Quality of care and patient safety in the UK: the way forward after Mid Staffordshire

See **Editorial** page 571

In the past decade, quality of care and patient safety in British hospitals have become the focus of increasing public, professional, political, and regulatory concern. The 2001 inquiry into paediatric cardiac surgery at Bristol Royal Infirmary concluded that the Department of Health was unable to respond to an issue of quality of care, even though the Department of Health accepted that ultimate responsibility rests with it and the Secretary of State for Health.[1] The Bristol Royal Infirmary Inquiry warned that quality of care problems could recur in the National Health Service (NHS) in future. After the recommendations of an external investigation of Bristol were implemented, the adjusted death rate at the paediatric cardiac surgery unit dropped from 29% to 3% within 3 years.[2] The families of children who underwent cardiac surgery at Bristol should have been told of the lower mortalities at other units.

In 2001, the Dr Foster company published the first of their annual *Good Hospital Guides* in UK national newspapers: these included hospital standardised mortality ratios (HSMR).[3–5] The HSMR is the ratio of the number of observed deaths in a hospital over a certain time to the number that would be expected if the hospital had the national death rate accounting for the adjustment factors, such as age, sex, diagnosis, and emergency admission. Although it has limitations, the HSMR is a trigger to ask hard questions and understand where performance may be falling short. Since 2003, the Dr Foster website also reported monthly mortality alerts[6] for particular diagnoses or procedures for NHS organisations and professionals. From April 2007, these alerts were sent by letter from Imperial College London to the chief executives of any English NHS hospital trust that was found to have a risk-adjusted death rate for a particular condition that was double the national rate in the preceding 3 months, and the chance of it being a false alarm was less than 1 in 1000. The letters were copied to the hospital regulator, the Healthcare Commission (and now to its successor the Care Quality Commission [CQC]).

In 2007, when the Mid Staffordshire General Hospitals NHS Trust was supported by its oversight Strategic Health Authority for Foundation Trust status, its HSMR published in the *Good Hospital Guide* was the fifth highest of English acute trusts.[3] The Department of Health cautioned the public against using HSMRs to judge the relative safety of hospitals.[7] The Department of Health was not informed of the high HSMR or mortality alerts at Mid Staffordshire when they agreed, in June, 2007, to approve the trust's application to Monitor, the Foundation Trust regulator, for final approval.[8] Monitor was told by the trust that Mid Staffordshire's apparently high HSMR was an artifact of coding.[8] David Nicholson, initially Chief Executive of the Strategic Health Authority and later of the NHS, said the data that were available to the regulators did not indicate a problem at Mid Staffordshire,[9] even though the trust had logged on and seen its mortality alerts 847 times.[10] Nicholson considered Mid Staffordshire "singular" and not illustrative of a systemic problem, an attitude described by the Mid Staffordshire NHS Foundation Trust Public Inquiry Counsel as very dangerous and not supported by evidence to the Inquiry.[11] The trust is now considered by Monitor to be neither clinically nor financially sustainable.[12]

Robert Francis' inquiry into the problems at, and regulation of, Mid Staffordshire NHS Foundation Trust found a widespread culture of denial, and he, his Harvard experts, and Bruce Keogh, Medical Director of the NHS, all considered that monitoring HSMRs had provided

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grounds for investigating the trust.[8,13] The Department of Health chief analyst suggested it was a "system failure" not to have done so, and Keogh agreed that problems at Mid Staffordshire would have been spotted earlier by the Department of Health had that happened.[8] The Francis report documented the appalling care received at that trust[8] and as a result the Prime Minister David Cameron asked Keogh to investigate the 14 trusts with the highest death rates.[14] Keogh's report found that none of the trusts could be given a clean bill of health and action plans were produced for each.[14] 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.[15] 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.[3,15] I notified seven of the 14 hospitals to the then Secretary of State for Health in 2010 and he referred them to the CQC.[10] 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. That is a regulatory gap that should be closed.[8]

As with the Bristol Royal Infirmary, the national systems for ensuring quality and patient safety had failed at Mid Staffordshire and nationally. Why did that happen? Before the Bristol Royal Infirmary Inquiry there were systems in place that dealt with performance management and clinical outcomes,[10] and after Bristol there were great promises[16] with the formation of the National Patient Safety Agency (NPSA) and the Commission for Health Improvement (CHI), which detected the problems at Mid Staffordshire in 2002.[8] However, between 2003 and 2004 things went wrong. Ian Kennedy referred to what Gordon Brown described in a 2005 speech as a "bonfire of the regulators".[17] CHI was abolished and replaced by the Healthcare Commission, which was slow to detect the appalling events at Mid Staffordshire.[8,18] The NPSA acknowledged significant under-reporting of safety incidents[18] and was abolished, with its functions incorporated into the CQC. The Independent Review Panels that investigated patients' complaints about hospital services not resolved at the hospital were abolished, and in 2011–12 only one of 375 written hospital complaints had been formally investigated by the Ombudsman.[19] The independent Community Health Counsels were abolished in 2003. During the Mid-Staffordshire Public Inquiry, the chairmen of the three main health-care regulators commented on the difficulties they faced. Ian Kennedy, 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."[20] Barbara Young, 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."[21] William Moyes, of Monitor, stated: "The culture of the NHS, particularly the hospital sector, I would say, is not to embarrass the minister."[22] 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."[23]

Since the publication of the Francis Report[8] things are changing. The CQC Chairman, Chief Executive, and most of the Board have been changed and, with the Chief Inspector of Hospitals for England, the CQC will undertake thorough inspections in future using trained, professional investigators.[24] 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.[25] There is an intention to abolish the widespread so-called gagging clauses that undermine the culture and transparency of the NHS.[26] 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.[8] However, as Don Berwick's recent report on patient safety for the Department of Health makes clear, it is important that this judicial intent does not lead to punishing or criminalising clinicians for unintentional mistakes or involvement in failed systems.[27] The existing criminal law can deal with bad cases. Continuous learning and improvement,[28] monthly mortality alerts, adjusted death rates,[8,27] regular patient and staff feedback, and targeted, skilled hospital investigations could lead to a safe NHS, ideally without a culture of denial[8] or gagging clauses.

To improve the quality of care in UK hospitals I would reintroduce the Independent Review Panels and Community Health Councils and develop monthly complaints alerts similar to the mortality alerts.

Regulation would be more independent if the CQC reported in public to Parliament, and there would be better communication if it were integrated with Monitor. Additionally, it is important to ensure there are minimum staff-to-patient levels[12] of doctors and nurses, with 65% trained nurses[3] and regulation of health-care assistants. I would aim for total physicians per head of population at the EU average.[29] Ideally I would also like to see training introduced for the boards of trusts and for them to have equal representation of patients, clinicians, finance, and managers. There has been a decade of concerns about the quality of care in our hospitals: patients have been ignored, the regulatory systems have failed, and there has been a culture of denial. With political will the proposed reforms could lead to marked improvements.

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