D2/E2: Political Pressure: A Barrier to Safety in Health Care Systems

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This session should help participants to:

- Identify the barriers that have contributed to patient harm in national inquiries and appreciate the influence of external political pressures
- Review the professional commitment to protect patients
- Articulate the consequences of a culture of blame and secrecy and its effect on patient safety
Time allocation

2. Brian - background to the Mid Staff Inquiry
3. Julie - tells the story of her mother’s care and death, how she formed Cure the NHS [9:45 & 11:30]
7. Finish [10:45 & 12:30]

Background to Mid Staffs: the Bristol Inquiry 1999-2001

- 1986-1995 At Bristol the children’s heart surgery unit was thought, for a decade, to be poor
- 1992-1995 Steve Bolsin, a whistleblower, and Private Eye magazine drew attention to the problems: patients complaints eventually heard
- 1995 Two external cardiac surgeons did a one month investigation and made recommendations
- 1994/5 to 1996/7 mortality dropped 29% to 3.5%
- 1999-2001 Bristol Royal Infirmary Public Inquiry
Bristol Inquiry: concerns per year about Paediatric Cardiac Surgery 1986 to 1994

1986 ‘it is no secret that their surgical service is regarded as being at the bottom of the UK league for quality’.
CMO Wales expressed concerns to the CMO of England

New anaesthetist, Dr Bolsin, expressed repeated concerns - 1989 to 1995 both locally and nationally

1987 BBC Wales TV ‘Heart Surgery - 2nd class Service’


Article in Daily Telegraph, 5/4/1995


1993 1994

Paediatric cardiac surgical mortality in England after Bristol:
BMJ 2004; 329 : 7 October 2004
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Who was responsible for monitoring quality of care?

- Clinical outcomes Group
- Performance Management Directorate
- Bristol Inquiry: “…the Department of Health accepts that it is responsible and is accountable for any failings of the systems that were in place during the period covered by the Inquiry. Ultimate responsibility rests with the Department of Health and the Secretary of State.”
- Bristol Inquiry conclusion: "There was no systematic mechanism for monitoring the clinical performance of healthcare professionals or of hospitals.”
Department of Health mechanisms for monitoring quality of care to 2000

Bristol report, 2001, Chapter 12, “Concerns” paragraph 6:-
• “In short, there was no effective national system for monitoring outcomes. This situation was compounded by the assumption by a number of the respective organisations that it was not their responsibility but that of some other body. This meant, in turn, that the absence of, and need for, a national system was not recognised nor acknowledged at the time.”

Bristol Inquiry main findings, 2001

• “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.”
2001 Imperial College Dr Foster unit and Dr Foster Intelligence

- B Jarman statement to Mid Staffs Inquiry para 35: “My conclusion regarding having systems for “quality audit” of care in hospital was that the Department of Health was not fit for purpose.”
- Dr Foster unit formed 2001 to calculate, and Dr Foster Intelligence to publish, Hospital Standardised Mortality Ratios (HSMRs) etc
- Monthly mortality alerts for individual diagnoses and procedures on web from 2003, sent to trust Chief execs from April 2007 and copied to Healthcare commission.

Commission for Health Improvement

- As a result of Bristol Inquiry the Commission for Health Improvement (CHI) was formed
- CHI's aim was “to improve the quality of patient care”
- It lasted from 2001 until 2004
Organisations involved in monitoring NHS quality of care during 2005-9

Organisations having a role in commissioning, regulation, advice-giving or training

• the Care Quality Commission [previously Healthcare Commission and CHI],
• Monitor (for Foundation Trusts),
• the PCT [to be abolished],
• the SHA [to be abolished],
• the various patient support bodies,
  – AvMA [Action against Medical Accidents],
  – PALS [Patient Advice and Liaison Services],
  – PPF [Patient and Public Involvement Forum], Patients Association,
  – Commission for Patient and Public Involvement in Health (CPPHI)
  – Independent Complaints Advocacy Service (ICAS) – POhWER
  – LINk [Local Involvement Network],
• the oversight and scrutiny committees [Local Authority based],
• the NHSLA [NHS Litigation Authority],
• the GMC [General Medical Council],
• the NMC [Nursing and Midwifery Council],
• the HSE [Health and Safety Executive],
• The National Confidential Inquiry into Patient Outcome and Death,
• The National Patient Safety Agency [abolished 2010],
• the PMETB [Postgraduate Medical Education Training Board – abolished 2010],
• the universities responsible for training nurses,
• the relevant unions,
• the Royal Colleges [inspect for quality of training offered],
• the coroner,
• the Parliamentary and Health Service Ombudsman.

Problems at Mid Staffs

• On 3 Aug 2001 the Chief Executive (CE) of the South-western Staffordshire PCT stated (Mid Staffs Public Inquiry, William Price's exhibit WP1):
  • "the leadership at Mid Staffs hospitals" was not competent: this has an "impact on patient care"
Problems at Mid Staffs

- In Jan 2002 (Ian Cumming's exhibit IRC20) the Commission for Health Improvement (CHI) clinical governance review of Mid Staffs stated: "Urgent action required" regarding emergency admissions, staff training, open culture, complaints, etc.

- On 20 May 2003 the Shropshire and Staffordshire SHA peer review of critically ill children (Ms C J Eminson's exhibit CJE2) had concerns regarding "triage of children", resuscitation equipment, staff concerns regarding critical incidents etc.
2004 CHI was replaced by the Healthcare Commission

- Statement Sir Liam Donaldson, Chief Medical Officer, para 72
- Sir Liam Donaldson explained that a number of Chief Executives had complained to the Department that the CHI inspections were too burdensome, and they had no time to do anything else apart from prepare for the CHI visit (Donaldson statement para 72). He said:
- “I think it was largely due to these complaints that the Government decided to abolish CHI and replace it with the HCC. I think it was felt that CHI had been too bureaucratic. The mantra of ‘light touch’ regulation became the order of the day. In the long term, however, this transition meant there wasn’t as much focus on clinical governance under the HCC as there had been under CHI…”

Problems at Mid Staffs

- On 11 Jan 2006 the SHA peer review of critically ill children (Ms C J Eminson’s exhibit CJE10) found “immediate risks to clinical safety or clinical outcomes” regarding low levels of trained staff, insufficient senior medical and nursing staff in A&E, etc.
Healthcare Commission

- Based its assessments largely on self-assessments of Annual Health check
- Two thirds of the assessments for ‘at risk’ trusts were said to be incorrect

Mid Staffs Inquiry Counsel written Closing Submission on 9 December 2011, page 407:-

- “13. Insofar as there were mechanisms that were designed to detect poor quality care, for example the Healthcare Commission’s Annual Health Check, they appear to have been fundamentally flawed due to an overreliance on self-assessment...”

Problems at Mid Staffs – cont’d

- Mid Staffs significantly high HSMR from 1997/98 (just under significant in 2000/01)
- Telegraph publication of HSMRs April 2007 plus mortality alerts led HCC to investigate March 2008-March 2009.
- From July to November 2007 Imperial College DFU sent the Mid Staffs CE four mortality alerts (& on web from Feb 2006)
The 2007 HSMRs and mortality alerts were at the time Mid Staffs was applying for Foundation Trust status

- “In July and August 2006, Sir Andrew [Cash, director general of provider development, DH] wrote to all SHA Chief Executives asking them to nominate acute and mental health trusts that they believed would be able to achieve FT status by July 2007. He sent a letter he to Cynthia Bower at WMSHA in July 2006.159 The letter stated: One thing we are keen to press ahead on is the NHS Foundation Trust rollout programme.”
- “The Trust was nominated to apply for FT status by WMSHA in December 2006 in the fifth wave of FT applications.”
- On 18 May 2007 the West Midlands SHA supported the Mid Staffs’ application for Foundation Trust status to the DH (even though in Jan 2006 Mid Staffs was told it was at least 2 years away)
- The DH agreed the application on 7 Jun 2007 but were not told of the high HSMRs at the trust. Sir Andrew Cash's statement para 61 - “…at the time of our consideration of Mid Staffordshire's application on 7 June 2007, the Applications Committee were not aware of any of the Dr Foster reports on mortality rates.”
- Monitor authorised the Trust for FT status in February 2008 and the HCC began its investigation the following month.

Foundation Trust status and quality of care

Inquiry Closing Submission 9 Dec 2011:-

- “The drive for FT status in effect did nothing to improve patient care. It is an inescapable conclusion that the Trust should have been focused first and foremost on improving quality and safety as opposed to pursuing the perceived prestige of FT status.”
- “Martin Yeates [CE, Mid Staffs] stated that he felt uncomfortable in putting forward to the SHA the reasons why the Trust was ready for FT status as part of this process, because he knew that it wasn't...he said: "I was subject to a direct chain of command from the SHA and they wanted the diagnostic to happen when it did...”
- “One group that was not leading the drive for FT status was the clinicians.”
- “Alex Fox [Chair of South Staffordshire Primary Trust] stated that the PCT would never have “approved” the Trust’s application for FT status had it known about the HCC’s mortality alerts at the time.”
What are Hospital Standardised Mortality Ratios (HSMRs)

- The HSMR measures the adjusted rate of death in a given hospital during a given time period relative to the hospital death rate for the whole of the country in a fixed year e.g. 2000 or the country in the year of measurement.
- Several factors are used to estimate the probability of death for individual hospitalised patients. These are factors such as age, sex, primary/principal admission diagnosis, admission type (elective/planned or non-elective/unplanned), and secondary diagnoses.
Variables for logistic regression adjustment to adjust for important factors

- **Age group** (<1, then 5-year bands to 90+)
- **Sex**
- **Admission method/type (emergency, elective etc)**
- **Admission source (home, transfers etc)**
- **Deprivation quintile (based on postcode)**
- **Diagnosis subgroup (CCS sub-groups within each CCS group)**
- **Comorbidity (Charlson score)**
- **Emergency admissions in previous 12 months Palliative care (any episode that has a treatment function code 315 or any Z515 ICD10 diagnosis code)**
- **Month of admission**
- **Year of discharge**
- **(Day cases are excluded from the risk models ~ 70 deaths/year)**
- [http://www.drfosterintelligence.co.uk/newsPublications/HSMRMethodology.asp](http://www.drfosterintelligence.co.uk/newsPublications/HSMRMethodology.asp)

Hospital Standardised Mortality Ratios (HSMRs) details

- **Calculated from 1996 by Imperial College**
- **HSMRs cover 80% or 100% of hospital IP deaths nationally**
- **The national review of the hospital standardised mortality ratio (HSMR), established on behalf of the National Quality Board, recommended using 100% deaths (published 04 Nov 2010)**
- **100% deaths HSMRs correlate with 80% with correlation coefficients 0.98**
- **Gives an overview of a hospital**
  - Part of variation of HSMRs is by chance
  - Remainder may be coding, risk adjustment or quality of care.
  - Should be used with mortality alerts and SMRs for individual diagnoses.
- **Hospital Episode Statistics (now SUS - Secondary Uses Service ) data goes to Imperial College to calculate HSMRs**
- **From Jan 2001 Dr Foster company has published HSMRs in national newspapers annually, with hospital names.**
- **Dr Foster also do a wide range of other analyses for hospitals using their monthly hospital admission data.**
Making the best use of HSMRs

- Dr Foster Real Time Monitoring
  - Uses monthly national data from all English hospitals
  - Gives adjusted SMRs for all conditions broken down by age, sex, etc
  - Has ‘cusum’ alerts
  - Has data available to the individual patient level (to the clinician)
- Imperial College monthly mortality alerts
  - Sent by letter (that they have to respond to under the rules of Clinical Governance).
  - To the CEOs of hospitals with significantly high death rates for particular diagnoses and procedures.
  - Use a False Alarm Rate (FAR) of 0.1% (1 in 1000) that the fully adjusted SMR for the condition is double the national SMR.

3 July 2007 mortality alert Dr Foster Unit sent to Mid Staffs CEO: ‘Operations on jejunum’
Problems at Mid Staffs - RCS

- In 2007 and 2009, the Royal College of Surgeons did two 'invited reviews'.
- "151. The 2009 Report found significant concerns with the cases of four of the five surgeons.
- "152. There was reference within the report to the Trust providing care that was "grossly negligent"."
- The RCS reviews were confidential to the trust and not followed up by RCS.
- Mr Black, President RCP, was asked about the College’s failure to follow up the recommendations in his oral evidence (27 June 2011, p149):
  - "Q. How did you follow up that the trust had acted upon the recommendations that the reviewers made?"
  - "A. I believe we wrote to them, and we never subsequently made sure that the recommendations had been carried out.
  - "Q. Do you recognise that for a member of the public listening to that, that is to say unacceptable, to put it mildly?"
  - "A. I would accept that."

Healthcare Commission investigation of Mid staffs

- In 2007 Mid Staffs had a significantly high HSMR and many monthly mortality alerts.
- The high HSMR and monthly mortality alerts prompted the Healthcare commission to investigate Mid Staffs March 2008- March 2009.
- Other regulators considered the care at Mid Staffs was good.
- The HCC investigation found the quality of care found to be ‘appalling’.
Robert Francis’ comment to the Secretary of State submitting his Mid Staffs Independent Inquiry Report, 24 Feb 2010

• “The high HMSR at Mid Staffs, however provided compelling grounds for an investigation of the type carried out by the HCC.”
• “It became apparent throughout the inquiry that many staff during the period under investigation did express concern about the standard of care being provided to patients. The tragedy was that they were ignored.”
• “Finally and perhaps of most concern, I found a widespread culture of denial.”

Some of the problems at Mid Staffordshire. Professor Sir George Alberti. 29 April 2009

• Understaffing of A&E - too few consultants, middle-grade doctors and nurses
• Initial patient assessment by untrained receptionists
• Poor supervision of junior doctors
• Weak leadership of nurses and inadequate nurse training
• Poor equipment in A&E
• Long delays and tendency to move patients to the Emergency Assessment Unit (EAU), Clinical Decision Unit (CDU) and “assess and treat” area in order to meet the 4 hour target before they had been investigated or any diagnosis made
• Lack of protocols and clear pathways
• Chaotic, large, understaffed EAU with little training for the nurses
• Poorly equipped EAU
• Poor handover from EAU to medical and surgical wards
• Insufficient beds for coronary care or strokes
• Major delays for emergency operations
• Inadequate numbers of experienced surgeons with poor 24/7 cover
• Poor post-operative care
• Very poor patient care on the medical and surgical wards
• Inadequate handling of patient complaints
In 2009 Healthcare Commission was replaced by Care Quality Commission

- The month after the Healthcare Commission inspection found appalling care at Mid Staffs the HCC was replaced by the Care Quality Commission.
- Statement of Ian Kennedy, paragraph 60
- "The decision to merge the Healthcare Commission was in fact made as early as May 2005. I banned the word merge" as really we were to be abolished. We were described by some as collateral damage and a target of the Chancellor’s speech on regulation in the private sector that was primarily addressed to other sectors.

Care Quality Commission: formed Apr 2009

- The Care Quality Commission (CQC) was created as a result of the merger of three organisations – The Commission for Social care Inspection, The Healthcare Commission and the Mental Health Act Commission.
- “We check all hospitals in England to ensure they are meeting national standards, and we share our findings with the public.”
- CQC currently regulates more than 21,000 care providers operating services
- from more than 36,000 locations across England.
### Care Quality Commission: regulates

- NHS Hospital Provider Trusts. 378
- Ambulance Trusts.
- Adults residential homes. >10,000
- Mental Health Act providers.
- Dental care providers.
- GP primary medical services practices. >8,000
- Has powers of entry and inspection, require production of documentation and information, carry out special reviews and investigations
- Powers to send an improvement letter, compliance letters, warning notices, variations of conditions, fines, prosecution, suspend and cancel registration but not suspend a regulated activity at a location level as well as activity level.
- Uses Quality and Risk Profiles (QRPs)

### Care Quality Commission:

- The 2008 Act requires the CQC to determine whether an organisation is compliant with the essential standards of quality and safety and if not to use its enforcement to make those organisations complaint.
- “The SHA’s role is to assist improvement. CQC does not have a broader improvement role” but “to look at and take a view as to whether the 16 essential standards are being met.”
Care Quality Commission

- Mid Staffs Inquiry Counsel written Closing Submission on 9 December 2011, page 407
- “271. Dr Jarman raises this concern in relation to the approach taken by the CQC ‘the reality is that the CQC’s 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…even though the CQC’s enforcement activity gives them greater powers than the HCC, that is only relevant in this context if a potential clinical failure is detected in the first place’.”

CQC and Basildon

- “Basildon had received a favourable rating under the AHC for 2008-2009 in October 2009. The CQC however was aware of mortality alerts which were of concern and post dated the period covered. A hygiene inspection had also revealed serious concerns.
- “The HSMR published by Dr Foster showed that the Trust was one of the worst performing in the country. Nevertheless the CQC published the favourable AHC report with a ‘Good’ rating for quality of services on 15 October 2009 whilst launching what was in effect an investigation.
- “The CQC wrote to Monitor four days later expressing the fact that the CQC did not have confidence in the management of that Trust.”
Dr Heather Wood (Chief inspector CQC)
Mid Staffs Public Inquiry 10 may 2011 Day81/page161

- Q. In the new world of the CQC, what confidence do you have that the system would identify and investigate the sort of issues that you uncovered at Mid Staffordshire?
- A. Well, as I have said – said in my statement, I'm afraid I don't have great confidence in either of those things happening.

Julie Bailey - CuretheNHS

- On 8 November 2007, Julie Bailey's mother died in Mid Staffs. Julie had been with her mother in the hospital for the last weeks of her mother's life and saw poor care when she was there. She tried to make complaints about the care her mother received but found the system for doing so unsatisfactory see “From Ward to Whitehall: the Disaster at Mid Staffs Hospital” [available at IHI bookshop]
- She formed 'Cure the NHS' with other local people who also had complaints about the treatment at Mid Staffs.
- On 19 May the CE and Chairman of the Healthcare Commission went to see the CE of the NHS and told him that they had had "an overwhelming response from local people on the questions of quality of care" at Mid Staffs. He cautioned them that they should "remain alive to something which was simply lobbying ...as opposed to widespread concern'2008 [Nigel Ellis’ exhibit NE40]
‘Cure the NHS’, a patients’ group, response to the Mid Staffs Public Inquiry

“It is this professional commitment which has collapsed in the NHS, across the professions represented by a series of royal colleges, colleges, and unions, principally UNISON. They failed utterly at Stafford Hospital to protect patients they continue to fail to this day. They have been and continue to fail at acute hospitals across the country.”

The Mid Staffs Public Inquiry

- CuretheNHS pushed for a Public Inquiry.
- After the May 2010 General Election the Mid Staffordshire NHS Foundation Trust Public Inquiry was announced, following the Statement to the House of Commons on 9 June 2010 by the Secretary of State for Health (Andrew Lansley MP).
‘Cure’ – The start

Julie Bailey’s story
Mid Staffs Inquiry implications

- Largest Inquiry ever into the NHS (456 mentions of ‘hindsight’, Bristol only 120)
- Oral hearings Nov 2010 to Dec 2011
- 193 witnesses, 139 days of hearings
- Due to report Jan/Feb 2013
- 650,000 lines of written evidence
- Cost Apr 2010-Aug 2012: £12,959,390
- http://www.midstaffspublicinquiry.com/

Mid Staffs Public Inquiry

- “This Inquiry, governed by the Inquiries Act 2005, will examine the commissioning, supervisory and regulatory ORGANISATIONS in relation to their monitoring role at Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. It will consider why the serious problems at the Trust were not identified and acted on sooner, and will identify important lessons to be learnt for the future of patient care.”
1. Adjusted death rates are high for ~10 years
   a) Complaints by clinicians (whistleblowers may suffer themselves)

2. Internal investigation
   a) Reassurance by the various regulators
   b) Rationalisation away of high death rates as e.g.
      1. Coding problems
      2. Casemix issues (eg Down’s syndrome at Bristol etc)
   c) Decision to ignore high death rates

3. Publication of results (various media)

4. Patients’ groups’ complaints emerge

5. On-site investigation by external investigators finds an appalling standard of care

6. Public Inquiry makes recommendations

7. Quality improvement leading to a reduction of high death rates

8. The ‘hindsight’ cycle restarts if lessons not learned.

Pattern at Bristol and Mid Staffs revealed by Inquiries

Similarities and differences between Mid Staffs and Bristol

- **Similarities:**
  - Both ignore 10 years high mortality and internal investigations that indicate quality of care problems
  - Act on external investigation showing ‘appalling’ care

- **Differences:**
  - Bristol: clinicians instigate changes and mortality drops from 29% to 3.7% in 3 years
  - Mid Staffs: political pressures are paramount, change coding of deaths with consequent reduction of HSMR and employ a university to discredit the mortality data.
  - Mid Staffs: SHA employed Birmingham University to ‘discredit’ HSMR methodology
University of Birmingham report

• The Mid Staffs Independent Inquiry: “Furthermore, the University of Birmingham reports, though probably well-intentioned, were distractions. They used the Mid Staffordshire issue as a context for discrediting the Dr. Foster methodology.” “However, we believe that in the case of Mid Staffordshire, there were so many different warning flags from different entities, using different approaches, and over multiple time periods, that it would have been completely irresponsible not to aggressively investigate further.”

• 9 Nov 2010 [Day 2, page 112, line 9]: “Monitor was well aware of this [the high HSMR]. However, they were provided by the trust with the Birmingham University’s report in relation to these figures, and appear to have accepted the trust’s explanation of the figures being down to coding issues.”

• Mid Staffs Public Inquiry Closing Submission 9 December 2011 “It is, broadly speaking, accepted by the SHA...that this was the wrong emphasis.”

Why did the regulators not identify and act on Mid Staffs and Bristol sooner?

• Adequate evidence of problems for 10 years
• After CHI found problems it was disbanded
• HCC Annual Health Check Mid Staffs ‘good’
• HCC investigated after HSMRs and mortality alerts, found ‘appalling’ care then HCC disbanded
• Mid Staffs results came at an inconvenient time
• Evidence of political pressure for good news story
• Even after HCC investigation reported, the Cabinet discussion sought to minimise effects
"The engagement of the Department of Health was one of interest, but the impression I got was that a concentrated focus on the collection and analysis of information about the safety and quality of the care provided by the NHS was not part of their agenda."

“The reason the government didn’t like tough reports was because they were running the services that were being reported upon, ... There was huge government pressure, because the government hated the idea that -- that a regulator would criticise it by dint of criticising one of the hospitals or one of the services that it was responsible for. And that was part of the problem of the nature of the Care Quality Commission, when it was established, and that was it was regulating -- it was one of the few regulators in British public life that regulates something that is directly run by the government, and that was always going to be a real problem.”
“The culture of the NHS, particularly the hospital sector, I would say, is not to embarrass the minister. That -- that's a big pressure and has been on managers in the NHS almost since its creation. Don't do anything to embarrass the minister.”

“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, …”

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.**

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David Nicholson, CE NHS, statement para 301,2 re JCI report & exh DN47

- “‘significant flaws in the current quality oversight mechanisms.’ I would accept - elements of truth”
- "'weaknesses of current data collection, data quality monitoring and data use processes.' I would agree"
- “David [N] has feedback [from Bradshaw] that 'this should be treated as a local issue' I did think the case was local"
John Holden (head FT unit, DH) exhibit JH9: email 9/3/09 (HCC Investigation published 18/3/09)

- “…the Secretary of State is tomorrow briefing the Cabinet on the issues arising at Mid Staffs. The key issue being considered is how regulation is working in the NHS, and whether the difficulties at Mid Staffs are evidence that more needs to be done.”

- "the Trust received a 127 mortality rate for 2005/06 from Dr Foster. This has reduced to c. 101 between May and August 2007/08 as a result of significant improvements to coding for co-morbidities;”

  [This information is incorrect: HSMR May-Aug 2007/08 = 108.7 Inquiry hearings 13 June 2011, p91,l4 & Exhibit BJ83]

- “III. Monitor’s Compliance process and Mid Staffs
  o Supported the Board in its engagement of PWC … assurance that actions were being implemented appropriately .”

  PriceWaterhouseCooper report stated "Mortality: high SMR (127) appears to be coding (20-30% due to wrong coding)."

Sir Bruce Keogh - Exhibit BK49, 30/4/09

- When the HCC report on Mid Staffs was published
  HSMRs were discussed at Cabinet level and Ben Bradshaw, Minister of State for Health, was briefed to say that HSMRs were only published from 2007 (though told was from 2001): this was repeated by the DH people giving evidence:

- "In April 2007, the Dr Foster’s Good Hospital Guide classified the Trust as having a High Hospital Standardised Mortality Rate. (The Good Hospital Guide was first published in 2001)"
Finally – where were the doctors – where was the professional commitment?

- Since Griffiths 1983 report on NHS management the medical profession have been emasculated by over-powerful managers and “Stalinist” control from the centre.
- A “culture of fear appears to pervade the NHS and at least certain elements of the Department of Health.”
- “At present, if you whistleblow, you will be dismissed—it’s as simple as that! . . . Once doctors are dismissed, it is virtually impossible to find employment back in the NHS.”
- A doctor, incorrectly reported to the GMC by a manager may have trouble find in NHS work again.
- Managers sit on Clinical Excellent Award committees.
- If doctors can’t speak out, combined with “Don’t do anything to embarrass the minister” this is bad for patients.

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**Risk in Human Activities**

*Five System Barriers to Achieving Ultrasafe Health Care*

- NICU
- Pedi Cardiac Surgery
- Patient ASA 3-5
- Hymalaya mountaineering
- Fatal iatrogenic adverse events
- ED/ Medical risk (total)
- Chartered Flight
- Civil Aviation
- Nuclear Industry
- Chemical Industry (total)
- Railways (France)
- Road Safety
- Microlight spreading activity
- Anesthesiology ASA1
- *Very unsafe* $10^{-2}$
- Unsafe $10^{-3}$
- Safe $10^{-4}$
- Ultra safe $10^{-5}$
- Ultra ultra safe $10^{-6}$
Normalized Deviance in Healthcare

- Bristol Royal Infirmary
- Mid Staffordshire Inquiry
- Dutch Radboud Hospital Investigation
- NSW Garling Report
- Manitoba Pediatric Cardiac Surgery inquiry

The Normalization of Deviance: Do We (Un)Knowingly Accept Doing the Wrong Thing?

- Failure to wash the hands before and after patient contact.
- Patient not seen on weekends by consultants
- Failure to follow recognized isolation procedures and protocols.
- Incomplete and wrongful documentation.
- Handoffs of care at vital times (emergence, induction, separation from cardiopulmonary bypass, etc.).
- Wearing hospitals scrubs home
Een onvolledig bestuurlijk proces: hartchirurgie in het UMC St Radboud
Rapport Onderzoeksraad voor de Veiligheid 2008

Toezicht op hartcentrum schoot tekort

If an error is possible, someone will make it. The designer must assume that all possible errors will occur and design so as to minimize the chance of the error in the first place, or its effects once it gets made

Normalized Deviance

- By a deviant organizational behavior, we refer to “an event, activity or circumstance, occurring in and/or produced by a formal organization, that deviates from both formal design goals and normative standards or expectations, either in the fact of its occurrence or in its consequences.”

- Once a community normalizes a deviant organizational practice, it is no longer viewed as an aberrant act that elicits an exceptional response; instead, it becomes a routine activity that is commonly anticipated and frequently used.

Normalized Deviance Spread

- Research into organizational misconduct has demonstrated that deviant behavior
  - may not only grow within an organization, but also may spread between organizations that work closely with each other (Vaughan, 1996; Zey, 1993, 1998)
  - spreads between organizations that operate in the same industry (Geis, 1977; Baucus and Near, 1991; Simpson, 1986).
- Based on a similar logic, we hypothesize that, all else being equal, managers operating in communities with a higher prevalence of deviance will be more likely to engage in deviant behavior than will managers operating in communities with a lower prevalence.

Results - Safety Culture in the OR

- 3 academic Surgical teams were “surveyed” on:
  - Adverse event reporting
  - OR management
  - Safety culture
- 72% response rate
- Significant differences in sense of empowerment, safety and organizational backing
  - 45% felt that outcomes were not safe
  - 33% felt that errors of the same kind keep on recurring
  - 47% felt that administration was not sensitive to patient safety issues
  - 40% felt the patient was not told the whole story about their care

How does it start?

- The normalization literature distinguishes between factors that lead to the genesis of organizational deviance and factors that cause deviance to become routine, rather than idiosyncratic, behavior.

- A permissive ethical climate, an emphasis on financial goals at all costs, and an opportunity to act amorally or immorally, all contribute to managerial decisions to initiate deviance.

DOES THE DAY OF WEEK MATTER?

*Annals of Surgery • Volume 246, Number 5, November 2007*

*Original Articles*

Mortality After Nonemergent Major Surgery Performed on Friday Versus Monday Through Wednesday

Marc M. Zare, MD,*† Kamal M. F. Hani, MD,*‡ Tracy L. Schiffner, MS,‡ William G. Henderson, PhD,‡ and Shubri F. Khuri, MD,*§

Operations performed on Fridays were associated with a higher 30-day mortality rate than those performed on Mondays through Wednesdays: **2.94% vs. 2.18%;**

Odds ratio, 1.36; 95% CI, 1.24–1.49)
Variation caused by Trainees-July Effect

- Anesthesia registrars in first 4 months at the Alfred Hospital, had worse patient outcomes than in the subsequent 8 months of the year
- This relationship held for 1-5th year registrars.


FEB 1, 2003  8:59 EST

Space shuttle Columbia, re-entering Earth’s atmosphere at 10,000 mph, disintegrates

- All 7 astronauts are killed
- $4 billion spacecraft is destroyed
- Debris scattered over 2000 sq-miles of Texas
- NASA grounds shuttle fleet for 2-1/2 years
Columbia- The Organizational Causes

- NASA had received painful lessons about its culture from the Challenger incident
- CAIB found disturbing parallels remaining at the time of the Columbia incident… these are the topic of this presentation

“In our view, the NASA organizational culture had as much to do with this accident as the foam.”

CAIB Report, Vol. 1, p. 97

STS-107 Columbia Space Shuttle

- STS-107 Columbia Space Shuttle
- February 1, 2003 Space Shuttle Columbia and its 7-member crew are lost re-entering the Earth’s atmosphere
- The Columbia Accident Investigation Board’s independent assessment takes seven months
“Cultural norms tend to be fairly resilient…the norms bounce back into shape after being stretched or bent. Beliefs held in common resist alteration….This culture acted over time to resist externally imposed changes. By the eve of the Columbia accident, institutional practices that were in effect at the time of the Challenger accident had returned to NASA.”
Stages in the development of a safety culture

- **CALCULATIVE**: We have systems in place to manage all hazards.
- **PROACTIVE**: Safety leadership and values drive continuous improvement.
- **REACTIVE**: Safety is important, we do a lot every time we have an accident.
- **PATHOLOGICAL**: Who cares as long as we’re not caught.

Stages in Deviance

- **Institutionalization** refers to the process by which initial deviant decisions or acts become embedded in organizational structures and processes;
- **Rationalization** to the process by which new ideologies develop to justify and perhaps even valorize corruption; and
- **Socialization** refers to the process by which newcomers come to accept deviance as permissible if not desirable.

Each process “reinforces and in turn is reinforced by the other two.”

Stakeholder Reactions

- Social control agents, whistle-blowers and workers have all been shown to successfully challenge or reverse normalization processes.
- Institutionalized deviance typically continues until stopped from inside or outside the organization.
- Internally, whistle blowers may step forward with accusations and evidence of wrongdoing.
- Externally, the media, prosecutors, or victims may challenge organizational actions.
- Actions of “social control agents”: The identification of external challengers to organizational deviance, such as the media and prosecutors;
- If community leaders and regulators do not forcibly respond to organizational deviance, then organizational members are likely to conclude that there are few regulatory consequences or normative improprieties in violating formal standards of behavior.

-- Ermann and Lundman (2002)

The Role of Managers

- Normative standards of behavior are not simply imposed on managers by more powerful organizations such as the state or professional organizations.
- Managers themselves are participants in the construction of the commonly accepted standards of behavior under which they operate.
- A process of social learning and observation moves an organizational practice from an innovation that requires active efforts of sense-making to a routine behavior that operates as a habitual response to common organizational problems.
Indicators Of Organizational Culture Weaknesses

The following slides provide examples of indicators that emerged in the inquiries around Bristol, Mid Staffs, Garling, Nijmegen...

Establish An Imperative for Safety

- The shuttle safety organization, funded by the programs it was to oversee, was not positioned to provide independent safety analysis
- The technical staff for both Challenger and Columbia were put in the position of having to prove that management’s intentions were unsafe
  - This reversed their normal role of having to prove mission safety

“When I ask for the budget to be cut, I’m told it’s going to impact safety on the Space Shuttle ... I think that’s a bunch of crap.”

Daniel S. Goldin, NASA Administrator, 1994
Ensure Open and Frank Communications

- Management adopted a uniform mindset that foam strikes were not a concern and was not open to contrary opinions.
- The organizational culture
  - Did not encourage “bad news”
  - Encouraged 100% consensus
  - Emphasized only “chain of command” communications
  - Allowed rank and status to trump expertise

I must emphasize (again) that severe enough damage... could present potentially grave hazards... Remember the NASA safety posters everywhere around stating, “If it’s not safe, say so”? Yes, it’s that serious.

Memo that was composed but never sent

...NOT Preventing the Normalization of Deviance

- Allow operations outside established safe operating limits without detailed risk assessment
- Willful, conscious, violation of an established procedure is tolerated without investigation, or without consequences for the persons involved
- Staff cannot be counted on to strictly adhere to safety policies and practices when supervision is not around to monitor compliance
- Tolerating practices or conditions that would have been deemed unacceptable a year or two ago
...NOT Ensuring Open and Frank Communications

- The bearer of “bad news” is viewed as “not a team player”
- Safety-related questioning “rewarded” by requiring the suggested to prove he / she is correct
- Communications get altered, with the message softened, as they move up or down the management chain
- Safety-critical information is not moving laterally between work groups
- Employees can not speak freely, to anyone else, about their honest safety concerns, without fear of career reprisals.

...NOT Maintaining a Sense of Vulnerability

- Safety performance has been good… and you do not recall the last time you asked “But what if…?”
- Assume your safety systems are good enough
- Treat critical alarms as operating indicators
- Allow backlogs in addressing RCA, FMEA of critical equipment
- Actions are not taken when trends of similar deficiencies are identified.
...NOT Establishing An Imperative for Safety

- Staff monitoring safety related decisions are not technically qualified or sufficiently independent
- Key process safety management positions have been downgraded over time or left vacant
- Recommendations for safety improvements are resisted on the grounds of cost or schedule impact
- No system is in place to ensure an independent review of major safety-related decisions
- Audits are weak, not conducted on schedule, or are regarded as negative or punitive and, therefore, are resisted

...NOT Performing Valid/Timely Hazard/Risk Assessments

- Availability of experienced resources for hazard or risk assessments is limited
- Assessments are not conducted according to schedule
- Assessments are done in a perfunctory fashion, or seldom find problems
- Recommendations are not meaningful and/or are not implemented in a timely manner
- Bases for rejecting risk assessment recommendations are mostly subjective judgments or are based upon previous experience and observation.
...NOT Learning and Advancing the Culture

- Recurrent problems are not investigated, trended, and resolved
- Investigations reveal the same causes recurring time and again
- Staff expresses concerns that standards of performance are eroding
- Concepts, once regarded as organizational values, are now subject to expedient reconsideration