that of Mrs Astbury? On the face of it, the HSE’s age old problem of drawing the line between “systemic” failures where it might take action, and clinical or care standards failures, where it would be unlikely to get involved, appears still to be a live one.
43. Those operating in this area will need to keep a careful eye out for news of the proposed agreements between the CQC and HSE which should help to demarcate more clearly the areas of responsibility of these two bodies. Then, of course, one will have to observe how the HSE interprets its new role and priorities for the enforcement of health and safety law.
44. At present, though, what is clear is that both the CQC and the HSE will be actively involved in enforcing health and safety-style law in hospital trusts for the foreseeable future, and that this really is a new era of enforcement in a sector that has largely escaped criminal sanctions until now.

¹⁹ *Hard Truths: The Journey to Putting Patients First*, the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 2 page 80.