

Learning from failure: the need for independent safety investigation in healthcare

Carl Macrae PhD

Health Foundation Improvement Science Fellow, Centre for Patient Safety and Service Quality, Imperial College London, 5th Floor Medical School Building, Norfolk Place, London W2 1PG, UK

carlmacrae@mac.com | @CarlMacrae

Charles Vincent PhD

Professor of Psychology, Department of Experimental Psychology, University of Oxford, Tinbergen Building, 9 South Parks Road, Oxford OX1 3UD, UK

The final, definitive version of this paper has been published in JRSM, 2014 by SAGE Publications Ltd, All rights reserved. © RSM.

Journal of the Royal Society of Medicine. DOI: 10.1177/0141076814555939

The online version of this article can be found at:

<http://jrs.sagepub.com/content/early/2014/10/22/0141076814555939>

COMPETING INTERESTS:

Carl Macrae: Declares consultancy in patient safety for NHS and other healthcare organisations.

Charles Vincent: Declares consultancy in patient safety for NHS and other healthcare organisations.

FUNDING: This work was supported by Health Foundation, an independent charity working continuously to improve the quality of health care in the UK. Carl Macrae is a Health Foundation Improvement Science Fellow. Charles Vincent is Health Foundation Professorial Fellow.

ACKNOWLEDGEMENTS: We thank the Health Foundation, an independent charity working continuously to improve the quality of health care in the UK, for supporting this work. The Health Foundation had no role in the design or preparation of this article. The views expressed are those of the authors.

ETHICAL APPROVAL: None required.

GUARANTOR: Carl Macrae

CONTRIBUTIONSHIP: This article was prepared following discussions about the recommendations of the Francis inquiries and the Berwick review in conjunction with analysis of the regulatory and improvement architectures in the NHS as part of Health Foundation funded research. CM had the idea for the paper and both authors contributed to the literature review, analysis and drafting.

Tragedies are powerful motivators for learning and improvement. The only honourable response to the victims is to try to ensure that similar tragedies are not repeated in the future. In the NHS the report that led to the National Reporting and Learning System was entitled ‘An Organisation with a Memory’ precisely because of the ambition to capture the learning inherent in tragic incidents.[1] The recent Berwick review into patient safety in the NHS similarly speaks of ‘A Promise to Learn’ but also, tellingly, of a ‘Commitment to Act’.[2] We clearly need a capacity for intelligent, thoughtful reflection on the causes of tragic events and, still more, a capacity for using this hard won knowledge to build a safer healthcare system. In this paper we suggest that this would be most effectively achieved by the creation of a small, permanent independent agency charged with coordinating major inquiries and safety investigations in the NHS. Such a model, if successful, could be applied in other healthcare systems.

Safety investigation in the NHS

The NHS currently has no consistent approach to investigating and learning from safety issues. There is a smorgasbord of approaches to investigate and address systemic safety issues at various levels of the healthcare system with little apparent consistency, logic or strategy underlying their design or execution. These span locally managed independent investigations, commissioning and regulatory investigations, rapid reviews, service reviews and independent and public inquiries (see supplemental file for details).

Individual NHS trusts conduct large numbers of investigations into serious safety incidents, sometimes with the assistance of external advisers. These investigations can lead to important local safety improvements, particularly when linked to a broader safety strategy. However the scope of these investigations is necessarily focussed on a specific trust. With occasional exceptions,[3] local investigations rarely encompass the wider systemic factors that can contribute to serious failures of care, such as ambiguous regulatory requirements or inappropriate commissioning.

Regulators, commissioners, and other NHS and professional bodies all conduct their own different forms of safety investigation. These provide important insights into patient safety from the perspective of the agency involved.[4] However, these investigations are necessarily conducted by organisations that may themselves inadvertently contribute to the emergence of system-wide safety issues and recommendations from these inquiries tend to focus on punitive sanctions, regulatory enforcement and performance management.

At a national level efforts to learn from major tragedies take a variety of forms. The most high-profile approaches are independent or public inquiries, such as those into the failures of care at Mid Staffordshire NHS Foundation Trust.[5, 6] Inquiries can have considerable impact and provide much-needed public explanation after terrible events.[7] However, each one starts afresh and determines its own unique approach rather than building on systematic and established methods of safety investigation.[8, 9] Inquiry teams are short lived and are dissolved once the report is complete; they therefore have no capacity to independently review progress against recommendations. And the

legal orientation of independent and public inquiries is not well suited to developing strategies for improving safety. In practice the question of building a safer system may only be given serious consideration late in the process. Public inquiries appear to spend 90% of the time examining what happened and 10% of the time considering the future; arguably this allocation of time and resource should be reversed.

Investigation in safety-critical industries

Safety-critical industries such as aviation, shipping and the railways all face the risk of major failures causing tragic losses of life. The approach that these industries take to the investigation of major incidents is instructive. Each of these industries is served by an independent and permanently staffed organisation that is explicitly charged with investigating serious safety risks and major failures. These organisations have typically emerged following an unacceptable accident or serious disaster within the industry. (Box 1).

These independent investigators are responsible for coordinating all major safety investigations in their industry. They have a remit to investigate the entire industrial complex, encompassing design of equipment, the culture and practices of delivery organisations such as airlines or shipping companies, and the role of regulators and government.[10] Their independence is essential to their effectiveness. It allows them to routinely investigate the full range of factors that underlie major failures, irrespective of whether those are rooted in the behaviour of an individual professional or the design of an entire regulatory system.

These agencies have developed substantial expertise and sophisticated methodologies of safety investigation.[11] They routinely provide their industry with independent, public and non-punitive investigations which address the full spectrum of causes and which target recommendations at all relevant organisations throughout the industry.[12] They are responsible for determining when safety investigations are required, disseminating the lessons learnt, developing recommendations and holding organisations publicly accountable for making necessary improvements.

Despite these important and wide-ranging responsibilities, these agencies are lean organisations that operate with relatively small budgets. They are staffed by relatively small teams of highly skilled investigators who are specialists in incident investigation and safety analysis. To conduct major investigations, these teams co-opt and coordinate the expertise that exists within the industry, working constructively with all organisations and sectors involved in an incident. They lead, coordinate and oversee the work of safety investigation. This collaborative approach not only draws on safety expertise across the industry but actively builds and spreads that expertise too.[13]

Principles of independent investigation

The NHS can draw on the well-established principles of independent investigation in other industries to develop an investigation agency for healthcare. First and foremost such an agency needs to be independent, authoritative, and open in its practices and recommendations. Investigations must be trusted, impartial, credible and lead to practical change. At the same

time, investigators need to be deeply immersed in the world of healthcare and have intimate knowledge of practice and policy.

A clear mandate and criteria for intervention needs to be established. These criteria should throw the net wide, spanning serious individual patient safety incidents and major healthcare disasters, but also allowing proactive investigations into emerging sources of systemic risk.

The agency needs the authority and expertise to investigate all aspects of the healthcare system and have access to all relevant parties and information. We know from analyses of both single incidents and major tragedies that the functioning of any part of the healthcare system can play a part in both the causes of a problem and its resolution. The agency needs the authority to direct recommendations at any and all organisations that operate within the healthcare system—from regulators and commissioners to providers of care and manufacturers of equipment.[2] However, while the agency needs to produce recommendations and monitor implementation, it should not be involved in enforcement as this would dilute its independence. The agency should have no stake in the regulatory, financial or operational aspects of the healthcare system that it is required to investigate.

Investigations should be focused on learning and improvement. They should not attribute blame or liability for the causation of safety issues and there should be clear agreements that punitive proceedings will not be taken against staff based on findings of any safety investigation. And as in other industrial sectors, safety investigations should be legally privileged; findings should not be used in the proceedings of attempted prosecutions.

The agency should communicate openly with the media and the public, regularly publishing its findings and publicly hold all organisations in the healthcare system to account for safety improvement—from policymakers to regulators to providers to manufacturers. Investigations should provide practical recommendations to specific organisations, and ensure that those organisations are held accountable for implementing improvements.

Establishing an NHS safety investigation agency

What might independent safety investigation look like in the NHS? An investigation agency needs to be a permanent organisation: it must stand ready to both rapidly initiate investigations within hours when required, and monitor the implementation of recommendations over years if necessary. It should also be lean, staffed by personnel with deep expertise in patient safety, systems analysis, human factors and healthcare practice[14] with the authority to co-opt and coordinate a wide range of resources across the system when conducting investigations[15]. (Box 2).

The agency need not be expensive; indeed it would probably save money. The annual budget of the US National Transport Safety Board Office of Aviation Safety, which investigates 1,750 aviation accidents and incidents each year, is around £30m.[16] This compares favourably with the £13m cost of the Francis inquiry. The model of a core investigative body drawing on wider expertise and resources is important not only because it reduces cost, but because engaging a range of local, regional and national actors across the NHS itself drives processes of learning and cultural change.[17]

All the organisations required to improve following an incident need to be involved in the investigative process. The purpose of investigation is not simply to find out what happened [18] but from the very beginning to consider what improvements would be appropriate and to engage with the organisations that might implement them. Learning is a participatory process and begins at the start of an investigation, not at the end of it.[13] The experts employed by such an agency therefore need to be skilled in building productive relationships, managing networks and communicating effectively—just as much as they need to be experts in analysing safety.

Investigations must be based on a clear-eyed collection and analysis of the facts. This data collection and analysis should be structured and organised using established models of organisational safety, human factors and system accidents.[19, 20] The investigative process should be oriented to producing new knowledge and building practical theory: clearly explaining the causes of events, the sources of risk and the gaps in safety in ways that provide broader lessons for the whole NHS.

Finally, investigations should focus relentlessly on developing specific, practical and unequivocal improvement recommendations based on the facts collected and the analytical account produced. Recommendations should be targeted at all relevant organisations across the healthcare system, from device manufacturers to regulators to healthcare providers to educators and professional bodies. Investigators should provide regular public updates on progress as required. Urgent or interim actions should be circulated rapidly, and full information on the data collected, analysis conducted and

recommendations developed should be widely circulated and publicly accessible.

A promise to learn, a commitment to act

The NHS remains dependent on one-off independent or public enquiries to learn from the most serious of system-wide failures—such as those contributing to the tragedies at Mid Staffordshire. But these inquiries are rare, costly, conducted years after the events occurred and have no capacity to drive the organisational change necessary to implement their recommendations. A huge range of other safety investigations are conducted across the NHS but none has the remit, capacity or authority to drive true system-wide learning. Patients and the public deserve better. Establishing a truly independent, expert investigative body would allow the NHS to rigorously investigate and routinely improve safety across the entire healthcare system. Such an agency would draw widely on existing expertise across the NHS—and would actively develop and spread that expertise too. The work of such an agency could truly capture the widely shared ambition of learning from the past to improve the future.[1,2]

REFERENCES

- 1 Department of Health. An Organisation With a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer. London: Department of Health 2000.
- 2 National Advisory Group on the Safety of Patients in England. A Promise to Learn—A Commitment to Act. London: Department of Health 2013.
- 3 Toft B. External Inquiry into the Adverse Incident that Occurred at Queen’s Medical Centre, Nottingham, 4th January 2001. London: Department of Health 2001.
- 4 Healthcare Commission. Investigation into Mid Staffordshire NHS Foundation Trust. London: Healthcare Commission 2009.
- 5 Francis R. Independent Inquiry into Care Provided by Mid Staffordshire NHS Foundation Trust January 2005–March 2009. London: The Stationery Office 2010.
- 6 Francis R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London: The Stationery Office 2013.
- 7 Black N, Mays N. Public inquiries into health care in the UK: a sound basis for policy-making? J Health Serv Res Policy 2013;18(3):129-31.
- 8 Walshe K. The use and impact of inquiries in the NHS. BMJ 2002;325:895–900.
- 9 Department of Health. The Morecambe Bay Maternity and Neonatal Services Investigation: Statement of Methods. London: Department of Health 2013.
- 10 ICAO. Annex 13 to the Convention on International Civil Aviation, Aircraft Accident and Incident Investigation. Montreal: International Civil Aviation Authority 2007.

- 11 ATSB. Analysis, Causality and Proof in Safety Investigations. Canberra: Australian Transport Safety Bureau 2007.
- 12 Michaelides-Mateou S, Mateou A. Flying in the Face of Criminalization: The Safety Implications of Prosecuting Aviation Professionals for Accidents. Aldershot: Ashgate 2010.
- 13 Macrae C. Close Calls: Managing Risk and Resilience in Airline Flight Safety. London: Palgrave 2014.
- 14 Vincent C, Burnett S, Carthey J. Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety. *BMJ Qual Saf*; in press.
- 15 Macrae C. Early warnings, weak signals and learning from healthcare disasters. *BMJ Qual Saf* 2014;23:440-445.
- 16 NTSB. National Transportation Safety Board Fiscal Year 2013 and 2012 Performance and Accountability Report. Washington, DC: National Transport Safety Board 2013.
- 17 Macrae C. Learning from patient safety incidents. *Health Risk Soc* 2008;10(1): 53-67.
- 18 Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Health Care* 2004;13(4):242–243.
- 19 Vincent CA. Incident reporting and patient safety. *BMJ* 2007;334:51–51.
- 20 Reason. Managing the Risks of Organizational Accidents. Aldershot: Ashgate 1997.

Box 1**Examples of independent investigation in safety critical industries***United Kingdom, Aviation: Air Accidents Investigation Branch (AAIB).*

The AAIB operates as an independent branch of the Department of Transport and the Chief Inspector reports directly to the Secretary of State. The first Inspector of Accidents was appointed in 1915. The AAIB is charged with investigating accidents and incidents and making recommendations for improvement. It operates within a legislative framework that ensures that safety investigations are distinct from procedures to establish legal liability. This framework is shaped by internationally agreed conventions governed by the United Nations International Civil Aviation Organisation. High profile investigations include the engine fire on an Airbus A319 over London in May 2013 and the crash of a helicopter onto a London street in January 2013.

United Kingdom, Railways: Rail Accident Investigation Branch.

The RAIB was established in 2005 following an enquiry into the Ladbroke Grove rail accident of 1999. It is an independent branch of the Department of Transport and the Chief Inspector reports directly to the Secretary of State. The RAIB can direct recommendations to any organisation or person including railway and non-railway, private and public sector organisations. Investigations include the catastrophic derailment of an InterCity service in Cumbria in 2007 that caused one death and 30 serious injuries, and a fatal collision between a car and train on a level crossing near Taunton in March 2013.

United Kingdom, Maritime: Marine Accident Investigation Branch.

The MAIB was established in 1989 following the inquiry into the capsizing of the ferry Herald of Free Enterprise in 1987, which claimed 193 lives. The MAIB is a

functionally and operationally independent branch of the Department of Transport and reports directly to the Secretary of State. It is a small organisation that conducts around 50 investigations each year. These include high profile cases such as the the *Marchioness* disaster on the river Thames in August 1989 in which 51 people died.

United States, Aviation: National Transport Safety Board, Office of Aviation Safety

The NTSB is an independent federal agency responsible for investigating accidents in all modes of transportation including aviation, roads and pipelines. The NTSB Office of Aviation Safety is responsible for investigating all domestic US air accidents—around 1,750 each year. It is also responsible for participating in the investigation of international accidents that involve US airlines or US manufactured or designed equipment. This includes leading the investigation of the Boeing 777 crash at San Francisco in July 2013, and the investigation of battery-related issues that grounded the global Boeing 787 fleet in January 2013.

Box 2**Effective Independent Investigation****Principles**

- Independent and impartial. No executive, regulatory, commissioning or performance management functions.
- Transparent. Clear, timely, open communication of findings of investigations, recommendations and monitoring of implementation.
- Established as permanent body able to investigate and follow up recommendations over years.
- Collaborative and cooperative. Working in partnership with those being investigated.
- Authority to access all sites, organisations, staff and information across the NHS.
- Non-punitive. Separated from assignment of blame or liability and legally protected.
- Accountable. Reporting directly to Secretary of State for Health.

Operational Practice

- Clear mandate and criteria for initiating investigations and for proactive risk management.
- Application of established, evidence based but evolving methodologies.
- Ongoing engagement with all national NHS bodies and organisations
- Investigations encompass all aspects and all levels of the healthcare system.
- Capacity to respond immediately to major events.
- Ability to direct recommendations at individuals and organisations across the healthcare system.
- Long term monitoring of progress on implementing recommendations.

- Holding organisations to public account and challenge when improvements required.

Structures and staffing

- Small core staff with high levels of expertise.
 - Expertise in clinical disciplines and safety sciences.
 - Multidisciplinary, led by safety experts with deep practical understanding.
 - Budget sufficient to both investigate major incidents and monitor recommendations.
 - Lean organisation drawing widely on external expertise.
-

ONLINE SUPPLEMENTAL MATERIAL

Current approaches to the investigation of major safety incidents and concerns in the NHS

1. Local independent investigation or review

Initiated by NHS trust involved in serious incident or concern. Typically led by external senior clinician or senior healthcare managers undertaking site visits, interviews and data and documentary review. Duration of several months. Investigation reports to the trust, usually with disclosure of findings to patients, relatives and carers as well as commissioning and regulatory bodies but not commonly publicly reported.

Examples:

[Independent Review on the care given to Mrs Elaine Bromiley on 29 March 2005](#)

[Colchester Hospital University NHS Foundation Trust independent investigation into concerns about cancer waiting times, 2014](#)

2. National independent investigation

Initiated by and reporting to the Department of Health. Typically led by a senior clinician supported by a small team undertaking interviews and data and documentary review. Duration around 1 year. Investigation reports to the Department of Health and final findings reported in public.

Examples:

[University Hospitals of Morecambe Bay NHS Foundation Trust \(UHMBT\) Maternity and Neonatal Services Investigation, 2014](#)

[External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, January 2001](#)

3. Independent inquiry

Initiated by and reporting to the Secretary of State. Typically led by an experienced legal professional supported by secretariat and expert panel. Duration typically 1-2 years. Final report including recommendations and lessons learnt is usually made public in its entirety.

Example:

[Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust, 2010](#)

4. Public inquiry

Initiated by and reports to the Secretary of State. High profile enquiries typically led by an experienced legal professional supported by secretariat and expert panel. Duration typically 2-3 years. Final report and recommendations made public.

Examples:

[The Mid Staffordshire NHS Foundation Trust Public Inquiry, 2013](#)

[Bristol Royal Infirmary Inquiry, 2001](#)

5. House of Commons Health Committee Investigation

Initiated by parliamentary committee in response to serious safety concerns or performance issues. Conducted by members of parliamentary committee. Duration typically 1-2 months. Evidence, final report and recommendations made public.

Examples:

[Urgent and Emergency Services July 2013](#)

[Patient Safety June 2009](#)

6. Keogh Mortality Review

Initiated by Prime Minister and Secretary of State in response to serious concerns regarding trusts deemed to be persistent outliers on mortality indicators. Led by senior clinician supported by large team of experts. Duration over several months. Findings and recommendations reported publicly.

Example:

Review into the quality of care and treatment provided by 14 hospital trusts in England

[Overview report, 16 July 2013](#)

[Methodology and approach](#)

7. Care Quality Commission regulatory investigation

Initiated by the regulator in response to concerns and indications of poor performance. Led by regulatory investigators supported by external expert advisors. Duration typically of 3-6 months. Final report and recommendations published publicly.

Example:

[Investigation report—University Hospitals of Morecambe Bay NHS Foundation Trust, July 2012](#)

8. Parliamentary and Health Service Ombudsman investigation

Initiated in response to patient, family or carer complaints about the administration, investigation, handling and remedy of serious safety events. Conducted by the ombudsman. Typical duration around 1 year.

Example:

Four investigation reports concerning the University Hospitals of Morecambe Bay NHS Foundation Trust, February 2014

9. Royal College invited review

Initiated at the request of a trust to review aspects of safety and quality of services. Typically conducted confidentially and led by a small team of experts and clinicians through site visits and data and documentation reviews. Duration can be 3-6 months. Findings and recommendations are reported to the trust in private, and may be shared by the trust with commissioners and regulators.

Example:

Royal College of Anaesthetists Anaesthesia Review Team

10. NHS England led Incident Management Team Review

Initiated by NHS England in response to failings identified during regulatory inspection. Typical duration of 1 month. Rapid investigation into serious failings. Led by national commissioning body (NHS England) and including regional and local commissioning groups, clinical networks, county council and expert members through clinically led visits and review. Reported publicly.

Example:

Report into the Immediate Review of Cancer Services at Colchester Hospital University NHS Foundation Trust, 2013

11. NHS England Rapid Response Review

Initiated by NHS England in response to Quality Surveillance Group concerns, or due to concerns raised during a regulatory inspection. Led by experienced clinicians through site visits of several days and review over several weeks. Findings and recommendations publicly reported.

Example:

Rapid responsive review into the quality of care and treatment provided by Wye Valley NHS Trust, 2013

12. NHS England Services Review

Initiated by national commissioning body (NHS England) in response to urgent concerns raised regarding safety issues from mortality data, patient complaints and concerns. Involves action to temporarily suspend services. Duration of several months, including site visits and mortality case review. Key findings publicly reported.

Example:

Leeds Children's Heart Surgery Services Review, 2013-2014