



House of Commons
Public Administration Select
Committee

**Investigating clinical
incidents in the NHS**

Sixth Report of Session 2014–15

*Report, together with formal minutes relating
to the report*

*Ordered by the House of Commons
to be printed 24 March 2015*

The Public Administration Select Committee

The Public Administration Select Committee (PASC) is appointed by the House of Commons to examine the reports of the Parliamentary Commissioner for Administration and the Health Service Commissioner for England, which are laid before this House, and matters in connection therewith, and to consider matters relating to the quality and standards of administration provided by Civil Service departments, and other matters relating to the Civil Service.

Current membership

[Mr Bernard Jenkin MP](#) (*Conservative, Harwich and North Essex*) (Chair)

[Mr Nigel Evans MP](#) (*Conservative, Ribble Valley*)

[Paul Flynn MP](#) (*Labour, Newport West*)

[Mrs Cheryl Gillan MP](#) (*Conservative, Chesham and Amersham*)

[Sheila Gilmore MP](#) (*Labour, Edinburgh East*)

[David Heyes MP](#) (*Labour, Ashton under Lyne*)

[Mr Adam Holloway MP](#) (*Conservative, Gravesham*)

[Kelvin Hopkins MP](#) (*Labour, Luton North*)

[Greg Mulholland MP](#) (*Liberal Democrat, Leeds North West*)

[Lindsay Roy MP](#) (*Labour, Glenrothes*)

[Mr Andrew Turner MP](#) (*Conservative, Isle of Wight*)

Powers

The Committee is one of the departmental select committees, the powers of which are set out in House of Commons Standing Orders, principally in SO No 146. These are available on the internet via www.parliament.uk/.

Publication

Committee reports are published on the Committee's website at www.parliament.uk/pasc and by The Stationery Office by Order of the House.

Evidence relating to this report is published on the Committee's website at www.parliament.uk/pasc.

Committee staff

The current staff of the Committee are Sian Woodward (Clerk), Philip Aylett (Committee Specialist), Sarah Taylor (Committee Specialist), Luanne Middleton (Committee Specialist), Clare Genis (Senior Committee Assistant), Ian Blair (Committee Assistant) and Jessica Bridges-Palmer (Media Officer)

Contacts

All correspondence should be addressed to the Clerk of the Public Administration Select Committee, Committee Office, 14 Tothill Street, House of Commons, London SW1H 9NB. The telephone number for general enquiries is 020 7219 2784; the Committee's email address is pasc@parliament.uk

Contents

Report	<i>Page</i>
Summary	3
1 Introduction	5
Background	5
2 The current situation	8
The impact on patients and their families	8
Current patient safety initiatives	9
Who does what	12
Terminology	18
Complaints handling and the current effectiveness of clinical incident investigation	19
Complexity	19
Culture	20
Patient and family involvement	21
Quality	22
How investigations are carried out	23
How complaints are handled	24
The priority given to complaints	25
The Parliamentary and Health Service Ombudsman’s handling of complaints	26
Legal liability	28
The Duty of Candour	29
Public inquiries	31
3 Reducing the risk of untoward clinical incidents through learning	34
The Department for Transport’s Air Accidents Investigation Branch	34
The importance of an open and just culture	36
The importance of good local investigation	38
The importance of independence	39
The importance of accountability	40
Building the capacity to carry out investigations	42
The importance of learning and sharing lessons	44
A new body - what it should do and how it should relate to other bodies?	46
Where should a new body be located?	49
A ‘whole system’ approach	49
4 Conclusion	54
Conclusions and recommendations	55

Annex	61
Formal Minutes	64
Witnesses	65
Published written evidence	66
List of Reports from the Committee during the current Parliament	68

Summary

The Secretary of State for Health estimates there are 12,000 avoidable hospital deaths every year. More than 10,000 serious incidents are reported to NHS England, out of a total of 1.4 million mostly low-harm or no-harm incidents annually. There were 338 recorded “never events” (such as wrong site surgery) during 2013-14 and NHS England received 174,872 written complaints. The NHS Litigation Authority’s latest estimate of clinical negligence liabilities is £26.1 billion. The cost of the Francis Inquiry into the Mid Staffordshire NHS Foundation Trust was £13.6 million.

Patients and NHS staff deserve to have untoward clinical incidents investigated immediately at a local level, so that facts and evidence are established early, without the need to find blame, and regardless of whether a complaint has been raised. This requires strengthened investigative capacity locally in most of the NHS, supported by a new, single, independent and accountable investigative body to provide national leadership, to serve as a resource of skills and expertise for the conduct of patient safety incident investigations, and to act as a catalyst to promote a just and open culture across the whole health system.

We commend the Secretary of State for Health’s determination to tackle the culture of blame and defensiveness which pervades much of the NHS, and which prevents lessons being learned and adopted following clinical failure. This is not to undervalue recent initiatives, such as those led by NHS England’s Patient Safety Domain, which aim to promote patient safety. There are examples we found of good investigative practice in some areas. However, the processes for investigating and learning from incidents are complicated, take far too long and are preoccupied with blame or avoiding financial liability. The quality of most investigations therefore falls far short of what patients, their families and NHS staff are entitled to expect. Many bodies promote safety in the NHS, including the Care Quality Commission and the Parliamentary and Health Service Ombudsman, and scores of bodies play a role in complaints and safety investigation. There is no systematic and independent process for investigating incidents and learning from the most serious clinical failures. No single person or organisation is responsible and accountable for the quality of clinical investigations or for ensuring that lessons learned drive improvement in safety across the NHS.

We therefore welcome the Secretary of State for Health’s engagement with this inquiry and the fact that in response to our inquiry he has asked Dr Mike Durkin, Director of Patient Safety in NHS England, to look at the possibility of setting up a national independent patient safety investigation body. This must provide three key elements, which are currently lacking. First, it must offer a safe space: strong protections to patients and staff, so they can talk freely about what has gone wrong without punitive reprisals. Second, it must be independent of providers, commissioners and regulators, and so able to investigate whether and how the system as a whole was instrumental in contributing to clinical failure. Third, for transparency and accountability, and to drive learning and improvement, it must have the power to publish its reports and to disseminate its recommendations. It should be for the Care Quality Commission and other executive, regulatory and

commissioning bodies to ensure they are implemented.

Our main recommendation is that the Secretary of State for Health should bring forward proposals, and eventually legislation, to establish a national independent patient safety investigation body. The cost of this body will be relatively small, compared to the costs and liabilities arising from clinical incidents at present. This will involve the development of a body of professionally qualified administrative and investigative staff, who, over time will be able to provide a substantial infrastructure in support of all investigation of clinical incidents. There should be formal examinations and qualifications similar to those formerly made by the Institute of Health Service Administration and the Association of Medical Records Officers. Experience in other safety critical industries demonstrates how resources devoted to investigating and learning to improve clinical safety will save unnecessary expense by reducing avoidable harm to patients. Investigations should be conducted locally, but local resolution is too often slow, conflicted, defensive and of poor quality. The new body must be primarily a centre of expertise and promoter of good investigatory practice and expertise. It must have its own substantial investigative capacity, so that it can lead by example, oversee local investigations and conduct its own investigations when necessary.

There will have to be clear criteria for deciding which incidents it should investigate, to avoid being overwhelmed by the large number that require routine investigation across the NHS. However, all untoward clinical incidents must be investigated: the only question is how and by whom. Therefore, the relevant provisions of the Coroners and Justice Act 2009 should be implemented, to create the post of Independent Medical Examiner in every local area. Dr Alan Fletcher became the first medical examiner in England and Wales in 2008 when a pilot scheme was established in Sheffield in response to the Shipman case, but few others have since been appointed. One should be appointed for every Clinical Commissioning Group, to examine hospital deaths, to keep families of the deceased informed, and to alert the coroner to cases of concern. In time, such Examiners should refer cases for investigation to the proposed new body.

1 Introduction

1. The Public Administration Select Committee (PASC) scrutinises the work of the Parliamentary and Health Service Ombudsman (PHSO), which is the final adjudicator of NHS complaints in England.¹ Many of the PHSO's adjudications are based on evidence about clinical incidents. There has been increasing concern that some of its adjudications have not been based on reliable evidence, and that this reflects an inadequate capacity for investigating and reporting on clinical incident investigations across the whole of the NHS. This Report follows our inquiry into how the system for investigating clinical incidents is working in the NHS and what can be learned from other sectors that need to investigate safety lapses or incidents that cause injury or death. Our inquiry was prompted by a paper on this topic in the *Journal of the Royal Society of Medicine* by Carl Macrae and Charles Vincent.² Our report is addressed to the NHS in England, but we believe our findings are also relevant to the rest of the health sector, and to the NHS in Scotland, Wales and Northern Ireland.

Background

2. A number of reviews and reports in recent years provide the context for this inquiry. These have focused on the need to create systems and cultures that support open and effective learning in the NHS. Following a public inquiry into failings at Mid-Staffordshire NHS Foundation Trust between January 2005 and March 2009, Robert Francis QC published his final report on 6 February 2013. It concluded that a fundamental culture change was needed.³ In July 2013 Professor Sir Bruce Keogh, the NHS Medical Director for England, published his review of the quality of care and treatment provided by trusts that were persistent outliers on mortality indicators.⁴ This called for a concerted improvement effort and a focus on clear accountability. In August 2013 the Department of Health published the report of Don Berwick's review into patient safety, which studied the Francis report and distilled the lessons learned for the Government and the NHS, and changes needed.⁵ It called for the NHS to become "a system devoted to continual learning and improvement of patient care, top to bottom and end to end".⁶ The Government published its response to Robert Francis' inquiry in January 2014.⁷ This stated that there would be stronger professional responsibility, and openness about mistakes and 'near misses'; "following the example of the airline industry in building an open culture that learns from errors and corrects them."⁸

1 [Health Service Commissioners Act 1993](#)

2 Macrae C and Vincent C, 'Learning from failure: the need for independent safety investigation in healthcare' *Journal of the Royal Society of Medicine*; 2014, 107(11) 439-443

3 [Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry](#), HC 947, February 2013

4 NHS Choices, [The Keogh Mortality Review](#), July 2013

5 Department of Health, [A promise to learn – a commitment to act: improving the safety of patients in England](#), August 2013

6 As above

7 Department of Health, [Hard Truths The Journey to Putting Patients First](#), January 2014

8 As above

3. There have been a number of policy developments since we announced our inquiry on 17 December 2014. New patient safety initiatives have been announced, and the Government has accepted the need for an independent safety investigation unit. On 11 February this year the Department of Health published *Culture change in the NHS*, which stated that:

It makes sense to concentrate and consolidate national expertise and capability on safety within a single organisation that can provide strategic leadership across the whole healthcare system.⁹

4. The Government accepted Sir Robert Francis' recommendation that trusts should appoint a person to receive concerns and offer advice, to ensure cases are properly investigated and issues addressed without repercussions for the person who raised an issue.¹⁰ These will be known as Freedom to Speak Up Guardians. The Secretary of State for Health explained these would be "part of the organisation but just there, so that, if you do not want to tell your line manager, you have someone else you can talk to in the Trust."¹¹ There will also be, he explained, a national Freedom to Speak Up guardian, "so there is someone outside the hospital if you ultimately needed it."¹²

5. In the House of Commons on 3 March 2015, following his appearance to give evidence before us on this inquiry, the Secretary of State for Health Jeremy Hunt MP said he was asking the Director of Patient Safety in NHS England, Dr Mike Durkin, to draw up and publish "much clearer guidelines for standardised incident reporting".¹³ He continued:

But I also believe the NHS could benefit from a service similar to the Air Accidents Investigation Branch of the Department for Transport. Serious medical incidents should continue to be instigated and carried out locally, but where trusts feel they would benefit from an expert independent national team to establish facts rapidly on a no-blame basis they should be able to.¹⁴

6. The relationship between complaints, clinical incident investigation, and patient safety is complex. All serious patient safety incidents are supposed to be investigated by healthcare provider organisations, as the Serious Incident Framework sets out.¹⁵ However, at present, patients or their relatives often need to complain in order to prompt the investigation of an incident.¹⁶ Patients often do not complain due to lack of confidence in complaints handling, so that safety issues go unresolved.¹⁷ Poor investigation of clinical incidents

9 Department of Health, [Culture change in the NHS – Applying the lessons of the Francis Inquiries](#), February 2015

10 Sir Robert Francis QC, [Freedom to speak up: an independent review into creating an open and honest reporting culture in the NHS](#), February 2015 and Hansard (2015) 3 Mar : Column 835

11 Q 284

12 As above

13 Hansard (2015) 3 Mar : Column 835

14 As above

15 NHS Commissioning Board (now NHS England), [Serious Incident Framework](#), March 2013

16 Q 171 [Katherine Rake]

17 Q 312 [Jeremy Hunt MP]

locally leads to more complaints being escalated to the Parliamentary and Health Service Ombudsman.¹⁸

7. The comprehensive evidence base that would be provided to the Ombudsman if local investigations were more effective would speed up the Ombudsman's work, allowing it to publish its findings more quickly.¹⁹ It would also enable more complaints about clinical incidents to be resolved without the PHSO's intervention. Complaints may be unfounded, and doctors may be negligent. But it is usually safe to assume good faith. Murray Anderson-Wallace and others, a small group of people with personal experience of avoidable harm in healthcare, wrote to us to say that "in the vast majority of circumstances citizens and healthcare staff share the same goals and aspirations. Both are significantly affected by poor quality investigation and adversarial approaches to avoidable harm."²⁰ Things can usually be put right through proper complaints handling and effective investigations. Effective investigations can reduce the number of complaints.²¹ The Ombudsman, Dame Julie Mellor, described the relationship as follows:

There is an under-reporting of incidents and therefore an under-investigating of incidents, and therefore continuing risk to patient safety and the learning not happening.²²

8. Written submissions and transcripts of our three oral evidence sessions are available on our website at www.parliament.uk/pasc. We are grateful to all those who gave evidence and to our Specialist Adviser, Dr Carl Macrae, for his help with this inquiry.²³

9. This inquiry has received much evidence concerning individual cases that we cannot address individually, but which together paint a grim picture of grief and anger caused by denial, defensiveness and evasion. We have read all these submissions carefully in order to see what we can learn from them. We pursue this topic in the hope of achieving quicker and more effective resolution of incidents of clinical failure locally, leading to faster learning and more positive change, without the need for a complaint, and therefore a substantial reduction in the number of people whose cases reach as far as the Ombudsman.

10. We are grateful for the openness and dialogue we have had with the Secretary of State for Health, who has become an advocate for a new body along the lines we have been discussing.

18 Parliamentary and Health Service Ombudsman [[CCF61](#)] and Action against Medical Accidents [[CCF23](#)]

19 Parliamentary and Health Service Ombudsman [[CCF61](#)]

20 Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everton, Stephen Richards and James Titcombe [[CCF87](#)]

21 Action against Medical Accidents [[CCF23](#)]

22 Q 214 [Dame Julie Mellor]

23 Dr Carl Macrae is a social psychologist and an honorary senior research fellow at the Centre for Patient Safety and Service Quality, Imperial College London. He was appointed as a Specialist Adviser for this inquiry on 27 January 2015. He declared the following interests: advisory and research contracts with The Health Foundation; an advisory contract with and expert steering group member for NHS England; expert patient safety content advisor for BMJ Group; Special Advisor with Haelo, a regional healthcare improvement organisation.

2 The current situation

The impact on patients and their families

11. Untoward clinical incidents can cause terrible suffering for patients, their families, and medical professionals. For patients, if not clinicians, these impacts include death and serious injury, as in the case of three year old Sam Morrish, whose death from sepsis in 2010 was found to have been avoidable.²⁴ This had a devastating impact on his parents and family. Doctors too, we heard, “are usually devastated. When something goes wrong, they feel awful. They are usually their own worst critics and what they are desperate to do is work out what they should be doing, what steps they should follow, who they should speak to and how they should go about beginning to address what has occurred and hopefully be able to put it right.”²⁵ The Health Select Committee recently concluded that:

Most of those who complain about NHS services do not seek financial redress. They do so because they wish to have their concerns and experiences understood and for any failings to be acknowledged and put right so that others do not suffer the same avoidable harm.²⁶

12. This harm and distress is often heightened by the complaints process.²⁷ Katherine Rake of Healthwatch described to us the experience of the complainant:

Where you have a concern or complaint, you are often ill or you have been recently bereaved. Emotionally and physically, it can be a very difficult thing to do. It can make you feel very fearful and, because people do not have trust and confidence in the system, exactly as you say, they do not trust that their on-going care will be unaffected.²⁸

A common theme found in the stories submitted to us by the consumer group Which? was a feeling of vulnerability and a fear of victimisation that patients feel when considering submitting a complaint.²⁹ These include fears of being labelled as the ‘difficult patient’ or of being struck off or blacklisted from accessing a public service such as a GP surgery.³⁰ Once they have entered the complaints process, we were told that “a complainant must be totally committed to the process, driving it forward every step of the way. They must in fact dedicate their life to achieving justice for their loved one and improvement for those who follow.”³¹ However, all being well, a constructive response that ensures that a particular

24 Parliamentary and Health Service Ombudsman, [An avoidable death of a three-year-old child from sepsis](#), June 2014

25 Q 129 [Michael Devlin]

26 Health Select Committee, Fourth Report of Session 2014-15, [Complaints and Raising Concerns](#), HC 350, January 2015

27 Q 207 [Katherine Murphy]

28 Q 177 [Katherine Rake]

29 Which? [[CCF55](#)]

30 Which? [Make complaints count](#), March 2015

31 PHSO Pressure Group [[CCF7](#)]

mistake is not repeated can help give meaning to a loss, and bring a small degree of closure.³²

Table 1: Figures

What	Number or amount	Details
Complaints about the NHS	174,872	All written complaints received by NHS organisations in 2013/14, reported to the Health and Social Care Information Centre. ³³
Complaints about the NHS accepted for investigation by the Parliamentary and Health Service Ombudsman	3,075	Of the 17,964 health-related enquiries the PHSO received in 2013-14, 6,093 were assessed and 3,075 were accepted for investigation. ³⁴
Incident reports on NHS England's National Reporting and Learning System	1.4 million	Per year, of which 1.3 million are 'low harm' or 'no harm'. ³⁵ Of the total, 1,421 deaths were reported following incidents, 49,000 resulted in moderate harm; 4,500 resulted in severe harm. ³⁶
Serious incidents	10,000+	More than 10,000 serious incidents are reported to the National Recording and Learning System annually which require investigation under current arrangements. ³⁷
Never events	338	Occurred between 1 April 2013 and 31 March 2014. ³⁸
Avoidable deaths in the NHS	Unknown	The Secretary of State for Health has stated that there are an estimated 12,000 avoidable deaths in NHS hospitals each year, but it is not known which deaths these are among the total of 250,000 hospital deaths. ³⁹
Clinical negligence liabilities	£26.1 billion	The NHS Litigation Authority's estimate of the public funds that will be needed for current (£10.5 billion) and potential future (£15.6 billion) claims relating to treatment delivered up to 31 March 2014. ⁴⁰

Current patient safety initiatives

13. The NHS is complicated and contains scores of bodies that play a role in complaints, patient safety and investigating incidents. More than 70 bodies play a role in complaints handling.⁴¹ This section of the report outlines the patient safety initiatives in place at present, though recent policy developments mean these are changing and many new national initiatives are in their early, design or pilot phases.

32 Sands, the stillbirth and neonatal death charity [CCF47]

33 Health and Social Care Information Centre, *Data on Written Complaints in the NHS - 2013-14*, August 2014

34 Parliamentary and Health Service Ombudsman, *The Ombudsman's Annual Report and Accounts 2013-14*, July 2014

35 Q 17

36 Ken Lownds [CCF52]

37 Care Quality Commission [CCF57]

38 A 'never event' is a serious, largely avoidable patient safety incident that should not occur if the available preventative measures are implemented. NHS England, *Never Events reported as occurring between 1 April 2013 and 31 March 2014*, December 2014

39 Q 272 [Jeremy Hunt MP] and Department of Health [CCF64] and 'Jeremy Hunt orders yearly study of 'avoidable' hospital deaths', *BBC News*, 8 February 2015

40 NHS Litigation Authority, *Report and accounts 2013/14*, July 2014

41 Q 157 [Katherine Rake]

14. The National Reporting and Learning System, which is the responsibility of NHS England, is a collection of data from local incident reporting systems in all NHS healthcare settings.⁴² It provides a knowledge base about what can go wrong in patient care.⁴³ Mike Durkin told us that his organisation, NHS England, reviews all deaths and severe harms reported through the System on a monthly basis, “and we will also mine and identify through the data significant trends on a number of different major areas”.⁴⁴ The Department of Health told us that this system “supports the vital role of identifying, understanding and managing risks that pose a danger to patients.”⁴⁵ However, we heard from Peter Walsh of Action against Medical Accidents that the System “is not used as much as it should be.”⁴⁶ Dr Durkin of NHS England said the System “is seen by the rest of the world as an amazing achievement over the last 10 years to collect that, but it is pretty sector-specific. It is pretty specific to the hospital system, because hospital systems have reporting mechanisms that allow staff freely to report confidentially. We do not open it up to patients yet, but we are building a new system and they will certainly be part of that.”⁴⁷ The Department told us that risks identified through the System are used as the basis of safety information issued to providers via the National Patient Safety Alerting System.⁴⁸

15. This National Patient Safety Alerting System was launched by NHS England in January 2014.⁴⁹ It aims to alert the whole NHS to newly identified patient safety risks and issues, to provide advice and guidance on risk mitigation, and to require organisations to take action, NHS England told us.⁵⁰ Since January 2014, 21 patient safety alerts have been issued, for example, on the risk of severe harm and death from unintentional interruption of non-invasive ventilation, issued 16 February 2015.⁵¹ This year NHS England will be piloting an initiative called Safety Action Force England, an “independent and non-judgmental expert capability and support” to aid local organisations in improving their safety.⁵² Safety Action Force England, the Department of Health told us, will use two approaches: a ‘safety culture approach’ that will assess an organisation’s processes, leadership and culture in order to target support; and a ‘solution development approach’ involving an in-depth study of a clinical issue, to assess an organisation’s approach to safety, and give appropriate support.⁵³

42 Department of Health [\[CCF64\]](#) and NHS England [\[CCF62\]](#)

43 Department of Health [\[CCF64\]](#)

44 Q 17

45 Department of Health [\[CCF64\]](#)

46 Q 178 [Peter Walsh]

47 Q 15

48 Department of Health [\[CCF64\]](#)

49 NHS England, [National Patient Safety Alerting System](#), undated

50 NHS England [\[CCF62\]](#)

51 NHS England, [Patient safety alert: Risk of severe harm and death from unintentional interruption of non-invasive ventilation](#), February 2015

52 Department of Health [\[CCF64\]](#)

53 As above

16. Datix Ltd is a company specialising in patient safety and healthcare risk management software, which aims “to help our customers protect patients from harm by creating opportunities to learn from things that go wrong”.⁵⁴ Its customers include more than 75% of the NHS, with many trusts using a Datix form to report patient incidents.⁵⁵ The Royal College of Anaesthetists however told us there is dissatisfaction with elements of the form’s design, as it uses “very limited” mandatory drop down menus and has minimal space for free text, leading sometimes to inaccurate description of incidents and challenges in searching for clinically relevant incidents without specific training:

It is very difficult to search Datix for clinically related incidents, without specific training on how to use the system, making all the information recorded in the database largely inaccessible.⁵⁶

17. NHS England has responsibility for formulating and supporting NHS policy on responses to patient safety incidents, including investigations.⁵⁷ The Secretary of State for Health told us that it “is the central place where all the learning should be assembled and disseminated.”⁵⁸ It coordinates, commissions and oversees patient safety improvement initiatives, including the new Patient Safety Collaborative programme.⁵⁹ Dr Mike Durkin of NHS England described this to us. Fifteen patient safety learning networks are being set up, which together have £12 million funding a year for the next five years.⁶⁰ These will use the data from the National Reporting and Learning System to identify priorities for action, “to support system learning in every sector and every setting, so this is for hospitals, primary care, community settings and mental health settings.”⁶¹ Dr Durkin also described an NHS England/Health Foundation initiative, a new system of 5,000 “patient safety improvement fellowships”, to be introduced over the next five years.⁶² In the interests of patient safety improvement NHS England also publish monthly data on ‘never events’ and publishes key patient safety indicators by hospital.⁶³

18. NHS England’s Serious Incident Framework is a publication that “seeks to support the NHS to ensure that robust systems are in place for reporting, investigating and responding to serious incidents so that lessons are learned and appropriate action is taken to prevent future harm”.⁶⁴ NHS England’s current pilot of a Patient Safety Investigations Branch looks into a small number of investigations in depth to provide insights on investigation improvement and to identify solutions for common incident types.⁶⁵

54 Datix Ltd [CCF26]

55 Datix Ltd [CCF26] and Royal College of Anaesthetists [CCF21]

56 Royal College of Anaesthetists [CCF21]

57 NHS England [CCF62]

58 Q 305 [Jeremy Hunt MP]

59 NHS England [CCF62]

60 NHS England [CCF62] and NHS England, *Patient Safety Collaboratives*, undated

61 As above

62 Q 17 and NHS England [CCF62]

63 NHS England [CCF62]

64 Department of Health [CCF64]

65 As above

Who does what

19. This section outlines the roles of the key organisations in patient safety, complaints and clinical incident investigation. These organisations include the Parliamentary and Health Service Ombudsman, the Care Quality Commission, the Department of Health, NHS England, Healthwatch, and the Confidential Reporting System for Surgery.

Department of Health

20. The Department of Health told us they receive several hundred complaints from the public about the NHS and social care every month.⁶⁶ It wrote “the Department has no role in the NHS complaints procedure, but this is not always clear to members of the public.”⁶⁷ However, the Department is responsible for “overseeing the running of the NHS” as a whole, as Professor Chris Ham of the King’s Fund told us.⁶⁸ South West Whistleblowers Health Action Group told us that the Department is “currently part of the problem”:

In 2000 the Department of Health published a document called *An organisation with a memory*. It is a 108 page report of an expert group on learning from adverse events in the NHS. The fact that the Committee is carrying out an inquiry into complaints and clinical failure nearly 15 years after this report was produced is a testament to the failure of the Department of Health and Governments since 2000 to drive forward improvements.⁶⁹

NHS England

21. Dr Mike Durkin, National Director of Patient Safety at NHS England, is responsible for patient safety. Dr Durkin’s branch looks after what it calls the ‘patient safety domain’ of the NHS Outcomes Framework. This is one of five sections of a set of published indicators (the others concern prevention, quality of life for people with long-term conditions, recovery from ill health or injury, and the experience of care).⁷⁰ We challenged Sir Mike Richards, the Care Quality Commission’s Chief Inspector of Hospitals, on this:

Chair: Is it not odd that the patient safety domain has been moved into NHS England, which is itself a commissioner and to some extent unconsciously a regulator?

Professor Sir Mike Richards: There will be people within NHS England who might agree with you on that, but I welcome the fact that the emphasis on safety is somewhere.⁷¹

66 Department of Health [CCF64]

67 As above

68 Oral evidence taken on 24 June 2014, (2014-15), HC 110, Q 335

69 South West Whistleblowers Health Action Group [CCF40]

70 For example, one indicator in the prevention domain is five year survival from all cancers among children. Department of Health, *The NHS Outcomes Framework 2014/15*, November 2013.

71 Q 252

Katherine Rake of Healthwatch set out the perceived conflict of interest for us. She said that, in relation to a proposed new body for incident investigation, “for NHS England, given that they have some direct complaints resolution, they would effectively be marking their own homework.”⁷²

Parliamentary and Health Service Ombudsman (PHSO)

22. The Parliamentary and Health Service Ombudsman is responsible for considering complaints by the public that UK Government departments, public bodies and the NHS in England have not acted properly or fairly or have provided a poor service. Technically the PHSO comprises the offices of the Parliamentary Commissioner for Administration and the Health Service Commissioner for England. The Ombudsman is appointed by the Crown on the recommendation of the Prime Minister and is accountable to Parliament. The Ombudsman is independent of both the Government and the Civil Service and reports annually to both Houses of Parliament. The current Ombudsman is Dame Julie Mellor who has held the post since January 2012.⁷³

23. The office of Health Service Ombudsman was created by the NHS Reorganisation Act 1973 following pressure for an effective resolution of grievances, given the exclusion of the NHS from the 1967 Parliamentary Commissioner Act, as outside the direct responsibility of what was then the Minister of Health. The office was subsequently modified by the Parliamentary and Health Service Commissioners Act 1987, the Health Service Commissioners Act 1993 and the Health Service Commissioner (Amendment) Act 1996. This last Act considerably broadened the scope of the Ombudsman’s investigations by enabling the Health Service Commissioner to investigate all aspects of NHS care and treatment, including clinical judgement. It was designed to place the Ombudsman at the top of a unified NHS complaints procedure.

24. Complainants can refer their case directly to the Health Service Ombudsman and do not have to go through their MP. Cases can continue to be referred to the Ombudsman during a pre-general election dissolution period.

25. The Ombudsman’s current remit gives the Ombudsman power to investigate in certain circumstances, including in relation to a complaint made to the Commissioner by or on behalf of someone who has sustained injustice or hardship due to:

- a failure in a service provided by a health service body;
- a failure of such a body to provide a service which it was a function of the body to provide; or
- maladministration connected with any other action taken by or on behalf of such a body.⁷⁴

72 Q168 [Katherine Rake]

73 Public Administration Select Committee, Ninth Report of Session 2010-12, [Pre-appointment hearing for the post of Parliamentary and Health Service Ombudsman](#), HC 1220-I, July 2011

74 [Health Service Commissioners Act 1993](#), chapter 46, section 3

PHSO cannot investigate maladministration or service failure in health providers paid for privately. This has led to cases in which it can be hard or impossible for PHSO to investigate and to adjudicate fairly, due to the fact that responsibility for the health outcome is shared, partly within, and partly outside, PHSO's jurisdiction.

26. There is no right of appeal against decisions of the Ombudsman. As the office is independent of Government and Parliament, decisions on cases cannot be overruled by a government minister or a parliamentary committee. The House of Commons Standing Order relating to this Committee gives us the power to "examine the reports" of the PHSO, not to review or question individual adjudications, but we do seek to understand the work of the PHSO better by hearing informally about individual cases on occasion.⁷⁵ Decisions of the Ombudsman, as with ministerial decisions and the decisions of the lower law courts, are subject to judicial review.

27. PHSO has adopted a policy to increase the number of cases it considers. In its 2013-14 annual report the PHSO stated that:

Last year, we fundamentally changed the way we handled complaints, enabling us to move from investigating hundreds to thousands of complaints.⁷⁶

Most (78%) of its investigations were about the NHS; the remainder were about other government departments and agencies.⁷⁷ The PHSO reports that:

Previously, we only investigated if the evidence showed that we were likely to uphold the complaint. Now we investigate if there is a case to answer. We have achieved this by shortening the assessment process we use to decide whether to take on a complaint or not, and moving this resource into the investigation stage.⁷⁸

While such changes have meant that the PHSO has been able to take on more cases, the percentage of complaints which the Ombudsman upholds has declined from 86% in 2012-13 to 42% in 2013-14. However, overall PHSO upheld 854 complaints in 2013-14, over double the number of complaints upheld in the previous year.⁷⁹

The Care Quality Commission (CQC)

28. The Care Quality Commission is a non-departmental public body of the Department of Health, and is the regulator of health and social care services in England. Part of the CQC's inspection method concerns patient safety. They told us that one of their "key lines of enquiry" is asking "are lessons learned and improvements made when things go wrong?" Professor Sir Mike Richards, the CQC's Chief Inspector of Hospitals, told us that the CQC

75 Standing Order 146. *Standing Orders of the House of Commons*, December 2013

76 Parliamentary and Health Service Ombudsman, *The Ombudsman's Annual Report and Accounts 2013-14*, July 2014

77 As above

78 As above

79 As above

“look at what things go wrong, and they are a very important part of our inspection process. Those clinical incidents contribute to our key question about whether care is safe.”⁸⁰ He said that, on every inspection, the CQC looks into how well incidents and complaints are managed.⁸¹ An external observer, Michael Devlin of the Medical Defence Union, confirmed to us that management of safety is one of the first things the CQC looks at in their inspections.⁸² CQC inspection teams use the following questions to inform their assessment:

- Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
- When things go wrong are thorough and robust reviews or investigations carried out? Are all relevant staff and people who use services involved in the review or investigation?
- How are lessons learned and is action taken as a result of investigations when things go wrong?
- How well are lessons shared to make sure action is taken to improve safety beyond the affected team/service?⁸³

29. We asked Sir Mike about the CQC’s role with respect to investigations. He said “we do not do the investigations per se. We look to see whether they are a learning organisation.”⁸⁴ He said they “look at a sample of the files on those complaints and incidents, and we will choose which ones we look at—we will not just let the hospital choose for us—so that we can see whether they have conducted the investigation properly and whether the documentation is there.”⁸⁵ He explained that, if they rate a trust as “requiring improvement” or “inadequate”, this puts pressure on it to improve.⁸⁶

80 Q 213

81 Q 213 [Professor Sir Mike Richards]

82 Q 141

83 Care Quality Commission [[CCF57](#)]

84 Q 259

85 Q 231 [Professor Sir Mike Richards]

86 Q 260

The General Medical Council

30. The General Medical Council (GMC) registers and licenses doctors in the UK. For doctors and consultants, discussions about patient safety incidents and complaints form part of their annual appraisal. This is a key part of securing revalidation and a continuation of their licence to practise.⁸⁷ Incidents that give rise to concern may come to the GMC's attention via patients, clinicians themselves, or their colleagues, and can result in an investigation "to see if the doctor is putting the safety of patients, or the public's confidence in doctors, at risk". This can result in a decision to bar someone from being allowed to practice as a clinician in the UK.⁸⁸ Such decisions are subject to a hearing before a tribunal. Dr Margaret McCartney told us the GMC often takes "years to investigate incidents and uses a formal, legalistic process of blame which, as it can strike doctors off, creates defensiveness".⁸⁹

31. Dr Alan Fletcher became the first Independent Medical Examiner in England and Wales in 2008 when a pilot scheme was established in Sheffield in response to the Shipman case, but few others have since been appointed.⁹⁰ Independent Medical Examiners have also been piloted successfully in Gloucester, Powys, North London and Leicester: the Secretary of State for Health has said that "the availability of an independent examiner has been shown in the trials we have run to be very effective".⁹¹ The Shadow Secretary of State for Health, Andy Burnham MP, called in March 2015 for the introduction of a new system of independent medical examination of all deaths not referred to a coroner, as previously legislated for. Andy Burnham suggested there should be a mandatory review of case notes for every death in hospital, and a look at how a standardised system of case note review can support learning and improvement in trusts.⁹²

The Confidential Reporting System for Surgery

32. The Confidential Reporting System for Surgery (CORESS) is a charity, founded ten years ago by the Association of Surgeons of Great Britain and Ireland, which aims to promote safety across all surgical disciplines in the NHS and the private sector.⁹³ The Association told us that CORESS receives confidential incident reports from surgeons and theatre staff; confidential means the identity of the reporter is kept secret. These are analysed by an advisory committee, which extracts lessons from these events. The charity then publishes safety lessons in the surgical literature to educate surgeons and reduce the chance of repeat incidents, and disseminates information to other interested parties

87 MDU Services Ltd [CCF11]

88 General Medical Council, [Our role](#), undated

89 Dr Margaret McCartney [CCF8]

90 'No guarantee another Shipman couldn't happen again', *Channel 4 news*, 21 January 2015

91 Hansard (2015) 3 Mar : Column 843 and Department of Health, [Death Certification Reforms: New Duty on Local Authorities](#), August 2011

92 As above

93 Association of Surgeons of Great Britain and Ireland (ASGBI) and the Confidential Reporting System for Surgery (CORESS) [CCF63]

including, for example, administration staff.⁹⁴ CORESS also hosts training courses on safer surgical practice and human factors.⁹⁵

Other bodies

33. The Department of Health also discussed the role of the Health and Safety Executive in its written evidence to us. This body may consider investigating a patient or service user's death or serious injury, where there is an indication that a breach of health and safety law was a probable cause or a significant contributory factor.⁹⁶ Finally, the Department noted that its Executive Agency the Medicines and Healthcare Products Regulatory Agency is responsible for the safety of medicines.⁹⁷

34. A number of advocacy groups help members of the public with their complaints, such as POhWER, which told us in written evidence that: “our role is to enable clients’ voices to be heard, speaking for them when they can’t and supporting them when they can. [...] We provide expert knowledge and advice to individuals to help resolve their concern or complaint.”⁹⁸

35. Within trusts, Patient Advice and Liaison Services (PALS) can give information on NHS complaints procedures.⁹⁹ Many have no faith in the PALS system for raising concerns, Ken Lowndes told us, a campaigner for and contributor to the Mid Staffs Public Inquiry, writing in a personal capacity.¹⁰⁰

The independent healthcare sector

36. The Chair had an informal meeting with the Association of Independent Healthcare Organisations to learn about the independent healthcare sector's attitude to clinical safety management and incident investigation. The independent sector's approach is different in one fundamental respect, in that it has no obligation to carry out treatment or procedures on any patient which is not regarded as safe, so it is easier to ensure that safety is paramount. Such cases are referred to the NHS, which has an obligation to provide the best treatment available, often in a cost constrained environment.

37. Independent healthcare providers are subject to inspection by the CQC in the same way as NHS funded providers, and clinicians are subject to registration and regulation by the same professional bodies, such as the General Medical Council. However, they are responsible for their own complaints procedures and PHSO has no jurisdiction over them in respect of complaints. We learned from one PHSO case that this can lead to an incomplete investigation by PHSO when a patient's mainly NHS treatment also has included an episode or incorrect diagnosis paid for privately.

94 As above

95 As above

96 Department of Health [[CCF64](#)]

97 As above

98 POhWER, a complaints advocacy provider [[CCF45](#)]

99 NHS Choices, [What is PALS \(Patient Advice and Liaison Service\)?](#), undated

100 Ken Lowndes [[CCF52](#)]

The Public Administration Select Committee (PASC)

38. Under the Standing Orders of the House of Commons, we have a remit to “examine the reports” of the Parliamentary and Health Service Ombudsman.¹⁰¹ The predecessor to this Committee was given this remit in 1997. PHSO’s reports include its annual report and accounts, so this has been taken to mean that we also scrutinise the operation and performance of PHSO. We recommended in 2014 that the Public Accounts Commission, or a similar body, should take primary responsibility for scrutiny of PHSO, including examining corporate plans, budget and resources.¹⁰² We recommended that the Standing Order relating to this Committee should be amended to require us to use the intelligence gathered by the PHSO to hold to account the administration of Government.

Terminology

39. Chairman and founder of the NHS Complaint Managers Group John Dale told us different terms are used in different organisations to describe clinical incidents (see Table 2):

Serious incidents; serious adverse incidents; untoward clinical incidents, etc.
I am not sure anyone uses the word ‘accident’ [...] but would not be surprised if this is the case.¹⁰³

The Royal College of Physicians said that changing terminology may be one way to help improve the culture in the NHS. The term ‘clinical failure’ “could be replaced with ‘untoward clinical incidents’ similar to the terminology used for serious untoward clinical incidents. This may help in reducing the defensive nature in which investigations are viewed.”¹⁰⁴

101 Standing Order 146. [Standing Orders of the House of Commons](#), December 2013

102 Public Administration Select Committee, Fourteenth Report of Session 2013-14, [Time for a People’s Ombudsman Service](#), HC 655, April 2014, paragraphs 86-88

103 John Dale [\[CCF15\]](#)

104 Royal College of Physicians [\[CCF24\]](#)

Table 2: Definitions of terms

Term	Meaning
'Patient safety incident'	An unintended or unexpected event that could have or did lead to harm for one or more patients. ¹⁰⁵
'Patient safety domain'	An area of NHS England's activity with a 'system leadership role' for patient safety in the NHS. ¹⁰⁶ In addition, patient safety is one of five domains in the NHS Outcomes Framework published by the Department of Health, which sets out the outcomes and corresponding indicators used to hold NHS England to account. ¹⁰⁷
'Serious incident'	An incident that occurs during NHS funded healthcare that results in; <ul style="list-style-type: none"> • unexpected or avoidable death or severe harm of one or more patients, staff or members of the public; • a never event; • a scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services; • allegations, or incidents, of physical abuse and sexual assault or abuse; and/or • significant loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.¹⁰⁸
'Never event'	A serious, largely avoidable patient safety incident that should not occur if the available preventative measures are implemented. ¹⁰⁹
'Accident'	An incident that happens unexpectedly and unintentionally, and which may result in damage or injury.
'Independent investigation'	Investigations where the investigator and all members of the investigation team are independent of the provider in question and were commissioned independently of the organisation whose actions and processes are being investigated.
'Human factors'	An approach to system design and analysis which considers the characteristics and abilities of the people who work in the system and how to organise them effectively so that the system works. ¹¹⁰
'Root cause analysis'	A longstanding incident analysis method widely used in healthcare settings that tries to identify the root causes of faults, problems or events, increasingly recognised to have limitations as the importance of other methods has become understood (see human factors, above).
'Just culture'	In a just culture there is a balance between learning and accountability, achieved in part by a clear separation between the bodies responsible for regulation and enforcement, and those responsible for investigation and learning. ¹¹¹

Complaints handling and the current effectiveness of clinical incident investigation

Complexity

40. A large number of organisations are involved in complaints handling, inhabiting a complicated landscape, with what appear to be overlapping responsibilities between different organisations.¹¹² An Ombudsman's report may be one of several enquiries into a single clinical incident, including those by the NHS body where it occurred, the coroner,

105 NHS England [CCF62]

106 NHS England, *Patient safety*, undated

107 Department of Health, *NHS Outcomes Framework 2014-15*, November 2013

108 As above

109 NHS England, *Never events*, undated

110 Royal College of Nursing, *Human factors - what are they?*, undated

111 Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everton, Stephen Richards and James Titcombe [CCF87]

112 Royal College of Physicians [CCF24] and Q 5 [Dr Durkin]

the police, the CQC, the GMC or other regulatory body, the Health and Safety Executive, and NHS England Area Teams.¹¹³ Healthwatch has found that:

There are in excess of 70 organisations involved in any individual’s complaint. No wonder the public finds that bewildering and confusing.¹¹⁴

Healthwatch told us that “consumers often spend months trying to route their complaint to the body who can address it.”¹¹⁵ Complainant Peggy Banks’ written evidence suggested to us that a single investigation branch would address what she called a “passing the parcel regime”.¹¹⁶ We heard that even medical professions can be confused and feel “totally on their knees in front of the complaints system”.¹¹⁷ Some cases require separate investigations by the PHSO and the Local Government Ombudsman, adding to the complexity and in some cases the distress of patients or the families.

41. The NHS Confederation, a membership body for commissioners and other NHS bodies, has called on NHS England to provide clearer information about the complaints process, “which has been made more difficult to understand” due to the complexity of the new commissioning landscape and the more diverse range of providers.¹¹⁸ Public understanding of these bodies and processes is low and signposting for patients is poor.¹¹⁹ This can mean patients fail to recognise where they deserved a better response to their complaint.¹²⁰ Public confidence in the system is also low. Denis Wilkins, the founder of CORESS, told us that the public “do not feel that their complaints—their voice—are being listened to and that something has happened as a result.”¹²¹ Nic Hart, whose daughter Averil received treatment from a number of NHS organisations before her death in 2012, wrote to describe the practical impact of this: it “forces grieving family members to go over upsetting times repeatedly in order to have their voices heard, particularly where several separate NHS trusts are involved.”¹²²

Culture

42. The culture of the NHS is a key barrier to improvement, we heard. Scott Morrish described a “universal, despairing and fatalistic acceptance that culturally the NHS was either indifferent or impotent, and that it was too big and too complicated to change”.¹²³ Part of this culture, he wrote, is defensiveness:

113 MDU Services Ltd [CCF11]

114 Q 157 [Katherine Rake]

115 Healthwatch [CCF50]

116 Peggy Banks [CCF68]

117 Q 158

118 NHS Confederation [CCF49]

119 Q 157 [Katherine Murphy] and NHS Confederation [CCF49]

120 Nic Hart [CCF42]

121 Q 14 [Denis Wilkins]

122 Nic Hart [CCF42]

123 Scott Morrish [CCF79]

The NHS's instinctive and, in human terms, rational response to perceived threat is to retreat and defend itself, its employees, and organisations - giving rise to a bunker-mentality that allows the protection of reputations to take precedence over the best interests of patients or staff.¹²⁴

43. This culture of defensiveness described by many of our witnesses can make mistakes in clinical practice hard to admit. The Secretary of State for Health accepted that part of the problem was that:

It is incredibly difficult for Ministers to admit they ever make a mistake, because they know that they will be on the floor of the House of Commons and be utterly castigated for it. [...] Part of the defensiveness throughout the NHS may come from defensiveness by Ministers and that culture feeds its way down.¹²⁵

Mr Hunt contrasted that with the “culture of openness and transparency in health care that they have developed in other industries [...] too many doctors, nurses and midwives think that, if they are found responsible for a death or a serious incident, they will be fired. He said that “the culture that we need is, ‘If you do not tell the truth and help us to understand what happened, then you will be fired.’”¹²⁶

Patient and family involvement

44. There are shortcomings in patient and family involvement in complaints and investigations, we heard. This is “the most common problem” seen by Action against Medical Accidents, its Chief Executive Peter Walsh told us.¹²⁷ Sands, the stillbirth and neonatal death charity, told us that parents “are the experts in their own cases, yet many report feeling excluded from any investigative process”.¹²⁸ Action against Medical Accidents told us that:

Proper involvement of patients/families from the beginning of an investigation not only improves the transparency and hence public confidence in the process, but is vital to avoid investigations going off on the wrong track and adding rigour and objectivity to the process.¹²⁹

The organisation has come across cases where the patient or, in the case of a death, the patient's family “had not even been informed that an investigation was being conducted.”¹³⁰

124 As above

125 Q 322

126 Q 281

127 Q 156 [Peter Walsh]

128 Sands, the stillbirth and neonatal death charity [CCF47]

129 Action against Medical Accidents [CCF23]

130 Q 156 [Peter Walsh]

Quality

45. Many people described to us the wide variation they have found in how incidents are investigated and how complaints are managed.¹³¹ Shortcomings in investigations and complaints took a number of forms, but all relate to quality or effectiveness. As the Secretary of State for Health Jeremy Hunt MP acknowledged, safety incidents are “not investigated very well all the time.”¹³² Dame Julie Mellor, the Ombudsman, told us that:

Our evidence shows that, all too often, the quality of local investigations into serious incidents and avoidable harm is not good enough or is not happening.¹³³

46. Some of this relates to staff attitudes and behaviour. Despite the evidence that many stillbirths are avoidable, the charity Sands told us there is still a misapprehension among some NHS staff that stillbirths are unavoidable tragedies: “because of this, parents report a tendency for staff to patronise them and discount their legitimate concerns as ‘just the grief speaking’.”¹³⁴ The East London Patients Forum, a support network, reported that staff failed to take account of the “huge, long-lasting and permanent impact of the harm and distress” they had experienced.¹³⁵ Scott Morrish, the father of Sam Morrish, wrote “I don’t believe the NHS was intentionally heartless or cruel, although at times it felt like it was both.”¹³⁶

47. Some of our written evidence criticised delays and staff turnover in complaints handling. The PHSO Pressure Group wrote that NHS complaint managers appears to see their role as one of damage limitation: “these managers are expert in delay tactics [yet] delay impacts upon patient safety.”¹³⁷ Katherine Rake of Healthwatch said that waiting three years in order to get a full resolution to a complaint is “not untypical”.¹³⁸ The Royal College of Physicians told us that investigation teams “often change by the time investigations are complete which undermines shared learning from mistakes.”¹³⁹

48. Some of our witnesses cited shortcomings in training and expertise. Ed Marsden of Verita, which among other things carries out independent investigations, told us that, as complaints and investigations are best resolved at the front line, “people in trusts need to be equipped to carry out that kind of work to a decent standard.”¹⁴⁰ Professor Brian Toft, who is experienced in clinical incident investigation, described how “the people who do these initial investigations have very little training or no training whatsoever. They have no understanding. Even if it screams at them, ‘This is the problem,’ they cannot see it.”¹⁴¹

131 For example, Royal College of Physicians [\[CCF24\]](#) and Q 213 [Professor Sir Mike Richards]

132 Q 165

133 Q 225 [Dame Julie Mellor]

134 Sands, the stillbirth and neonatal death charity [\[CCF47\]](#)

135 East London Patients Forum [\[CCF76\]](#)

136 Scott Morrish [\[CCF79\]](#)

137 PHSO Pressure Group [\[CCF81\]](#)

138 Q 177 [Katherine Rake]

139 Royal College of Physicians [\[CCF24\]](#)

140 Q 102 [Ed Marsden]

141 Q 101

49. Another practical shortcoming in current complaints handling was raised by the campaign group Heal the Regulators: “many patients who are unable to read and write English are unable to use the complaints system.”¹⁴²

How investigations are carried out

50. There is wide variation in the quality of current incident investigations across the NHS. In many cases, investigations into clinical failure are successfully handled. Michael Devlin of the Medical Defence Union told us that, in his organisation’s experience, local investigations are “carried out very well. Patients are told what has happened; an apology is given; matters are put right, if that is possible. If it proceeds to a complaint, then again they are given a written account of what has happened.”¹⁴³ POHWER, a complaints advocacy provider, described the process in successful cases in acute care settings. The hospital, they wrote, will hold a local resolution meeting with the patient or their family, in which their concerns are listened to and the hospital demonstrates its learning from the issue. The case is then closed, without the need for referral to the Parliamentary and Health Service Ombudsman, as the patient has achieved the outcome they needed.¹⁴⁴ The Ombudsman described their expectations of local NHS investigation to us, including:

- a good description of what happened;
- an investigation into the root causes;
- for things to be put right; and
- for the provider to make it clear what learning has taken place to prevent the same thing happening again.¹⁴⁵

51. Professor Toft described to us how he carries out an investigation:

I do background reading. I visit the medical director and see what has gone on. I read their reports, which usually have gaps in them, in my experience. I then set out a whole set of questions—a semi-structured questionnaire. I then go and interview the people, take the interviews and analyse them, go back where necessary and clarify, and then produce a report.¹⁴⁶

However, the current system is “terribly inconsistent” in the words of Peter Walsh of Action against Medical Accidents; “we see examples of good practice, but we also see examples of very poor incident investigation.”¹⁴⁷

52. Investigations are voluntary, Ed Marsden of Verita explained to us; “professional staff in the NHS do not have to participate in these investigations, but, by and large, they do.”

142 Heal the Regulators [CCF85]

143 Q 122 [Michael Devlin]

144 POHWER, a complaints advocacy provider [CCF45]

145 Parliamentary and Health Service Ombudsman [CCF61]

146 Q 97 [Professor Brian Toft]

147 Q 156 [Peter Walsh]

He said staff want to speak openly about what has happened and are often concerned about what they have done, if they think they have made an error.¹⁴⁸ He went on to explain that employers can require staff to participate in investigations but the process is “in terms that we would use, voluntary”.¹⁴⁹

53. Many investigations into clinical incidents are carried out as a result of complaints. This was seen by some of our witnesses as encouraging defensiveness. For example Sands, the stillbirth and neonatal death charity, told us of one bereaved father who said that “complaints are seen as a financial and reputational risk, rather than an opportunity to learn lessons and save lives in future.”¹⁵⁰ Equally, other families affected by serious adverse events described how resorting to complaints or litigation were the only options open to them: “we had to complain or litigate to get the level of disclosure that we deserved.”¹⁵¹

How complaints are handled

54. Regulations govern the handing of complaints about GPs, dentists and NHS bodies in England.¹⁵² A complaint must be investigated and must culminate in a written response to the complainant detailing the investigation’s findings and any remedial action that will be taken.¹⁵³ The organisation must maintain a record of each complaint received and its outcome, and must give NHS England an annual report detailing these. This report must summarise “any matters of general importance arising out of those complaints” and “any matters where action has been or is to be taken to improve services as a consequence of those complaints”.¹⁵⁴

55. Complaints handling has a number of competing objectives, and is both forward and backward looking. Those handling complaints aim at the same time to establish the truth, assign blame if necessary, develop recommendations, determine compensation, and ensure it does not happen again to someone else. The Patients Association hear from patients and their relatives that the complaints system is “too bureaucratic, it is complex, it is confusing and it very often adds to the pain and to the grief that patients are already suffering. Patients tell us that it is very time-consuming; it is difficult for them to speak to the person who they need to talk to.”¹⁵⁵

56. Variation in the quality and effectiveness of complaints handling was cited in some of the evidence we received. John Dale of the NHS Complaint Managers Group told us that the only way to achieve greater consistency was “clearer central guidance and one national course at degree level for organisational complaint managers and their main investigators.

148 Q 130 [Ed Marsden]

149 As above

150 Sands, the stillbirth and neonatal death charity [CCF47]

151 Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everton, Stephen Richards and James Titcombe [CCF87]

152 MDU Services Ltd [CCF11]

153 As above

154 As above

155 Q 156 [Katherine Murphy]

At present there is [...] a myriad of private organisations providing a varied and inconsistent level of courses.¹⁵⁶

57. Written evidence from Maureen Dineen, who carries out serious incident investigations on behalf of NHS England, argued that many staff involved in NHS investigations are frontline practitioners without the time or competencies to conduct an appropriate, proportionate, evidence-based investigation: “They make good ‘specialist advisors’ but not always good investigators. Not because they are uncommitted but because it is not what they trained for.”¹⁵⁷

The priority given to complaints

58. We heard evidence that only a minority of trusts prioritise complaints handling.¹⁵⁸ Katherine Murphy of the Patients Association said those which do tend to have a director of nursing or a director of patient experience who decides to take a lead on the issue.¹⁵⁹ The effect of this can be seen in trusts taking part in peer reviews, working with the Patients Association on complaints standards, visiting the homes of people who have complained, and showing an “appetite to learn”, Katherine Murphy told us.¹⁶⁰ She cited the North Derbyshire Clinical Commissioning Group, University Hospitals Bristol NHS Foundation Trust and the Nottingham University Hospital NHS Foundation Trust as exhibiting good practice.¹⁶¹

59. However, other issues are prioritised elsewhere. The Berwick review of patient safety concluded that incorrect priorities cause damage: “other goals are important, but the central focus must always be on patients.”¹⁶² The Royal College of Nursing told us that “evidence from extensive studies and experience of investigations into patient safety such as the Francis, Keogh and Berwick reports, show a strong correlation between inadequate staffing levels and poor quality of care, and, therefore, complaints.”¹⁶³ The Francis review concluded that “the demands for financial control, corporate governance, commissioning and regulatory systems are understandable and in many cases necessary. But [...] any system should be capable of caring and delivering an acceptable level of care to each patient treated.”¹⁶⁴

156 John Dale [CCF15]

157 Maureen Dineen [CCF71]

158 Q 173 [Katherine Murphy]

159 As above

160 Q 172

161 Q 176 and communication with the Patients Association

162 Department of Health, *A promise to learn – a commitment to act: improving the safety of patients in England*, August 2013

163 Royal College of Nursing [CCF51]

164 *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*, HC 947, February 2013

The Parliamentary and Health Service Ombudsman's handling of complaints

60. The Parliamentary and Health Service Ombudsman's handling of complaints has been the focus of much of the written evidence we received. In the case of Ian Alexander, who wrote to us about the suboptimal care and poor complaints handling he experienced from Addenbrookes Hospital, he had a "very good experience of the PHSO process. I was very reassured by the fairness and independence of the PHSO investigation, after such a bruising experience of local processes."¹⁶⁵ However, most of the written evidence we received which discussed the Ombudsman was critical. We previously concluded in *Time for a People's Ombudsman Service* that reform of PHSO was needed if PHSO, or any future public services ombudsman, was to deliver a more effective, responsive and proactive service.¹⁶⁶ Expectations and need for the service provided by the Ombudsman outstrip its current capability.¹⁶⁷

61. The complaints advocacy provider POHWER told us that the Ombudsman is unwilling to make reasonable adjustments for people who are unable to meet their 12 month time limit for cases due to disability or emotional inability due to grief following a loss:

Many of our clients who have experienced clinical failure are recovering from their treatment or have ongoing medical problems which makes raising a complaint extremely difficult. For those who have suffered a loss, many are unable emotionally to make a complaint whilst grieving and dealing with their loss. The Ombudsman does not take account of this in their decision whether to investigate or not.¹⁶⁸

62. The evidence we received concerned the quality of the Ombudsman's work, its professionalism, and its ethos. MDU Services Ltd, a mutual which provides medico-legal benefits to doctors and dentists, told us that, in its experience, "the quality of Ombudsman's investigations has deteriorated over the last few years—in terms of the detail and analysis provided in the report and because there are often long delays that did not happen in the past".¹⁶⁹ John Dale of the NHS Complaint Managers Group remarked in his evidence to us that "the PHSO has recently lost a number of staff and yet taken on the obligation to investigate more complaints. These two aspects do not compute unless the investigations are not as thorough as they once were."¹⁷⁰ The PHSO Pressure Group outlined the shortcomings they see at the Ombudsman in their written evidence. They told us "PHSO is not staffed by experts in the field, nor is it led by an experienced clinician. The investigative process at PHSO is largely a desk exercise and evidence presented by trusts is not robustly challenged."¹⁷¹ They also cited a lack of professionalism and a "poor quality

165 Ian Alexander [CCF84]

166 Public Administration Select Committee, Fourteenth Report of Session 2013-14, *Time for a People's Ombudsman Service*, HC 655, April 2014

167 Scott Morrish [CCF79]

168 POHWER, a complaints advocacy provider [CCF45]

169 MDU Services Ltd [CCF11]

170 John Dale [CCF15]

171 PHSO Pressure Group [CCF81]

investigation process” seen in “a failure to look beyond the version of events presented by the Trust”.¹⁷² This acceptance of the health service’s version of events, for complainant Derek Payne, meant the PHSO “came across as an NHS apologist.”¹⁷³ The Patients Association attributed the Ombudsman’s shortcomings to “its ethos” as “the organisation lacks an understanding of the concerns of patients, particularly their motivation in bringing complaints and of the need to understand those concerns and meet those concerns in the way in which the investigation of complaints is carried on.”¹⁷⁴ For the Medical Protection Society, the organisation “gives the appearance of being defensive”.¹⁷⁵

63. John Driskel criticised the Ombudsman on the basis that, to challenge one of her decisions, a complainant like himself has recourse only to costly judicial review: “it is unreasonable that Government expect the individual citizens to finance the quality control of a public body.”¹⁷⁶

64. Some also questioned the focus adopted by the PHSO. In Scott Morrish’s case this focus was on “arriving at a ‘robust adjudication’ based on comparing ‘what is documented to have happened’ with ‘what should have happened’ without regard to ‘how’ or ‘why’.”¹⁷⁷ This, he wrote, “deprives everyone of an opportunity to learn, reduce avoidable harm, or to move forward.”

65. Despite the Ombudsman’s independent status as a Parliamentary body, the Government has also commented on its performance. In June 2014 the Secretary of State for Health wrote to the Ombudsman, criticising the time taken to deal with a case, and for not apologising for mistakes made during the investigation.¹⁷⁸ The Department of Health told us in written evidence that, in future, it “would expect to see demonstrable improvements in PHSO; particularly in relation to its pace and responsiveness in handling complaints and increased patient and public confidence in its work.”¹⁷⁹

172 PHSO Pressure Group [CCF7]

173 Derek Payne [CCF74]

174 Patients Association (PA) and Irwin Mitchell LLP (IM) [CCF53]

175 Medical Protection Society [CCF46]

176 John Driskel [CCF66]

177 As above

178 ‘Jeremy Hunt rebukes health watchdog over three-year-old Sam’s death’, *Daily Telegraph*, 28 June 2014

179 Department of Health [CCF64]

66. In her oral evidence to us Dame Julie acknowledged a need for change: “we need to address things like the “why” question, training all our staff who do our most serious investigations in root-cause analysis and human factors science.”¹⁸⁰ The PHSO’s strategic plan for 2015-16 to 2017-18 aims to achieve “more impact for more people”.¹⁸¹ It focuses on improving the quality and accessibility of PHSO services, improving how it uses its insight to bring about change, and continuing to work towards the creation of a more streamlined public Ombudsman service.¹⁸²

67. Just as we are completing this Report, the Government is publishing its full response to our previous Report, *Time for a People’s Ombudsman Service*, as a consultation paper on Ombudsman reform. We have not had an opportunity to consider this.

Legal liability

68. It is not unusual for patients to pursue clinical negligence claims because they have been dissatisfied with the response to a complaint.¹⁸³ There are a number of legal aspects to patient safety and incident investigation. In particular, witnesses commented on the relationship between legal proceedings and incident investigations. In their article ‘Learning from failure’ Macrae and Vincent argued that safety investigations should be legally privileged; findings should not be used in the proceedings of attempted prosecutions, and furthermore:

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.¹⁸⁴

There are limits on this proposed special status for investigations. As the Secretary of State for Health pointed out to us, even the Air Accidents Investigation Branch does not maintain secrecy or immunity if they discover that someone has broken the law.¹⁸⁵ Helen Vernon of the NHS Litigation Authority told us that saying sorry should be separate from redress:

Recently we published some guidance to trusts called ‘Saying Sorry’, which highlights the need for an appropriate and clear apology at an early stage, irrespective of what might follow. We would not refuse to indemnify a trust where that organisation had put an apology forward.¹⁸⁶

180 Q 216 [Dame Julie Mellor]

181 Parliamentary and Health Service Ombudsman, [More impact for more people – progress so far](#), December 2013

182 Parliamentary and Health Service Ombudsman, [A summary of our strategic plan 2015-16 to 2017-18](#), undated

183 Slater & Gordon Lawyers [CCF44]

184 Macrae C and Vincent C, ‘Learning from failure: the need for independent safety investigation in healthcare’ *Journal of the Royal Society of Medicine*; 2014, 107(11) 439-443

185 Q 312 [Jeremy Hunt MP]

186 Q 127 [Helen Vernon]

Katy Peters of the University of Surrey told us that clinical negligence is a complex area of the law; arguments about legal liability can be incomprehensible to patients.¹⁸⁷ Claims are sometimes settled and compensation payments made before cases reach court. This is not always a satisfactory conclusion if a patient feels “bought off” and clinical staff feel resentful that a claim was settled even though their care was not found to have been negligent.¹⁸⁸ Ken Lownds, writing to us in a personal capacity, noted that the very large sums in compensation paid for safety failures could be reduced by investment ‘upstream’ in preventing failures from occurring.¹⁸⁹ Dame Julie Mellor, the Parliamentary and Health Service Ombudsman, felt that a “safe space” was needed for the new body: “If you create that safe space to get at the facts of what happened and why, that is how we will get a learning culture.”¹⁹⁰

69. We heard from Peter Walsh of Action against Medical Accidents that complaints, and subsequent investigations, are separate from legal proceedings, but this has not always been made clear:

Last year, we achieved our goal of getting the DH [Department of Health] to issue clear guidance to the effect that the NHS complaints procedure should be open to anyone, irrespective of whether they have a potential negligence claim, for example, or even if they are pursuing a complaint, because the complaint is looking at very different issues.¹⁹¹

He claimed that this message had not reached all parts of the complaints system:

Whilst that has been achieved, we have the ludicrous situation whereby the Ombudsman is still giving out advice to people to the effect that, if they are taking legal action for criminal negligence or considering doing so, she cannot investigate.¹⁹²

The Duty of Candour

70. The obligation to be open and transparent is among the professional duties of a doctor. The General Medical Council has for a long time required clinicians to be open and transparent with patients.¹⁹³ The Secretary of State described the latest position to us:

We have changed the professional codes of doctors and nurses, so that they get protection if they speak out, and it is much more explicit that they have a responsibility to speak out. We have made it a criminal offence for hospitals not to tell patients when they have harmed them or their families. We are

187 Katy Peters [\[CCF36\]](#)

188 As above

189 Ken Lownds [\[CCF52\]](#)

190 Q 267

191 Q 158 [Peter Walsh]

192 As above

193 Q 147 [Helen Vernon]

looking at removing hospitals' immunity from litigation fees if they make a mistake but they have not been honest with the family from the start.¹⁹⁴

Since November 2014 there has been a statutory requirement for the NHS to inform patients or their families when there has been an incident that is suspected to have caused or may lead to harm.¹⁹⁵ This is called the Duty of Candour and entails an apology and an explanation, and a written record of these.¹⁹⁶ Professor Brian Toft commented that, following the Wayne Jowett case in which a doctor was sentenced to 8 months in prison (see Box 2), “it should come as no surprise that many doctors and healthcare workers practice ‘defensive’ medicine and show a reticence to publicly advertise any inadvertent errors they might make even though a Duty of Candour is now in place”.¹⁹⁷

71. The quality of complaints handling can be seen as an indicator of the quality of a healthcare provider more generally. More complaints can mean better quality, but, as we concluded in *More complaints please*, a failure to recognise the importance of complaints leads to insufficient redress and alienation for individuals, and limited improvement to public services.¹⁹⁸ We found that the best performing organisations welcome complaints as a way of engaging consumers. Professor Sir Mike Richards of the Care Quality Commission told us that “there are some trusts that really encourage reporting of incidents, and so a high number of incidents being reported by a trust is often a good thing, particularly if there are a high number of incidents with low harm or no harm.”¹⁹⁹ As Katherine Rake of Healthwatch put it, complaints handling is an “incredibly good indicator” of “how well or how poorly a hospital is performing generally”.²⁰⁰ The Secretary of State for Health gave us an example of good practice:

The best example I have seen of NHS complaints is in my local hospital, Frimley Park, in Camberley [...] the first hospital in the country to be given a CQC “outstanding” [rating]. I was very encouraged by that, because basically I know that it is run by someone who is very open and very hungry to learn from every mistake that is made in his Trust.²⁰¹

72. There are also good practice examples in incident investigation, and in disseminating local learning from investigations. Doncaster and Bassetlaw Hospitals NHS Foundation Trust published a video clip on YouTube entitled ‘The Human Factor: Learning from Gina's Story’ in September 2014.²⁰² This provides a learning resource for staff and organisations across the NHS and offers an example of the lessons that can be learnt from local investigations. There was rapid implementation of most of the recommendations

194 Q 302 [Jeremy Hunt MP]

195 Action against Medical Accidents [CCF23]

196 Q 147 [Helen Vernon]

197 Professor Brian Toft [CCF30]

198 Public Administration Select Committee, Twelfth Report of Session 2013-14, *More complaints please!*, HC 229, April 2014

199 Q 213 [Professor Sir Mike Richards]

200 Q 170 [Katherine Rake]

201 Jeremy Hunt MP [Q 323]

202 <http://patientsafety.health.org.uk/resources/human-factor-learning-ginas-story>

made following the investigation into Wayne Jowett's death, despite delays in implementation of one of Professor Toft's recommendations (see Box 2), resulting in no further deaths in England due to wrong route spinal chemotherapy.²⁰³

Box 1: Example of a never event: wrong site surgery

Wrong site surgery is a surgical intervention performed in the wrong place. Incidents range from an incision being made in the wrong place at the beginning of surgery then immediately spotted and corrected, to operating on the wrong limb or organ.²⁰⁴ For example, in five cases between 1 April 2014 and 31 January 2015, the patient's wrong eye was operated on.²⁰⁵ The patient may require further surgery, on the correct site, and/or may have complications following the wrong surgery.²⁰⁶

The NHS England Never Events Taskforce was an expert panel established to conduct a review of the occurrence of never events and to recommend how these events can be eradicated. This task force's report was published in 2014.²⁰⁷ A key recommendation was to establish an independent incident investigation panel.

The Secretary of State for Health told us that, "approximately once a fortnight we put the wrong prosthesis onto someone; once a week, we operate on the wrong part of someone's body—wrong-site surgery; and twice a week, we leave a foreign object in someone's body. This is much more frequent than the term "never event" would suggest."²⁰⁸

Public inquiries

73. There has not been a public inquiry into an aviation accident since the early 1970s, Keith Conradi told us.²⁰⁹ Numerous health investigations have taken place, in contrast, including the £13.6 million Mid Staffordshire NHS Foundation Trust public inquiry.²¹⁰ The Association of Surgeons of Great Britain and Ireland argued that "sporadic enquiries in response to major failures, such as [...] Mid Staffs, although valuable, are an inefficient and traumatic way of bringing about the steady incremental improvement in safety and quality that are the hallmark of properly functioning institutions."²¹¹ Macrae and Vincent

203 Professor Brian Toft [CCF30] and NHS England, [Patient safety alert on non-Luer spinal \(intrathecal\) devices for chemotherapy](#), February 2014

204 NHS England, [Detailed data on "never events" will help NHS care become even safer, says NHS England](#), December 2013

205 NHS England, [Provisional publication of Never Events reported as occurring between 1 April 2014 and 31 January 2015](#), February 2015

206 National Patient Safety Agency (now NHS England), [Wrong site surgery](#), undated

207 NHS England, [Standardise, educate, harmonise: Report of the NHS England Never Events Taskforce](#), February 2014

208 Q 157

209 Q 93

210 To March 2013. The Mid Staffordshire NHS Foundation Trust Public Inquiry, [Inquiry Costs](#), undated

211 Association of Surgeons of Great Britain and Ireland (ASGBI) and the Confidential Reporting System for Surgery (CORESS) [CCF63]

and others believe public inquiries represent poor value for money as a way to bring about improvement.²¹²

74. Complainants need to feel heard, whether they are patients, relatives or staff. They deserve the opportunity to contribute to learning in the system that will prevent a repeat of the same failure. Instead, they too often feel their issue is managed or avoided, to minimise reputational damage to individuals and organisations, or to avoid financial liability. The system is unacceptably complicated, with an unresolved tension between the desire for an open ‘no blame’ culture and the demand for the clear accountability the public is entitled to expect from a public service. There is a clear requirement for a single body to provide a single focus for accountability for driving local improvement.

75. Complainants deserve an Ombudsman they can have confidence in. There are serious questions about the capacity and capability of the Ombudsman’s office, in particular in relation to complaints involving clinical matters. We are aware of considerable anguish and disquiet where Parliamentary and Health Service Ombudsman investigations fail to uncover the truth, and of pain inflicted by the Ombudsman’s defensiveness and reluctance to admit mistakes. This underlines the need for improved competence and culture change throughout the system, including in the PHSO. PHSO leadership is aware of the need for this change, but it is proving more challenging than expected. We welcome the PHSO’s aim to improve the quality and accessibility of its services. However, the Ombudsman’s office is under considerable strain. Fundamental reform of the Ombudsman system is needed.

76. We reiterate our conclusion, in *Time for a People’s Ombudsman Service*, that change is urgently needed. Some of the PHSO’s shortcomings are systemic and can only be addressed through legislation, which is needed early in the next Parliament. However, unhappiness with the Ombudsman also underlines the need for improved capacity for clinical incident investigations in response to complaints, long before they reach the Ombudsman. The Ombudsman must acknowledge current concerns, and the need for larger reforms must not delay necessary practical improvement.

77. Much external criticism of PHSO concentrates on its handling of past cases, which has encouraged the organisation to devote considerable resource to reviewing these cases. Poor adjudications based upon inadequate evidence underline that PHSO was not established to conduct clinical investigations, but to adjudicate on maladministration and service failure based on evidence provided to it by others. We therefore recommend that PHSO should concentrate its energy on improving its internal culture and competence in respect of its current adjudications, rather than on reviewing or justifying past adjudications. PHSO needs to reflect upon how it wishes the public to perceive its role: how it balances the independence of its adjudications with the wish to support complainants and to respond to public criticism. We expect the PHSO to make its internal change programme its main effort. The PHSO’s

²¹² Macrae C and Vincent C, ‘Learning from failure: the need for independent safety investigation in healthcare’ *Journal of the Royal Society of Medicine*; 2014, 107(11) 439-443, and Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everton, Stephen Richards and James Titcombe [CCF87]

leadership must avoid becoming distracted by other issues, such as the proposed review in its legislative framework, which will take some years to complete. The internal change programme is essential and urgent, with or without legislative change. We expect to see clear signs of significant progress early in the next Parliament.

78. It is time for PASC to take another look at our role in relation to the Ombudsman. Parliament expects PASC to pay close attention to the effectiveness of the service provided by the Ombudsman, so we have the authority to set out our expectations for its performance. Our successor Committee in the next Parliament should examine PHSO's internal change programme and make recommendations about how to reinforce and to accelerate much needed change in the behaviour, attitudes and competence of PHSO staff. This scrutiny should be forward-looking. This Committee cannot be a court of appeal in respect of PHSO's adjudications nor can it seek in any way to influence decisions in individual cases because this would compromise the independent quasi-judicial role of PHSO. However, our scrutiny role in this Parliament has been enhanced by understanding previous cases and this learning should continue in future. We reiterate our previous recommendation in Time for a People's Ombudsman Service that the Public Accounts Commission or a similar body should take primary responsibility for scrutiny of PHSO, including examining corporate plans, budget and resources. But this does not absolve us from looking at the Ombudsman's:

- *quality of adjudications;*
- *competence in respect of evidence, investigation and legal interpretation; and the*
- *leadership and development of the service.*

79. We hope that our successor Committee will return to the question of the boundaries between the Ombudsman and other regulatory and investigatory bodies, including the proposed new central investigative body.

80. We recommend that our successor Committee should ask the National Audit Office to assist with an inquiry on the value for money of the Parliamentary and Health Service Ombudsman.

81. We recommend that the Ombudsman's change programme be its main priority in the immediate future. The Ombudsman should publish proposals on the progress of its change programme, set out the form it will take from now on, what it is intended to achieve, and by when. These proposals should be published in time for our successor Committee to consider them.

3 Reducing the risk of untoward clinical incidents through learning

The Department for Transport's Air Accidents Investigation Branch

82. The Air Accidents Investigation Branch (AAIB) came up frequently in the evidence we received, and much of the commentary was very positive.²¹³ The Branch is functionally independent but part of the Department for Transport, which provides “pay and rations” for its staff.²¹⁴ The AAIB is responsible for investigating civil aircraft accidents in the UK. Following investigations, it addresses safety recommendations to relevant organisations, which must respond saying how they intend to act. The AAIB tracks these actions and reports their status through an Annual Safety Report. The Chief Inspector of Air Accidents, Keith Conradi, reports directly to the Secretary of State for Transport. The Secretary of State for Health explained how things work in air accident investigation:

It is very straightforward: every single death is investigated by the Air Accidents Investigation Branch, and every single death is avoidable. In that industry, as in the nuclear industry and the oil industry, the presumption is zero deaths, and so, when there is a death, it immediately triggers a process.²¹⁵

83. Keith Conradi, the AAIB's Chief Inspector of Air Accidents, described to us the status of his investigations, which have, he said, earned the trust of people working in the sector:

People [...] have learned that, if they actually report these things, when they come to our attention, they are dealt with in a very much no-blame environment. We go to great lengths to ensure that our reports and our investigations do not carry any blame or liability.²¹⁶

The Secretary of State for Health told us that the “processes that we are trying to create have been modelled on those in the airline industry, which are designed to make it incredibly easy for pilots to speak up.”²¹⁷

84. The AAIB appoints an Investigator-in-Charge for each investigation it undertakes.²¹⁸ This person is the point of contact for victims and their families. For each major investigation, the AAIB publish a 'special bulletin' or initial report, normally with 14 days of the accident, and an investigation culminates with the publication of a final report.²¹⁹

213 Professor Graham Braithwaite, Cranfield University [CCF33]

214 Q 46 [Keith Conradi]

215 Q 275 [Jeremy Hunt MP]

216 Q 25 [Keith Conradi]

217 Q 283 [Jeremy Hunt MP]

218 Transport Select Committee, Sixth Special Report of Session 2014-15, *Offshore helicopter safety: Government, CAA and Oil & Gas UK Responses to the Committee's Second Report of Session 2014-15*, HC 717, October 2014

219 As above

Survivors and relatives are informed prior to each publication. The AAIB's investigations are confidential but result in public reports, as Mr Conradi explained:

What is transparent is the final report that is made public. Everybody who is involved in that report has a chance to comment on it before it goes public, and then we make it public and disseminate it just as widely as we possibly can.²²⁰

85. Some felt that, in many ways, there is a useful read-across from air accident investigation to medical incident investigation, while others felt the differences between the two sectors meant that caution should be exercised in learning lessons. NHS England noted the parallel with other sectors; the prison and probation services and police already have independent investigatory bodies to support learning from deaths and complaints.²²¹

86. The Association of Surgeons of Great Britain and Ireland felt that “practices in aviation are similar to those in medicine, and particularly within surgery, to the extent that many of the principles incorporated by aviation could be readily applied to medical practice and would bring about change in the long term.” The Association explained that:

Both require lengthy and demanding training; the acquisition and maintenance of a complex knowledge base; high order psychomotor skills; a highly professional approach to the discharge of responsibilities; excellent interpersonal/leadership (team) skills and the ability to exercise sound judgement under pressure.²²²

The Patients Association also supported the comparison. It cited a former Chief Medical Officer who believed that the NHS should compare its patient safety statistics with the passenger safety statistics of the aviation industry and seek to learn from the comparison and from the ‘check-list’ analogy, due to the resemblance of pre-flight and pre-surgical checks. The Patients Association argued that this seemed “likely to drive improvement by stressing and seeking to emulate the significantly more integrated safety culture of the aviation industry.”²²³

87. Others felt differently. The Care Quality Commission thought that “any new, separate investigation branch could not investigate more than a fraction” of the safety incidents reported annually that currently require investigation.²²⁴ The Secretary of State for Health said that “I do not think you would want” a system where all the 3,500 annual reported serious incidents involving deaths are centrally investigated.²²⁵ Professor Brian Toft stated that “it can take a considerable amount of time to conclude a high quality investigation into a clinical failure” because “when investigated they are typically far more complex in nature

220 Q 43 [Keith Conradi]

221 NHS England [CCF62]

222 Association of Surgeons of Great Britain and Ireland (ASGBI) and the Confidential Reporting System for Surgery (CORESS) [CCF63]

223 Patients Association (PA) and Irwin Mitchell LLP (IM) [CCF53]

224 Care Quality Commission [CCF57]

225 Q 163 and Q 274

than originally envisaged.”²²⁶ He provided examples in his written evidence of the time taken to complete typical investigations:

- Investigation into four young children being inadvertently administered too much of the blood thinning medicine ‘heparin’ - 55 working days over a six month period;
- Investigation into ‘vinorelbine’ (chemotherapy) being administered to a young child at 10 times the concentration prescribed - 25 working days over three months; and
- Investigation into four clinical errors made during an assisted conception treatment - 100 working days over 20 months.²²⁷

Some family members carry out considerable amounts of investigative work at present. Nic Hart told us that:

Throughout the last two years, it has felt like a full time job working out what happened to [my daughter] Averil. Looking through folder after folder of medical records, requesting copies of internal e-mails (running to thousands of pages), sending hundreds of e-mails, and carefully putting together sets of questions about the care Averil received has taken up a significant amount of time.²²⁸

88. PHSO Pressure Group noted the difference in risk exposure, in that, when an accident occurs in aviation, shipping and railways, staff have an equal incentive to improve safety. The NHS, they wrote, does not have “the same life or death consequences for staff.”²²⁹ Dr Margaret McCartney described how:

I have to ‘take off’ even if environmental conditions (40 extra patients needing to be seen) are unfavourable. If my cabin crew (nurses or receptionists) are off sick at short notice, we simply have to make do. Aircraft respond to well tested and simulated protocols. Human beings are highly complex, do not always fit protocols.²³⁰

The importance of an open and just culture

89. An open and just culture is one in which incidents and failures are openly and honestly discussed by staff, patients and families, creating an environment where the causes of serious events can be established and lessons can be widely learned.²³¹

226 Professor Brian Toft [CCF30]

227 As above

228 Nic Hart [CCF42]

229 PHSO Pressure Group [CCF7]

230 Dr Margaret McCartney [CCF8]

231 National Patient Safety Agency (now part of NHS England), *Seven steps to patient safety*, August 2004

90. Professor Sir Mike Richards of the Care Quality Commission suggested that local NHS bodies varied widely in the extent to which they had succeeded in developing an open culture:

When we are holding focus groups of junior doctors, we always ask them about incidents and whether they report incidents. All too often what they tell us is, “Oh, well, I did report one or two, but I did not get any feedback, so I actually stopped. It was not that easy to do it. It took up time,” so it was not made easy for them. In the best hospitals that is not the case. They really are encouraging it; they learn from it; they feed back and it is a completely different culture.²³²

91. The Secretary of State told us that he and Mike Durkin of NHS England have put together a report containing data on “whether trusts have an open and honest reporting culture.”²³³ This shows that around 20% of trusts do not have this.²³⁴ Mr Hunt said that there should ultimately be no need for whistleblowers, because “we should have a culture where people want to find out that things have gone wrong and why they have gone wrong, and to learn from them. You only have whistleblowers when you have a system which is not doing that.”²³⁵

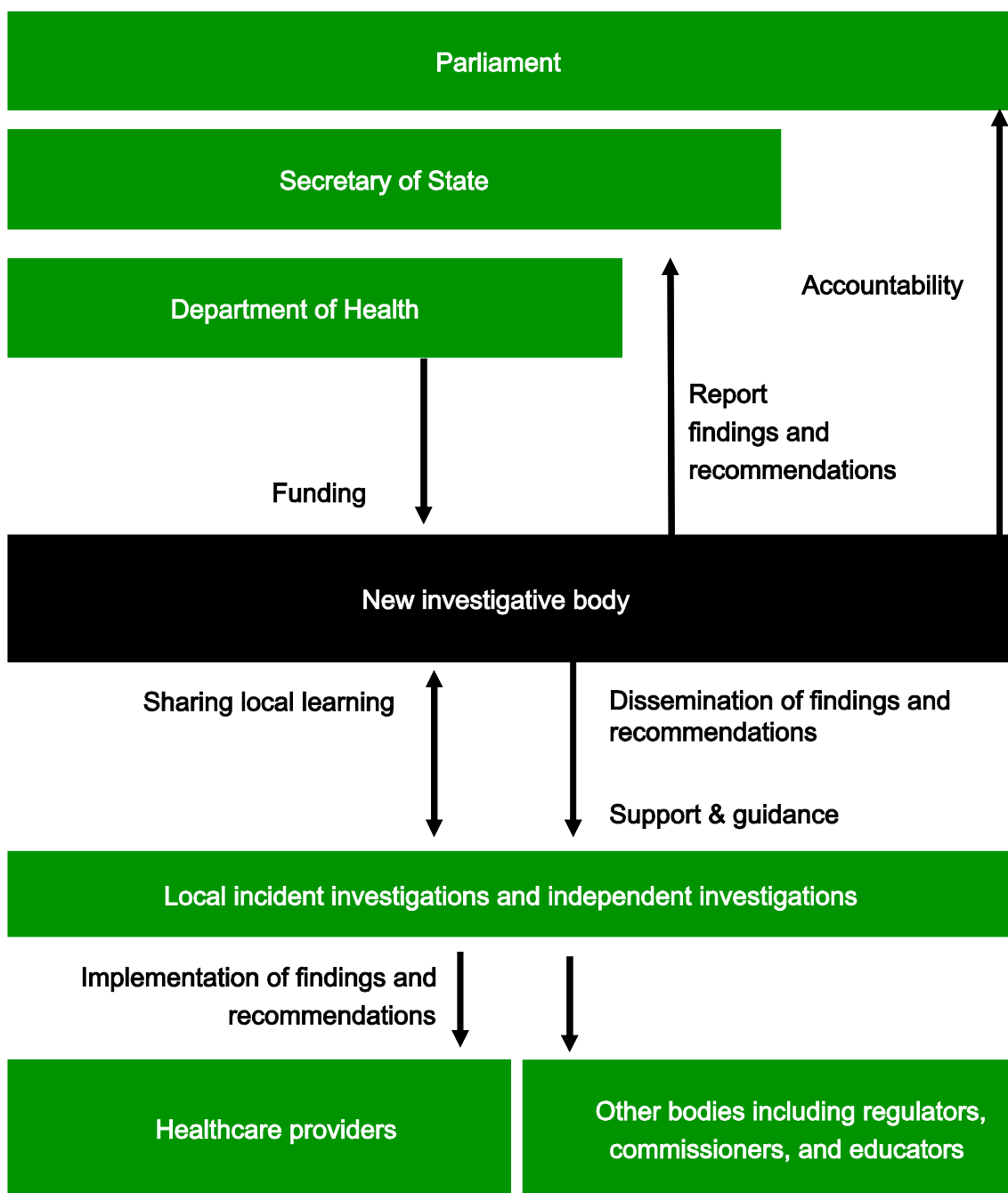
232 Q 213

233 Q 209

234 As above

235 Q 271

Figure 1: Proposed new system



The importance of good local investigation

92. Rapid, routine and systematic investigation of adverse incidents locally is essential to ensuring that local causal factors are understood and that there is local responsibility for making improvements. Michael Devlin of the Medical Defence Union made a case for emphasising local investigation of clinical incidents, saying that “those who have treated

the patients understand their local systems” and said that it was helpful to be able to examine the local safety culture.²³⁶

93. Making all those involved with NHS bodies responsible for openness was seen as important to good local investigation. The NHS Confederation said that it was “essential we deliver a culture of openness and transparency right across the whole system and everyone, from ward to board level, is responsible for delivering this cultural change”.²³⁷ This was echoed by the Health Foundation, who wrote that “it should be the ambition to build a critical mass of people with specialist investigation skills, and local systems that support high quality investigation, across the NHS.”²³⁸

94. A model for supporting and strengthening local investigation might be found in the aviation industry. Keith Conradi of the Air Accidents Investigation Branch said: “safety teams in airlines often report at board level on their findings and recommendations, and that is a key part to making this work.”²³⁹ Mr Conradi said that pilots did not feel “negativity” about the reports of his Branch. The conclusion he drew from this was that in the NHS investigators should aim to gain the support of boards and “from the very highest level” in order to persuade those in senior roles to “sell” investigation findings.²⁴⁰

95. We were told that aviation aspires to a ‘just culture’ in which learning and accountability are balanced, achieved in part through a clear separation between the bodies responsible for regulation and enforcement, and those responsible for investigation and learning.²⁴¹

The importance of independence

96. Local investigation is essential but would not be enough in some cases. Even when a local investigation is carried out by another NHS body, the problem may not be solved. Sands reported a bereaved father as saying that “procuring an ‘independent’ report from a neighbouring trust that is known to use the same policies ensures that nothing will be learned and is a huge missed opportunity.”²⁴² The Patients Association and Irwin Mitchell LLP expressed a sweeping scepticism, telling us that “the public have no confidence in the NHS investigating itself.”²⁴³

97. There is sometimes a need for an independent investigation so that causal factors or patterns of failure can be analysed across a region, system or entire country. These broader, system-wide issues often fall outside of the purview of a local investigation conducted within a single individual healthcare provider organisation, and can require that remedial actions to be taken by a number of different organisations. Verita, which among other

236 Q 105

237 NHS Confederation [CCF49]

238 Health Foundation [CCF27]

239 Q 31

240 Q 80

241 Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everton, Stephen Richards and James Titcombe [CCF87]

242 Sands, the stillbirth and neonatal death charity [CCF47]

243 Patients Association (PA) and Irwin Mitchell LLP (IM) [CCF53]

things carries out investigations, told us that such an investigation may be required because:

The issues raised by an incident are wider than purely local as they are systemic or cultural across the organisation, raise wider public interest issues, deal with very serious or sensitive matters or are part of a pattern that affects organisations across the region or country as a whole. There is an important role for those less directly connected to day-to-day events in trusts, such as non-executive directors, to take a view on whether an incident needs a review from a wider independent perspective.²⁴⁴

98. NHS England explained the reasons why investigations are currently carried out independently:

Independent investigations are usually commissioned for mental health homicides and some mental healthcare related suicides of concern, and for issues of significant national concern or media interest, or where provider organisations choose to outsource duties to investigate in this way for reasons of objectivity or operational integrity.²⁴⁵

99. The independence – and the wide reach – of bodies such as the Air Accidents Investigation Branch were seen by Dr Carl Macrae and Professor Charles Vincent as “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.”²⁴⁶

The importance of accountability

100. One of the most prominent themes in our evidence was the importance of accountability for both the effective investigation of incidents and for subsequently making improvements to systems and processes. This was seen by NHS England as primarily a matter for local NHS bodies:

For serious incidents, NHS policy is that an investigation must take place according to good practice methodologies [...] and that providers are accountable to the commissioner of the care within which the serious incident occurred for ensuring they undertake a robust response. Commissioners should hold providers to account for their response to serious incidents in order to ensure the processes and outcomes of serious incident investigations include the identification and implementation of improvements that will prevent recurrence of serious incidents.²⁴⁷

244 Verita Consultants LLP [CCF25]

245 As above

246 Macrae C and Vincent C, ‘Learning from failure: the need for independent safety investigation in healthcare’ *Journal of the Royal Society of Medicine*; 2014, 107(11) 439-443

247 NHS England [CCF62]

101. This is easier said than done. Katherine Murphy of the Patients Association told us that “it is very easy to come up with recommendations and actions [...] it is much harder to demonstrate that you are carrying out the recommendations and actions. That is where perhaps accountability should lie.” Ms Murphy also indicated the importance of a different form of accountability; “I also think that it is really important that family and relatives are kept informed and are involved. Patients and the public deserve an honest and compassionate investigation.”²⁴⁸

102. Questions of ownership and personal responsibility were closely linked to accountability in our evidence, with Denis Wilkins of CORESS complaining that “clinicians do not seem to have the ownership of the problems that perhaps they might.”²⁴⁹

103. For several of our witnesses, accountability was seen as being hampered by the complex threads of responsibility surrounding the various bodies with responsibility for patient safety and complaints. Complexity and indeed fragmentation characterise the current system, the Royal College of Nursing indicated:

The fragmented nature of current safety investigations in the NHS limits the opportunities for actionable learning. Different forms of investigation exist and are carried out by different agencies addressing different perspectives of the investigation. It is unsurprising, therefore, that we lack a coherent picture of the wider systemic factors leading to failures of care. Fragmentation and inconsistency limit meaningful understanding of challenges and hinder ability to learn from these and to develop a culture that openly learns from mistakes.²⁵⁰

Recent research highlighted to us by the Health Foundation has emphasised the need for integration and learning as key elements of any approach to gather and using data to improve patient safety.²⁵¹ Yet Michael Devlin of the Medical Defence Union said: “there is a lot of information there that is being fed to various bodies, but it is all really not joined up.”²⁵²

104. Information gathered in investigations of clinical incidents and the results of separate inquiries into complaints are not sufficiently integrated, some of our witnesses told us. The Report of the Morecambe Bay Investigation by Dr Bill Kirkup, published in March 2015, expressed disappointment in the Parliamentary and Health Service Ombudsman for not working in a more joined up way with the Care Quality Commission in respect of James Titcombe’s case.²⁵³ The relationship between the investigation of individual complaints and the systemic problems they exemplify gave the inquiry concern, as seen in this “breakdown in communication” between the CQC and PHSO.²⁵⁴ Following the publication of Dr

248 Q 161

249 Q 8

250 Royal College of Nursing [[CCF51](#)]

251 Health Foundation [[CCF27](#)]

252 Q 150

253 Morecambe Bay Investigation, [Morecambe Bay Investigation Report](#), March 2015

254 As above

Kirkup’s report the PHSO issued a statement saying it “stood by their investigation”, saying the report had not questioned their findings. Later the PHSO revised its statement, saying “the Morecambe Bay investigation had access to more evidence, including a range of interviews and over 15,000 documents from 22 organisations and therefore it’s not surprising that he reached different conclusions.”²⁵⁵

105. At the broader level of policy and guidance, the situation also appeared fragmented to some of our witnesses, with accountability far from clear. Katherine Rake of Healthwatch told us that some information is available about “the quantity of complaints, but [there is] very limited understanding about the quality of the complaints handling and indeed the nature of the complaints underneath it.”²⁵⁶ Dr Rake confirmed that there was no-one with overall responsibility for overseeing the quality of complaints handling and resolution.

106. The problem appeared to some of our witnesses as structural and systemic. The establishment of different investigatory and regulatory bodies had led to a system that was “currently mind-boggling” according to Katherine Rake.²⁵⁷ “People are a bit lost and do not know where to start. It has been put in the ‘too difficult’ box for a very long time.” Dr Rake said that “we need some root-and-branch here; we need to really simplify” and she called for “broader reform” and a “broader look at the complexity of the system.”²⁵⁸ Peter Walsh of Action against Medical Accidents illustrated the point:

You will speak to one agency, say NHS England, and say, “We really would like this done about complaints”—for example, national clear guidance on delivering the NHS complaints procedure—and they might say, “Well, that’s not us”. You go to the CQC, and the CQC will say, [...] “it is not our role to actually do the improvement work”, and then you have the Department of Health and the other regulators. It is very confusing, and the system would be helped if it was clarified who had direct overall responsibility for holding the ring on investigations.²⁵⁹

107. Several witnesses urged the Government, in establishing a new central investigative body, to avoid doing anything that might weaken the responsibility of local NHS providers to carry out effective investigations. Dr Durkin of NHS England was clear about this, telling us, “We should not undermine the process of local accountability through the boards of the hospitals of the NHS, which are absolutely responsible for the quality of care.”²⁶⁰

Building the capacity to carry out investigations

108. If the NHS is to improve its investigations, it will need the right people and resources to carry them out. We heard interesting evidence on the high quality of staff in the field of

255 [‘Health watchdog accused by patients of taking NHS’s side’](#), *The Telegraph*, 15 March 2015

256 Q 163

257 Q 198

258 Q 196 and Q 198 [Katherine Rake]

259 Q 166

260 Q 55

air accident investigation. Professor Graham Braithwaite of Cranfield University told us that Air Accidents Investigation Branch inspectors are regarded in the industry as credible and trustworthy: “it is a role that is seen by many as the pinnacle of their careers and staff turnover is low.”²⁶¹

109. Training is important: Professor Braithwaite told us that experience from the accident investigation training programme at Cranfield University is that a combination of traditional teaching methods and practical, hands-on training, including the use of wreckage, along with actors as witnesses and documentary evidence, has the greatest impact.²⁶² Keith Conradi of the Air Accidents Investigation Branch told us the benefit of using professionals in investigations was that they—in this case airline pilots—“can talk the same language and they are speaking at the same level.”²⁶³

110. The quality of investigators in the NHS caused concern to some of our witnesses. We heard a variety of evidence suggesting that NHS bodies needed to deploy more and better qualified staff on the investigation of complaints and clinical incidents. Peter Walsh of Action against Medical Accidents said that “if you look at the salary grades, even, of complaints staff and other staff who are given the responsibility of carrying out investigations, they are very inconsistent, sometimes on administrative scales.”²⁶⁴

111. In Colin Rock’s experience of complaining to the Parliamentary and Health Service Ombudsman, its staff, lay caseworkers without knowledge of clinical practice, “simply did not understand the nature of failures.”²⁶⁵ Dr Elizabeth Gould, who had personal and professional experience of NHS complaint handling, called for greater expertise to be employed in the investigations carried out by the Ombudsman:

An extensive set of technical competencies is required for serious, protracted and entrenched cases. There is no evidence that existing caseworkers have anything like the competencies required for a comprehensive, robust and trustworthy investigation.²⁶⁶

112. We heard a number of suggestions for improving the quality of investigations. Witnesses did not see clinicians as necessarily taking the lead in each future investigation. Katherine Rake of Healthwatch said that “we need a mix in all of this,” and Katherine Murphy of the Patients Association agreed, commenting that “the opinions of clinicians can be brought in when needed, but [an investigation] certainly does not need to be led by clinicians.”²⁶⁷

113. Indeed clinical skills might not be the only expertise sought by investigation teams. Keith Conradi of the Air Accidents Investigation Branch said that he might look for assistance from flight data specialists and experts in “human factors analysis [...] more

261 Professor Graham Braithwaite, Cranfield University [[CCF33](#)]

262 As above

263 Q 31

264 Q 156

265 Colin Rock [[CCF56](#)]

266 Dr Elizabeth Gould [[CCF041](#)]

267 Q 190

often than not we go out to consultants, specialists in the field in the particular area that we are interested in.” These would typically be psychologists or psychiatrists.²⁶⁸ Experience in other industries suggests that safety investigations should be conducted by multi-disciplinary teams and that safety investigators need a range of technical skills and specialist training, as well as non-technical skills such as tenacity and empathy.²⁶⁹

114. We heard some evidence of the importance of “root cause analysis [RCA] [...] as a diagnostic tool.”²⁷⁰ A good quality RCA investigation was said to be “characterised by a systems approach (i.e. looking at the role of systems in the incident rather than solely looking at the role of individuals).”²⁷¹ However, we were told that the term is now used to mean little more than ‘do an investigation’, and that many local investigations over-rely on RCA, rather than simpler and potentially more effective methods such as The Human Factors Analysis Classification System.²⁷² Denis Wilkins of CORESS lamented the fact that in the past “we did not place enough emphasis on training in human factors and the importance of an open culture of reporting.” However he was encouraged that “it is happening now; I know that it is embedded in the training of the young minds, the young people coming through.”²⁷³

The importance of learning and sharing lessons

115. The need to learn lessons from clinical incidents and complaints was a point regularly mentioned in our evidence as the primary purpose of conducting investigations. The Royal College of Anaesthetists told us that “in the experience of many respondents small incidents often go unreported, and some have reported how even major incidents involving the death of patients, have not led, despite investigations, to any clear lessons being cascaded down to staff.”²⁷⁴

116. Peter Walsh was concerned that “even when there is a good complaints investigation, we find that the biggest challenge is that closing of the circle so that there are real clinical improvements to services and patient safety”. He described this lesson-learning as “probably the weakest part of the system.”²⁷⁵ Denis Wilkins commented that “I do think we are much better at picking up complaints these days and also picking up incidents.” However, “it is what we do with them that is the problem.”²⁷⁶ Dr Durkin of NHS England described the difficulty of communicating lessons learned as “our greatest challenge.”²⁷⁷

268 Q 70-72

269 Professor Graham Braithwaite, Cranfield University [CCF33]

270 Royal College of Anaesthetists [CCF21]

271 As above

272 Maria Dineen [CCF71] and Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everson, Stephen Richards and James Titcombe [CCF87]

273 Q 39

274 Royal College of Anaesthetists [CCF21]

275 Q 174

276 Q 7

277 As above

117. This failure to learn from incidents and disseminate lessons has been a long-standing weakness of the NHS, we heard. Professor Toft told us of his experience of an investigation into stillbirths at a hospital. In his background reading Professor Toft discovered that shortcomings in perinatal care identified as widespread in the NHS in 1991 were similarly reported in 2005. These included failings as serious as inadequate foetal monitoring, a lack of involvement by senior staff, inadequate medical records and some women being ignored and given too little information. Professor Toft commented, “if they had put in place the recommendations from that report in 1991, I might not have had to make my report in 2004.”²⁷⁸ It can take a long time for lessons to be fully disseminated (Box 2).

Box 2: Wayne Jowett: case study

Wayne Jowett died in 2001 at the age of 18 following a preventable clinical failure. At Queen's Medical Centre in Nottingham a chemotherapy drug, Vincristine, was injected into his spine rather than his vein, causing nerve damage and paralysis, leading to Wayne's death four weeks later.

Professor Brian Toft described the part he played in the case. He was commissioned by the then Chief Medical Officer Sir Liam Donaldson as the first ever 'lay' person to chair an investigation into the death of a patient in the NHS.²⁷⁹ Although Professor Toft's report did not allocate blame, following its publication, under pressure from Wayne Jowett's family, the supervising doctor was charged with 'Gross Negligence Manslaughter'. At trial the doctor pleaded guilty and was sentenced to eight months in prison, though having already spent 11 months on remand, he did not go to prison.²⁸⁰

Professor Sir Mike Richards told us he was responsible for the “many years of work” that followed, “trying to get the health service to implement the recommendations that came out of Professor Toft's report.”²⁸¹ These efforts were successful, according to Sir Mike and Professor Toft, and led to “significant changes being made to the procedures involved with the spinal administration of chemotherapy throughout England and Wales” including “the manufacture and implementation of a new safer medical device for the administration of spinal chemotherapy throughout NHS England”.²⁸² As a result, “there have been no further deaths in England and Wales since the implementation of the report's recommendations.”²⁸³

In February 2014, NHS England issued a patient safety alert instructing hospitals to only use 'non-Luer' connectors for treatment like that received by Wayne Jowett, as these physically prevent mixing up spinal and intravenous devices.²⁸⁴ This updated and followed related alerts issued in 2009 and 2011. Commenting on the 13 years that elapsed from Wayne Jowett's death in 2001 and the issuing and updating of alerts into

278 Q 149

279 Professor Brian Toft [CCF30]

280 '[Anger as fatal jab doctor freed](#)', BBC News, 23 September 2003

281 Q 220

282 Professor Brian Toft [CCF30] and Q 220 [Professor Sir Mike Richards]

283 Professor Brian Toft [CCF30]

284 NHS England, [Patient safety alert on non-Luer spinal \(intrathecal\) devices for chemotherapy](#), February 2014

2014, the Secretary of State for Health commented “that completely sums up everything that is wrong: the fact that it takes that long.”²⁸⁵

A new body – what it should do and how it should relate to other bodies?

118. Dr Macrae and Professor Vincent, in the article which prompted this inquiry, urged the establishment of:

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.²⁸⁶

NHS England discussed the criteria a new body could adopt:

Any national ‘investigation branch’ would need to be selective about the incidents it investigates by using clear criteria to select a shortlist of incident types to consider. Incident types could be selected on the basis of reported frequency, degree of harm, setting, and representation via other feedback routes including patient complaints, the findings of inspectors, regulators and supervisory organisations, and through engagement with other stakeholders. Further discriminating criteria that could be applied include the profile of a particular event, the potential for learning, or the sense that an incident represents an emerging risk.²⁸⁷

119. Peter Walsh of Action against Medical Accidents said his organisation would “support the principle that there needs to be a central resource with an expertise in investigations that both could carry out completely independent investigations in some of the most serious cases”, but it should also “act as a resource for the rest of the system and drive up the quality of local complaints and other incident investigations.”²⁸⁸

120. The power to initiate investigations irrespective of whether a complaint has been raised was important to some. Scott Morrish argued that:

The burden of learning should not fall upon the shoulders of patients, or depend upon them for impetus, especially at times when most in need of support and least able to cope: their energy will be needed elsewhere. Learning should take place irrespective of whether there is a complaint.²⁸⁹

285 Q 290

286 Macrae C and Vincent C, ‘Learning from failure: the need for independent safety investigation in healthcare’ *Journal of the Royal Society of Medicine*; 2014, 107(11) 439-443

287 NHS England [[CCF62](#)]

288 Q 184 [Peter Walsh]

289 Scott Morrish [[CCF79](#)]

121. The Secretary of State for Health, Jeremy Hunt MP, rejected “the idea of a single clinical investigation branch based at the Department of Health that would be responsible for looking into all serious incidents.” He said he did not think that it is “logistically feasible” for a single body to investigate every single serious incident that occurs across the NHS due to the large number of events and he believed that the Department of Health was not “the right place for it to sit.”²⁹⁰ Mr Hunt objected partly because “hospitals do a lot of local investigations very satisfactorily and well, and we should allow them to continue to do that, because it is important there is local responsibility for safety records.” He did, however, appear to be moving towards the proposed new body in his evidence to us on 25 February 2015, when he accepted that “there may be something to be said for having a central function of the scale of the Air Accidents Investigation Branch for cases where there is a dispute or where there is a lack of trust or where the relationship has broken down and where you need a rapid expert view.”²⁹¹

122. Katherine Rake of Healthwatch also set out the functions that need to be carried out:

We need a proper system of local resolution with local support. We need a decent place to appeal, across health and social care—so an Ombudsman for health and social care—and then we need a national body that captures the learning, drives improvement, monitors quality and does those investigations.²⁹²

290 Q 307 [Jeremy Hunt MP]

291 As above

292 Q 196

123. Dr Rake argued that consolidation at the top of the complaints system was needed as part of the reforms she called for:

The cases that we hear are often a complex mix across health and social care, so there is a very strong case for having a single Ombudsman for health and social care.²⁹³

The Health Select Committee recently called for integrating complaints about health and social care under the same umbrella in the form of a single Ombudsman.²⁹⁴ The consumer group Which? recently called for a single public services Ombudsman, replacing the current bodies, with a role in ensuring a fair and accessible complaints system at the local level, and driving improvements in public services through their recommendations and insights gained from complaints.²⁹⁵ Dame Julie supports the idea of a single public service Ombudsman for England “that will serve the public better and achieve better value for money.”²⁹⁶

124. Peter Walsh called for “a realignment, a reform, but a reform to a more simplified system, as opposed to adding more and more tiers. What we have to be careful with if there is a new agency, or a new function in another body of investigation, is that if it has its investigations legally privileged—I hope it will not—it will set up a situation where any independent adviser of a complainant, a family or a patient who had had a problem would have to advise them, ‘Don’t rely on that route, because you cannot do anything with the information it is going to look at’. You would be forcing people down the complaints route.”²⁹⁷

125. The need for the new body to become a centre for expertise about clinical incidents was stressed by several witnesses. For example Peter Walsh said:

One of the benefits of a new agency would be the creation of a bank of clinical expertise, which could be called upon, for example by the Ombudsman in her investigations, because, as we have already discussed, good-quality clinical input is absolutely essential to any of these complex clinical investigations.²⁹⁸

126. Mr Walsh strongly advised against the work of a new body, “being made legally privileged. That would be entirely inconsistent with the duty of candour that the Government has championed.”²⁹⁹

293 Q 197

294 Health Select Committee, Fourth Report of Session 2014-15, [Complaints and Raising Concerns](#), HC 350, January 2015

295 Which? [Make complaints count](#), March 2015

296 Parliamentary and Health Service Ombudsman, [The Ombudsman’s Annual Report and Accounts 2013-14](#), July 2014

297 Q 197

298 Q 199

299 Q 184 [Peter Walsh]

Where should a new body be located?

127. There was much support for the idea of a patient safety investigation body which would act as a centre of knowledge and expertise, encourage improvement in local investigations and carry out investigations itself in the most serious and systemic of cases. There were, however, a number of conflicting views on where such a body might sit, and the nature of its accountability.

128. Some witnesses said that accountability for disseminating learning needed to rest with the Secretary of State for Health. Among these were Professor Toft.³⁰⁰ However, the Health Secretary Jeremy Hunt MP said that if an equivalent system to the Air Accidents Investigation Branch sat in the Department of Health, “we would have a conflict that the Department for Transport does not have, which is that we run the hospitals.”³⁰¹

129. Peter Walsh of Action against Medical Accidents also harboured doubts about a location in the Department of Health, saying: “I agree with the principle of accountability but, on whether a body might be more independent if it is at arm’s length rather than reporting directly to the Secretary of State, you might say that there is a difficulty with a direct relationship to the Secretary of State. These are difficult issues. We do not have any one answer for it.”³⁰²

A ‘whole system’ approach

130. Katherine Rake of Healthwatch pressed us to examine the whole system, warning that there was a risk in simply adding a new body, which would be the 71st of its type in the NHS. She favoured “simplification in the round and begin[ning] to take out some of this complexity, rather than add to it.”³⁰³ Murray Anderson-Wallace and others wrote to us to say that the local investigations they experienced “proved to be seriously flawed by their inability—by definition—to identify the wider error producing conditions”.³⁰⁴

131. Dr Rake said that the complete system for ensuring patient safety needed to be examined and consulted upon: “if you were to get the kind of whole-scale reform that we are talking about that would be subject to a Green Paper or White Paper, I would suggest, actually, that we ask the public where they would get most reassurance from and take our lead directly from them. Propose different models within the consultation and ask for public views on that.”³⁰⁵

132. We welcome the call for a ‘whole-system’ approach. Too many recent reforms of patient safety arrangements in the NHS, while reasonable in themselves, have not taken account of the impact on other parts of the system. Reliance upon a single method of investigation such as root cause analysis is not enough to get to the heart of a case.

300 Q 153

301 Q 279

302 Q 201

303 Q 184

304 Murray Anderson-Wallace, Clare Bowen, Martin Bromiley, Holly Jones, Scott Morrish, Lisa Richards-Everton, Stephen Richards and James Titcombe [\[CCF87\]](#)

305 Q 201

Investigative staff must be competent and confident if local investigation is to be effective. We wish to see a clarification of the current processes for complaints and investigations of clinical incidents. This must make it easier for patients and families to complain and understand what is happening to their complaint.

133. We welcome the proposal for 'Freedom to Speak Up Guardians' recently accepted by the Government, but in order for them to be effective, the information given to Guardians must be protected from disclosure, so that information cannot be used to publish or penalise those making whistleblowing reports to Guardians; that will require legislation.

134. We welcome the decision of the Secretary of State for Health, who has followed our inquiry closely, to invite Dr Mike Durkin of NHS England to look at the possibility of setting up a new independent patient safety investigation body in order to conduct clinical investigations. This will not solve all the problems we have identified, but is an essential step.

135. We are struck by the fact that no public inquiry has taken place into an aviation accident since the 1970s, where just such a body exists in the form of the Air Accidents Investigation Branch of the Department for Transport. The present situation in the NHS, where investigations of clinical incidents and complaints are tangled together and often prove hard for the patient and their family to navigate, needs to be replaced by a more rational and easy-to-understand system.

136. We therefore conclude there is a need for a new, permanent, simplified, functioning, trusted system for swift and effective local clinical incident investigation conducted by trained staff, so that facts and evidence are established early, without the need to find blame, and regardless of whether a complaint has been raised. This would greatly reduce or remove the need for costly major inquiries into clinical failure. The reformed system should provide three key elements:

- it must offer a safe space: strong protections to patients, their families, clinicians and staff, so they can talk freely about what has gone wrong without fear of punitive reprisals. They must be afforded legal immunity for what they say as part of an investigation, and such evidence should be exempt from the Freedom of Information Act, reflecting the practice of investigation bodies in aviation and other industries. This does not mean that anyone remains immune from prosecution on the basis of the findings of an investigation.
- it must be independent of providers, commissioners and regulators, and so able to investigate whether and how the system as a whole was instrumental in contributing to clinical failure. In order to be able to carry out comprehensive investigations in all cases, it must be free to investigate non-NHS funded healthcare as well as the NHS. Exclusion of the independent sector from the jurisdiction of the new body would not be consistent with a whole system approach, which many witnesses regard as essential. Other health bodies, such as the Care Quality Commission, cover both NHS and independent health care providers.

- for transparency and accountability, and to drive learning and improvement, it must have the power to publish its reports and to disseminate its findings and recommendations.

137. Such a single, independent, investigative body would provide national leadership and support of local capability and act as a catalyst to promote a just and open culture across the whole health system. It would proactively investigate the most serious patient safety issues, encourage improvement in the quality of local investigations, better capture and disseminate learning from them and serve as a resource of skills, expertise and experience for the conduct of clinical incident investigations.

138. We have some concerns that changing structures in the NHS can sometimes obscure the Secretary of State for Health's ultimate accountability for the NHS. We have no doubt that the Secretary of State for Health is accountable to Parliament for safety in the NHS. The new body's reports should therefore be received by the Secretary of State, who should be accountable for the implementation of their recommendations through such bodies as NHS England and the Care Quality Commission. The new body itself should be accountable to a Select Committee such as PASC, which would scrutinise its reports, performance and operation, and provide assurance of its independence.

139. The new body should be permanent and independent to ensure a dispassionate and system-wide view of safety, and to ensure that witnesses do not fear punitive consequences. To ensure a safe space for disclosure, witnesses should be given legal immunity for what they say and evidence should be exempt from the Freedom of Information Act.

140. The new body must be an enabler and promoter of good investigatory practice. It must have its own substantial investigative capacity, so that it can demonstrate best practice and lead by example, serving as an on-call resource to conduct investigations when required. The sole objective of its investigations should be to prevent incidents and to improve patient safety, and not to apportion blame or liability. A clear mandate and set of clear criteria would need to be established regarding when it should undertake an investigation, to avoid it becoming overwhelmed by the volume of clinical incidents requiring investigation while ensuring that particularly severe incidents or high risk issues with the potential for producing system-wide learning receive appropriate attention. The new body should therefore have a lead role in capturing and disseminating learning from local incident investigations. The new body should aim to determine the causes of the most serious patient safety issues, be they due to individual mistakes, negligence or wider systemic problems such as the actions of management, commissioners, regulators and politicians. Each investigation should be conducted by trained and expert investigators, including or drawing on expertise in clinical disciplines, human factors and the safety sciences. Each investigation should publish safety recommendations that are intended to prevent recurrence and improve patient care, not to apportion blame. These recommendations should be directed at any organisation that is required to learn and improve in response to a serious safety issue.

141. The new body should establish a single set of incontestable evidence. If it subsequently emerges that the new body's report may be based on incomplete or

inaccurate evidence or assessment, then it should be for that body to reopen its own investigation, not for another organisation to second-guess its judgement. Its investigations should have the capacity to examine all aspects of healthcare and their contribution to patient safety, paying attention to transitions of care and interfaces between different parts of the system. There must be a duty to provide relevant information to its investigators in a timely fashion.

142. The new body should complement existing NHS bodies, so the Department of Health should work with NHS England, the Care Quality Commission and others to draw up Memoranda of Understanding between the new body and existing bodies.

143. The new body should be funded by the Department of Health, not by trusts and Clinical Commissioning Groups, as this would act as a financial disincentive to raise concerns and create conflicts of interest. In order to fund its investigation of non-NHS funded health provision, a levy on the independent sector could be considered, but not any kind of direct charge, for the same reasons as above. We anticipate that the cost of this body will be relatively small, compared to the costs and liabilities arising from clinical incidents at present. In any case, the Secretary of State agrees that all serious clinical incidents in the NHS must be investigated thoroughly, and the only question is how and by whom, so the NHS must bear this cost one way or another.

144. We therefore recommend that the Secretary of State for Health should start consulting on this proposal immediately. To establish this new investigative body as independent and system-wide, ensuring it can work across the NHS, the Government should set up a cross-organisation working group including safety experts and representatives of key NHS organisations including the Care Quality Commission, NHS England, the Department of Health, and representatives of providers, commissioners, and patients and their families, with an independent chair. This group should be charged with making rapid progress in refining the working model, investigative criteria and protections provided by this body. Precursor bodies should be set up to start work as soon as possible and draft legislation should be published for scrutiny early in the next Parliament.

145. *We also recommend that Independent Medical Examiners, as provided for in the Coroners and Justice Act 2009, should be appointed for every Clinical Commissioning Group, to examine hospital deaths, to keep families of deceased relatives informed, and to alert the coroner to cases of concern. In time, such Examiners should refer cases for investigation to our proposed new body.*

146. *Finally, we recommend that educators, professional bodies and Royal Colleges should ensure that Human Factors and incident analysis modules are introduced as part of the training of healthcare professionals, with regular tutorials involving role play to increase understanding of how human factors can affect patient safety. We also recommend the development of a body of professionally qualified administrative and investigative staff, who, over time will be able to provide a substantial infrastructure in support of all investigation of clinical incidents. There should be formal examinations and qualifications similar to those formerly made by the Institute of Health Service Administration and the Association of Medical Records Officers.*

4 Conclusion

147. Our inquiry has considered a complicated and changing landscape of enormous importance to some people and potential consequence to anyone. Despite pockets of best practice, good intentions and strong leadership, clinical incident investigation and complaints handling fall far short of what patients, their families, clinicians and NHS staff are entitled to expect. A culture of defensiveness and blame, rather than a positive culture of accountability, pervades much of the NHS. Despite the efforts to implement change, the same atmosphere extends to the Parliamentary and Health Service Ombudsman, which also needs to change.

148. Clinical incident investigations are often too slow, substandard and in too many cases they exclude patients. No body currently exists to improve them, and nobody is accountable for their quality at a national level or for ensuring that lessons are learned across the NHS. We have identified three key features the proposed new independent patient safety investigation body must have. These are, first, confidentiality, in offering a safe space to talk about what went wrong; second, independence of the rest of the system; and third, transparency, in that its reports, findings and recommendations must be published and disseminated.

149. Our aim in making these proposals is to improve the system to reduce unnecessary suffering among patients and their families in future. The next Government must reform the structures as well as continuing to lead by example in driving culture change. Patients and NHS staff deserve to have incidents investigated properly, without the need to find blame, and regardless of whether a complaint has been raised.

Conclusions and recommendations

Background

1. This inquiry has received much evidence concerning individual cases that we cannot address individually, but which together paint a grim picture of grief and anger caused by denial, defensiveness and evasion. We have read all these submissions carefully in order to see what we can learn from them. We pursue this topic in the hope of achieving quicker and more effective resolution of incidents of clinical failure locally, leading to faster learning and more positive change, without the need for a complaint, and therefore a substantial reduction in the number of people whose cases reach as far as the Ombudsman. (Paragraph 9)
2. We are grateful for the openness and dialogue we have had with the Secretary of State for Health, who has become an advocate for a new body along the lines we have been discussing. (Paragraph 10)

Public inquiries

3. Complainants need to feel heard, whether they are patients, relatives or staff. They deserve the opportunity to contribute to learning in the system that will prevent a repeat of the same failure. Instead, they too often feel their issue is managed or avoided, to minimise reputational damage to individuals and organisations, or to avoid financial liability. The system is unacceptably complicated, with an unresolved tension between the desire for an open ‘no blame’ culture and the demand for the clear accountability the public is entitled to expect from a public service. There is a clear requirement for a single body to provide a single focus for accountability for driving local improvement. (Paragraph 74)
4. Complainants deserve an Ombudsman they can have confidence in. There are serious questions about the capacity and capability of the Ombudsman’s office, in particular in relation to complaints involving clinical matters. We are aware of considerable anguish and disquiet where Parliamentary and Health Service Ombudsman investigations fail to uncover the truth, and of pain inflicted by the Ombudsman’s defensiveness and reluctance to admit mistakes. This underlines the need for improved competence and culture change throughout the system, including in the PHSO. PHSO leadership is aware of the need for this change, but it is proving more challenging than expected. We welcome the PHSO’s aim to improve the quality and accessibility of its services. However, the Ombudsman’s office is under considerable strain. Fundamental reform of the Ombudsman system is needed. (Paragraph 75)

5. We reiterate our conclusion, in *Time for a People's Ombudsman Service*, that change is urgently needed. Some of the PHSO's shortcomings are systemic and can only be addressed through legislation, which is needed early in the next Parliament. However, unhappiness with the Ombudsman also underlines the need for improved capacity for clinical incident investigations in response to complaints, long before they reach the Ombudsman. The Ombudsman must acknowledge current concerns, and the need for larger reforms must not delay necessary practical improvement. (Paragraph 76)

6. Much external criticism of PHSO concentrates on its handling of past cases, which has encouraged the organisation to devote considerable resource to reviewing these cases. Poor adjudications based upon inadequate evidence underline that PHSO was not established to conduct clinical investigations, but to adjudicate on maladministration and service failure based on evidence provided to it by others. We therefore recommend that PHSO should concentrate its energy on improving its internal culture and competence in respect of its current adjudications, rather than on reviewing or justifying past adjudications. PHSO needs to reflect upon how it wishes the public to perceive its role: how it balances the independence of its adjudications with the wish to support complainants and to respond to public criticism. We expect the PHSO to make its internal change programme its main effort. The PHSO's leadership must avoid becoming distracted by other issues, such as the proposed review in its legislative framework, which will take some years to complete. The internal change programme is essential and urgent, with or without legislative change. We expect to see clear signs of significant progress early in the next Parliament. (Paragraph 77)

7. It is time for PASC to take another look at our role in relation to the Ombudsman. Parliament expects PASC to pay close attention to the effectiveness of the service provided by the Ombudsman, so we have the authority to set out our expectations for its performance. Our successor Committee in the next Parliament should examine PHSO's internal change programme and make recommendations about how to reinforce and to accelerate much needed change in the behaviour, attitudes and competence of PHSO staff. This scrutiny should be forward-looking. This Committee cannot be a court of appeal in respect of PHSO's adjudications nor can it seek in any way to influence decisions in individual cases because this would compromise the independent quasi-judicial role of PHSO. However, our scrutiny role in this Parliament has been enhanced by understanding previous cases and this learning should continue in future. We reiterate our previous recommendation in *Time for a People's Ombudsman Service* that the Public Accounts Commission or a similar body should take primary responsibility for scrutiny of PHSO, including examining corporate plans, budget and resources. But this does not absolve us from looking at the Ombudsman's:
 - quality of adjudications, their;
 - competence in respect of evidence, investigation and legal interpretation; and the
 - leadership and development of the service. (Paragraph 78)

8. We hope that our successor Committee will return to the question of the boundaries between the Ombudsman and other regulatory and investigatory bodies, including the proposed new central investigative body. (Paragraph 79)
9. We recommend that our successor Committee should ask the National Audit Office to assist with an inquiry on the value for money of the Parliamentary and Health Service Ombudsman. (Paragraph 80)
10. We recommend that the Ombudsman's change programme be its main priority in the immediate future. The Ombudsman should publish proposals on the progress of its change programme, set out the form it will take from now on, what it is intended to achieve, and by when. These proposals should be published in time for our successor Committee to consider them. (Paragraph 81)

A 'whole system' approach

11. We welcome the call for a 'whole-system' approach. Too many recent reforms of patient safety arrangements in the NHS, while reasonable in themselves, have not taken account of the impact on other parts of the system. Reliance upon a single method of investigation such as root cause analysis is not enough to get to the heart of a case. Investigative staff must be competent and confident if local investigation is to be effective. We wish to see a clarification of the current processes for complaints and investigations of clinical incidents. This must make it easier for patients and families to complain and understand what is happening to their complaint. (Paragraph 132)
12. We welcome the proposal for 'Freedom to Speak Up Guardians' recently accepted by the Government, but in order for them to be effective, the information given to Guardians must be protected from disclosure, so that information cannot be used to publish or penalise those making whistleblowing reports to Guardians; that will require legislation. (Paragraph 133)
13. We welcome the decision of the Secretary of State for Health, who has followed our inquiry closely, to invite Dr Mike Durkin of NHS England to look at the possibility of setting up a new independent patient safety investigation body in order to conduct clinical investigations. This will not solve all the problems we have identified, but is an essential step. (Paragraph 134)
14. We are struck by the fact that no public inquiry has taken place into an aviation accident since the 1970s, where just such a body exists in the form of the Air Accidents Investigation Branch of the Department for Transport. The present situation in the NHS, where investigations of clinical incidents and complaints are tangled together and often prove hard for the patient and their family to navigate, needs to be replaced by a more rational and easy-to-understand system. (Paragraph 135)

15. We therefore conclude there is a need for a new, permanent, simplified, functioning, trusted system for swift and effective local clinical incident investigation conducted by trained staff, so that facts and evidence are established early, without the need to find blame, and regardless of whether a complaint has been raised. This would greatly reduce or remove the need for costly major inquiries into clinical failure. The reformed system should provide three key elements:
 - it must offer a safe space: strong protections to patients, their families, clinicians and staff, so they can talk freely about what has gone wrong without fear of punitive reprisals. They must be afforded legal immunity for what they say as part of an investigation, and such evidence should be exempt from the Freedom of Information Act, reflecting the practice of investigation bodies in aviation and other industries. This does not mean that anyone remains immune from prosecution on the basis of the findings of an investigation.
 - it must be independent of providers, commissioners and regulators, and so able to investigate whether and how the system as a whole was instrumental in contributing to clinical failure. In order to be able to carry out comprehensive investigations in all cases, it must be free to investigate non-NHS funded healthcare as well as the NHS. Exclusion of the independent sector from the jurisdiction of the new body would not be consistent with a whole system approach, which many witnesses regard as essential. Other health bodies, such as the Care Quality Commission, cover both NHS and independent health care providers.
 - for transparency and accountability, and to drive learning and improvement, it must have the power to publish its reports and to disseminate its findings and recommendations. (Paragraph 136)
16. Such a single, independent, investigative body would provide national leadership and support of local capability and act as a catalyst to promote a just and open culture across the whole health system. It would proactively investigate the most serious patient safety issues, encourage improvement in the quality of local investigations, better capture and disseminate learning from them and serve as a resource of skills, expertise and experience for the conduct of clinical incident investigations. (Paragraph 137)
17. We have some concerns that changing structures in the NHS can sometimes obscure the Secretary of State for Health's ultimate accountability for the NHS. We have no doubt that the Secretary of State for Health is accountable to Parliament for safety in the NHS. The new body's reports should therefore be received by the Secretary of State, who should be accountable for the implementation of their recommendations through such bodies as NHS England and the Care Quality Commission. The new body itself should be accountable to a Select Committee such as PASC, which would scrutinise its reports, performance and operation, and provide assurance of its independence. (Paragraph 138)

18. The new body should be permanent and independent to ensure a dispassionate and system-wide view of safety, and to ensure that witnesses do not fear punitive consequences. To ensure a safe space for disclosure, witnesses should be given legal immunity for what they say and evidence should be exempt from the Freedom of Information Act. (Paragraph 139)
19. The new body must be an enabler and promoter of good investigatory practice. It must have its own substantial investigative capacity, so that it can demonstrate best practice and lead by example, serving as an on-call resource to conduct investigations when required. The sole objective of its investigations should be to prevent incidents and to improve patient safety, and not to apportion blame or liability. A clear mandate and set of clear criteria would need to be established regarding when it should undertake an investigation, to avoid it becoming overwhelmed by the volume of clinical incidents requiring investigation while ensuring that particularly severe incidents or high risk issues with the potential for producing system-wide learning receive appropriate attention. The new body should therefore have a lead role in capturing and disseminating learning from local incident investigations. The new body should aim to determine the causes of the most serious patient safety issues, be they due to individual mistakes, negligence or wider systemic problems such as the actions of management, commissioners, regulators and politicians. Each investigation should be conducted by trained and expert investigators, including or drawing on expertise in clinical disciplines, human factors and the safety sciences. Each investigation should publish safety recommendations that are intended to prevent recurrence and improve patient care, not to apportion blame. These recommendations should be directed at any organisation that is required to learn and improve in response to a serious safety issue. (Paragraph 140)
20. The new body should establish a single set of incontestable evidence. If it subsequently emerges that the new body's report may be based on incomplete or inaccurate evidence or assessment, then it should be for that body to reopen its own investigation, not for another organisation to second-guess its judgement. Its investigations should have the capacity to examine all aspects of healthcare and their contribution to patient safety, paying attention to transitions of care and interfaces between different parts of the system. There must be a duty to provide relevant information to its investigators in a timely fashion. (Paragraph 141)
21. The new body should complement existing NHS bodies, so the Department of Health should work with NHS England, the Care Quality Commission and others to draw up Memoranda of Understanding between the new body and existing bodies. (Paragraph 142)
22. The new body should be funded by the Department of Health, not by trusts and Clinical Commissioning Groups, as this would act as a financial disincentive to raise concerns and create conflicts of interest. In order to fund its investigation of non-NHS funded health provision, a levy on the independent sector could be considered, but not any kind of direct charge, for the same reasons as above. We anticipate that the cost of this body will be relatively small, compared to the costs and liabilities arising from clinical incidents at present. In any case, the Secretary of State agrees that all serious clinical incidents in the NHS must be investigated thoroughly, and

the only question is how and by whom, so the NHS must bear this cost one way or another. (Paragraph 143)

23. We therefore recommend that the Secretary of State for Health should start consulting on this proposal immediately. To establish this new investigative body as independent and system-wide, ensuring it can work across the NHS, the Government should set up a cross-organisation working group including safety experts and representatives of key NHS organisations including the Care Quality Commission, NHS England, the Department of Health, and representatives of providers, commissioners, and patients and their families, with an independent chair. This group should be charged with making rapid progress in refining the working model, investigative criteria and protections provided by this body. Precursor bodies should be set up to start work as soon as possible and draft legislation should be published for scrutiny early in the next Parliament. (Paragraph 144)
24. We also recommend that Independent Medical Examiners, as provided for in the Coroners and Justice Act 2009, should be appointed for every Clinical Commissioning Group, to examine hospital deaths, to keep families of deceased relatives informed, and to alert the coroner to cases of concern. In time, such Examiners should refer cases for investigation to our proposed new body. (Paragraph 145)
25. Finally, we recommend that educators, professional bodies and Royal Colleges should ensure that Human Factors and incident analysis modules are introduced as part of the training of healthcare professionals, with regular tutorials involving role play to increase understanding of how human factors can affect patient safety. We also recommend the development of a body of professionally qualified administrative and investigative staff, who, over time will be able to provide a substantial infrastructure in support of all investigation of clinical incidents. There should be formal examinations and qualifications similar to those formerly made by the Institute of Health Service Administration and the Association of Medical Records Officers. (Paragraph 146)

Annex

Current key approaches to healthcare investigation

Dr Carl Macrae and Professor Charles Vincent outlined a number of approaches to healthcare investigations in their article 'Learning from failure'.³⁰⁶ These are:

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.

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 Maternity and Neonatal Services Investigation, 2014.

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.

³⁰⁶ Macrae C and Vincent C, 'Learning from failure: the need for independent safety investigation in healthcare' *Journal of the Royal Society of Medicine*; 2014, 107(11) 439-443

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.

6. Keogh Mortality Review

- Initiated by Prime Minister and Secretary of State for Health 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.

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

Formal Minutes

Tuesday 24 March 2015

Members present:

Mr Bernard Jenkin, in the Chair

Paul Flynn
Mrs Cheryl Gillan
Sheila Gilmore

Kelvin Hopkins
Greg Mulholland

Draft Report (*Investigating clinical incidents in the NHS*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 149 read and agreed to.

Annex and Summary agreed to.

Resolved, That the Report be the Sixth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[The Committee adjourned.]

Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the Committee's [inquiry page](#).

Tuesday 3 February 2015

Question number

Keith Conradi, Chief Inspector of Air Accidents, Air Accidents Investigation Branch, **Dr Mike Durkin**, Director of Patient Safety, NHS England, and **Denis Wilkins**, Founder of CORESS

[Q1-94](#)

Helen Vernon, Chief Executive Officer, NHS Litigation Authority, **Professor Brian Toft**, Professor of Patient Safety, Coventry University, **Michael Devlin**, Head of Professional Standards and Liaison, Medical Defence Union, and **Ed Marsden**, Verita LLP

[Q95-154](#)

Tuesday 10 February 2015

Katherine Murphy, Chief Executive, Patients Association, **Katherine Rake**, CEO, Healthwatch England, and **Peter Walsh**, Chief Executive, Action against Medical Accidents (AvMA)

[Q155-207](#)

Dame Julie Mellor DBE, Parliamentary and Health Service Ombudsman, and **Professor Sir Mike Richards**, Chief Inspector of Hospitals, Care Quality Commission (CQC)

[Q208-267](#)

Wednesday 25 February 2015

Rt Hon Jeremy Hunt MP, Secretary of State, Department of Health

[Q268-336](#)

Published written evidence

The following written evidence was received and can be viewed on the Committee's [inquiry web page](#). CCF numbers are generated by the evidence processing system and so may not run consecutively.

- 1 Action against Medical Accidents ([CCF0023](#), [CCF0104](#))
- 2 Anonymous ([CCF0100](#))
- 3 Anonymous ([CCF0092](#))
- 4 Anonymous ([CCF0102](#))
- 5 Association of Surgeons of Great Britain and Ireland ([CCF0063](#))
- 6 Cardiff University and Wales Centre for Primary and Emergency Care Research ([CCF0038](#))
- 7 Care Quality Commission ([CCF0057](#))
- 8 Colin N Rock ([CCF0056](#))
- 9 Cranfield University ([CCF0033](#))
- 10 Datix Ltd ([CCF0026](#))
- 11 David William Rapp ([CCF0002](#))
- 12 Department of Health ([CCF0064](#))
- 13 Derek Payne ([CCF0074](#))
- 14 East London Patients Forum ([CCF0076](#))
- 15 Elizabeth Gould ([CCF0041](#))
- 16 Freedom From Gagging Campaign ([CCF0108](#))
- 17 Heal the Regulators UK-wide Health Campaign ([CCF0085](#))
- 18 Health Foundation ([CCF0027](#))
- 19 Healthwatch England ([CCF0050](#))
- 20 Ian Alexander ([CCF0084](#))
- 21 John Dale ([CCF0015](#))
- 22 John Driskel ([CCF0066](#))
- 23 Katy Peters ([CCF0036](#))
- 24 Kenneth Lownds ([CCF0052](#))
- 25 Kevin Riley ([CCF0093](#))
- 26 Dr Margaret McCartney ([CCF0008](#))
- 27 Maria Dineen ([CCF0071](#))
- 28 MDU Services Ltd ([CCF0011](#))
- 29 Medical Protection Society ([CCF0046](#))
- 30 Michael Cole ([CCF0070](#))
- 31 Minh Alexander ([CCF0043](#))
- 32 Miss Fiona Watts ([CCF0059](#))
- 33 Mr F Biard ([CCF0018](#))
- 34 Murray Anderson-Wallace ([CCF0087](#))
- 35 Narinder Kapur ([CCF0010](#))
- 36 NHS Confederation ([CCF0049](#))
- 37 NHS England ([CCF0062](#))
- 38 NHS Providers ([CCF0028](#))

- 39 Nic Hart ([CCF0042](#))
- 40 Parliamentary and Health Service Ombudsman ([CCF0061](#))
- 41 Patients Association ([CCF0053](#))
- 42 Peggy Banks ([CCF0068](#))
- 43 PHSO Pressure Group ([CCF0007](#), [CCF0081](#), [CCF0095](#) and [CCF0094](#))
- 44 POhWER ([CCF0045](#))
- 45 Professor Brian Toft OBE ([CCF0030](#))
- 46 Registration Council for Clinical Physiologists ([CCF0067](#))
- 47 Richard von Abendorff ([CCF0037](#))
- 48 Robin Bastin ([CCF0054](#))
- 49 Rosemary Cantwell ([CCF0035](#) and [CCF0106](#))
- 50 Royal College of Anaesthetists ([CCF0021](#))
- 51 Royal College of Nursing ([CCF0051](#))
- 52 Royal College of Physicians ([CCF0024](#))
- 53 Sands, The Stillbirth and Neonatal Death Charity ([CCF0047](#))
- 54 Scott Morrish ([CCF0079](#))
- 55 Slater & Gordon Lawyers ([CCF0044](#))
- 56 South West Whistleblowers Health Action Group ([CCF0040](#), [CCF0110](#))
- 57 Verita Consultants LLP ([CCF0025](#))
- 58 W Morris ([CCF0065](#))
- 59 Which? ([CCF0055](#))

List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the Committee's website at www.parliament.uk/pasc.

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2014–15

First Report	Who's accountable? Relationships between Government and arm's-length bodies	HC 110 (HC 1129)
Second Report	Appointment of the Chair of the Advisory Committee on Business Appointments	HC 759
Third Report	Leadership for the long term: Whitehall's capacity to address future challenges	HC 669
Fourth Report	Developing Civil Service Skills: a unified approach	HC 112
Fifth Report	Lessons for Civil Service impartiality from the Scottish independence referendum	HC 111
First Special Report	Business Appointment Rules: Government Response to the Committee's Third Report of Session 2012-13	HC 563
Second Special Report	Too soon to scrap the Census: Government and UK Statistics Authority Responses to the Committee's Fifteenth Report of Session 2013–14	HC 601
Third Special Report	More Complaints Please! and Time for a People's Ombudsman Service: Government Responses to the Committee's Twelfth and Fourteenth Reports of Session 2013-14	HC 618
Fourth Special Report	Caught red-handed: Why we can't count on Police Recorded Crime statistics: UK Statistics Authority Response to the Committee's Thirteenth Report of Session 2013-14	HC 645
Fifth Special Report	Statistics and Open Data: Government Response to the Committee's Tenth Report of Session 2013-14	HC 620

Session 2013–14

First Report	Communicating statistics: not just true but also fair	HC 190 (HC 573)
Second Report	Public engagement in policy-making	HC 75 (HC 986)
Third Report	The role of the Charity Commission and "public benefit": Post-Legislative scrutiny of the Charities Act 2006	HC 76 (HC 927)
Fourth Report	Engaging the public in National Strategy	HC 435
Fifth Report	Appointment of the Chair of the Committee on Standards in Public Life	HC 516
Sixth Report	Government Procurement	HC 123 (HC 105)
Seventh Report	Migration Statistics	HC 523
Eighth Report	Truth to Power: how Civil Service reform can succeed	HC 74 (HC 955)

Ninth Report	Latest proposals for ministerial involvement in permanent secretary appointments: PASC's recommendations	HC 1041
Tenth Report	Statistics and Open Data: Harvesting unused knowledge, empowering citizens and improving public services	HC 564
Eleventh Report	The failure of the Cabinet Office to respond to our Report on the Business Appointment Rules	HC 1156
Twelfth Report	More complaints please!	HC 229
Thirteenth Report	Caught red-handed: Why we can't count on Police Recorded Crime statistics	HC 760 (Cm 8910)
Fourteenth Report	Time for a People's Ombudsman Service	HC 655
Fifteenth Report	Too soon to scrap the census	HC 1090
First Special Report	Public Trust in Government Statistics: A review of the operation of the Statistics and Registration Service Act 2007: Government and UK Statistics Authority Responses to the Committee's Ninth Report of Session 2012–13	HC 77
Second Special Report	Special advisers in the thick of it: Government Response to the Committee's Sixth Report of Session 2012–13	HC 515
Session 2012–13		
First Report	The Big Society: Further Report with the Government Response to the Committee's Seventeenth Report of Session 2010–12	HC 98
Second Report	The Honours System	HC 19
Third Report	Business Appointment Rules	HC 404
Fourth Report	Appointment of the Chair of the Charity Commission	HC 315-I
Fifth Report	End of term report: 2011–12	HC 316
Sixth Report	Special advisers in the thick of it	HC 134
Seventh Report	The Honours System: Further Report with the Government Response to the Committee's Second Report of Session 2012–13	HC 728
Eighth Report	The Role of the Cabinet Secretary and the Resignation of the Chief Whip	HC 864 (HC 968)
Ninth Report	Public Trust in Government Statistics, A review of the operation of the Statistics and Registration Service Act 2007	HC 406 (HC 77)
First Special Report	Public Appointments: regulation, recruitment and pay: Government Response to the Committee's Fourteenth Report of Session 2010–12	HC 18
Second Special Report	Leadership of change: new arrangements for the roles of the Head of the Civil Service and the Cabinet Secretary: Further Report: Government Response to the Committee's Twenty Third Report of Session 2010–12	HC 313
Third Special Report	Strategic thinking in Government: without National Strategy, can viable Government strategy emerge? Government Response to the Committee's Twenty Fourth Report of Session 2010–12	HC 573

Fifth Special Report	The Prime Minister's Adviser on Ministers' Interests: independent or not? Government Response to the Committee's Twenty Second Report of Session 2010–12	HC 976
----------------------	--	--------

Session 2010–12

First Report	Who does UK National Strategy?	HC 435 (HC 713)
Second Report	Government Responses to the Committee's Eighth and Ninth Reports of Session 2009–10: Goats and Tsars: Ministerial and other appointments from outside Parliament and Too Many Ministers?	HC 150
Third Report	Equitable Life	HC 485 (Cm 7960)
Fourth Report	Pre-appointment hearing for the dual post of First Civil Service Commissioner and Commissioner for Public Appointments	HC 601
Fifth Report	Smaller Government: Shrinking the Quango State	HC 537 (Cm 8044)
Sixth Report	Who does UK National Strategy	HC 713
Seventh Report	Smaller Government: What do Ministers do?	HC 530
Eighth Report	Cabinet Manual	HC 900 (HC 1127)
Ninth Report	Pre-appointment hearing for the post of Parliamentary and Health Service Ombudsman	HC 1220
Tenth Report	Remuneration of the Parliamentary and Health Service Ombudsman	HC 1350
Eleventh Report	Good Governance and Civil Reform: 'End of Term' Report on Whitehall plans for structural reform	HC 901
Twelfth Report	Government and IT—"a recipe for rip-offs": time for a new approach	HC 715
Thirteenth Report	Change in Government: the agenda for leadership	HC 714
Fourteenth Report	Public Appointments: regulation, recruitment and pay	HC 1389
Fifteenth Report	Smaller Government: What do Ministers do? Further Report with the Government Response to the Committee's Seventh Report of Session 2010–12	HC 1540
Sixteenth Report	Appointment of the Chair of the UK Statistics Authority	HC 910
Seventeenth Report	The Big Society	HC 902
Eighteenth Report	Change in Government: the agenda for leadership. Further Report	HC 1746
Nineteenth Report	Leadership of change: new arrangements for the roles of the Head of the Civil Service and the Cabinet Secretary	HC 1582
Twentieth Report	Government and IT—"a recipe for rip-offs": time for a new approach. Further Report	HC 1724 (HC 1930)
Twenty-first Report	Future oversight of administrative justice: the proposed abolition of the Administrative Justice and Tribunals Council	HC 1621

Twenty-second Report	The Prime Minister's adviser on Ministers' interests: independent or not?	HC 1761
Twenty-third Report	Leadership of change: new arrangements for the roles of the Head of the Civil Service and the Cabinet Secretary. Further Report	HC 1914
Twenty-fourth Report	Strategic thinking in Government: without National Strategy, can viable Government strategy emerge?	HC 1625