How did we miss the warnings?

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Organisations which had a role in commissioning, regulation etc at Mid Staffs

- Healthcare Commission (CQC from April 2009)
- SHA - responsible for performance management of trusts
- Monitor – financial regulator but ? of quality of care
- PCT – ‘World Class Commissioning’
- Parliamentary and Health Service Ombudsman
- Patient support PPIF, LINk, POhWER, the oversight and scrutiny committees, the NHSLA, the GMC, the NMC, the HSE, National Confidential Inquiry into Patient Outcome and Death, National Patient Safety Agency, Patients Association, the deaneries responsible for training graduate doctors, the PMETB, the universities responsible for training nurses, the relevant unions, the Royal colleges, the coroner.
Healthcare Commission (CQC from April 2009)

- Used the Annual Health Check (AHC)
- AHC depended on (inaccurate) self-reporting
- Also used Imperial College monthly mortality alerts – prompted HCC to contact Mid Staffs.
- Nigel Ellis, Head of Investigations at the Healthcare Commission, says in paragraph 96 of his statement to the Inquiry "The concerns from local patients obviously added significantly to our level of concern about the Trust but it is important to clarify that these concerns were raised with us after the mortality alerts had caused HCC to contact the Trust."
Strategic Health Authority

- SHA - responsible for performance management of trusts

Health Select Committee, 5 March 2013
Sir David Nicholson, CE SHA then NHS

- Question Q203
- Barbara Keeley: You could order up the data. Anybody in your structure, anybody in the PCT, could have said, “We have an issue here. We have a set of issues here. Things are going badly wrong. Let’s not leave it to them. Let’s ask some questions. Let’s get the data.”

- Sir David Nicholson: The point is that the data that was available to the PCT, to the general practitioners, to the regulators, to all of those, did not indicate at that time that there was a problem in that organisation.
The information available that indicated the problem at Mid Staffs

1. Hospital Standardised Mortality Ratios (HSMRs) were published in national newspapers annually from 2001.

2. SHA acute hospital trusts had contracts with Dr Foster and logged on to the Dr Foster Real Time Monitoring system over 8000 times and saw the mortality alerts as the default.

3. Mid Staffs CE received 4 mortality alert letters from Imperial Jul to Nov 2007.
Mortality alert from Imperial College to CE Mid Staffs 29 June 2007

Mid Staffordshire General Hospitals NHS Trust

Operations on jejunum
G58, G68-G71, G78

This chart indicates that on at least one occasion in April 2007, risk-adjusted mortality of double the expected rate was recorded at this trust for this diagnosis or procedure.
Anonymised version of a monthly alert letter
Sent to trust Chief Executive (copied to the CQC)

Dear,

MORTALITY OUTLIERS

We are writing to share with you in confidence an analysis of mortality data which indicates higher than average mortality rates within your hospital trust (Appendix 1).

The Dr Foster Unit at Imperial College (DFU) routinely analyses Hospital Episode Statistics (HES) and Secondary Uses Service (SUS) data for a wide range of diagnoses and procedures, computing risk-adjusted mortality rates for hospitals. In the course of this work we have come across examples of mortality rates in various trusts significantly in excess of what would be expected, given the risk profile of the relevant patients.

There are a number of possible reasons for these results, including random variation, poor data quality or coding problems, and case-mix issues, and we draw no conclusions as to what lies behind the figures. However, as clinicians we believe we have a duty under the GMC Good Medical Practice code to alert trusts to this analysis since there is a possibility that it indicates areas where patients may be at risk.

We therefore piloted a system of mortality alerts to trusts in 2007 and received very valuable feedback. As a result of the pilot we have made a number of changes for the roll-out of the alert system. First, we have limited the procedures and diagnoses we monitor for the purposes of this alert system, as we wish to restrict alerts to areas where there is most likely to be a clinical issue. Second, we have increased the amount of information supplied with the alerts. The short briefing note at Appendix 2 explains our methodology and alert process in more detail, including the criteria we have used for alerting trusts.

Third, we have decided to share alerts routinely with the Care Quality Commission. The general view of the trusts we consulted in our pilot was that it was appropriate for the Commission to receive this information as part of the wide range of data it receives about individual trusts. The Commission has said that it will consider these alerts using its own internal analytical process and then decide whether or not they represent a concern in the context of all the other information it holds with respect to the trust. The Commission will follow these up by writing to you either asking for further information or to inform you that it has no current concerns.

Yours sincerely,

[Signatures]

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Monitor and the PCT

- **Monitor** - The Trust’s application for FT status largely focused on financial and governance rather than quality issues.
- The senior leadership of the SHA was aware of critical diagnostic findings, and yet did not think to look at whether a trust with such problems was actually delivering safe and acceptable care.
- The assessment process leading up to the Minister giving his support did not provide him with adequate information. No mention of the HSMR of 127 or quality of care problems.
- The HCC was unaware at national level that an application for FT status was pending (although the HCC’s regional team was aware of the application).
- Monitor remained unaware of the HCC’s concerns about the Trust until after it authorised the Trust as an FT.
- **PCT** – ‘World Class Commissioning’
- Joint Commission report on NHS, commissioned by DH: ‘Quality today does not drive or even influence commissioning decisions.’
HSE, CQC, PHSO

- **HSE** - Health & Safety Executive decided not to involve itself in healthcare cases

- **CQC** – Care Quality Commission - primary responsibility is to regulate against the essential standards and correct care that is not compliant. It is not to investigate possible individual instances of clinical failure or clinical quality.

- Francis 6/2/13, p60 1.91: “This has led to a regulatory gap which needs to be closed.”

- **PHSO** – Ombudsman did not investigate any complaints relating to events that occurred during the period by the Mid Staffs Public Inquiry.
A more detailed breakdown of inquiries received about the Trust and the outcomes appear in the tables below.

Table 3.2: Inquiries received by the PHSO about the Trust

<table>
<thead>
<tr>
<th>Time period</th>
<th>Inquiries received by the Ombudsman</th>
<th>Inquiries closed as not made in line with legislation</th>
<th>Inquiries withdrawn by the complainant</th>
<th>Premature inquiries returned to the Trust or the HCC</th>
<th>Inquiries for which the Ombudsman used its discretion not to investigate</th>
<th>Complaints accepted for investigation by the Ombudsman</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/4/05-31/3/09</td>
<td>17</td>
<td>2</td>
<td>2</td>
<td>8</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1/4/09-31/3/10</td>
<td>33</td>
<td>12</td>
<td>3</td>
<td>13</td>
<td>5</td>
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<tr>
<td>1/4/10-30/6/10</td>
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<td>3</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>0</td>
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<td>Total</td>
<td>62</td>
<td>17</td>
<td>5</td>
<td>26</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>
Other warnings

- **Loss of star rating** – In 2004, the Commission for Health Improvement (CHI) re-rated the Trust, and it went from a three star trust to zero stars.

- **Peer reviews** – Peer reviews, including the Cancer Peer Review in 2005, the Care of Critically ill and Critically Injured Children’s Peer Review in 2006, and a follow up of the Children’s Peer Review, were conducted during this period. Each of these reviews identified a number of concerns, often serious concerns, with the Trust’s ability to deliver a safe service, and raised questions about management capability.

- **Surveys** – The HCC commissioned annual surveys of staff and patient opinion conducted by the Picker Institute. The results of the survey taken for the previous year were published in about April the following year. The 2007 inpatient survey, while identifying many areas in which the Trust did well or performed satisfactorily, in several areas rated the Trust as being in the worst performing 20% in the country.

- **Whistleblowing** – It is clear that a staff nurse’s report in 2007 made a serious and substantial allegation about the leadership of A&E - known to the Royal College of Nursing (RCN) because of its involvement with the personnel involved.

- **Royal College of Surgeons** report in January 2007 – The RCS reached critical conclusions about the operation and management of the Trust’s surgical department, which it described as “dysfunctional”. The report itself was known at the time only to the Trust and the relevant staff, and the Royal College. It showed a state of affairs which would have been expected to cause serious concern to the public, and any regulator, if known to them.

- **Trust’s financial recovery plan** and the associated staff cuts – Savings in staff costs were being made in an organisation which was already identified as having serious problems in delivering a service of adequate quality, and complying with minimum standards.
Had we been warned?

• The findings of the Bristol Inquiry into paediatric cardiac surgery 1999-2001 had many of the findings of the 2103 Francis

• There was a relaxation of some regulatory levers in the mid-2000s

• The Department of Health commissioned reports from 3 independent, respected US organisations for the 2008 Darzi review of safety in the NHS were critical.
Bristol Royal Infirmary

• The report of the Inquiry into paediatric cardiac surgery failings at Bristol Royal Infirmary, published in 2001, decided that
• "At a national level there was confusion as to who was responsible for monitoring quality of care."
• The Department of Health (DoH) accepted "that it is responsible and is accountable for any failings of the systems that were in place during the period covered by the Inquiry."
• The Inquiry concluded "The DoH, for historical and structural reasons, was simply unable adequately to respond when an issue of the quality of care was being raised. This is profoundly unsatisfactory."
• "It would be reassuring to believe that it could not happen again. We cannot give that reassurance. Unless lessons are learned, it certainly could happen again, if not in the area of paediatric cardiac surgery, then in some other area of care."
Bristol Royal Infirmary

• An external investigation at Bristol led to improvements and the adjusted death rate dropped from 29% to 3% within three years.

• The parents of children operated on at Bristol should have been told that they could get a third of the mortality at another unit fairly near Bristol.
Paediatric cardiac surgical mortality in England after Bristol:
With the safety changes made after Bristol why Mid Staffs occur?

• The independent Community Health Councils were abolished in 2003.

• The Commission for Health Improvement (which detected problems at Mid Staffs in 2002) was abolished in 2004 and replaced by the Healthcare Commission, which was slow to detect the appalling events at Mid Staffordshire.

• The Independent Review Panels that investigated patients’ complaints about hospital services not resolved at the hospital were abolished in 2004, and in 2011–12 only one of 375 written hospital complaints had been formally investigated by the Ombudsman.

• The National Patient Safety Agency (NPSA) acknowledged significant under-reporting of safety incidents and was later abolished, with its functions incorporated into the CQC.
Summary of selected findings of the IHI, Joint Commission International & Rand 2008 reports on NHS, commissioned by DoH

1. Culture of fear pervades the NHS management - Managers “look up, not out.”

2. Light-handed regulation – ‘annual on-site review sample is approximately 4%...’ ‘(20% of 20%)’ ‘This is generally worrisome, but it is of even greater import in the light of the fact that in the at-risk on-site evaluations, two-thirds of the assessments of standards compliance do not conform with the organization’s self-assessment findings,…’

3. Process of the Healthcare Commission is regulatory and gives no improvement advice or expectation of use of the core standards to drive improvement – ‘Quality today does not drive or even influence commissioning decisions.’

4. Poor clinical data

5. Virtual absence of mention of patients and insufficient data for patients to make informed choices Public engagement in the commissioning process is lacking.

6. Too much change and restructuring

HSMRs and mortality alerts had provided grounds for investigating the trust.

- The Department of Health chief analyst suggested it was a “system failure” not to have done monitored HSMRs, and Sir Bruce Keogh agreed that problems at Mid Staffordshire would have been spotted earlier by the Department of Health had that happened.

- “I am reasonably confident that the process which is now in place would have picked up the situation at the trust before it was granted Foundation Trust status. The HSMR information and the question in the staff survey about whether the member of staff would be happy for someone in their family to be treated at the hospital are two examples of where the problems at the Trust would have been identified by the current position.”

- Mid Staffs Public Inquiry, Statement of Sir Bruce Keogh, p 68, para219
Pressures mentioned by the 3 Regulators’ Chairmen:

1. Ian Kennedy, Chair of the Healthcare Commission, stated: “The engagement of the Department of Health was one of interest... quality of the care provided by the NHS was not part of their agenda.”

2. Barbara Young, Chair of the CQC, stated: “The reason the government didn’t like tough reports was because they were running the services that were being reported upon.”

3. William Moyes, Chair of Monitor, stated: “The culture of the NHS, particularly the hospital sector, I would say, is not to embarrass the minister.”

- The then Minister Andy Burnham said: “The impression of us all was that we would just, you know, constantly do what was meant to be the thing that Number 10 wanted or that we were all, you know, unthinkingly piling this stuff through. We weren’t.”
Sir David Nicholson’s statement to the Mid Staffs Inquiry:

The Board of Mid Staffordshire failed in its statutory duties to provide good quality care to its patients and managing within the resources provided. That no other hospitals failed so profoundly and persistently in this period, serves to emphasise the singular rather than systemic nature of this case.

Mid Staffs Inquiry Counsel Closing Submission, Dec 2011:

- “With respect to him, this seems to us to be a very dangerous attitude to take”
- “As we indicated in our closing address to you the assumption should , we submit, be the very opposite.”
Action when the Francis Report was published

- On the day of the Francis report (6 Feb 2013), which documented the appalling care received at Mid Staffs, the Prime Minister David Cameron asked Sir Bruce Keogh to investigate the 14 trusts with the highest death rates.
- Keogh’s report found that none of the trusts could be given a clean bill of health and action plans were produced for each [he did not find Mid Staffs singular]
- Each trust needed to address an urgent set of actions in order to raise standards of care
- The Secretary of State for Health Jeremy Hunt announced that 11 of the trusts would be placed into special measures for fundamental breaches of care.
Firstly, we gathered and conducted detailed analysis of a vast array of hard data and soft intelligence held by many different parts of the system. This helped identify key lines of enquiry for the review teams, allowing them to ask penetrating questions during their site visits and to focus in on areas of most concern.

Secondly, we used multidisciplinary review teams to conduct planned and unannounced site visits. These teams, around 15-20 strong, were composed of patient and lay representatives, senior clinicians, junior doctors, student nurses and senior managers. The diverse make-up of these teams was key to getting under the skin of the organisations.

Thirdly, these review teams placed huge value on the insight they could gain from listening to staff and patients as well as to those who represented the interests of the local population, including local clinical commissioning groups and Members of Parliament. Unconstrained by a rigid set of tick box criteria, the use of patient and staff focus groups was probably the single most powerful aspect of the review process and ensured that a cultural assessment, not just a technical assessment, could be made.

Finally, once the teams had completed their reviews, we convened a meeting of all involved statutory parties - a Risk Summit - to agree with each trust a coordinated plan of action and support to accelerate improvement.
Could action have been taken earlier?

- The HSMRs of 11 of the trusts had been identified in the 2007 Dr Foster *Good Hospital Guide* as significantly high, including ten of the 11 that were placed into special measures in 2013.

- I notified seven of the 14 hospitals to the then Secretary of State for Health in March 2010 and he referred them to the CQC.

- However, individual cases of clinical quality were, and are, not investigated by the CQC or the Health and Safety Executive; the NHS has no investigator of poor clinical care [though that is changing].

- Francis [para 1.91, p 67] said that is a ‘regulatory gap that should be closed’
### The 11 of 14 trusts put into special measures

<table>
<thead>
<tr>
<th>Trusts included in The Keogh Mortality Review 2013</th>
<th>High HSMR April 2007</th>
<th>Special measures Jul 2013</th>
<th>code</th>
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<tbody>
<tr>
<td>BASILDON AND THURROCK UNIVERSITY HOSPITALS NHS FT</td>
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<td>yes</td>
<td>RDD</td>
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<tr>
<td>BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TR</td>
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<td>yes</td>
<td>RXL</td>
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<tr>
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<td>yes</td>
<td>RJF</td>
</tr>
<tr>
<td>EAST LANCASHIRE HOSPITALS NHS TRUST</td>
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<td>yes</td>
<td>RXR</td>
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<td>MEDWAY NHS FOUNDATION TRUST</td>
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<td>yes</td>
<td>RPA</td>
</tr>
<tr>
<td>NORTHERN LINCOLNSHIRE AND GOOLE HOSPITALS NHS FT</td>
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<td>yes</td>
<td>RNL</td>
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<tr>
<td>TAMESIDE HOSPITAL NHS FOUNDATION TRUST</td>
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<td>yes</td>
<td>RJL</td>
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<tr>
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<tr>
<td>BUCKINGHAMSHIRE HEALTHCARE NHS TRUST</td>
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<td>RWD</td>
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</table>
Measuring hospital performance Mortality rates

This table shows standardised mortality ratios for NHS acute trusts in England. Trusts are listed alphabetically and by low, average and high mortality ratio. Trusts are determined high or low if they fall outside 99.8 per cent (3 sigma) control limits on a funnel plot.

<table>
<thead>
<tr>
<th>Trust</th>
<th>Three-Year Mortality</th>
<th>Three-Year 95% Confidence Intervals</th>
<th>One-Year Mortality</th>
<th>One-Year 95% Confidence Intervals</th>
<th>Percentage Change (%)</th>
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</thead>
<tbody>
<tr>
<td>Aintree University Hospitals NHS Foundation Trust</td>
<td>87</td>
<td>85 – 90</td>
<td>86</td>
<td>81 – 90</td>
<td>-5.7</td>
</tr>
<tr>
<td>Airedale NHS Trust</td>
<td>87</td>
<td>84 – 91</td>
<td>91</td>
<td>84 – 98</td>
<td>-0.9</td>
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<tr>
<td>Ashford and St Peter’s Hospitals NHS Trust</td>
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<td>90 – 96</td>
<td>96</td>
<td>90 – 101</td>
<td>-3.0</td>
</tr>
<tr>
<td>Barts and The London NHS Trust</td>
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<td>82 – 88</td>
<td>89</td>
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<tr>
<td>Bradford Teaching Hospitals NHS Foundation Trust</td>
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<td>Brighton and Sussex University Hospitals NHS Trust</td>
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<td>81 – 90</td>
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<td>88</td>
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<td>88</td>
<td>80 – 97</td>
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<tr>
<td>City Hospitals Sunderland NHS Foundation Trust</td>
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<td>92 – 97</td>
<td>91</td>
<td>86 – 100</td>
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<td>93 – 98</td>
<td>95</td>
<td>91 – 100</td>
<td>-3.9</td>
</tr>
<tr>
<td>East Cheshire NHS Trust</td>
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<td>88 – 96</td>
<td>93</td>
<td>86 – 100</td>
<td>-10.6</td>
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<td>89 – 101</td>
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<td>69 – 74</td>
<td>75</td>
<td>71 – 80</td>
<td>5.8</td>
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DATA EXPLAINED

Mortality indicators explained

One-year mortality

The adjusted Hospital Standardised Mortality Ratio (HSMR) for 2005/06.

One-year confidence intervals

The lower and upper confidence intervals given year-to-year variations in the expected number of deaths for 2005/06.

Three-year mortality

The adjusted Hospital Standardised mortality ratio (HSMR) for 2003/06 for the conditions that lead to 80 per cent of deaths. 120 shows 20 per cent more deaths than expected. 80 represents 20 per cent fewer deaths than expected from Hospital Episode Statistics (HES) and NHS-Wide Clearing services (NWCS).
Combined HSMR of 10 trusts put into special measure in 2013 and also high in 2007.
Funnel plot showing change of NWLH HSMR 2006-7 to 2007-08

HSMRs 2007/08: NWLH 2006/07 HSMR shown with blue diamond, 2007-08 HSMR with red diamond (all HSMRs use year 2007/08 England HES data as reference baseline)
Some of the changes since the Francis Report (6 February 2013)

- The CQC Chairman, Chief Executive, and most of the Board have been changed and, with the Chief Inspector of Hospitals for England (Sir Mike Richards), the CQC will undertake thorough inspections in future using trained, professional investigators.
- The Parliamentary Health Service Ombudsman has called for improvements in the way hospital complaints are handled and said that she will formally investigate ten times as many patient complaints.
- There is an intention to abolish the widespread so-called gagging clauses that undermine the culture and transparency of the NHS.
- Francis has recommended a statutory obligation to observe a duty of candour for health-care providers and registered medical and nursing practitioners, and a criminal offence for non-compliance.
- Don Berwick’s report (August 2013) on patient safety for the Department of Health makes clear that it is important that this judicial intent does not lead to punishing or criminalising clinicians for unintentional mistakes or involvement in failed systems.
- I think there has been a marked change of attitude since the Francis Report.