Chapter 13
Partners in Progress: Patient Safety in the UK

In 1997, Britons were shocked by a report from the General Medical Council (GMC) of a series of deaths from bungled surgery at the Bristol Royal Infirmary. In response to parents' complaints, the GMC had launched an investigation into the high mortality of cardiac surgery of children at the Infirmary. It found that of 53 children who were operated on, 29 had died and 4 suffered severe brain damage. Three surgeons were found guilty of serious professional misconduct, and two were stricken from the medical register [1].

The public and the profession were shocked that this could happen in the National Health Service (NHS). Richard Smith, editor of the BMJ, wrote, "All changed, changed utterly. British medicine will be transformed by the Bristol case." [2]

Transforming the NHS was already on the mind of Tony Blair and the Labour Party when they took over the government that same year. Britons were unhappy with the quality of care in the NHS, especially long wait times. A recent OECD report had shown that the UK was underperforming its competitors. Blair made improving quality of care and increased funding of the NHS a keystone of his campaign. The Bristol case added fuel to his fire.

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A National Commitment

One of Blair's first acts was to appoint Liam Donaldson chief medical officer (CMO) in 1998. Donaldson was a surgeon who had retrained in public health. He had been CEO of the country's northern regional authority, where he received occasional notifications from hospitals of "accidents" in which patients had been harmed or died from a complication of medical care. As he read them, he recognized that the purpose of the reports was not learning from the incident but to cover the hospitals' leaders backs if the case became public.

These hospital reports were eye-opening for Donaldson, who was previously only dimly aware of the problem. Like your author, another surgeon converted to public health a few years earlier, he began to read about accidents in other industries. He discovered the work of James Reason and human factors experts and became excited about applying lessons from industry to medicine. He asked local managers to report all incidents and set up a database to learn more. He began to develop a list of safety measures that needed to be implemented.

When Blair was elected, Donaldson shared this information and his ideas with him. Shocked, Blair and his new health ministers also

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recognized that this was just what he needed politically. He appointed Donaldson as CMO and gave him his full support.

Although the government commitment was new, interest in patient safety in the UK went back at least to 1985 when Charles Vincent began work on avoidable mishaps in medicine, which he published in 1986. Vincent later wrote an editorial in BMJ in 1989 about systems changes [3], followed by a book that he edited with Maeve Ennis and Bob Audley, *Medical Accidents*, in 1993, in which he introduced the concept of applying human factors principles and systems analysis to healthcare [4].

Vincent referenced the findings of the Harvard Medical Practice Study and called for more research into the causes of medical accidents and the development of a comprehensive safety program. Two years later, in 1995, he further expanded these ideas in *Clinical Risk Management* [5]. Risk managers began to think about patient safety, but, as in the USA, the medical profession in general had little interest in these developments. They were fixated on the problem of malpractice litigation and worried that investigation of errors would expose them to more risk. Not much happened.

The Patient Safety Movement

Donaldson would change that. In early 2000, within months of the publication of the IOM report in the USA, he launched the patient safety movement in the UK by releasing his own report, *An Organisation with a Memory* [6].

The report was the product of a panel with a wide-ranging set of disciplines and expertise, including people from other industries. It coupled a comprehensive analysis of the quality and safety problems in the NHS with strong recommendations about what needed to be done. Based on another study done by Charles Vincent [7], it estimated that 11% of hospitalized Britons suffered an adverse event each year, at a cost of one billion pounds for additional hospital stays alone.

An Organisation with a Memory echoed the IOM report in condemning the typical approach when things go wrong of blaming the individual and made the case for a systems approach. The report cited

the organizational culture and the lack of an effective reporting system as major barriers. It also acknowledged that some of the existing systems in the UK did work well, especially the confidential inquiries and reporting systems for medical devices.

An Organisation with a Memory called for a fundamental rethinking of the way the NHS approached the challenge of learning from adverse events (AEs). It called for four specific changes: a unified mechanism for reporting and analysis of AE, a more open culture where people can safely report and discuss errors, mechanisms for putting recommended changes in place, and wider appreciation of the systems approach.

About this time, at the urging of Donaldson and BMJ editor Richard Smith, the British Medical Association and the NHS hosted the first UK national symposium on medical error. It was timed to coincide with the publication of a special BMJ issue on patient safety that Smith had conceived of a year earlier and Don Berwick and I edited (Chap. 17). The conference drew a wide audience from Britain and European countries. For many, this was their introduction to the problem of medical errors. Beth Lilja, later the driving force behind the Danish patient safety movement, told me that it was a defining moment for her.

Donaldson came to the CMO job with a passion and an agenda. He recognized that what he had in mind for patient safety would not succeed if it were absorbed into the NHS bureaucracy. The effort needed a full-time commitment and independence. He persuaded the Department of Health to establish an independent Special Health Authority, the National Patient Safety Agency (NPSA). Its mission was to improve patient safety by "encouraging voluntary reporting of medical errors, conducting analysis and initiating preventative measures." [8]

It is worth noting to American readers that the British response to the error threat reflected the ability of the NHS to make changes rapidly and to implement them nationwide. It stands in stark contrast to the USA, where Congress has long been resistant to all forms of regulation and grudging in its support of safety.

The National Patient Safety Agency (NPSA)

The NPSA was designed to identify problems and recommended solutions, not to implement them. There were two major divisions: reporting and solutions. Two experienced administrators, Sue Osborn and Sue Williams, the "two Sues," were given joint responsibility for leading the new agency.

The first priority was to establish the National Reporting and Learning System (NRLS). Like many others, Donaldson believed that a national reporting system was essential to making progress in patient safety. Reporting and analysis could not only lead to increased awareness but also produce actionable recommendations. Getting the NRLS going was a massive information technology challenge that dominated everything else at NPSA.

The NPSA declared its objective was "to promote an open and fair culture in hospitals and across the health service, encouraging doctors and other staff to report incidents and 'near misses'." It was made clear that the purpose of reporting was to enable healthcare providers to learn lessons from each other in order to improve safety—not to identify individuals to punish [9].

The system was set up to receive and analyze reports from all sources (including, later, the public) and to recommend changes. Reporting of adverse events was already well-established in the UK. Hospitals were required to report adverse events to their regional authorities. The NPSA required the reports to also be sent to a central authority, the NRLS, so that the whole NHS could learn from them. The system soon received hundreds of thousands reports, later over a million, annually.

Its success proved to be its undoing. The huge volume and the logistics of categorizing reports impaired its ability to do meaningful analysis as Donaldson had hoped. What the system could do, however, was identify problems requiring action. This information was passed on to the solutions division that then issued alerts with recommendations for implementation of safe practices. NPSA later

established a national register to which hospitals were required to report what they did in response to the alerts and why.

Alerts covered the full range of safety issues. *Warning* alerts were issued in response to a new or under-recognized patient safety issue with the potential to cause death or severe harm and asked healthcare providers to coordinate an action plan to deal with them. *Directive* alerts concerned issues for which there were proven effective safe practices. Healthcare organizations were required to implement them. Examples included removal of concentrated potassium chloride (KCl) from nursing units, safe practices for vaccines, blood transfusion competencies, safer patient identification, and the surgical checklist.

The solutions division encouraged the creation of a "no-blame culture" through various publications and extensive educational programs, including training in root cause analysis and disclosure. In 2004 it published *Seven Steps to Patient Safety* that NHS organizations should take to improve patient safety [10]. It emphasized policy measures aimed at removing the blame culture and encouraging the reporting of incidents and near misses without fear of reprimand. The NPSA also advanced safety by training patient safety workers in rapid process change, the just culture, and root cause analysis.

Additional Safety Efforts

In 2001, while the NPSA was actively improving safety, Blair established another arm of the government to address quality of care: the Modernisation Agency. It was challenged to make recommendations to improve quality of care.

The Modernisation Agency appointed "czars" for key issues, such as waiting times, cardiovascular disease, orthopedics, and cancer. Regional strategic health authorities were established as the working arms to manage performance and implement health policy. Don Berwick was enlisted as the only non-UK member of the Modernisation Board to bring in further quality improvement expertise. Using lessons from IHI's experience, clinician-led collaboratives were organized by specialty networks to address specific issues. With funding

from the Health Foundation, the Safer Patient Initiative included 20 trusts; it was a large-scale collaborative that worked on five areas: ICU, perioperative care, general hospital care, medication safety, and leadership [11]. Berwick was later knighted by the Queen for his contributions.

A separate UK agency, the National Institute for Health and Clinical Excellence (NICE), also plays an important role in patient safety by assessing the benefits and risks of treatments. It was established in 1999 as an independent organization to produce guidance on public health, health technologies, and clinical practice, which it does by rigorous analysis of evidence. In addition to practice guidelines, it evaluates the safety and efficacy of procedures through its Centre for Health Technology Evaluation.

NICE and NPSA cooperated in risk assessment of new technology, monitoring safety incidents associated with procedures and providing solutions if adverse outcomes are reported. In addition, NICE and NPSA shared reporting in "confidential enquiries" including surgical mortality, maternal and infant deaths, childhood deaths to age 16, deaths in persons with mental illness, and perioperative and unexpected medical deaths.

Despite strong national leadership and extensive efforts to improve patient safety, local leaders were less engaged, and many of the changes were resisted by the medical profession. They roundly bashed the creation of the NRLS, for example, and later objected to the steady barrage of alerts and suggestions "telling us what to do." Safe practices could be mandated, but enforcement was sometimes undermined by resistance and evasion. The public was more supportive but reluctant to abandon the blame mode. When errors were made public, there were still calls for punishment of the individuals responsible.

Support for the NPSA gradually eroded, and in 2005 the two Sues departed and were replaced by Martin Fletcher (a World Health Organization safety leader). He reduced the scope of the agency to focus primarily on the reporting system. NPSA was given responsibility for safety aspects of hospital design and cleanliness and food, as well as safe research practices through the National Research Ethics Service. It took on performance of individual doctors and dentists through the National Clinical Assessment Service (NCAS).

Patient Safety in Scotland

Ironically, in 2008, while the NPSA was under attack, patient safety in Scotland took a giant step forward. Under Derek Feeley's leadership, NHS Scotland launched the *Scottish Patient Safety Programme (SPSP)*, a 5-year national initiative to reduce patient harm. This was the first attempt to implement a patient safety program across a whole healthcare system. Its stated aim was to reduce mortality by 15 percent and adverse events by 30 percent across Scotland's acute hospitals by the end of 2012 [12].

In partnership with IHI, Jason Leitch led SPSP to focus on reducing adverse events in acute care hospitals. It was amazingly successful in reducing the number of cases of bloodstream infections associated with central lines, ventilator-acquired pneumonia, and the length of time patients were staying in intensive care [13, 14]. It also managed one of the most successful implementations of the surgical checklist.

SPSP was one of IHI's most successful initiatives [15]. Don Berwick's later praise was justifiably effusive: "The Scottish Patient Safety Programme, marks Scotland as a leader, second to no nation on earth, in its commitment to reducing harm to patients, dramatically and continually." [12]

Reorganization

Back in England, in 2010, as Liam Donaldson was stepping down after 12 years as CMO, major changes were underway. The Labour Government led by Tony Blair's successor, Gordon Brown, lost a general election, and the Conservative Party took over control. As part of its vaunted commitment to smaller government, it directed each ministry to reduce the number of agencies.

The NPSA was completely abolished for reasons entirely unrelated to its performance or value. Its key functions were transferred to a new division called NHS Improvement; later it became integrated into the central body running the entire health system, NHS England [16]. Safety was relegated to a new agency, the Healthcare Safety

Investigative Branch under NHS Improvement. It conducts independent investigations of patient safety concerns through two programs, national and maternity. It investigates up to 30 incidents a year and makes recommendations to improve healthcare systems and processes.

The NRLS was temporarily managed by a London teaching hospital before itself being absorbed into NHS Improvement. The solutions division of the old NPSA was given to NICE.

The chaos of an NHS reorganization that its CEO said was so big that "It could be seen from space" made patient safety an "also ran" in NHS priorities. Under Donaldson's leadership, the UK was one of the few countries to make a meaningful national commitment to safety and back it up with structural changes and funding. His strong commitment gave safety visibility and stature. This was lost with the abolition of the NPSA and the redesign of the CMO post to no longer have responsibility for quality and patient safety in the NHS.

But all was not lost. The arrival of a new health secretary, Jeremy Hunt, in 2012 brought a new passion and concern for patient safety at the political level. Hunt reached out to high-profile victims of harm, righting serious injustices, and stimulated new policies in patient safety in the NHS. He also promoted action at the global level by initiating a series of global ministerial summits. Patient safety is still on the agenda even though pursued with less vigor than in the past.

Conclusion

Managing patient safety, like all of healthcare in the UK, was a political process. While this made rapid implementation of changes possible, the downside was that it needed to be owned by the leadership and frontline staff in the NHS. Thus, patient safety had rapid ups and downs according to the motives and values of the political party in power and the healthcare workforce's perceptions of it. It could not live up to one of Deming's fundamental tenets for success: "constancy of purpose for improvement." When governments changed, it was buffeted and tangled up by the dead hand of bureaucratic change. In spite of all this, the progress in patient safety in Britain was impressive and, importantly, continues.

References

1. Vincent C, Benn J, Hanna GB. High reliability in health care. BMJ. 2010;340:225–6.
2. Smith R. All changed, changed utterly. BMJ. 1998;316:1917–8.
3. Vincent C. Research into medical accidents: a case of negligence? BMJ. 1989;299:1150–3.
4. Vincent C, Ennis M, Audley RJ. Medical accidents. 1st ed. Oxford. New York: Oxford University Press; 1993.
5. Vincent C. Clinical risk management. London: BMJ Books; 2001.
6. U.K. Department of Health. An organisation with a memory: report of an expert group on learning from adverse events in the NHS. London; 2000.
7. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. Br Med J. 2001;322:517–9.
8. Secretary of State for Health. The national patient safety agency (establishment and constitution) order 2001 no. 1743: National Health Service; 2001.
9. U.K. Department of Health. Building a safer NHS for patients: implementing an organisation with a memory. London: Department of Health; 2001.
10. National Patient Safety Foundation. Seven steps to patient safety: a guide for NHS staff. London: The National Patient Safety Agency; 2003.
11. The Health Foundation. Learning report: safer patients initiative. London; 2011.
12. Scottish Patient Safety Programme. The improvement hub. Accessed 12 Apr 2020, at https://ihub.scot/improvement-programmes/scottish-patient-safety-programme-spsp/.
13. Hospital patient safety improving. BBC News, 9 September 2009. Accessed 12 Apr 2020, at http://news.bbc.co.uk/2/hi/uk_news/scotland/tayside_and_central/8245738.stm.
14. Crosshouse Hospital reports 18% drop in mortality rates. BBC News. 28 February 2011.
15. Haraden C, Leitch J. Scotland's successful national approach to improving patient safety in acute care. Health Aff. 2011;30:755–63.
16. Transfer of Patient Safety function to the NHS Commissioning Board Authority. NHS; 2012. Accessed 12 Apr 2020, at https://www.england.nhs.uk/2012/05/npsa-transfer/.