BMJ

BMJ 2013;346:f3029 doi: 10.1136/bmj.f3029 (Published 23 May 2013)

FEATURE

COMPENSATION

The long road to ensuring patient safety in NHS hospitals

As part of a series on compensation for clinical errors, **Clare Dyer** looks at efforts, past and present, to monitor and prevent mistakes that harm patients

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In 1995, 18 month old Joshua Loveday was scheduled to undergo a complicated "switch" heart operation at Bristol Royal Infirmary. But behind the scenes, desperate last minute attempts were being made by an anaesthetist, a surgeon from outside Bristol, and a senior official from the Department of Health to persuade the hospital not to go ahead with the operation. Unknown to Joshua's parents and the public generally, figures kept by Bristol anaesthetist Stephen Bolsin suggested that the hospital's mortality rates for such operations were much higher than those at other units. The operation went ahead anyway, and Joshua died on the operating table.[1]

His death led to a public inquiry, which in 2001 found that 30 to 35 more babies under 1 year old died having open heart surgery at Bristol between 1991 and 1995 than would have died if they had had their operations at a typical unit. The mortality rates for children under 1 year were probably double the rate in England as a whole, the inquiry found, and even higher for children younger than 30 days.[2] Bristol's poor results were an open secret in the hospital: Bolsin had been trying to raise concerns about them for years. In the end, he found himself frozen out in the UK and took a job in Austrialia. At the Bristol inquiry, the chair of the regional health authority responsible for the Bristol Royal Infirmary admitted that from the data available she would not know how many patients had died in a particular hospital**;** her concern was "throughput."

Spool forward to 2013 and the day after NHS England's medical director Bruce Keogh learnt of preliminary data suggesting that death rates during paediatric heart surgery at Leeds General Infirmary might be twice as high as the national average. He ordered children's cardiac surgery to be immediately suspended while concerns were investigated. It was not restarted until 11 days later, after the hospital supplied missing data and surgery was pronounced safe. For the national medical director to intervene so rapidly, proactively, and transparently marks a huge shift from the way the NHS has traditionally operated.

In the 18 years between the two episodes, the NHS has been groping its way towards a culture in which safety is accorded the priority most patients would expect. It has not happened as quickly as many would like but has been given a new impetus by the events at Mid Staffordshire NHS Trust, where a public inquiry found hundreds of excess deaths between 2005 and 2009, unnoticed by regulators or Department of Health officials.[3]

Since Bristol clinical audit has greatly improved and much more data are available, enabling problems to be detected more quickly and corrected. But the Mid Staffordshire inquiry has highlighted the danger that the data may be ignored or questioned. So can the health service learn from its mistakes and stop the same errors happening over and over again?

Past attempts

Serious efforts have been made in the past to introduce safety nets, with limited success. More than a decade ago, Liam Donaldson, then chief medical officer for England, set out to put a new emphasis on safety. His landmark publication, *An Organisation with a Memory*, published in 2000, estimated that more than 850 000 adverse events occur in NHS hospitals each year in which patients are harmed, with a cost in additional hospital stays alone of more than £2bn (€2.4bn; $3bn).[4] The Department of Health announced the creation in 2001 of the National Patient Safety Agency with a system for reporting adverse events and "near misses." Donaldson suggested that the agency's system of identifying and analysing adverse events would lead to a "more blame-free, open NHS" where lessons would be shared and learnt.

In 2003-04 the agency introduced the National Reporting and Learning System to enable trusts—and, anonymously, healthcare staff—to report patient safety incidents. Donaldson had recommended a mandatory system for organisations, but in the event it was voluntary. The result, as Robert Francis, QC, chairman of the Mid Staffordshire public inquiry, pointed out in his report in February, was that "NHS organisations can

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choose whether to report, how much to report and what to report."

The scheme sends healthcare providers regular patient safety alerts derived from analysing incident reports and other safety information. Reporting is mandatory for "never events": a list of serious, preventable incidents, such as operating on the wrong site or leaving a foreign body inside the patient after surgery, that should never happen. More than 300 never events were reported in 2011-12. Reporting has also been mandatory since 2010 for serious patient safety incidents—those leading to severe harm or death, which topped 10 000 in 2011-12.

The 2006 Department of Health report *Safety First* concluded that safety "was not always given the same priority as other major issues such as reducing waiting times, implementing national secure frameworks and achieving financial balance."[5] However, since the early 2000s concern has grown, both in the UK and internationally, that healthcare is an inherently dangerous enterprise that has not focused as strongly on safety as have other high risk industries such as aviation. Researchers are busy trying to identify what factors affect the riskiness of healthcare and how it can be made safer. One suggestion is that lessons learnt from the aviation industry could be applied to healthcare. These include an emphasis on human factors, the discipline that studies the relations between human behaviour, system design, and safety. But healthcare is more complex than aviation and "everybody involved in this area underestimated the challenge of the improvement side and why it's so difficult," Charles Vincent, professor of clinical safety research at Imperial College London, told the Mid Staffordshire inquiry.

Aviation and other high risk industries rely on a safety culture where the organisation acknowledges that mistakes will happen, wants to know about things that go wrong, and acts to try to prevent recurrence. Too often in the NHS safety warnings have gone unheeded, and those who have brought problems to light have been blamed and scapegoated.

Safety was "deemed the responsibility of individual clinicians rather than seen as an organisational issue," noted the Health Foundation, an independent charity. In 2004 it launched the four year Safer Patients Initiative to test ways of improving safety in intensive care, general ward care, perioperative care, medicines management, and critical care. Later work has looked at how to reduce harm in maternity services, mental health services, and general practice.

Cost of mistakes

Failing to prioritise safety is expensive, not only in extra care for patients who experience adverse incidents, but in spiralling compensation costs. The bill for clinical negligence claims has ballooned, reaching £1.28bn in 2011-12.[6] This year the NHS Litigation Authority launched an initiative to learn safety lessons from legal claims, with the appointment of Suzette Woodward, former director of patient safety at the National Patient Safety Agency, to a new post as the Litigation Authority's director of learning, safety, and people.

Surgery is the area giving rise to the largest number of clinical negligence claims against NHS trusts in England—twice as many as the next highest, obstetrics and gynaecology. The World Health Organization's surgical safety checklist, issued in 2008, has been shown to reduce deaths and complications,[7] and the National Patient Safety Agency required all NHS organisations to adopt it by February 2010. But the checklists were "handed down on high by diktat . . . without frontline clinicians being convinced of their effectiveness," suggested a 2009 report on patient safety from the Commons Health Committee.[8] "In some operating theatres it is absolutely routine; in others not at all," Vincent told the Mid Staffordshire public inquiry.

Lessons from Mid Staffordshire

In his 2008 *Next Stage Review* Ara Darzi, professor of surgery at Imperial College London and then a health minister in the House of Lords, set out a long term vision for the NHS, making the quality of services, including safety, a top priority.[9] Since then the NHS has been focusing more on clinical audit of outcomes and trying to develop the information sources that can help it expose and tackle unsafe variations in care. As events at Mid Staffordshire laid bare, there is still much progress to be made.

Mid Staffordshire stood out in the league table of hospital standardised mortality ratios produced by the Dr Foster Unit at Imperial College. Yet managers were in denial, insisting the poor figures were down to coding errors. The reliability of hospital mortality figures as a warning signal that something might be wrong was questioned by officials and NHS managers for years, yet it was these figures that finally persuaded the Healthcare Commission to go into Stafford Hospital in 2009 and uncover "appalling" standards of care.

More attention is now being paid to mortality data. Fourteen other trusts with higher than expected mortality rates for two years are being reviewed by a team headed by Keogh. Brian Jarman, director of the Dr Foster Unit and an adviser to the investigation into the 14 trusts, estimated in a BBC interview that there had been "tens of thousands of avoidable deaths in those hospitals alone over the last 10 years."

Keogh pledged in April when giving the go ahead for children's heart surgery to resume at Leeds, "I want to be clear that NHS England will do everything in its power to make sure that measuring clinical outcomes will be given priority in the new NHS. Organisations cannot know they are providing effective or safe care unless they are measuring and monitoring their services." Heart surgeons have taken the lead in publishing the outcomes of individual surgeons, a move which has driven up standards. NHS England's mandate for the next two years includes shining a spotlight on variation and unacceptable practice, starting with publishing outcomes in eight more surgical specialties as well as cardiology.

The quality, reliability, safety, and teamwork group at Oxford University is conducting a range of studies, including one looking at ways of reducing preventable complications of surgery. The unit is testing a range of interventions from other industries—such as crew resource management training from aviation, "lean manufacturing" from process engineering at Toyota, and standard operating procedures—and applying them to healthcare.

At Mid Staffordshire, a key factor in the dangerous care provided was inadequate staffing levels, particularly of nurses, as the trust strove to cut its deficit to win foundation trust status. And there are warning signs that staffing is a more general problem. Legal claims over birth errors cost the NHS £3.1bn between 2000 and 2010, according to an analysis by the NHS Litigation Authority.[10] Many claims arose from the interpretation of cardiotocographs when women were cared for by midwives alone or with junior doctors. There is evidence that deliveries outside the normal working week are associated with a higher risk of neonatal death,[11] and the Royal College of Obstetricians and Gynaecologists has called for more consultants to be available round the clock on labour wards. Information governance puts hurdles in the way of linking different NHS databases, but a research team has applied for funding to look

at the link between time of birth and adverse outcomes in England and Wales.

Risks are high with NHS trusts under pressure to achieve cost savings at the same time as the health service undergoes the largest reorganisation in a generation. Yet the new architecture, with a bigger role for clinicians in commissioning healthcare services, could provide another chance to put safety at the heart of the NHS. Keogh has established a reference group "to identify how human factors could be embedded in the future NHS." He told the first meeting, "We've been talking about human factors for 10 years, but done nothing . . . Given the current changes in the NHS and the obvious need for improvement, now is a good time to explore how we can embed human factors in the new landscape."

Ending a culture of fear

The Department of Health has set up a new national advisory panel on the safety of patients, headed by Don Berwick, former head of the US based Institute for Healthcare Improvement and a world authority on patient safety. The panel is due to report its recommendations in July. Berwick will be working with NHS England "to ensure a robust safety culture and a zero tolerance of avoidable harm is embedded in the DNA of the NHS," the government has promised.

His key role holds out some hope of action on what may be the biggest challenge—ensuring that NHS staff can raise safety concerns in the future without risking career suicide. Berwick's team from the Institute for Healthcare Improvement produced a report for the Department of Health in 2008, *Achieving the Vision of Excellence in Quality*. It highlighted a "culture of fear and top-down control" in the NHS, rather than of "learning, innovation and enthusiastic participation in improvement," and warned that "fear impedes learning and dampens co-operation."[12]

Vincent, a member of the Berwick advisory panel, told the *BMJ*, "If you've got people saying "I don't want to hear bad news, then you've got a dangerous organisation immediately." He believes NHS organisations need to mount their own safety programmes locally, "looking hard at what's going on day to day" rather than just responding to regulators. "The balance is wrong at the moment in the NHS. We need more effort, more safety improvement generated and led by clinicians and managers in the organisations they work for, rather than simply saying 'if we've met what the regulator says then that's it, we're safe.'"

Nevertheless, he finds the transformation in the landscape "unbelievable" since he started working on healthcare safety in the mid-1980s and is hopeful for the future. "I think what's happening now is we're realising this is much tougher than people thought and there's a certain realism coming across the board—clinicians, managers, everybody—but no particular loss of effort. So I'm more optimistic now than I would have been a few years ago."

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

Provenance and peer review: Commissioned; not externally peer reviewed.

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Cite this as: *BMJ* 2013;346:f3029