THIRWALL INQUIRY

EXPERT REPORT

PART ONE

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1. Introduction

I am Sir Robert Anthony Francis KC. I have been instructed on behalf of the Chair of the Inquiry to prepare a report advising the inquiry on the answers to certain questions posed to me concerning the overall context in which an NHS Foundation Trust would have been operating in 2015 and since then. I append the letter of instruction at Appendix 1. That letter contains a declaration of interests I had made in advance of receiving those instructions. As I have updated the list since then, for convenience, at Appendix 2, I produce an updated version of this declaration.

I have reminded myself of the duty of an expert witness and reread the summary of those duties set out in Appendix A of the letter of instruction and confirm that to the best of my ability I have prepared this report in accordance with those duties.

I set out a full curriculum vitae of my career and experience in Appendix 3. In summary I have been a barrister at the Bar of England and Wales for 50 years and was in self-employed practice at what is now Serjeants' Inn Chambers from 1974 to 2020, when I retired from full-time practice and ceased to be registered with the Bar Standards Board, I continue to offer my expertise in medical and healthcare related issues on a consultancy basis and to give presentations and talks on such issues in this country and abroad to audiences in and outside the healthcare sector. For the vast majority of my life in full-time practice I specialised in medical law, including clinical negligence, patient decision-making, professional discipline, healthcare regulation and public inquiries. Since starting to prepare this report I have been appointed interim Chair of the Infected Blood Compensation Authority.

I have been involved as counsel, or chaired a number of healthcare related public inquiries, a full list of which appears in Appendix 3. I have been a Recorder, and a deputy High Court Judge. I am a past Chair of the Professional Negligence Bar Association, and in 2023 I was Treasurer of the Honourable Society of the Inner Temple. In the healthcare field I was a non-executive director of the Care Quality Commission for 8 years, and Chair of Healthwatch England for 4 years. I am President of the Patients' Association.

I have answered as best I can the questions posed to me in my instructions. I have sought to reference in footnotes a source for all factual statements I have made, but generally not more than one. For ease of handling I have divided the report into three separate parts, the first addressing the first two questions, the second the rest of the questions posed to me, and the third the appendices.

The subject-matter of the questions asked of me is very broad and the NHS is a highly complex and ever-changing entity. While I have done my best to ensure that I have referred to the most up to date relevant material I cannot guarantee that I have succeeded in that ambition.

I have usually identified an internet reference and when this was accessed or downloaded. Those documents stated to have been downloaded I have in possession

electronically. Evidence of the each such fact could probably found in many other places. As is doubtless already apparent to the Inquiry, the NHS is subjected to a constant flow of policy documents, legislation, mandates, codes and other material, including inquiry reports. Accordingly it is impractical and probably unhelpful to burden this already long report with an attempt to reference all documents which might support a point; therefore I have generally only taken a selection. I have not been instructed to undertake a literature review. Where I have expressed an opinion it is my personal opinion and I make no claim that my views would be universally accepted.

Inevitably I will have omitted material that others may consider important. This wealth, if that is the correct word, of material also makes it challenging to trace through changes in practice and requirements, between specific dates, still more so to establish what any particular health service leader is likely to have been aware of at any particular time, The exercise of writing this report has brought home forcefully to me once again how difficult it must be for the leadership of an NHS provider to keep track of all that they are required to take into account in their work.

Finally I would like to make clear formally that this report is written solely for the purposes of this inquiry and is not intended to be relied on by any third party as legal or any other form of advice.

2. Questions

(a) Please review the Inquiry's summary table and indicate for the Mid-Staffordshire NHS Foundation Trust Inquiry onwards if you agree or disagree with the summary about whether each highlighted recommendation has, or has not, been implemented, either in full or part? Please let me know if you disagree with any aspect of the Inquiry summary before you draft your report.

(b) To the extent that you agree that a recommendation has not been implemented, either in full or part, please explain your view on:

(i) why a recommendation has not been implemented at all? Or

(ii) why a recommendation has been partially implemented? Or

(iii) why a recommendation has, in full or part, been implemented but not at the speed or in the manner that was suggested? And

(iv) how that has impacted on the four areas for improvement set out in the introduction.

The Inquiry has provided me with a comprehensive schedule[1] of 29 inquiries and a helpful list of their many recommendations on which to comment. To comment individually on

[1] This draft refers to Version 2 – as at 13 February 2024 I have appended the Schedule as Appendix 4.

each recommendation made would be a formidable task, and not one I could complete within the time available. I have accordingly looked in detail at some only of the inquiries leading up to and including the Freedom to Speak Up Review. I have mainly focussed on my own Inquiries but have picked out other recommendations which had resonance with what I found at Mid-Staffordshire. I will refer more broadly to other inquiries when answering some of the questions which follow in Part 2 of this report.

Some of the answers refer in some detail to policies and regulations which are also relevant to the questions 3 onwards, and the reader will then be referred to the answers to questions 1 and 2 to avoid repetition.

It might be thought that finding out whether a recommendation has been implemented would be a relatively easy task: after all in almost every case, as recorded in the Schedule, the Government has published at least one response, if not more than one. However that this is really only the start of a consideration of the question. It is one thing for the Government to say it has accepted a recommendation, it is quite another to discover whether and if so how it has been implemented. The NHS and its regulators mesh together in a highly complex and ever-changing pattern, which some may describe as a "system" but perhaps more accurately should be seen as a series of planets revolving around each other, not always with a point of contact, planets which sometimes disappear, or are absorbed into each other. Many of them frequently issue new policies, instructions, and guidance. It is therefore sometimes easier to look at themes, and consider whether organisational, legal or cultural changes have been made which reflect recommendations, particularly when the context in which they were made may have changed radically. Bearing those difficulties in mind it is often impractical to say whether the Schedule is correct in saying a recommendation has or not been implemented, except by reference to an apparent direction of policy travel.

3. Clothier Inquiry

Although this inquiry predated the Mid Staffordshire inquiries, I anticipate that this Inquiry will consider it to be of considerable relevance. Therefore I have taken the liberty to offer some comment on it.

I note from the statement made in Parliament by the Secretary of State for Health on the publication of the Clothier inquiry report, which I quote from below, that the Government had earlier published a response which was placed in the House of Commons library. It is not digitally reproduced and to date I have not accessed it. While there has been much commentary on the case in the media, I have been unable to locate much open source professional literature on the lessons to be drawn from the case itself, but a response was published by the British Paediatric Association which again I have been unable to access. My commentary on the recommendations and their implementation is therefore not as informed as it might be possible for it to be. The Inquiry may feel it would be beneficial to obtain advice from a specialist in the diagnosis of factitious illness in children and how to approach this in a clinical setting.[2] While the specific diagnosis of a condition leading a person to harm a child in hospital is considerably beyond my expertise, the literature may give some indicators of warning signs which could otherwise be missed.

3.1 Recommendation 1: *For all those seeking entry to the nursing professions, the most recent employer or place of study should be asked to provide a record of time taken off on grounds of sickness*

(a) This recommendation preceded the Equality Act 2010. The guidelines referred to by the Secretary of State for Health in November 1994 now exist in the form of the *Employment history and reference checks standard* [NHSE 2023]. §2.3 sets out the information that should be sought. It does not explicitly require information about a record of sickness, but the templates include one which includes a request for absence records to be used after a conditional offer of employment has been made. Paragraph 2.2.4 counsels caution in asking about health records and refers to the work health assessment standard.[3] This points out that under the Equality Act it is unlawful to ask about an applicant's health or disability prior to making an offer of employment other than in exceptional circumstances. The standard requires a work health assessment for all individuals doing any type of work for the NHS including volunteers, including when taking up their first NHS position or nan existing employee moving to a new job. This must be proportionate to the risks associated with the type of activities they will be required to undertake as part of their normal role.

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[2] An example of literature on this subject is Stirling, Committee on Child Abuse and Neglect, *Beyond Munchausen Syndrome by Proxy: Identification and Treatment of Child Abuse in a Medical Setting.* 1 May 2007 Pediatrics (2007) 119(5): 1026-1030.

[3] The standard is available at https://www.nhsemployers.org/system/files/2023-04/work-health-assessments-standard-%281849%29.pdf

(b) Detailed guidance is given as to the required assessment process.[4] No individual should be refused employment on health grounds unless expert OH advice has been sought, the applicant has had the chance to discuss the issues raised with an OH professional, and the recruiting manager has given full consideration to the facts.[5]

(c) These references in the Employment history and reference checks standard do not appear to have been amended since the inception of the document. I am unable to determine when it was first published.

3.2 Recommendation 2: *Post-mortem reports should be sent to consultant responsible for treatment of the deceased*

(a) I have not found a circular from the SOSH commending this recommendation to coroners, and the legal position is that the report may be disclosed by the coroner to an interested person on request, and The Coroners (Investigations) Regulations 2013 SI 1629 reg 16 provides that:[6]

> *Unless authorised in writing by the coroner, the suitable practitioner who made the post-mortem examination may not supply any other person with the post-mortem examination report or any copy of that report.*

(b) Regulation 24 requires the coroner, where they decide to conduct an investigation into the death, or to direct a post-mortem of, a child, to notify the appropriate local Safeguarding Children Board or now the Child Death Review Partners,[7] and provide them with "*all information*". According to the statutory guidance this includes the post-mortem report.[8]

(c) Regulation 27(1) also allows the coroner to:

> *provide any document or copy of any document to any person who in the opinion of the coroner is a proper person to have possession of it.*

The nature of this discretion is prescribed by The Coroners (Inquests) Rules 2013 SI 1616 part 3, applied by the Investigations Regulations [above] regulation 13[9]

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[4] Work health assessment standard §2.1.1; Equality Act 2010 section 60

[5] Ibid §5.1.1

[6] 2013 SI 1629 https://www.legislation.gov.uk/uksi/2013/1629/regulation/16/made

[7] See below a summary of the child review requirements.

[8] 2023 guidance. [see below] §389

[9] https://www.legislation.gov.uk/uksi/2013/1616/part/3 . A report of the Justice Committee on the Coroners Service noted [paragaph72] that most bereaved people were unaware of this rule: House of Commons justice Committee, *The Coroners Service* First Report of Session 2021-22 18 May 2021 https://committees.parliament.uk/publications/6079/documents/75085/default/ [downloaded 12 February 2024] They recommended that the process for obtaining evidence is explained clearly to them – recommendation 9]. No mention appears to have been made of the need to share reports with the treating doctor.

> *1) Subject to rule 15, where an interested person asks for disclosure of a document held by the coroner, the coroner must provide that document or a copy of that document, or make the document available for inspection by that person as soon as is reasonably practicable.*
>
> *(2) Documents to which this rule applies include —*
>
> *(a)* any *post-mortem examination report;*

The request may be refused where[10]

> *(a) there is a statutory or legal prohibition on disclosure;*
>
> *(b) the consent of any author or copyright owner cannot reasonably be obtained;*
>
> *(c) the request is unreasonable;*
>
> *(d) the document relates to contemplated or commenced criminal proceedings; or*
>
> *(e) the coroner considers the document irrelevant to the investigation.*

(d) NHS guidance for the family of deceased patients states that if they want a copy of the pathologists report they can request this from the coroner, and it notes that:[11]

> *In some cases, the report may be sent to a hospital doctor or GP so they can discuss it with you.*

(e) In Northern Ireland government advice is that:[12]

> *When the final post-mortem report is completed it will be sent to the Coroner who will forward a copy to the deceased's doctor. The family will be informed when this happens and they may also request a copy of the final report from the Coroner. The report may contain complex medical terminology, and the family may wish to discuss the findings with their family doctor.*

(f) It appears to me that a combination of statutory requirements, discretion, and guidance result in there being no obstacle to the post-mortem report being shared with treating doctor and in any event it has to be shared with the safeguarding network which will include a senior paediatrician.

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[10] Ibid rule 15

[11] *Post Mortem* NHS https://www.nhs.uk/conditions/post-mortem/ [page last reviewed 21 June 2022] [downloaded 13 February 2024]

[12] *Coroners, post-mortems and inquests.* NI Direct https://www.nidirect.gov.uk/articles/coroners-post-mortems-and-inquests#toc-5

3.3 Recommendation 3: ***The provision of paediatric pathology services should be reviewed with a view to ensuring that such services be engaged in every case in which the death of a child is unexpected or clinically unaccountable, whether the post-mortem examination is ordered by a Coroner or in routine hospital practice***

(a) In 2002 in answer to a question in Parliament Lord Hunt of Kings Heath gave a summary of what had happened to the Strategic Review in general terms:[13]

> *Lord Clement-Jones asked Her Majesty's Government:*
>
> *What has been achieved as a result of the strategic review of pathology conducted by the Department of Health in 1995. [HL571]*
>
> *Lord Hunt of Kings Heath: The Strategic Review of Pathology Services, published by the then NHS Executive in 1995, focused on key issues relating to the provision and commissioning of NHS pathology services. The review emphasised local decision-making and provided a number of possible models. In addition, it flagged up some of the ways in which anticipated advances in technology were likely to impact on the pathology services, for example, through improved communication with service users and better collaboration between services. The report was widely disseminated to NHS pathology services to consider, in the light of the recommendations made, how to maintain and develop high quality, cost-effective clinical services responsive to the needs of patients and users.*
>
> *The NHS Plan, subsequently published in 1997, set out the vision for the NHS to offer people fast and convenient care delivered to a consistently high standard. This overtook the recommendations of the Strategic Review of Pathology Services. Where relevant, for example, on collaboration on service reconfiguration, appropriate access to 24-hour services, and developing guidance on specialised pathology, the recommendations have been implemented. The Department of Health recognised the critical role of pathology services in the effective treatment and care of patients, in protecting the public health and in national screening programmes. We also recognised the pressure on them to maintain quality in the face of increasing workloads and the challenges facing them of technological and scientific change. As part of our modernisation programme for the NHS, in 1999 we therefore established the pathology modernisation programme (PMP), a 10-year programme to modernise NHS pathology services.*

[13] Hansard 19 December 2002 Written Answers (Lords): https://api.parliament.uk/historic-hansard/written-answers/2002/dec/19/pathology-services-strategic-review

> *The first three years of the PMP (from 1999–2000 to 2001–02) concentrated on capital investment to support service modernisation: £28 million capital funding was awarded to 39 demonstration projects for smaller-scale service reconfigurations; technology and IT upgrades; rationalisation of specialist services; and larger-scale reconfiguration projects to support the development of managed pathology networks.*
>
> *In 2002 the PMP has developed and published for consultation draft guidance Pathology—the Essential Service for the NHS. We are currently considering the responses to the consultation and will publish final guidance, revised in the light of the views received, in 2003.*

(b) The Report of the Review itself does not appear to have been digitised and therefore I cannot comment on its content without further research. It does not appear to address the issue raised in this recommendation.

(c) A better resource is probably the guidance issued by the Royal College of Pathologists in 2004 and 2016.[14] While this guidance principally focussed on the syndrome of Sudden Unexpected Death of babies, mainly at home, following several notorious miscarriages of justice, the principles set out apply to any sudden, unexplained death of a baby or neonate. Indeed the 2016 guidance explicitly states this:[15]

> *While focusing primarily on sudden unexpected deaths in infancy (SUDI), the principles in these guidelines broadly relate to all unexpected deaths in children from birth (excluding stillbirths) to age 18. This includes unexpected deaths in the early neonatal period, unexpected deaths for which a natural cause is not immediately apparent, and deaths from external causes, including accidents, suicides and possible homicides… The principles also recognise that the exact process followed may require modification according to the age of the child and specific circumstances. This aligns with recommended child death review processes in Working Together.*[16]

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[14] Kennedy *Sudden Unexpected Death in Infancy: A multi-agency protocol for care and investigation. The report of a working group convened by The Royal College of Pathologists and The Royal College of Paediatrics and Child Health.* London: RCPath and RCPH, 2004; Kennedy *Sudden unexpected death in infancy and childhood* RCPath/RCPCH November 2016 https://www.rcpath.org/static/874ae50e-c754-4933-995a804e0ef728a4/Sudden-unexpected-death-in-infancy-and-childhood-2e.pdf

[15] 2016 guidance [above] page 8

[16] This statutory guidance, issued under *Children Act 2004* section 16Q, has the force of law [relevant legislation is listed at paragraph 7 of the 2018 version] and was originally published in 2015, with minor amendments made in 2017 and 2018. The earliest version I have relied on here is *A Guide to multi-agency working to help, protect and promote the welfare of children* HM Government July 2018 https://wscp.org.uk/media/1161/working_together_to_safeguard_children.pdf and again in December 2023 by a document with the same title:
https://assets.publishing.service.gov.uk/media/65803fe31c0c2a000d18cf40/Working_together_to_safeguard_children_2023_-_statutory_guidance.pdf
[downloaded 14 February 2024]

(d) The 2018 Working Together statutory guidance required a child death to be investigated with *"an appropriate balance between forensic and medical requirements and supporting the family at a difficult time"*[17] and identified a network of *"child death review partners"*. The statutory requirements when a child dies are set out in this guidance which include:[18]

- Child death review partners must make arrangements to review all deaths of children normally resident in the local area and, if they consider it appropriate, for any non-resident child who has died in their area.
- The purpose of a review and/or analysis is to identify any matters relating to the death, or deaths, that are relevant to the welfare of children in the area or to public health and safety, and to consider whether action should be taken in relation to any matters identified. If child death review partners find action should be taken by a person or organisation, they must inform them.
- The review partners may request information from any person or organisation for the purpose of the review and may take legal action to seek enforcement. A senior paediatrician should be appointed to any multi-agency panel as the designated doctor for child deaths, who should be notified of each child death and sent relevant information.[19]

(e) It appears from this not necessarily complete review of the legislation and guidance that the appointment of a senior paediatrician to be notified of all child deaths satisfies this recommendation.

3.4 Recommendation 4: *No candidate for nursing in whom there is evidence of major personality disorder should be employed in the profession*

I refer to the consideration of recommendation 1 above. The requirements for an occupational health assessment could be designed to detect personality disorders, but there does not appear to be any prohibition on the employment of a person with a disorder. Indeed a blanket prohibition might contravene the protections for disabled persons in the Equality Act.

3.5 Recommendation 5: *Nurses should undergo formal health screening when they obtain their first posts after qualifying*

I refer to the consideration of recommendation 1 above. A health assessment is required before appointment but after the conditional offer of employment. This would appear to address this recommendation.

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[17] 2018 guidance chapter 5 §2

[18] Ibid page 95. I have not reviewed the underlying legislation in detail at this stage

[19] 2018 guidance §10, 2023 guidance §385-386: *The designated doctor for child deaths should be a senior paediatrician who can take a lead role in the review process. Child death review partners should ensure a process is in place whereby the designated doctor for child deaths is notified of each child death and is sent relevant information.*

3.6 **Recommendation 6:** ***The possibility be reviewed of making available to Occupational Health Departments any records of absence through sickness from any institution which an applicant for a nursing post has attended or been employed by***

I have considered the procedures for work health assessments above. They provide for the candidate to be asked, after a conditional offer of employment, about any relevant health related matters, but I can see no requirement or entitlement to call for the health or absence records held by a previous employer. Consideration may need to be given to whether and in what circumstances such disclosure would be permissible under the GDPR.

3.7 **Recommendation 7:** ***Procedures for management referrals to Occupational Health should make clear the criteria which should trigger such referrals***

NHS Employers offers guidance on the commissioning of Occupational Health services in the NHS, and the principles that should be adopted.[20] These include a requirement to adopt the industry standard advocated by SEQOHS [Safe Effective Quality Occupational Health Service].[21] NHS Health at Work[22] is a network of OH teams working in the NHS. While it may not contain a specific list of "triggers" for referrals, NHS Employers online Sickness Absence Toolkit[23] contains very detailed guidance to managers about how to manage employee's health issues, including seeking occupational health support. NHS employers are likely to have an occupational health policy; see for example the policy of NHS Avon Partnership.[24]

[2020] NHS Employers *Commissioning occupational health services*, September 2023 https://www.nhsemployers.org/system/files/2023-10/commissioning-occupational-health-services-%282153%29.pdf [downloaded 14 February 2024]

[21] https://www.seqohs.org/Default.aspx

[22] https://www.nhshealthatwork.co.uk

[23] https://www.nhsemployers.org/toolkits/sickness-absence-toolkit 19 January 2024

[24] NHS Avon Partnership *Guidance Notes for Managers when making a referral* *https://www.apohs.nhs.uk/wp-content/uploads/2018/11/Guidance-to-Managers-making-a-Referral-via-paper-Nov-18.pdf* downloaded 14 February 2024

3.8 **Recommendation 8*: Further consideration be given to not accepting those for training that have shown signs of psychological disorder until they have shown the ability to live an independent life without professional support and been in stable employment for at least to 2 years***

(a) The NMC guidance referred to in the Schedule requires trainees to tell their education institution of any health conditions on application which might affect their ability to practise safely and effectively. The institution also has to provide a declaration in relation to health at the time a trainee applies to the NMC for registration. The NMC's guidance on health[25] refers to the statutory requirement that to be registered the applicant must meet the NMC's health and character requirements.[26] The Code of standards requires registrants and applicants to maintain a level of health needed to carry out their professional role.[27]

(b) While this regulatory structure contains no specific reference to psychological disorder it is clear that a registrant with a psychological disorder which in the opinion of the NMC resulted in an applicant or registrant being unable to fulfil their professional role could be refused registration, or, if registered, subjected to fitness to practice procedures. By way of comment the conditions proposed in this recommendation for acceptance for training would appear in themselves to prevent a person qualifying for training who presented a danger to patients.

3.9 **Recommendation 9: *Consideration should be given to how GPs might, with the candidate's consent, be asked to certify that there is nothing in the medical history of a candidate for employment in the NHS which would make the unsuitable for their chosen occupation***

I agree with the observations in the Schedule. I would comment that asking a general medical practitioner to express an opinion on a patient's suitability for work in the nursing profession could give rise to difficulties: operational issues would arise if, for example a candidate refused consent, or the GP refused to offer an opinion. GPs might understandably be reluctant to hold themselves accountable for an opinion about a profession in which they themselves had not been trained.

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[25] NMC *guidance on health and character* 23 January 2019 https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/guidance-on-health-and-character/

[26] Nursing and Midwifery Order 2001 2002 SI 253 as amended Article 5(2), 9(2)(b) The consolidated text of the order up to 8 March 2023 is at https://www.nmc.org.uk/globalassets/sitedocuments/legislation/the-nursing-and-midwifery-order-2001-consolidated-text.pdf?_t_id=rYSMkpZPgM-vDKRimNjqiQ%3d%3d&_t_uuid=nPqPcoWwTtGTLTzm55uZ5Q&_t_q=nursing+and+midwifery+order&_t_tags=language%3aen%2csiteid%3ad6891695-0234-463b-bf74-1bfb02644b38%2candquerymatch&_t_hit.id=NMC_Web_Models_Media_DocumentFile/_87f72bf7-4c77-4e74-8160-ee3bcfab8c2e&_t_hit.pos=3

[27] Guidance [see above] §19.5, NMC *The Code – professional standards of practice and behaviour for nurses, midwives and nursing associates,* §20.9 https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf

3.10 Recommendation 10: *The Department of Health should take steps to ensure that its guide "Welfare of Children and Young People in Hospital"[28] is more closely observed*

I have been unable to access a copy of the guide referred to. In the Hansard passage referred to in the Schedule the Secretary of State, Mrs Bottomley, as she then was, observed that the guide stated that hospitals should determine for themselves the number of staff required to look after the children in their care. She conceded there was a need for "*further improvement*". She said that 50% of hospitals met the recommendations and among the rest 40% had plans to increase numbers. In a literal sense it could be said that the very fact of this Government response was an implementation of the recommendation. Whether it is possible or practicable to define a patient-nursing staff ratio required for safety is a matter of controversy. At the time of my own inquiry into Mid Staffordshire NHS Foundation Trust I did not find a sufficient consensus to make a recommendation about this. However there are various publications to which the Inquiry may wish to refer:

3.10.1 Neonatal services

(a) *RCN Guidance on safe nurse staffing levels in the UK* (2010)[29]: This gave the minimum registered nurse to child ratio for patients under 2 years of age of 1:3. This paper referred to *DH guidance* (2003)[30] and BAPM 2001[31] and for neonatal services recommended a ratio of 1:4 in special care settings, 1:2 in high dependency units and 1: 1 in intensive care.

(b) *DH* best practice guidance on neonatal staffing (2009)[32] recommended one nurse coordinator on every shift in addition to those providing direct clinical care, and a minimum of two registered staff on duty at all times one of which hold qualifications in the speciality. It also recommended the same minimum staff rations for infant patients as did the RCN.

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[28] *Welfare of Children and Young People in Hospital* July 1991 SO

[29] RCN December 2010 https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/obselete/pub-003860.pdf?la=en [downloaded 14 February 2024]

[30] Department of Health (2003) *Report of the neonatal intensive care services review group*, London: DH.

[31] British Association of Perinatal Medicine (2001) *Standards for hospitals providing neonatal intensive and high dependency care (2nd edition) and categories of babies requiring neonatal care*, London: PABM. [not directly accessed by me]

[32] Department of Health (2009) *Toolkit for high-quality neonatal services*, London: DH.

3.10.2 Children's intensive care and high dependency services

(a) The RCN (2010) referred to the Paediatric Intensive Care Society's' recommendations for:

Level 1 (high dependency)	0.5:1 (1:1 in cubicles)
Level 2	1.5:1
Level 3	1.5:1
Level 4	2:1

(b) The RCN guidance listed a summary of staff planning tools.[33] It is fair to say that the RCN and others have been pursuing a campaign in relation to safe staffing requirements ever since.[34]

(c) The NHS has generally resisted attempts to prescribe numbers. NICE were commissioned to identify standards for safe staffing in hospital wards as announced by the Government, and published guidance in 2014.[35] This guidance emphasised the lack of research and evidence to support the various methods available for assessing staff needs.

(d) Later work by NICE was stopped at the request of NHS England, a step which attracted criticism from a number of quarters including myself.[36] In July 2016 the National Quality Board issued guidance on safe staffing generally.[37] Instead of numbers of staff this promoted a concept of care hours required per patient day [CHPPD] and the use of professional judgement, following a report by Lord Carter.[38]. The latest guidance on CHPPD was published on 15 November 2023.[39]

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[33] RCN guidance page 44

[34] For a summary of literature on this issue see RCN *Impact of staffing levels on safe and effective patient care – literature review* RCN 2023 https://www.rcn.org.uk/Professional-Development/publications/impact-of-staffing-levels-on-safe-and-effective-patient-care-uk-pub-010-665 [downloaded 14 February 2024]

[35] NICE, *safe staffing for nursing in adult inpatient wards in acute hospitals* 15 July 2014 https://www.nice.org.uk/guidance/sg1/resources/safe-staffing-for-nursing-in-adult-inpatient-wards-in-acute-hospitals-pdf-61918998469

[36] Campbell *NHS patient safety fears as health watchdog scraps staffing guidelines* 4 June 2015 The Guardian https://www.theguardian.com/society/2015/jun/04/nhs-patient-safety-fears-nice-scrap-staffing-level-guidelines-mid-staffs-scandal [downloaded 25 February 2024]

[37] National Quality Board *Supporting NHS providers to deliver the right staff, with the right skills, in the right place at the right time* July 2016 https://www.england.nhs.uk/wp-content/uploads/2013/04/nqb-guidance.pdf [downloaded 14 February 2024]

[38] Lord Carter of Coles February *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations February* 2016 https://assets.publishing.service.gov.uk/media/5a80bdfae5274a2e87dbb8f5/Operational_productivity_A.pdf [downloaded 25 February 2024]

[39] NHS England *Care Hours Per Patient Day (CHPPD): guidance for all inpatient trusts* 15 November 2023 https://www.england.nhs.uk/long-read/care-hours-per-patient-day-chppd-guidance-for-all-inpatient-trusts/ [downloaded 25 February 2024]

(e) In conclusion the discussion with regard to adequate staffing has been continuous since before the Clothier report and has reached no overall consensus. While the Inquiry may wish, if this is relevant to issues it has to determine, to seek expert paediatric medical and nursing advice, it is arguable that there has been a near consensus with regard to the required numbers in paediatric settings. The guidance referred to in the Clothier report, however, could be regarded as having been superseded.

3.11 Recommendation 11: *In the event of failure of an alarm on monitoring equipment, an untoward incident report should be completed and the equipment serviced before it is used again*

(a) The expert advisory group referred to by the Secretary of State in her response to this recommendation published a report in 1995.[40] I have been unable to access this report, but according to the government response, its recommendations went further that the Allitt report. I observe that in 2014 the MRHA issued a Patient Safety Alert.[41] This helpfully summarises the reporting requirements for equipment failure the terms of which would appear to include monitoring alarms:

> *There are currently two national reporting systems for incidents involving medical devices. One is operated by the Medicines and Healthcare Products Regulatory Agency (MHRA)2 and the other, the National Reporting and Learning System (NRLS)3, is operated by NHS England4.*
>
> *The NRLS defines a 'patient safety incident' as any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS care5. NRLS reports include many types of incidents such as falls, diagnosis, surgery, medication and medical devices.*
>
> *All serious incidents that have resulted in death or severe harm to a patient should be reported to the NRLS within two working days of the incident being identified in accordance with the NHS Serious Incident Framework6. Other incidents reporting moderate, low or no harm should be reported to the NRLS in accordance with local procedures. Ideally, this should be each week.*
>
> *The MHRA defines a reportable 'adverse incident' as 'any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.'*

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[40] Medical Devices Agency Expert Working Group *The report of the Expert Working Group on Alarms on Clinical Monitors in response to recommendation 11 of the Clothier report: the Allitt inquiry.* (1995) [not accessed]

[41] MRHA *Patient Safety Alert: Stage 3: Directive: improving Medical Device incident Reporting and Learning* 20 March 2014 https://www.england.nhs.uk/wp-content/uploads/2014/04/psa-med-dev-0414.pdf

Any event that meets these three basic reporting criteria should be reported to MHRA:

A. an event has occurred;

B. a medical device is suspected, or cannot be ruled out, as a contributory cause of the adverse incident; and,

C. the event led, or might have led, to one of the following outcomes, death of a patient, user or other person,

serious deterioration in state of health of a patient, user or other person.

(b) The alert announced that a new integrated system of reporting was to be introduced.

(c) Literature suggests that any reporting requirement for failure of medical devices is inconsistently observed.[42]

(d) While these developments do not expressly reference the Clothier recommendation it appears that there has since then been a requirement to report alarm failure as an incident, to either the MHRA or the NRLS.

3.12 Recommendation 12: *Reports of serious untoward incidents to District and Regional Health Authorities should be made in writing and through a single channel which is known to all involved*

The incident reporting mechanism is or should be well known to all who work in hospitals. It has probably changed at least once since 1994.

3.13* Recommendation 13: *Beverley Allitt's actions should serve to heighten awareness in all those caring for children of the possibility of malevolent intervention as a cause of unexplained clinical events

(a) This was described by Sir Cecil Clothier as the "principal recommendation" of his report, noting, however, that:[43]

a determined and secret criminal may defeat the best regulated organisation in the pursuit of his or her purpose

(b) I am unaware of any specific action taken with regard to this recommendation, and the Inquiry may wish to seek evidence about the extent to which, if at all, the history of this awful case remained in the corporate memory of the NHS.

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[42] Tase et al *Medical Device Error and failure Reporting: Learning from the car industry* June 2021 Journal of Patient Safety and Risk Management Vol 26, issue 3 pp 135-144 https://journals.sagepub.com/doi/epub/10.1177/25160435211008273

[43] See statement of Mrs Virginal Bottomley MP, Hansard 11 February 1004 col 586

4. Ashworth Inquiry

While this report made a number of recommendations relevant to patient safety, culture and governance, these all appear to be specific to the setting of a high security mental hospital. In my experience it would not be expected that such recommendations would be taken into consideration by the generality of NHS services unless specifically directed to. Therefore I shall refrain from commenting on the recommendations in this report. If there is any particular recommendation which the Inquiry wishes to be looked at I would naturally do that.

5. Royal Liverpool Children's Inquiry

5.1 Recommendations 1-10

These recommendations all relate to the desirability of a procedure for recording, investigating and addressing serious incidents. The Redfern report limits itself to describing the serious incident arrangements at Alder Hey Hospital rather than considering the national policy. The NHS has in fact for some time had a national framework for addressing serious incidents. The National Reporting and Learning System [NRLS] was set up in 2003 enabling incidents to be reported to a national data base from local risk management systems.[44] The first version of the Serious Incident Framework was published in 2010.[45] From that point the licensing requirements of the Care Quality Commission made it mandatory for all what were then called serious untoward incidents to be reported to the NRLS. There was an update of the framework in 2013. The 2015 version of the framework[46] is to be replaced by a Patient Safety incident Response Framework.[47] Both these documents set out how NHS providers are to prepare their plans and systems to address incidents. Therefore, to some extent these recommendations were superseded.

5.2 Recommendation 15: ***Whatever the underlying contractual position, the relationship between Universities and Trusts, in respect of individuals and departments with dual clinical and academic functions, shall be one of the utmost good faith in both directions***

5.3 Recommendation16: ***The duty of utmost good faith shall require either party to disclose to the other any substantial matter relating to the performance of the individual or department, whether clinical or academic***

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[44] In the time available it is challenging to acquire the policy documentation for this period, but an example of a regional protocol under the then arrangements is NHS North West *Serious Untoward Incident Reporting Protocol* November 2007 https://www.tameside.gov.uk/adultservices/incidentprotocol.pdf

[45] *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation* March 2010

[46] NHS England *Serious Incident Framework* 27 March 2015 https://www.england.nhs.uk/wp-content/uploads/2020/08/serious-incidnt-framwrk.pdf [downloaded 16 February 2024

[47] NHS England *Patient Safety Incident Response Framework* August 2022 https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-1.-PSIRF-v1-FINAL.pdf [downloaded 16 February 2024]

I am not aware of any specific action on these recommendations but the policies with regard to obtaining information and references before appointments are made, referred to above, set out expectations for applicants for combined positions.

5.4 **Recommendation 17:** ***Where there is any doubt as to whether a matter is of a substantial nature, if it relates to patient care the doubt shall always be resolved in favour of disclosure***

This is a very general statement arising out of very particular circumstances. It would now have to be considered in the light of the data protection legislation.

5.5 **Recommendations 18-21**

These recommendations appear to relate to the specific circumstance of joint academic and clinical appointments and not to more general recruitment.

5.6 **Recommendation 22:** ***There shall be formal annual appraisal of an individual by both parties. They shall share their information in line with the duty of utmost good faith in order to draw up a joint statement of aims in the following 12 months against which the next appraisal is to be judged***

There have been many recommendations by inquiries with regard to the need for proper appraisals. In the medical profession a safeguard has been introduced of revalidation overseen by the General Medical Council which provides a regular check on a doctor's performance and competence. More recently, in April 2016, revalidation has been introduced for nurses.[48] I deal with this in more detail in answer to question 11c with regard to senior managers.

5.7 **Recommendation 23:** ***Where there is disagreement each party shall reconsider bearing in mind that patient care is of paramount importance. In the event of continued disagreement an arbitrator may be appointed, but in any case the Trust shall take immediate steps to secure proper patient care***

I am not aware that this recommendation has been implemented.

[48] For details see https://www.nmc.org.uk/revalidation/overview/what-is-revalidation/ ; for a report on the first year of the process see NMC *Revalidation – Annual Data Report* https://www.nmc.org.uk/globalassets/sitedocuments/annual_reports_and_accounts/revalidationreports/revalidation-annual-data-report-2017.pdf [downloaded 16 February 2024]

5.8 Recommendations 28 – 30: ***Where there is good reason to believe that an individual or department may be failing and affecting patient care, it shall be the duty of the Trust with the co-operation of the university, and if appropriate on a joint basis, to investigate. Investigation shall continue until the problems are identified or it is found that in reality no problem exists. Where appropriate, independent outside assistance shall be obtained***

There are recognised methods of looking into or investigating concerns. A provider may request peer review by a relevant medical Royal College. Concerns can also be reported to the CQC who may decide to inspect. NHS England will intervene under its licensing powers it thought necessary. There are the mechanisms in place for incident investigation reporting and investigating mentioned above. Naturally none of these can be triggered without awareness that there is a matter of concern requiring investigation.

5.9 Recommendation 31: ***No clinician shall be appointed to a position of managerial authority in a hospital without having relevant clinical experience for the position***

Anyone appointed to a senior managerial position is likely to have to be accepted to be a fit and proper person in accordance with the requirements of the CQC regulations which were introduced in about 2014. This would include the need to have any relevant clinical experience. The regulation has been the subject of criticism in relation to its effectiveness [see below for more detail given in relation to the Mid Staffordshire Inquiries] and does not necessarily apply to clinical directors.

5.10 Recommendation 32: ***No clinician should take effective control of a management position until trained in all necessary management techniques and in any relevant legal requirements***

There are many recommendations concerning management training and many ways in which managers can seek and obtain training. I am not aware of any specific requirement to undertake specific training, apart from that implied by the fit and proper person test and the requirement to provide care and treatment in a safe way.[49]

5.11 Recommendation 33: ***No clinician shall be asked to take on responsibilities that impair the ability to carry out patient care to the appropriate standard***

I am unaware of any specific requirement in this regard, apart from generic advice concerning staff well-being, the priority to be given to patient safety and the professional obligation not to offer treatment beyond the competence of the individual to provide it.

[49] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Reg 12(1)

5.12 Recommendation 34: *Hospital managers shall be of a suitable background and calibre for the role expected of them, provided with all necessary training (including continued education) and themselves regularly appraised for the quality of their performance*

Similar recommendations were also made by the Mid Staffordshire inquiries. As to training see my comments above.

5.13 Recommendations 35-36: *For managers to seek medical advice on matters requiring it*

I am unaware of any specific implementation of this recommendations, although it might be regarded as a matter of common sense.

5.14 Recommendation 37: *Training on the requirements of the Coroners Act*

I am unaware whether there is any mandatory requirement for such training. There is certainly guidance – see the relevant part of the Mid Staffordshire Public Inquiry below.

6. Bristol Royal Infirmary Inquiry

6.1 Consent

6.1.1 *Recommendations 1, 24, 25-27*

R 1 *In a patient-centred healthcare service, patients must be involved, wherever possible, in decisions about their treatment and care*

R 24 recommends adoption of the DH reference guide to consent

R 25-27 refer to various aspects of the consent process.

(a) The consent guidance referred to was updated in 2009 to take account of legal developments including the Human Rights Act.[50] The requirement to obtain consent is now imposed on providers by the CQC conditions.[51] The CQC's own guidance[52] makes it clear that:

> *Consent must be treated as a process that continues throughout the duration of care and treatment, recognising that it may be withheld and/or withdrawn at any time.*

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[50] DoH *Reference guide to consent for examination or treatment* 2nd edition July 2009 https://assets.publishing.service.gov.uk/media/5a7abdcee5274a34770e6cdb/dh_103653__1_.pdf [downloaded 16 February 2024]

[51] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 11

[52] https://www.cqc.org.uk/guidance-providers/regulations/regulation-11-need-consent

(b) Likewise the General Medical Council guidance on consent[53] states that:

> *Shared decision making and consent are fundamental to good medical practice…*
>
> *Consent is a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. The exchange of information between doctor and patient is essential to good decision making. Serious harm can result if patients are not listened to, or if they are not given the information they need - and time and support to understand it - so they can make informed decisions about their care.*

(c) Patient involvement in their own care has, however, come to be recognised in government and health service policy and legislation as something broader than the legal requirements of consent. While much of this has been discussed in the context of involvement in the formulation of service delivery generally, it also has application in the patient's involvement in their own particular treatment and care. The extent to which this has been fully integrated into every day practice is open to question.[54]

(d) In England the Health Act 2006[55] places a duty on NHS England to promote patient involvement:

> *NHS England] must, in the exercise of its functions, promote the involvement of patients, and their carers and representatives (if any), in decisions which relate to—*
>
> *(a) the prevention or diagnosis of illness in the patients, or*
>
> *(b) their care or treatment.]*

(e) Involvement in this wider sense is also broadly reflected in the NHS Constitution.[56] One of the basic principles, Principle 4, is that:

> *The patient will be at the heart of everything the NHS does*

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[53] GMC *Professional standards*: *Decision making and consent* 9 November 2020 https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf

[54] For a useful summary of pronouncements in this area see Thompson *The managing of patient involvement and participation in health care consultations: A taxonomy* March 2007 Social Science and Medicine Vol 64 Issue 6 pp 1297-1310 [abstract] https://www.sciencedirect.com/science/article/abs/pii/S0277953606005776?via%3Dihub [downloaded 16 February 2024]

[55] Section 13H as added to the Act in 2012 under the Health and Social Care Act 2012 and amended under the Health and Care Act 2022 https://www.legislation.gov.uk/ukpga/2006/41/section/13H [downloaded 16 February 2024]

[56] The NHS Constitution for England updated 17 August 2023 (a summary of the updates since first publication in March 2012 can be seen on the website) https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england#principles-that-guide-the-nhs [downloaded 16 February 2024]

> *It should support individuals to promote and manage their own health. NHS services must reflect, and should be coordinated around and tailored to, the needs and preferences of patients, their families and their carers. …. Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment. The NHS will actively encourage feedback from the public, patients and staff, welcome it and use it to improve its services…*
>
> *You have the right to receive care and treatment that is appropriate to you, meets your needs and reflects your preferences.*

(f) Further detail is given in the Handbook[57] to the Constitution observing that:

> *It accentuates that, rather than being passive recipients of healthcare, patients also play a key role in managing their own health and should be actively supported by the NHS to do so. It recognises the need for patients, along with their families and carers, to be involved in discussions about their care, where it is appropriate to do so.*

(g) In Scotland there is a statutory recognition[58] of patient's rights and an obligation to publish a charter of such rights. These include the right to involvement in their own treatment:

> *3 Patient rights*
>
> *(1) It is the right of every patient that the health care received by the patient be as described in subsection (2).*
>
> *(2) Health care is to—*
>
> *(a) be patient focused: that is to say, anything done in relation to the patient must take into account the patient's needs,*
>
> *(b) have regard to the importance of providing the optimum benefit to the patient's health and wellbeing,*
>
> *(c) allow and encourage the patient to participate as fully as possible in decisions relating to the patient's health and wellbeing **[F1**(including, where the health care being provided includes a service provided under the 2021 Act, decisions mentioned in subsection (3A))**]**,*

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[57] DHSC *Handbook to the NHS Constitution for England* updated 1 October 2023 https://www.gov.uk/government/publications/supplements-to-the-nhs-constitution-for-england/the-handbook-to-the-nhs-constitution-for-england

[58] Patient Rights (Scotland) Act 2011 as amended sections 1, 3 https://www.legislation.gov.uk/asp/2011/5 ; NHS Scotland *The Charter of Patients Rights and Responsibilities* June 2022 Scottish Government https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2022/10/charter-patient-rights-responsibilities-revised-june-2022/documents/charter-patient-rights-responsibilities-revised-june-2022/charter-patient-rights-responsibilities-revised-june-2022/govscot%3Adocument/charter-patient-rights-responsibilities-revised-june-2022.pdf [downloaded 16 February 2024]

(d) have regard to the importance of providing such information and support as is necessary to enable the patient to participate in accordance with paragraph (c) and in relation to any related processes, taking all reasonable steps to ensure that the patient is supplied with information and support in a form that is appropriate to the patient's needs.

(3) It is the right of every patient to give feedback or comments, or raise concerns or complaints about health care received.

(h) The current edition of the Charter includes the following statements:

I have the right to safe, effective, person-centred and sustainable care and treatment.

My needs, preferences, culture, beliefs, values and level of understanding will be taken into account and respected when using NHS services. I have the right to ask those providing my care whether the care they suggest is right for me, and if they can suggest any alternatives

I have the right to be involved in decisions about my care and treatment.

(i) The Charter also gives considerable detail of what "involvement" means.

(j) Therefore, in England and Scotland it would appear that the Bristol recommendation has now been fully addressed in legal and policy terms: the extent to which it is integrated into everyday practice might be a matter for investigation.

6.1.2 *Recommendations 2-3 recommend training to "imbue" healthcare professionals with the idea of partnership with patients*

Given the requirements described above it would be surprising if most if not all professional training includes elements of this, but the extent of that would need to be established with the training authorities.

6.1.3 *Recommendation 4: recommends that information about treatment should be given in a variety of forms and over time*

The guidance on consent referred to above broadly recommends this and my sense is that this principle is recognised in practice, although hard pressed professionals may not always have the time they would like to undertake this as thoroughly as they would like.

6.1.4 *Recommendations 5, 6 Information should be tailored to the needs, circumstances and wishes of the individual*

Again the guidance referred to above reflects this, and the legal requirement in this regard has been reinforced by the case of *Montgomery v Lanarkshire Health Board.*[59]

6.1.5 *Recommendations 7, 8, 9 recommend improvement use of various forms and technologies*

The implementation of this is a matter for evidence.

6.1.6 *Recommendation 10 recommends the use if recordings for patient to take away a record of advice and discussions*

As noted this recommendation was rejected and I am not aware that any such facility is offered anywhere.

6.1.7 *Recommendation 11 recommended patients are always given the chance to ask questions*

This is encouraged by the guidance referred to, but the well-known shortages of staff and increased demands on their time must make this very difficult in practice.

6.1.8 *Recommendation 12 recommends information to enable patient participation*

I refer to my observations about patient involvement.

6.1.9 *Recommendation 13 explanations*

I refer to my observations above about consent processes.

6.1.10 *Recommendation15 Right to be accompanied*

If the Government has ensured information as described in the Schedule has been distributed I would regard this recommendation as having been implemented.

6.1.11 *Recommendations 17, 18 recommend patients/carers should be given copies of letters*

I believe that this is common practice, but I am not sure it is universal.

[59] [2015] UKSC 11 https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf

6.1.12 *Recommendation 18: Healthcare professionals responsible for the care of any particular patient must communicate effectively with each other. The aim must be to avoid giving the patient conflicting advice and information*

Sharing information about patients and their care remains a considerable challenge in the NHS because of the lack of integrated data systems. For a recent consideration of this problem see the recent Times Health Commission report.[60]

6.2 Support for patients

6.2.1 *Recommendation 20 Recommends the provision of counselling and support as part of a patient's care*

All hospital providers in the NHS will or should have a PALS office. They are meant to offer information and help resolve concerns and problems and offer referrals to support groups. I rather doubt any directly offer counselling. Reviews suggest[61] there is room for improvement in the service offered.[62]

6.2.2 *Recommendation 21 Every trust should have a professional bereavement service*

I believe that most if not all NHS hospitals have a bereavement service. How well resourced or effective these are is a matter for evidence.

6.2.3 *Recommendation 22 encourages the use and funding of voluntary organisations to provide care and support*

NHS England has recently published a report of the NHS Volunteering Taskforce which has articulated a five-year vision for volunteering in the NHS; this provides a helpful summary of the place volunteering has had and continues to have in the NHS.[63]

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[60] Times Health Commission *A Report into the state of health and social care in Britain* today February 2024 chapter 6 https://s3.documentcloud.org/documents/24398476/times-health-commission_report_2024.pdf

[61] Evans, Powell, Cross *Patient Advice and Liaison Services – results of an audit survey in England* 2008 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5060446/pdf/HEX-11-304.pdf [downloaded 16 February 2024]

[62] Shepard K, Buivydaite R, Vincent C. *How do National Health Service (NHS) organisations respond?*

to patient concerns? A qualitative interview study of the Patient Advice and Liaison Service (PALS). November 2021 BMJ Open 2021;11:e053239. doi:10.1136/ bmjopen-2021-053239

https://bmjopen.bmj.com/content/bmjopen/11/11/e053239.full.pdf

[63] NHS England *NHS Volunteering Report and Recommendations* June 2023 https://www.england.nhs.uk/wp-content/uploads/2023/06/PRN1596-volunteering-taskforce-report.pdf [downloaded 16 February 2024]

6.2.4 *Recommendation 28 recommends patients should be able to pass on views on the service received and feedback should be routinely sought in a systematic way*

There have been a number of initiatives for collecting feedback from patients, including the Friends and Family survey, which, in addition to the satisfaction survey, allows for text comments to be made by respondents. Most Trusts will have a feedback offer to patients, but Healthwatch England has expressed concerns at the lack of use of this data.

6.2.5 *Recommendation 29 recommends that patients must know where to find information*

I suggest that whatever concerns there may be as to PALS handling of complaints this service does uniformly provide a means for patients to obtain information they may require in hospital. In some premises it may be difficult to find the PALS office or other contact point.

6.2.6 *Recommendation 30 recommends establishment of PALS*

This has occurred: therefore this recommendation should be regarded as implemented. As noted above, dissatisfaction has been expressed in the effectiveness of many PALS offices.

6.2.7 *Recommendation 31 recommends publication of regular reports of patients views*

(a) All provider trusts are required to publish Quality Accounts annually. These accounts are:

> *a report published annually about the quality of services offered by an NHS healthcare provider, including trusts.*[64]

(b) I will comment further on Quality Accounts in the section on the Mid Staffordshire Public Inquiry.

6.2.8 *Recommendation 32 recommends the provision of patient advocacy services*

Advocacy services for patient who wish support in pursuing a complaint are available in theory, but the Mid Staffordshire inquiries found that the standard of provision was patchy and outsourced to charities and social enterprises which were not always well equipped. There was also a concern that services were reluctant to offer patient advice about their complaints.

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[64] See NHS *England Working in partnership with people and communities: Statutory guidance* 10 October 2022, updated 23 May 2023

6.3 Duty of Candour

6.3.1 *Recommendations 33, 34 recommend a duty of candour owed to patients who have been the subject of an adverse event*

While the Government accepted this recommendation as noted in the Schedule, no statutory provision was put in place until after the recommendation was repeated by the Mid Staffordshire Public Inquiry.[65] The recommendation could now be recognised as having been implemented. The statutory regulation imposed a duty on the provider, not the healthcare professionals who treat the patient. However the latter are bound by a professional duty laid down in the codes of conduct of the GMC and the NMC in particular. That duty existed before the Bristol inquiry, but in practice was not always easy to perform without the support of the provider/employer.

6.4 Complaints

6.4.1 *Recommendations 34, 35 concerned improving the complaints system*

While, as noted above, the introduction of PALS has produced a route by which patients can make a complaint while in hospital, it would be wrong to describe it as a "one stop" shop. There is a multiplicity of routes by which complaints can be made, including each of the professional regulators, the CQC, and NHS England. Considerable dissatisfaction continues to be expressed in the NHS complaints system.[66]

6.5 No fault compensation

6.5.1 *Recommendation 37 recommended a "no fault" compensation system for iatrogenic harm*

(a) As noted this recommendation was accepted and the Redress Act was enacted, but not brought into effect. This did not in any event remove the need to prove negligence. Recently the Government has in principle agreed to introduce a compensation scheme, not based on legal liability, for the directly and indirectly affected victims of the infected blood scandal and Baroness Cumberledge and the Patient Safety Commissioner have proposed[67] a no fault scheme for the victims of pelvic mesh and sodium valproate. There is no extant proposal for an overall no fault compensation scheme for iatrogenic injury. There has been recent Parliamentary criticism of the challenges facing victims in accessing effective dispute resolution and redress in cases of injustice generally.[68]

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[65] Health and Social Care Act (Regulated Activities) Regulations 2014

[66] See the latest report of the PHSO REF

[67] Cumberledge *First Do No Harm The report of the Independent Medicines and Medical Devices*

Safety Review 8 July 2020 recommendation 3; Patient Safety Commissioner *The Hughes Report* 7 February 2024

[68] Debate on Access to Redress Schemes, 18 April 2024, Hansard Vol 784 col 424 et seq https://hansard.parliament.uk/Commons/2024-04-18/debates/498F425F-217C-4219-8724-E8844E454CCB/AccessToRedressSchemes

Therefore I consider it incorrect to state that this recommendation has been implemented.

6.6 Regulation of quality of service and professional competence

6.6.1 *Recommendations 38, 39, 40 recommended the establishment of an independent framework of regulation of the quality of NHS care and the competence of professionals*

(a) Since 2001 a variety of bodies have been set up to regulate the quality and safety of care in the NHS, including the Commission for Health Improvement and the Healthcare Commission, which was succeeded by the Care Quality Commission (CQC). The CQC provides systemic regulation for all providers of healthcare, whether or not within the NHS, and social care. There has also been a National Patient Safety Agency, subsequently merged into NHS England, a Health Service Investigatory Branch [now a statutory body], and the National institute for Health and Care Excellence (NICE). Various major organisational reforms have been undertaken since 2001, including the introduction of the concept of Foundation Trusts [and their regulation by Monitor], the creation of NHS England, primary care trusts, clinical commission groups and other reforms in 2012 intended to distance the provision of healthcare from the Department of Health. Whether any of that has succeeded or clarified the role of the Department of Health and Social Care is a matter of judgement.[69]

(b) The professional regulation of competence has remained separate under different regulators for each registrable healthcare profession. However, as recommended by Professor Kennedy, an overarching super-regulator of professional regulators was created, now called the Professional Standards Authority. To my knowledge the Government has never accepted that the regulation of providers and professionals should be further joined together into one body. The Government has not accepted any recommendation for the regulation of managers, although this has now been recommended at least three times in the Bristol Royal Infirmary Inquiry, the Mid-Staffordshire NHS Foundation Trust Inquiry, and the Kark Review.

6.6.2 *Recommendation 41 recommended that all bodies regulating quality and the professions should be independent of the DH and report directly to Parliament*

I agree that this recommendation has been largely implemented.

6.6.3 *Regulation 42 All the various bodies and organisations concerned with regulation, besides being independent of government, must involve and reflect the interests of patients, the public and healthcare professionals, as well as the NHS and government*

[69] References can be suppled for these entities if required, but they all have websites.

I believe it is fair to say that all healthcare regulatory bodies would claim to prioritise the interests and the public and to reflect the interests of healthcare professionals. The extent of which this is actually the case in practice is a matter of debate.

6.7 Healthcare professionals terms of employment

6.7.1 Recommendation 43 The contractual relationship between trusts and consultants should be redefined. The trust must provide the consultant with the time, space and the necessary tools to do the job. Consultants must accept that the time spent in the hospital and what they do in that time must be explicitly set out

The website of NHS Employers conveniently gives access to all versions of the standard consultants' contract from 2003 to date.[70] The 2002 contract superseded terms and conditions first published in 1994.[71] These set out in detail the responsibilities of consultants, and paragraph 5 provides:

> *The employer will be responsible for ensuring that a consultant has the facilities, training development and support needed to deliver the commitments in the job plan and will make all reasonable endeavours to ensure that this support conforms with the standards set out in 'Improving Working Lives'.*

(a) This might be compared with the provisions of the previous contract paragraph 30 which might be thought to be less specific about the employer's responsibilities in this regard.

(b) The "Improving Working Lives", introduced in 2001,[72] has sought to offer more flexibility around working conditions for all NHS medical staff to recognise and accommodate their personal requirements and aspirations. Its introduction states:

> *The Improving Working Lives Standard summarises the commitment expected from NHS employers to create well- managed, flexible working environments that support staff, promote their welfare and development, and respect their need to manage a healthy and productive balance between work and life outside work. Achieving the Standard means making real and tangible improvements in the working lives of doctors, too.*

(c) All NHS employers were required to achieve the standard by 2003.[73]

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[70] *Terms and Conditions – Consultants (England) 2003* (Version 13, as amended to 31 January 2023_ https://www.nhsemployers.org/articles/consultant-contract-2003 [downloaded 19 February 2023]

[71] *Terms and Conditions of Service NHS Medical and Dental Staff (England) 2002.* https://www.nhsemployers.org/system/files/2021-06/Terms-and-Conditions-of-Service-2002-NHS-Medical-dental-staff.pdf [downloaded 19 February 2024]

[72] https://webarchive.nationalarchives.gov.uk/ukgwa/20040301091613/http://www.dh.gov.uk:80/assetRoot/04/07/42/91/04074291.pdf [downloaded 19 February 2024; For a survey exploring the effectiveness of the standard see Dornhorst et al, *Improving hospital doctors' working lives: online questionnaire survey of all grades*, Postgrad Med J 2005; 81; 49-54 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1743185/pdf/v081p00049.pdf [downloaded 19 February 2024]

[73] IWL page 5

(d) There has been regularly published guidance on consultant job planning since at least 2011.[74] The purpose of this is to clarify the work expected of consultant employees and the resources required to do it.

(e) Given the recent industrial dispute involving NHS consultants it may be questioned whether these measures have been entirely successful in practice.

6.7.2 *Recommendation 44 recommended a review of distinction awards to determine whether these could be an incentive for better standards of care for patients*

(a) Clinical excellence awards have been awarded at a local and national level. The national scheme has recently been replaced by the National Clinical Impact Scheme.[75] This awards achievement in five domains:

1. delivering and developing a high quality service;
2. leadership;
3. education, training and people development;
4. innovation and research;
5. additional national impact – here, tell us about high-quality work with nationally or internationally recognised impact that has a direct benefit to the NHS.

(b) Local clinical excellence award schemes are currently covered by Schedule 30 of the consultants standard terms and conditions [see above]. Such schemes are subject to local variation. These were one of the matters in dispute between the government and consultants, which has just been settled. The purpose of such awards was to:[76]

1.1 recognise and reward NHS consultants in England who perform over and above the standard expected of their role. Awards are given for quality and excellence, acknowledging exceptional personal contributions.

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[74] I have seen: *the National Health Service (Appointment of Consultants) Regulations – Good practice guidance,* January 2005, DH https://webarchive.nationalarchives.gov.uk/ukgwa/20130103004835/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4102750.pdf [downloaded 9 May 2024]. These regulations do not apply to Foundation Trust consultants' posts. *A guide to consultant job planning*, BMA/NHS Employers *https://www.nhsemployers.org/system/files/2021-11/Guide_to_consultant_job_planning%20July2011.pdf* [downloaded 9 May 2024]; *Consultant job planning: a best practice guide*, NHS Improvement *July 2017* [revised edition, https://www.england.nhs.uk/wp-content/uploads/2022/05/consultant-job-planning-best-practice-guidance.pdf [downloaded 9 May 2024]; 2023/2024 Checklist series – Consultant Job planning, MIAA [January 2024] https://www.england.nhs.uk/wp-content/uploads/2022/05/consultant-job-planning-best-practice-guidance.pdf [downloaded 9 May 2024]. See also NHS Employers *Guidance for the employment of medical and dental consultants*, 10 April 2024 https://www.nhsemployers.org/articles/guidance-employment-medical-and-dental-consultants [downloaded 9 May 2024] which brings much of this material together.

[75] DHSC *Applicant's Guide : 2023 awards round* https://www.gov.uk/government/publications/clinical-excellence-awards-application-guidance/guide-for-applicants-national-clinical-excellence-awards-2021-awards-round (updated 11 May 2023] downloaded 19 February 2024 For a summary see https://www.bma.org.uk/pay-and-contracts/pay/consultant-award-schemes/consultant-award-schemes-and-clinical-excellence-awards-cea [downloaded 19 February 2024

[76] BMA/NHS Employers *Local Clinical Excellence Awards Guidance 20189-21 (England)* July 2018 https://www.nhsemployers.org/system/files/2021-06/lcea-guidance-england.pdf

1.2 To be considered for an award, eligible doctors must demonstrate achievements in developing and delivering high-quality patient care and commitment to the continuous improvement of the NHS.

(c) In the agreement just reached between consultants and the NHS, local clinical excellence awards have been ended.[77] I have not in the time available been able to determine what if any research has been conducted into the impact of awards on the standard of patient care.

6.7.3 *Recommendation 46 recommended incorporation of nursing and medical codes of practice into contracts of employment*

I agree with the Department of Health's response as recorded in the Schedule. I believe that all doctors and nurses would have regarded their contracts as being on the basis they were not only properly registered with their professional regulator but that they should adhere to the relevant codes of practice,

6.7.4 *Recommendation 47 recommended that Trusts should be able to deal with breaches of professional codes of practice independently of action taken by the regulator*

(a) In 2006 the DH published guidance, *Maintaining High Professional Standards*, which set out processes expected to be followed all NHS employers. This required every employer to have a code of conduct setting out acceptable standards of conduct for all employees. Examples of misconduct were given, including:[78]

An infringement of the employer's disciplinary rules including conduct that contravenes the standard of professional behaviour required by doctors and dentists by their regulatory body.

(b) A footnote explicitly refers in this regard to the GMC's *Good Medical Practice* and the GDC's *Maintaining Standards*.

(c) I believe this meets this recommendation.

6.7.5 *Recommendation 48 recommends that the security of tenure of a chief executive and senior managers should be on a par with other senior professionals*

I consider this issue in more detail in part 2 of this report. At the time of the Bristol Inquiry the average tenure of an executive director was less than 2 years, and that remained the position at the time of my Inquiry. The position may have improved slightly today, but in my opinion the frequent response to adverse results or an adverse inspection report has

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[77] DHSC, *End of NHS consultant strike action as government offer accepted,* 5 April 2024 https://www.gov.uk/government/news/end-of-nhs-consultant-strike-action-as-government-offer-accepted [accessed 11 April 2024]

[78] DH *Maintaining High Professional Standards in the Modern NHS* 2006 *Part* III §4 https://www.elft.nhs.uk/sites/default/files/2022-01/mhps_policy.pdf

been the removal of the chief executive in circumstances where it is unlikely that officer is solely to blame, given the systemic context in which they have to work.

6.7.6 *Recommendation 49 recommended that appointments of executive directors should be on the ground of ability not seniority*

This may well have been the Government's intention as quoted in the Schedule, but it is a challenging aspiration given the paucity of candidates for some such positions. The Mid Staffordshire NHS Foundation Trust Inquiry found that the appointment of the chief executive at that hospital had been affected by this problem, and the short duration of, for example, chief executives, in their posts is likely to act as a disincentive to otherwise well qualified candidates applying.[79]

6.8 Leadership training

6.8.1 *Recommendations 50, 54 recommend that the NHS Leadership Centre develop training programmes for clinicians seeking managerial appointments and continued development*

NHS England now has an NHS Leadership Academy within its Workforce, Training and Education Directorate to offer such training.[80] I shall say more about leadership training later in this report.

6.8.2 *Recommendation 52 recommends that all new NHS non-executive directors should receive an induction programme*

NHS providers offers a one day induction course for new non-executives.[81]

6.8.3 *Recommendation 55 recommends that NHS chairs should have a source of independent advice*

NHS Providers organises a Chairs and Chief Executives network and regular associated events.[82]

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[79] For articles/papers on this topic see Anandaciva, Ward, Randhawa *Leadership in today's NHS* 18 July 2018 Kings Fund https://www.kingsfund.org.uk/insight-and-analysis/reports/leadership-todays-nhs [downloaded 19 February 2024]; Chambers, Exworthy *Long Serving NHS CEOS – what makes them tick and what keeps them going* February 2020 University of Manchester https://pure.manchester.ac.uk/ws/portalfiles/portal/177912487/Long_serving_NHS_chief_executives_report_final_Feb_2020.pdf [downloaded 19 February 2024]

[80] https://www.leadershipacademy.nhs.uk

[81] https://nhsproviders.org/boarddevelopment [site viewed 19 February 2024]

[82] https://nhsproviders.org/networks [site viewed 19 February 2024]

6.8.4 *Recommendation 56 recommends that NHS Board standing orders should ensure there is continuity in management between the departure of one Chair and the appointment of another*

NHS England has recently issued a revised code of Governance for NHS Boards, paragraph 2.5 of which requires the board to identify a vice chair who could be the senior independent director. Paragraph 4.11 requires them to ensure that the necessary skills exist across the directors and works with the governors to ensure there is appropriate succession planning.[83] A combination of these requirements suggests to me an expectation that the senior independent director will assume the role of interim chair unless some other arrangement is adopted. I deal with this in more detail in part 2 of this report.

6.8.5 *Recommendations 57, 58, 59, 60, 65, 66 recommend that greater priority should be given to training in communication, the principles of NHS organisation, teamwork, shared learning across professional boundaries and leadership, and competence in the non-clinical aspects of care should be assessed in the process of obtaining a professional qualification*

(a) I refer to the training described above. I expect that all these elements are intended to be addressed, but it may be a matter for evidence and judgement the extent to which this is effective or sufficient.

(b) This also implies a reference to the need for healthcare staff to be compassionate and empathetic in all their dealings with patients, carers and colleagues. I am confident that these matters are frequently addressed in such training, but less confident that this training invariably has the desired effect when staff face the everyday pressures of real life in today's NHS. I deal with these issues in more detail in Part 2 of this report.

6.8.6 *Recommendations 61, 62, 63, 64, 67, 69 jointly advocate training to be offered in multi-professional settings*

(a) In 2017 Health Education England published `*Multi-professional framework for advanced clinical practice in England.*[84] This set out the framework for healthcare workers of different backgrounds [other than doctors] to obtain new skills necessary for advanced clinical practice. Much of this concerns the need to work across professional boundaries and the training required to enable this. Health Education England's strategic plan[85] for 2022-23 had as its fifth objective:

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[83] NHS England *Code of Governance for NHS Provider Trusts* published 27 October 2022, updated 23 February 2023 https://www.england.nhs.uk/long-read/code-of-governance-for-nhs-provider-trusts/ [downloaded 19 February 2024]

[84] https://www.hee.nhs.uk/sites/default/files/documents/Multi-professional%20framework%20for%20advanced%20clinical%20practice%20in%20England.pdf [downloaded 19 February 2024]. See also https://www.nhsemployers.org/articles/advanced-practice

[85] https://www.hee.nhs.uk/about-2/work-us/hee-business-plan-202223/our-goals-objectives/future-workforce-goal

Deliver education and training reform to address health inequalities and facilitate multi-professional team working.

(b) Part of the plan was to "*overcome professional silos*" and therefore could be regarded as in part addressing these recommendations. However I am unaware of any significant initiative for training doctors together with other healthcare disciplines with whom they will have to work in practice, although there has been academic support for the development of such training.[86]

(c) I agree with Professor Kennedy on the need for multi-disciplinary training, and believe this to be a vital key to improving behaviours among clinicians and managers in the NHS.

6.8.7 *Recommendation 70 recommends one body responsible for each group of healthcare professionals*

As noted this recommendation was not accepted, and responsibilities for training remain shared between professional regulatory bodies and what is now Health Education England, which, having been an executive non-departmental public body, has since 1 April 2023 been merged into NHS England.[87]

6.9 Professional regulation

6.9.1 *Recommendations 70, 71,72, 73 recommend the setting up of a Council for the Regulation of Healthcare Professionals*

A body of this name was set up following the Kennedy report in response to these recommendations, which can therefore be said to have been implemented. Under the Health and Social Care Act 2012, this body was renamed the Professional Standards Authority.[88] It was not given the powers recommended in Recommendation 74.

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[86] See Chandrashekar and Mohan *Preparing for the National Health Service – the importance of teamwork training in the United Kingdom School medical school curriculum* Advances in Medical Education and Practice 2019:10:679-688 https://www.tandfonline.com/doi/epdf/10.2147/AMEP.S203333?needAccess=true [downloaded 19 February 2024]

[87] See https://www.hee.nhs.uk ; https://www.england.nhs.uk/2023/04/health-education-england-and-nhs-england-complete-merger/

[88] For a useful summary of regulatory reform up to 2020 see Professional Standards Authority, *Learning from the past, planning for the future: twenty years of regulatory reform in health and care professional regulation* (1 December 2020] https://www.professionalstandards.org.uk/docs/default-source/publications/learning-from-the-past-20-years-of-regulatory-reform.pdf?sfvrsn=8d1b7620_4 [downloaded 19 February 2024]

6.10 Multidisciplinary training

6.10.1 *Recommendations 75, 76, 77, 78 recommend various aspects of promoting common learning for aspiring healthcare professionals*

There may have been pilots as suggested by the Government in its response to this Inquiry, but to my knowledge there has been no widespread adoption of common learning in England. In 2002 Health Education England launched a report describing the issues with regard to blended learning across healthcare professions.[89] It appears to be a thorough examination of the training offered for all categories of healthcare professional, but I see no suggestion in its recommendations that common learning was at that stage widespread or applicable in particular to doctors. However a brief internet search suggests that many providers have since taken up blended learning as a concept to be applied to their education and training, although some of this may be focussed more on diverse methods of delivering training in particular areas rather than a common platform across disciplines.

6.10.2 *Recommendation 79 recommends that GMC's good medical practice guidance should inform all aspects of selection and criteria of medical schools*

I expect that medical school education will be consistently informed by the principles of *Good Medical Practice* as will the aptitude and other tests used for selection purposes.

[89] Health Education England, *Blended Learning for pre-registration and undergraduate healthcare professional education*, 2022 https://www.hee.nhs.uk/sites/default/files/documents/220405_Blended%20Learning%20Guidance%20Report_FINAL.pdf [downloaded 19 February 2024]. For further information see the publications listed at https://www.hee.nhs.uk/our-work/blended-learning

7. Mid Staffordshire NHS Foundation Trust Independent Inquiry

Before the Public Inquiry there was a non-statutory inquiry, which I also chaired.[90] This made 18 recommendations. While most recommendations were inevitably focussed on this particular Trust, recommendation 18 was that all NHS Trusts providing hospital services should review their own systems in the light of the report. The Public Inquiry arose out of recommendation 16 to the effect that there should be an independent examination of the role of commissioning, supervisory and regulatory bodies in monitoring Stafford Hospital.

The Independent Inquiry recommendations that might be considered relevant to this inquiry include:

7.1 Recommendation 1: *The Trust must make its visible first priority the delivery of a high-class standard of care to all its patients by putting their needs first. It should not provide a service in areas where it cannot achieve such a standard*

7.2 While directed at the Trust in particular, the recommendation contained an implied requirement for the NHS as a whole. The NHS Constitution [considered above] contains a requirement to put patients at the heart of everything it does.[91] It is also fair to point out that most staff [75.14% of respondents] think that care of patients is their organisation's top priority,[92] although this figure is lower than every year since 2019, except for 2022.

7.3 Recommendation 5: *The Board should institute a programme of improving the arrangements for audit in all clinical departments and make participation in audit processes in accordance with contemporary standards of practice a requirement for all relevant staff. The Board should review audit processes and outcomes on a regular basis*

A failure of the Board at this Trust to give due weight to mortality statistics and to audit the performance of departments which were outliers was a significant factor in the failures there. This was a lesson for the wider NHS community as well, but each Trust may have different ways of achieving this.

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[90] *Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 – March 2009*, 24 February 2010 HC375-1 https://www.gov.uk/government/publications/independent-inquiry-into-care-provided-by-mid-staffordshire-nhs-foundation-trust-january-2001-to-march-2009 [downloaded 20 February 2024]

[91] *NHS constitution 2023* Principle 4, page 5

[92] NHS *NHS Staff Survey 2023 National Results Briefing* March 2024 https://www.nhsstaffsurveys.com/results/national-results/.

7.4 **Recommendation 6:** ***The Board should review the Trust's arrangements for the management of complaints and incident reporting in the light of the findings of this report and ensure that it*:**

- *provides responses and resolutions to complaints which satisfy complainants.*
- *ensures that staff are engaged in the process from the investigation of a complaint or an incident to the implementation of any lessons to be learned all part of the recommendation.*
- *minimises the risk of deficiencies exposed by the problems recurring; and*
- *makes available full information on the matters reported, and the action to resolve deficiencies, to the Board, the governors and the public.*

While the later inquiry also made observations about complaints processes, this recommendation set out in summary form what I regarded as being required of an effective system. I am not confident these principles are followed everywhere even now. I address this issue in more detail in Part 2 of this report.

7.5 **Recommendation 7:** ***Trust policies, procedures and practice regarding professional oversight and discipline should be reviewed in the light of the principles described in this report***

(a) As can be seen from the text preceding this recommendation a number of things were required including:

(i) Swift action needed to be taken where unacceptable practice was identified or alleged on reasonable grounds;

(ii) Suspension of the practitioner alleged to have engaged in such practice should occur where such a step was necessary for patient safety, and in any case management should consider what necessary and proportionate action was required to protect patients and the public;

(iii) Where external reviews identified deficiencies with regard to staff immediate consideration should be given to what action was required to remedy the deficiencies and whether the issues under investigation had been sufficiently addressed.

(b) In my view these are matters which all Trusts needed to take on board.

7.6 **Recommendation 8:** ***The Board should give priority to ensuring that any member of staff who raises an honestly held concern about the standard or safety of the provision of services to patients is supported and protected from any adverse consequences, and should foster a culture of openness and insight***

The text preceding this recommendation identified an issue in the "very real reluctance on the part of staff at all levels of seniority to persist in raising concerns about unsafe or substandard services, colleagues' capability or conduct…". The requirements included a need:

(a) to dispel a widespread belief that protections for staff raising concerns were not real but theoretical; a culture of openness, self-criticism and teamwork had to be fostered;

(b) to lead by example in candour about errors and harm, welcoming constructive criticism, and debate on issues of concern, together with reinforcement of the formal protections for whistleblowers;

(c) to encourage staff to participate in regular reviews of practice;

(d) to remind staff of their obligation to assist the Trust in improving standards;

(e) to protect staff from adverse consequences when raising or reporting concerns about standards or safety, even where subsequent investigation finds no grounds for the concern.

7.7 **Recommendation 9:** ***In the light of the findings of this report, the Secretary of State and Monitor should review the arrangements for the training, appointment, support and accountability of executive and non-executive directors of NHS trusts and NHS foundation trusts, with a view to creating and enforcing uniform professional standards for such posts by means of standards formulated and overseen by an independent body given powers of disciplinary sanction***

(a) This recommendation advocated:

(i) defined criteria of the competences requited of executive officers;

(ii) training schemes to enable and empower candidates;

(iii) a professional ethos promoted by an association of executive leaders;

(iv) regulation ["an independent forum"] to determine allegations and complaints about the fitness to practice of executive and non-executive directors;

(v) a power to review an agreed termination of employment if serious deficiencies in conduct or competence are found within a specified period.

(b) I believe that much has been done to improve the training available to aspiring executives, but to my knowledge there is still no formal requirement of obtain a specified qualification and there is certainly no regulator with the powers I described as being required.

7.8 Recommendation 10: *The Board should review the management and leadership of the nursing staff to ensure that the principles described are complied with*

The principles were to ensure that:

(a) all front-line nurses are identified as part of a team with defined responsibilities and part of the success to which they are expected to contribute;

(b) each team should have leaders who lead by example, support team members and listen to and pass on concerns they express;

(c) the welfare of patients is their first priority through constant improvement in the standard of service and ready acceptance where an appropriate standard has not been attained;

(d) nurses are supported with training, mentoring and professional development;

(e) there is a system for transmitting nurses concerns to the Board where the Director of Nursing should be responsible for representing their views.

7.9 Recommendation 11: *Contained similar requirements to ensure that the Board were aware of doctors' concerns*

Since this report progress has been made with regard to the standards of nursing and medical training but there are still too many reported instances of concerns being raised but not reaching the Board and of insufficient protection being accorded to those who raise them.

7.10 Recommendation 14: *The Trust should ensure that its nurses work to a published set of principles, focusing on safe patient care*

I am not aware whether this recommendation was implemented at this Trust or elsewhere. The justification for it is contained in the preceding text.

7.11 Recommendation 15 *was for a review of the methodologies in mortality statistics*

This was and remains a matter of professional debate. A new form of overall hospital mortality statistics was subsequently produced and is in use now. I am not aware of evidence as to the extent to which such statistics are not understood or trusted by the public or what assistance has been provided to enable hospitals to use such statistics to examine particular areas of care.

8. Mid Staffordshire NHS Foundation Trust Public Inquiry

In order to consider the extent to which the recommendations of this Inquiry have been implemented I suggest it is necessary not just to look at the government's formal responses, which have been correctly and helpfully listed in the Schedule, but also at what has happened in the following 10 years. For example, my recommendation[93] with regard to nurses' uniforms was only begun to be implemented with a consultation in 2021[94], which acknowledged the contribution a standard uniform could make to patient safety and culture, with the designs announced to become available for distribution in the autumn of 2023.[95] While it might be argued that this is not a direct implementation of the letter of the recommendations, this measure certainly meets their spirit and therefore I would regard this is as a satisfactory implementation. I shall endeavour to take the same approach in my consideration of the most relevant of my other recommendations below.

[93] Recommendation 208

[94] NHS Executive *NHS Supply Chain to consult on standardised national uniform* 13 April 2021 https://www.nationalhealthexecutive.com/articles/nhs-supply-chain-standard-nhs-uniform [downloaded 20 February 2024]; NHS Supply Chain *NHS National Healthcare Uniform* https://www.supplychain.nhs.uk/categories/hotel-services/uniforms/nhs-national-healthcare-uniform/ [downloaded 20 February 2024]

[95] NHS Supply Chain *NHS National Healthcare Uniform Colourways Announced* https://www.supplychain.nhs.uk/news-article/nhs-national-healthcare-uniform-colourways-announced/

8.1 Recommendation 1: *Annual review of implementation*

This suggested that there should be an annual review by all organisations within healthcare, including the Department of Health, of their progress towards implementation, with follow up review by the House of Commons Select Committee. Including those listed in the schedule many organisations did so at least once, and NHS trusts, for example, included an account of their activity in one or more annual Quality Accounts, and the Select Committee also reported on implementation.[96] However, perhaps inevitably, such reviews effectively petered out, although the report has continued to be referenced in most discussions on improving the NHS and protecting patients from harm. Of course there have been many inquiries and reviews since, all with recommendations, some repeating or echoing the Mid Staffordshire ones, and others suggesting different ways of achieving the same goals. It might help the inevitable confusion if there was a more systematic way of consolidating inquiry and review recommendations as they are published into themes and then collectively monitoring their implementation and effect.

8.2 Recommendation 2: *Values*

With regard the five bullet points in this recommendation there is probably a mixed picture of implementation. I would suggest that:

(a) there is now a common set of core values as evidenced by the NHS Constitution [see above];

(b) it is doubtful whether all leadership is capable of involving all staff in those values, although much effort is put into that;

(c) the system undoubtedly recognises the need for the values of transparency, honesty and candour, all of which are enshrined in regulation and policy throughout the system, but whether these are universally applied may be open to question;

(d) there is much more information available on the attainment of values and standards though annual reporting requirements, incident reporting, safety investigations and CQC inspections, among other measures;

(e) there are tools available to measure organisations' culture, but I doubt any of them are applied consistently throughout the system. I believe that all healthcare providers would certainly be expected to adopt tools or methods to enable them to do this.

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[96] House of Commons Health Select Committee *After Francis: making a difference* 18 September 2013 HC 657 https://publications.parliament.uk/pa/cm201314/cmselect/cmhealth/657/657.pdf [downloaded 20 February 2024]

8.3 NHS Constitution

8.3.1 *Recommendation 3: Recommends that the NHS constitution should be the first reference for patients and staff*

(a) Provisions of the NHS constitution have been considered above. It was introduced and recognised by statute in 2009.[97] It is required to be reviewed every 10 years after a public consultation,[98] and its companion handbook is reviewed every three years.[99]

(b) Statute requires all state healthcare bodies to have regard to its provisions,[100] and the Secretary of State is under a duty to ensure that it "*continues to be available to patients, staff and members of the public*".[101] The Secretary of State is required to report to Parliament every three years how the Constitution has affected patients, staff, carers and members of the public. Following the Mid-Staffordshire report the Department of Health reported the public awareness of the constitution remained very low and had dropped from 27% in 2012 to 24% in 2015.[102] The then Secretary of State acknowledged my recommendation and committed himself to raising awareness and understanding of the Constitution. The latest report was published in January 2022[103] does not show very impressive improvement: public awareness was at 23%, and staff awareness at 49% of staff.

(c) Therefore, while the Government has implemented this recommendation legally and structurally, it might be argued that the Constitution has yet to make the full impact intended for it.

8.3.2 *Recommendation 4: Requires that the core values of the Constitution should be given priority of place and that the overriding value should be that patients are put first*

I refer to my observations above with regard to the analogous recommendations of the Bristol report.

8.3.3 *Recommendations 5, 6: Matters to be included in the Constitution*

I note and agree with the comments in the schedule.

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[97] Health Act 2009 section 1

[98] Health Act 2009 section 3(2), 4(2)

[99] Health Act 2009 section 5

[100] Health Act 2009 section 2

[101] Health Act 2009 section1

[102] Department of Health, *Report on the effect of the NHS Constitution* July 2015. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/440171/2904073_Report_on_the_NHS_Accessible_v0.1.pdf#:~:text=Yet%20public%20awareness%20of%20the%20NHS%20Constitution%20remains,Constitution%20as%20a%20means%20of%20exercising%20their%20rights.

[103] Department of Health, *Fourth report on the effect of the NHS Constitution* January 2022 https://assets.publishing.service.gov.uk/media/61f268acd3bf7f78dc2cd944/fourth-report-NHS-constitution.pdf [downloaded 21 February 2024]

8.3.4 *Recommendation 7 recommends that staff should be requirement to enter into a commitment to above by the NHS values in the constitution*

(a) The Government response in Hard Truths referred to in the Schedule appeared to focus on the supervision of staff by way of appraisal and performance management, rather than an express commitment being required at the commencement of employment.

(b) I have briefly reviewed the NHS Terms and Conditions of Service Handbook[104] and can find no reference to any such commitment. *Maintaining High Professional Standards* pre-dates this report and in any event appears to rely on individual employers drafting their own codes of conduct. I have not reviewed these but suspect that a variety of language and terms will be found, with little of it making direct reference to the constitutional values. It is likely therefore to be fair to conclude that staff are not generally requested to enter an express commitment, which is what I intended by this recommendation.

8.3.5 *Recommendation 8 recommends that contractors should be required to comply with the requirements of the Constitution*

I note the comments in the Schedule with which I agree, but I am unable from my own knowledge to assist whether this is happening in practice, and, if so, with what effect.

8.3.6 *Recommendations 9, 10 refer to the need to integrate the requirements to follow codes of practice and relevant guidance into managerial and staff obligations by reference to the NHS Constitution*

I am unaware of the extent if at all to which this has occurred. I suspect that many codes and forms of guidance are implicitly incorporated into contracts of employment, but my intention here was to ensure that the importance of such obligations was brought home to managers and staff from the outset of their employment. There cannot be much confidence that this is occurring on a widespread basis when awareness of the Constitution itself remains at a relatively low level among staff.

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[104] NHS Employers *NHS Terms and Conditions of Service Handbook*, Handbook amendment No 52 2 October 2023 https://www.nhsemployers.org/publications/tchandbook [accessed but not downloaded 21 February 2024]

8.3.7 *Recommendation 11 recommends that staff should be prepared to contribute to the development of standard procedures; managers should ensure they complied with them*

This recommendation arose out of the evidence[105] before the Inquiry that a safety culture required all staff to be committed to and "*own* the relevant standards, and that this was more likely to occur if the staff themselves were valued and believed they could contribute to that with their own expertise and experience. I also considered that individual professional dissent to adoption of standard procedures, where professional colleagues could not be persuaded of the merit of a departure, needed to be controlled. I believe the essence of this has been the subject of oversight by way of CQC inspections and ratings, but a glance at their reports will show variable success in introducing this and other associated principles.

8.4 Staff concerns

8.4.1 *Recommendation 12 reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.*

(a) I will address the issue of fundamental standards below, but the focus of this recommendation was the need to insist on staff reporting matters of concern and welcoming such action when they did so. Staff will be deterred from doing this if they believe no action will result or they will get into trouble. Therefore I considered it to be important that not only should raising concerns be encouraged, it should be an expectation; further, staff raising concerns should be assured they would be valued and kept safe, and would also receive feedback as to what had been done as a result, even if the concern proved to be unfounded.

(b) A measure of whether this has been successfully implemented is to be found in the annual NHS Staff Survey. The 2023 survey[106] showed mixed results:

(i) 71.59% of respondents felt able to make suggestions to improve their work, but only 51.24% said they were involved in deciding changes and 55.87% felt able to make improvements happen.

[105] See chapter 20 of the inquiry report.

[106] NHS *NHS Staff Survey 2023 National Results Briefing* March 2024. https://www.nhsstaffsurveys.com/results/national-results/ [downloaded 7 March 2024]

(ii) Only 62.31% of staff felt safe to speak up about anything that concerned them, although 71.28% would feel secure raising concerns about unsafe clinical practice. Only 50.07% were confident their organisation would address their concerns generally, rising to 56.81 % who were confident safety concerns would be addressed.

(iii) Of even greater concern, only 51.86% of staff who had experienced harassment, bullying or abuse said they or a colleague had reported it. 10.17% and 18.09% of respondents had experienced harassment, bullying or abuse from managers and colleagues, respectively. 3.84% of staff said they had been the target of at least one incident of unwanted behaviour of a sexual nature in the workplace in the last 12 months. The scores concerning conduct against staff by patients or the public were worse.

(iv) While 83.51% had received an appraisal or similar within the last 12 months, a mere 33.62% felt this had left them feeling valued.

(v) The importance of speaking up about safety is underlined by noting that 33.19% of staff had seen errors, near misses or incident that could have hurt staff and/or service users *in the last month*, but only 59.45% thought their organisation treats staff involved in such incidents fairly, and only 68.15% thought that if these were reported remedial action would be taken.

(c) 707,460 out of 1.4 million staff responded to the survey. That means that 420,584 respondents did not believe that staff were treated fairly if involved in an error, or, if the results are representative, 841,170 people did not trust their employer on this vital issue. This is not a climate in which there can be any confidence that safety issues will be raised.

8.5 Minimum and other standards

8.5.1 *Recommendations 13, 14, 15, 16, 17, 27, 28, 29: Standards*

These recommendations were for the introduction of fundamental standards, enhanced, more discretionary, standards, developmental standards setting out longer term, and governance standards. Recommendation 27 recommended the adoption of a low threshold of suspicion of non-compliance, and recommendations 28 and 29 suggested that a service incapable of meeting fundamental standards should not be allowed to continue, and that criminal liability should follow in some cases.

8.5.2 *Recommendation 18 required that doctors' and nurses' professional bodies should be fully involved in the formulation of these standards and the means of measuring compliance*

8.5.3 *Recommendations 30,31, 32, 33, 34 recommended that the regulator should be able to take immediate protective steps on suspicion of a breach of fundamental standards and that Monitor [now NHS England] should constantly review whether there is a need to use powers of intervention to protect patients*

These recommendations arose out of my finding that the system had largely assumed that the basics of compassionate, effective and safe care were fully embedded in the system and complied with by the staff working in it. The Mid-Staffordshire experience, and indeed the Bristol experience before that, showed that this was far from a safe assumption. Therefore I suggested that it was necessary to spell out those basic requirements, accepted as essential by all, and that there should be no excuse for not complying with them. These standards were to be the subject of regulation, and persistent non-compliance should have serious consequences. I emphasised[107] that all these standards should be fitted into a coherent system or structure to which providers and their staff were required to work rather than requiring them to seek out relevant standards from multiple and sometimes overlapping sources.

The concept of fundamental standards enforceable in law was given effect by the CQC's regulations[108] which contain a list of fundamental standards. In summary the standards are:

(a) Reg 9: care and treatment must be appropriate, meet patients' needs and reflect their preferences, and involve them.[109]

(b) Reg 10: service users must be treated with dignity and respect, including ensuring privacy.

(c) Reg 11*: Treatment must only be provided with consent.

(d) Reg 12**: Care and treatment must be provided in a safe way

(e) Reg 13**: Service users must be protected from abuse and improper treatment

(f) Reg 14**: Service users' nutritional and hydration needs must be met.

(g) Reg 15: Premises and equipment must be clean, secure, suitable, properly used and maintained and appropriately located.

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[107] Inquiry report chapter 21 §21.84

[108] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulations 8 to 20A. These regulations have been amended multiple times: a consolidated, current version appears at https://www.cqc.org.uk/sites/default/files/20150510_hsca_2008_regulated_activities_regs_2104_current.pdf [downloaded 22 February 2024]

[109] For a useful summary of how CQC interpreted the obligation to involve patients in their care see CQC, *Better care in my hands*, a review of how people are involved in their care, May 2016 https://www.cqc.org.uk/sites/default/files/20160519_Better_care_in_my_hands_FINAL.pdf [downloaded 28 March 2024]

(h) Reg 16*: Complaints must be investigations and receive necessary and proportionate action.

(i) Reg 17*: Good governance systems [defined] should be established and operated. This includes assessing, monitoring and mitigating risks relating to the health, safety and welfare of service users and others who may be at risk and maintaining necessary records on staff and management.

(j) Reg 18: there must be sufficient numbers of suitably qualified, competent, skilled and experienced persons deployed.

(k) Reg 19: those employed must be fit and proper persons which is defined as including being of good character and possessing the necessary qualifications, skill, competence and experience. Schedule 3[110] contains detail of the information required for this purpose; this includes satisfactory evidence of conduct in previous employment relating to health or social care, or children or vulnerable adults, including in the latter two cases the reason why that employment ended. There should also be a satisfactory explanation for any gaps in employment history, and information about any relevant physical or mental health conditions.[111] It should be noted that these requirements are different from the fit and proper person test applicable to directors, or the equivalent, of the registered provider which are more specifically set out in regulation 5 and will be considered separately below.

(l) Reg 20*: Providers must comply with the duty of candour as defined. Generally the provider must:

(i) act in an "*open and transparent way*" with regard to service users.

(ii) notify service users as soon as reasonably practicable of notifiable safety incidents [defined] and provide support to them.

(iii) The notification process must include an explanation of the incident, advice about further inquiries to be made, an apology and recorded in writing.

The duty is not only to servicer users but, in the case of children under the age of 16, to persons entitled to act for them.[112]

(m) Reg 20A*: Providers must display the CQC's latest rating of the providers performance.

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[110] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Schedule 3 §4

[111] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Schedule 3 §7, 8

[112] See the definition of "relevant persons" in regulation 2.

8.5.4 Breach of some standards can amount to a criminal offence on the part of the registered service provider and/or the registered manager.[113]

The scope of the offence does not, however, extend to employees whose conduct may have caused or contributed to the breach. That level of accountability is left to internal employment disciplinary, and external professional regulatory measures. All the fundamental standards can form the basis of regulatory intervention by the CQC and of an assessment of compliance which will form part of the overall assessment and rating of the provider.

(a) Fundamental standards cannot be enforced by individual patients, although a breach of these standards might be evidence of a breach of the common law duty of care, and as much is implied in the Government's guidance on the Constitution.[114]

(b) It is not clear what the threshold for acting on a suspicion is, but the CQC is now turning to a more risk-based approach to regulation.[115] With regard to findings of non-compliance with fundamental standards, many organisations have been rated inadequate, in some cases because of breach of these standards, but no NHS provider has, to my knowledge, had its registration withdrawn for such breaches. In some instances individual units, such as operating theatres have been closed at least temporarily. Trusts rated as "Inadequate" are placed into "special measures" and closely supervised by NHS England. While this is positive from the point of view of the patient and public interest, there is potential for concern than on many occasions the reaction to an adverse CQC inspection report has been the replacement of the Chief Executive or Chair of the provider, or both. One word ratings were not part of my recommendation, but a policy decision seeking to provide the public with a simple description of the quality of a provider, comparable to OFSTED ratings for schools. Concern is sometimes expressed by representatives of providers that the one word overall rating can be unfair and potentially misleading.[116]

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[113] Breach those regulations marked with one asterisk can give rise to an offence; breach of those marked with two asterisks can amount to an offence if the breach causes "avoidable" harm, or a "significant risk" of such harm occurring, or the loss of money or property of the service user.: regulation 22.

[114] *Handbook on the NHS Constitution* pages 17, 31.

[115] It has very recently been reported that the Government is intending to review of effectiveness of regulation by the CQC's and its transformation plans. Under the Public Bodies Review Programme: Townsend and /west, *Exclusive: Ministers trigger review of CQC inspection regime*, 8 May 2024, Health Service Journal, https://www.hsj.co.uk/policy-and-regulation/exclusive-ministers-trigger-review-of-cqc-inspection-regime/7037083.article [viewed 9 May 2024]. For guidance about what such a review involves see https://www.gov.uk/government/publications/public-bodies-review-programme/guidance-on-the-undertaking-of-reviews-of-public-bodies .

[116] See for example Ridout, *The CQC's rating of Addenbrooke's is wrong and unfair*, 30 September 2014, Health Service Journal https://www.hsj.co.uk/the-cqcs-rating-of-addenbrookes-is-wrong-and-unfair/5090728.article [accessed 26 March 2024]; NHS Providers, *Good Quality Regulation, How CQC can support trusts to deliver and improve: the impact of CQC's regulatory activities om providers*, Recommendation 7, March 2024 https://nhsproviders.org/good-quality-regulation-how-cqc-can-support-trusts-to-deliver-and-improve/the-impact-of-cqc-s-regulatory-activities-on-providers [accessed 26 March 2024]

8.5.5 Enhanced and developmental standards are reflected in NHS policy in a less direct way:

(i) The Secretary of State, NHS England and commissioning bodies are under a statutory duty[117] to secure continuous improvement in the quality of outcomes. Those outcomes are to include the effectiveness, safety and quality of services and the experience of patients. This is line with Lord Darzi's vision of high quality in the NHS.[118]

(ii) The NHS Constitution includes:

- As its Third Principle: *The NHS aspires to the highest standards of excellence and professionalism* a "*pledge that the NHS will identify and share best practice on the quality of care and treatments.*"[119]
- a Right for service users *to expect NHS bodies to monitor, and make efforts to improve continuously, the quality of healthcare they commission or provide. This includes improvements to the safety, effectiveness and experience of services.*[120]
- A Pledge to *identify and share best practice in quality of care and treatments.*[121]

(b) The Handbook sets out the references[122] in national level documents in which these expectations are said to be fulfilled. So it is safe to say that at least the principles of my recommendations about standards have been reflected in NHS related legislation and policy. The extent to which this has been translated effectively into practice throughout the service is a more difficult question to answer. To quote from the recent Times Health Commission report:[123]

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[117] National Health Service Act 2006, as amended section 1A, 1H, 1I, 13E, 14Z34. A consolidated version of the Act as amended up to 5 February 2024 is available at https://www.legislation.gov.uk/ukpga/2006/41/section/14Z34 [downloaded 25 February 2024

[118] As described in his report Darzi et al *High Quality Care for All: NHS Next Stage Review Final Report*, June 2008, Department of Health CM7432 https://assets.publishing.service.gov.uk/media/5a7c3a5b40f0b67d0b11fbaf/7432.pdf [downloaded 25 February 2024.

[119] *NHS Constitution* page 5 §3

[120] *NHS* Constitution page 11; Handbook page 34

[121] *NHS Constitution* page 11.

[122] Handbook page 34-36

[123] Times Health Commission *A Report into the state of health and social care in Britain* today February 2024 pages 8, 14 https://s3.documentcloud.org/documents/24398476/times-health-commission_report_2024.pdf

There are many brilliant, dedicated people doing fantastic work but there is also huge variation in performance and a persistent inability to spread innovation or ensure that the worst learn from the best. It is time for a radical rethink based not on irrational sentiment or ideological certainty but a hardheaded analysis about changing needs and the opportunities offered by new technology.

There are many extraordinary people doing exceptional things in the NHS, saving lives every day, but the system as a whole seems unable to learn from its innovators. The institutions have not adapted. Hospitals are disconnected from GPs and the NHS from local authorities, with patients shunted between the uncomprehending constituent parts. There is a culture of box ticking and risk aversion.

8.6 Regulation and monitoring

8.6.1 *Recommendations 19, 60, 61 64: Regulators*

(a) These recommendations proposed that there should be one regulator dealing with corporate governance, financial competence, and compliance with patient safety and quality standards.

(b) The Government rejected this recommendation and kept the existing regulatory system consisting of Monitor and the NHS Trust Development Authority, which oversaw corporate governance and financial control of NHS Foundation Trusts and NHS Trusts, including the power to appoint chairs and chief executives. As stated in the Schedule providers remained responsible for assessing the fitness of persons to be directors. The Care Quality Commission remained tasked with the oversight of compliance with standards. In 2021 Monitor and the Trust Development Authority, which by this time had both become part of a new body, NHS Improvement, were abolished and their functions subsumed into NHS England. In proposing the relevant legislative changes, Edward Argar, Minister of State, DHSC, argued:[124]

[124] House of Commons debate on the Health and Care Bill 21 September 2021 on clauses 26, 29. https://www.theyworkforyoum/pbc/2021-22/Health_and_Care_Bill/09-0_2021-09-21a.349.0. Enacted as Health and Care Act 2022 sections 33-39, Schedules 5

> *Establishing a single statutory body responsible for the health care system in England has several clear benefits. First, it will create a more joined-up approach across the NHS to provide national leadership and speak with one voice to set clear and consistent expectations for providers, commissioners and local health systems. Secondly, it brings services, support and improvement under a single regulatory and legislative framework. That will deliver improved care for patients, enabling better use of collective resources, removing unnecessary duplication and ultimately making better use of public money. The merger will provide clearer lines of accountability so that the public can be assured that any service they use meets the same requirements around safety and quality.*

(c) Therefore NHS England is now responsible for licensing and financial, governance, and performance oversight of NHS providers as well as the commissioning of services, whereas the Care Quality Commission is responsible for registration and inspection of all health and care providers, whether or not within the public sector, as well as now reviewing the performance of integrated care boards. CQC does inspect providers for the quality of their leadership, and indeed this is frequently the principal focus of their inspection and regulatory intervention. They also use their regulatory powers to oversee compliance with the fit and proper person requirements. However, any action required as a result has to be undertaken by NHS England. As stated elsewhere there have been recent proposals for regulating managers.

(d) Complaints about the regulatory burden imposed on providers persist.[125]

8.6.2 *Recommendations 19, 20, 26, 53, 55, 56, 57: Care Quality Commission*

(a) These recommendations were to the effect that the CQC should be responsible for policing compliance with the fundamental standards and the accuracy of information disseminated by providers about compliance with those standards. but not directly for compliance with any enhanced standards. I specifically recommended [Recommendation 53] that CQC should be retained as the quality and safety regulator and should not be abolished. CQC retains that responsibility today. I thought [Recommendation 54] that any discussion of regulatory action between CQC and other agencies should be recorded to avoid any suggestion of interference with its responsibilities and independence. I have seen no evidence since then of any such interference. Whether all interactions are recorded would be a matter for CQC to describe, but collaboration with other agencies, such as NHS England and the Health and Safety Executive is inevitably and frequently required. I also recommended [Recommendation 57] that CQC should review how it would detect and act on the warning signs which should have given cause

[125] Pulse, *CQC inspection process may be disproportionate, finds Government review*, 14 July 2013, https://www.pslhub.org/blogs/entry/5925-cqc-inspection-process-may-be-'disproportionate'-finds-government-review/ [viewed 9 May 2024]

for concern at Mid Staffordshire NHS Foundation Trust. I am not sure whether it did this explicitly, but it certainly reviewed its processes.

(b) I also recommended that the CQC should also be prepared to consider individual cases of gross failure as well as systemic causes for concern and that regulation required direct contact with patients, carers and staff and inspection rather than remote monitoring of policies and protocols.

(c) Following the report, the CQC changed its approach to regulation by employing inspectors who specialised in particular sectors and who undertook inspections which complied with the spirit of Recommendation 26, and the requirements of Recommendation 52. I recommended [Recommendation 50] that emphasis on inspection should be retained as the central method of monitoring non-compliance. This has been the approach of CQC since then, although it is now once again changing its emphasis to rely more on intelligence led regulation.[126] The intention, at least in the first instance, is to use intelligence to assess better the need and timing for inspection, while decreasing the use of routine inspections.

(d) The Schedule correctly observes that the Government accepted these recommendations only in part. While the CQC does indeed regulate and rate providers for their compliance with the CQC regulations, including the fundamental standards, it is more hesitant about investigating individual cases of failure. Thus when an individual has a complaint about, for example, harm brought about by a failure to observe the fundamental standards or has been prejudiced by a failure to observe the duty of candour, they will be told that the CQC will take their complaint into account in its regulation but are unable to investigate it directly. However CQC does have power to prosecute failures to comply with fundamental standards which result in harm to a patient. It does use these powers,[127] but sparingly: it has prosecuted 141 cases since 2009.[128]

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[126] CQC *A new strategy for the changing world of health and social care - Our strategy from 2021* https://www.cqc.org.uk/sites/default/files/Our_strategy_from_2021.pdf [downloaded 27 February 2024]. See above for the likelihood of a Government review of CQC's effectiveness.

[127] For a current example see BBC *Care plan for teen who took her life 'inadequate'* https://www.bbc.co.uk/news/uk-england-tees-68402158 26 February 2024

[128] CQC *List of prosecutions brought by CQC (last updated 6 February 2024* https://www.cqc.org.uk/about-us/how-we-do-our-job/prosecutions [spreadsheet downloaded 27 February 2024]

(e) The Schedule refers to the Government's observation that Monitor's [now NHS England's] licensing conditions require information provided to it should be accurate and not misleading. The Mid Staffordshire Inquiries found that there had been a failure in this regard by the Mid Staffordshire NHS Trust in its application to become a Foundation Trust. The Secretary of State has power to prepare and publish information standards which all health service providers must have regard.[129] NHS England's standard licensing conditions[130] also require licensees to procure and provide information requested NHS England and to

> *take all reasonable steps to ensure that information is*:
>
> *(a) In the case of information or a report, it is accurate, complete and not misleading.*
>
> *(b) In the case of a document it is a true copy of the document requested.*

(f) The effect of this condition is that NHS England has power to regulate the accuracy of information provided if it has requested this from the provider.

8.6.3 *Recommendations 22-23: NICE*

(a) These recommendations concerned the role of NICE in formulating standard procedures and practice for the measurement of compliance with standards and for the staff required to achieve this.

(b) I refer to the description given above in relation to comparable recommendation [recommendation 10] of the Clothier Inquiry. The upshot is that standards are now published by way of guidance, but this does not in the view of some meet what they regard to be a need for defined minimum numbers of staff/patient ratio.

8.6.4 *Recommendation 24 recommended that compliance with fundamental standards should be assessed by accessible and understandable measures*

The principal way in which it could be said that this recommendation has been complied with is that the CQC's inspection reports describe the overall safety and effectiveness of registered providers, and more broadly via its annual State of Care report.

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[129] Health and Social Care Act 2012 as amended section 250. A consultation on the process for doing this is currently being undertaken and closes on 28 March 2024 https://www.gov.uk/government/consultations/information-standards-for-health-and-adult-social-care/information-standards-for-health-and-adult-social-care-in-england . https://www.gov.uk/government/consultations/information-standards-for-health-and-adult-social-care/information-standards-for-health-and-adult-social-care-in-england

[130] *NHS Provider License Standard Conditions* Section 3 G1 §2-3 31 March 2023 Version 4 Publication reference PR00191 https://www.england.nhs.uk/wp-content/uploads/2023/03/PRN00191-nhs-provider-licence-v4.pdf [downloaded 25 February 2024]

8.6.5 *Recommendation 25 was for all specialities to develop outcome measures for their work*

(a) This recommendation arose out of what I perceived to be a reluctance on the part of some medical practitioners to be open about the effectiveness of their performance. Some specialties now collate and report comparative figures for individual practitioners on, for instance, post or perioperative mortality, or readmission rates for certain procedures. There are obvious challenges in many specialities in producing statistics that are fair and useful for much medical work, given the variability of presentation and pre-treatment condition of patients. Therefore there are understandable reasons why the adoption of this recommendation has not been more widespread. Nonetheless the Royal College of Surgeons (England) and various specialist surgical societies have published such data on multiple procedures. The College states that:[131]

> *The objective of publishing the data is to drive forward improvements in care and enable patients to understand far more about the nature of a surgeon's work and their recovery after an operation. For patients, the information shows you the number of times a given procedure has been performed by a surgeon over a year and how close their performance is to the average standard.*

(b) An example is the National Joint Registry which allows public access to surgeons' experience and outcomes.[132]

(c) There is a risk of unfair comparisons being made between surgeons if published in "*league*" tables, even where all are performing within an acceptable range of variation.[133] However this sort of information is capable of enhancing patient choice, if accompanied by accessible explanations of the possible reasons for divergence from the norm.

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[131] https://www.rcseng.ac.uk/patient-care/surgical-staff-and-regulation/surgical-outcomes/

[132] https://surgeonprofile.njrcentre.org.uk

[133] See National Health Executive *Surgeons performance data published in NHS league tables* 19 November 2014 https://www.nationalhealthexecutive.com/Health-Care-News/surgeons-performance-data-published-in-nhs-league-tables- [downloaded 26 February 2024]

8.6.6 *Recommendation 36 recommended that accurate performance information for providers should be collected in as near real time as possible and made available to stakeholders including the public*

The Schedule refers to the Health and Social Care Information Centre. This was set up under the Health and Social Care Act 2012.[134] It was required to set up a database of quality indicators for health and social care services.[135] It was renamed NHS Digital, and with effect from 1 February 2023 merged, along with NHSX, into NHS England, following a review by Laura Wade-Gery.[136] NHS England, via the National Reporting and Learning System [NRLS], reports statistics relating to serious incidents, now called patient safety incidents. As of September 2023 annual publication of this data has been "*paused*" following the creation of the Learn from Patient Safety Events Service (LFPSE).[137] The intention is that this will provide a single national system for recording patient safety events and provide better analysis of them.

8.6.7 *Recommendation 37 concerned the accuracy and scope of reports published by NHS Providers and recommended that wilfully or recklessly to provide false or misleading information in a quality account should be an offence*

(a) The main focus of this recommendation and the Government's response was on the Quality Accounts that NHS Trusts are required to publish annually, and share with the local Healthwatch[138] The CQC and NHS England have power to require corrections or errors and omissions in these reports. The report must include a long list of prescribed information including the provider's view of the quality of the services provided, areas and priorities for improvement, information about incidents of serious harm and death, and of the action intended to be taken as a result. The report must be signed by the most senior employee who must certify that to the best of that person's knowledge the information is correct.

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[134] The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 Part 3

[135] For information services now organised by NHS England see https://digital.nhs.uk/services

[136] https://digital.nhs.uk/about-nhs-digital/nhs-digital-merger-with-nhs-england ; Wade-Gery *Putting data, digital and tech at the heart of transforming the NHS* 23 November 2021 https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs [downloaded 26 February 2024]

[137] https://www.england.nhs.uk/patient-safety/patient-safety-insight/learning-from-patient-safety-events/learn-from-patient-safety-events-service/

[138] Health Act 2009 sections 8, 9 as amended; National Health Service (Quality Accounts) Regulations 2010 SI 279

(b) In response to this recommendation a new offence was created: a care provider (that is the organisation) commits an offence of strict liability, subject to a defence of due diligence, if they publish prescribed information, essentially information required to be published by legislation, which is false or misleading.[139] The offence is punishable on summary conviction with a fine or on indictment by imprisonment of not more than 2 years. The organisation can be ordered to publish corrections and the fact of the court proceedings. Where such an offence is committed by or with the consent or connivance, or attributable to, the neglect of a director, manager or secretary of the body, or a person purporting to act in that capacity, that person is also guilty of that offence and liable to a like sentence.[140] I have been unable for the purposes of this report to find out how many, if any, prosecutions there have been for this offence. There is evidence that NHS England declined a Freedom of Information request for such information on the ground that it does not hold it.[141] I suspect that the number is very small.

8.7 Complaints

8.7.1 *Recommendations 38, 39 recommended that CQC should obtain information about complaints from registered providers*

Providers are required by regulation[142] to investigate and take necessary and proportionate action in response to any failure identified by the complaint or the investigation. The CQC can request information about complaints and complaints procedures from providers and it is an offence to fail to comply with such a request. The information that CQC requires as a matter of course is about patient safety incidents, deaths or serious injury under treatment, but not, in the case of healthcare providers, complaints generally.[143]

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[139] Care Act 2014 sections 92, 93. For guidance on this offence see DH, *The False or Misleading Information Offence: Guidance for Providers* February 2015 https://assets.publishing.service.gov.uk/media/5a816f2fed915d74e33fe30b/FOMI_Guidance.pdf [downloaded 26 February 2024]

[140] Care Act 2014 section 94

[141] https://www.whatdotheyknow.com/request/number_of_nhs_staff_prosecutions

[142] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 16

[143] See CQC' guidance for providers https://www.cqc.org.uk/guidance-providers/notifications/guidance

8.7.2 *Recommendation 40: Suggested greater attention needed to be paid to the narrative contained in complaints data as well as the quantitative data*

In 2020 Healthwatch England, of which I was Chair at the time, published a review and report on the working of the system for patient complaints in the NHS. It was found that the way many trusts reported on and published information about the complaints they received was unsatisfactory, often containing little detail of either the nature of the complaints or the action taken in response. Some trusts did not meet the minimum regulatory requirements for an annual report, which in any event is not required to be published.[144] In 2022 in the face of general criticism about the way complaints were being handled, the PHSO published standards for NHS complaints handling.[145] These include an expectation that organisations will routinely share learning from complaints with other organisations.

8.7.3 *Recommendations 109 to 121 suggested other improvements in the handling of patient complaints*

(a) Guidance:

(i) The PSHO had, prior to my report, published principles of good complaint handling in 2009.[146]

(ii) In 2013 the PHSO published a paper on how to design a good complaints handling process.[147]

(iii) In 2014 PHSO, with Healthwatch England and the Local Government Ombudsman, published guidance on complaints handling.[148]

(iv) As noted above in 2022 the PHSO published further standards for complaints handling. He also published model procedures for NHS providers.[149] This made it clear that complaints investigations should not generally be delayed by other procedures taking place.

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[144] Healthwatch England, *Shifting the Mindset, a Closer Look at Hospital Complaints.* January 2020. https://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/20191126%20-%20Shifting%20the%20mindset%20-%20NHS%20complaints%20.pdf [downloaded 26 February 2024] The regulations are The Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 SI 309, in particular regulation 18 https://www.legislation.gov.uk/uksi/2009/309/contents/made

[145] PHSO *NHS Complaint Standards – Summary of Expectations* December 2022 https://www.ombudsman.org.uk/sites/default/files/NHS_Complaint_Standards_Summary_of_expectations_December_2022_Final.pdf [downloaded 26 February 2024]

[146] PHSO, *Principles of Good Complaint Handling*, and also *Principles for Remedy* 10 February 2009 https://www.ombudsman.org.uk/sites/default/files/page/0188-Principles-of-Good-Complaint-Handling-bookletweb.pdf https://www.ombudsman.org.uk/sites/default/files/page/Principles%20for%20Remedy.pdf [both accessed 29 February 2024]

[147] PHSO, *Designing good together – transforming hospital complaint handling* August 2013 https://www.ombudsman.org.uk/sites/default/files/Designing_good_together_transforming_hospital_complaints_handling.pdf [accessed 29 February 2024]

[148] PHSO et al, *My expectations for raising concerns and complaints*, 13 November 2014 https://www.ombudsman.org.uk/sites/default/files/Report_My_expectations_for_raising_concerns_and_complaints.pdf [downloaded 29 February 2024]

[149] https://www.ombudsman.org.uk/sites/default/files/MCHP_NHS_CS_Dec_2022.pdf [accessed 29 February 2024]

(v) NHS England has guidance for patients on its website about how to complain or offer feedback.[150]

(b) Complaints advocacy support

(i) Arrangement for the offer of advocacy support can be seen on the website referred to above. The service is generally outsourced to charities such as POhWER and VoiceAbility.

(ii) PALS remains a service available at all NHS hospitals to provide information about complaints procedures and to resolve concerns. Recent research suggests that improvements are required for this form of support to achieve its objectives, in particular in increasing awareness of its functions.[151]

(iii) I am not aware that any specialist expert support is offered to patient advocates or their organisations.

(c) Litigation: the complaints regulations make it clear that actual or threatened litigation is not a reason for delaying processing of a complaint.

(d) Concerns not phrased as complaints: the material referred to above makes it clear that a matter should be treated as a complaint if that is what it is, regardless of the terms in which it is expressed.

(e) Serious/patient safety incidents: the model procedures referred to above make it clear that a complaint may trigger other procedures such as a patient safety investigation or a safeguarding procedure. Where that occurs the investigation appropriate to such an incident would also be triggered.

(f) Arm's length investigation: as far as I am aware the extent to which a patient safety investigation, whether triggered by a complaint or otherwise, is conducted remains a matter of discretion. The Patient Safety Incident Response Framework[152] contains some guidance as to the level of investigation required but leaves the decision about methodology to the responsible provider.

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[150] https://www.nhs.uk/contact-us/how-to-complain-to-the-nhs/ ; https://www.england.nhs.uk/contact-us/feedback-and-complaints/complaint/ [both accessed 29 February 2024]

[151] Shepard, Buivydaite, Vincent, *How do National Health service (NHS) organisations respond to patient concerns? A qualitative interview study of the Patient Advice and Liaison Service (PALS)*, 2021, BMJ Open 2021;11:e053239. doi:10.1136/bmjopen-2021-053239; https://bmjopen.bmj.com/content/bmjopen/11/11/e053239.full.pdf [downloaded 29 February 2024]

[152] See https://www.england.nhs.uk/publication/patient-safety-incident-response-framework-and-supporting-guidance/#heading-8 [accessed 29 February 2024 for the suite of documents associated with PSIRF/

(g) Complaints reports: I am unaware that recommendation 118 has been implemented in the sense of anonymised reports being publicised by providers. I believe summary complaints data is available for Oversight and Scrutiny Committees. CQC inspectors may request information to assist their inspection and providers are obliged to comply. This requirement would include information about individual complaints.[153] The precise role patient complaints will have in CQC's new approach to regulation in its single assessment framework is unclear to me. CQC emphasises that the framework:[154]

> *focuses on what matters to people who use services, and organisations who represent them or act on their behalf, to share their experiences at any time.*

And that

> *People using services, their families, friends and advocates are the best sources of evidence about lived experience of care. This includes their perspective of h ow good their care is…*
>
> *If we receive feedback that people have poor experiences of care, we will always identify it as a concern…*
>
> *We analyse a range of sources such as data on demographics, inequalities and frequency of use for care services*

The CQC website lists sources from which people's experiences are gathered. These include surveys, experiences "*people are already sharing with others including with providers", trusted online spaces and from other sources*", relationships with trusted intermediaries, Healthwatch, advocates and experts by experience. While by implication this list probably includes patient complaints made to the provider, it is surprising this important source is not mentioned expressly, particularly as elsewhere CQC makes it

[153] For CQC's current inspection practice see https://www.cqc.org.uk/about-us/how-we-do-our-job/what-we-do-inspection [accessed 29 February 2024]

[154] https://www.cqc.org.uk/guidance-regulation/providers/assessment/single-assessment-framework/importance-peoples-experience, updated 23 February 2024, [viewed 12 May 2024]; see also https://www.cqc.org.uk/about-us/how-we-will-regulate/using-peoples-experience-our-regulation updated 4 July 2023 [view3d 12 May 2024]

clear that they expect providers to have an effective and responsive complaints system complying with the regulations.

8.8 Patient safety alerts

8.8.1 *Recommendation 41 suggested that the CQC should review decisions made by providers not to comply with patient safety alerts*

The processes and the problems identified with regard to patient safety alerts are described in Chapter 17 of the report. The Government, as stated in the Schedule, suggested that CQC was giving greater prominence to alerts in its revised model, but care needed to be taken to ensure that providers retained accountability for implementing alerts. The system for disseminating Safety Alerts has changed significantly since then. At the time of the events described in the Mid Staffordshire report alerts were published by the National Patient Safety Agency. By the time of the report the functions of the NPSA had been transferred to NHS England, formally called the NHS Commissioning Board. The NPSA administered the National Reporting and Learning System under which matters requiring a patient safety alert were identified. In 2018 CQC published a report[155] suggesting that providers did not always have strong systems for implementing alerts. It made recommendations for a new alerts system and committed itself to improving its patient safety expertise. Under NHS England, the responsibility for issuing patient safety alerts moved to a National Patient Safety Alerting Committee (NAPSAC). In response to the CQC report a system of accreditation for issuing alerts was produced.[156] Responsibility was later transferred to the National Patient Safety Committee.[157]

8.9 Serious/patient safety incidents

8.9.1 *Recommendations 42 and 44 recommended that information about serious untoward incidents should be shared with CQC and that the regulator should examine how any such incident was addressed and learned from by the provider*

Such information, if reported by the provider, is now available to CQC as explained above. While CQC does not usually examine how each incident has been addressed at inspections, it can consider who well incident investigation and learning from incidents are being conducted by the provider. This does not go quite as far as I intended by my recommendation. In my opinion it is important that any genuinely serious incident raising issues about patient safety should be investigated with a degree of independent external involvement. I considered at the time that CQC was the appropriate organisation to undertake that responsibility. Some but by no means all incidents are now investigated by HSSIB.

8.10 CQC use of intelligence

8.10.1 *Recommendation 43 recommended that CQC use intelligence gained from media reports*

I believe that CQC does now include such information in its intelligence.

8.10.2 *Recommendation 45 recommended that CQC should be notified of upcoming inquests raising issues about care and treatment*

I agree that this has been implemented by a Memorandum of Understanding.[158]

8.10.3 *Recommendation 46 is now redundant*

CQC has changed its criteria for inspection and assessment of risk. Its new criteria are explained on its website.[159] The Government has recently announced a review of the operational effectiveness of the new framework, which was put into operation in November.[160]

8.10.4 *Recommendations 47, 48 concerned CQC obtaining information from trust governors and scrutiny committees*

I believe that CQC routinely seeks information from these sources in preparation for inspections.

8.11 Patient and staff involvement in regulation

8.11.1 *Recommendations 57, 58 encouraged CQC to involve patients and representatives of the healthcare professions in the work of the CQC*

(a) With regard to patients, CQC has a scheme to train lay people as "*Experts by Experience*", who then take part in inspections.[161] It also maintains partnerships with various groups and national charities to obtain feedback about patients' experiences: these include Healthwatch England, local Healthwatch, Patient Participation Groups at GP practices, Carers UK, and the Patients Association.[162]

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[155] CQC *Opening the Door to Change* December 2018 https://www.cqc.org.uk/sites/default/files/20181224_openingthedoor_report.pdf [downloaded 26 February 2024]

[156] https://www.england.nhs.uk/patient-safety/national-patient-safety-alerting-committee/

[157] See https://www.england.nhs.uk/patient-safety/patient-safety-systems/committee/

[158] *Memorandum of Understanding between the Coroners' Society of England and Wales and the Care Quality Commission* 2016 https://www.cqc.org.uk/sites/default/files/mou_cqc_and_csocew_final_with_pagnination_and_numbered_paragraphs.pdf

[159] See CQC, *Single assessment framework*, updated 22 February 2024 https://www.cqc.org.uk/guidance-regulation/providers/assessment/single-assessment-framework [viewed 12 May 2024]

[160] Townsend and west, *Exclusive: Ministers trigger review of CQC inspection* regime, 8 May 2024, Health Service Journal https://www.hsj.co.uk/policy-and-regulation/exclusive-ministers-trigger-review-of-cqc-inspection-regime/7037083.article [viewed 12 May 2024]; Colivicchi, *Government set to review CQC "effectiveness"*, 9 May 2024, Management in Practice, https://managementinpractice.com/news/government-set-to-review-cqc-effectiveness/#:~:text=The%20CQC%20is%20set%20to%20face%20a%20review,the%20DHSC%20on%20behalf%20of%20the%20Cabinet%20Office. [viewed 12 May 2024]

[161] For details see https://www.cqc.org.uk/about-us/jobs/experts-experience updated 8 September 2023

[162] https://www.cqc.org.uk/get-involved/share-your-experience/tell-us-about-your-care-partnerships

CQC has also set up ad hoc advisory groups to address particular themes, such as a Children and Young People's Advisory Group, and a Mental Health Service user Reference Panel. There is a public engagement network. In the course of inspections CQC also hold engagement events with service users and their carers.

(b) In 2017 an independent academic review[163] was conducted into the involvement by CQC of service users in its activity by collecting individuals' experiences, use of experts by experience, and interaction with local service user groups. The reviewers found that many who had participated in these ways had not received any feedback about outcomes of inspections, or on how their contribution had resulted in change or action. They pointed to the challenges involved in getting the most out of the user voice:

> *Our findings highlight how difficult it can be to involve service users in health and social care regulation. National regulators are typically large, bureaucratic organizations with a culture that emphasizes consistent authoritative application of rules by inspectors, who should maintain some distance in order to be objective and avoid capture. While there are potential benefits, being responsive to local communities and their concerns makes the regulator-regulatee relationship more complex, placing additional demands on regulatory staff, who need to adopt a more flexible approach that is socially and politically aware, in order to engage service users in a productive process.*

[163] Richardson, Walshe et al, *User involvement in regulation: A qualitative study of service user involvement in Care Quality Commission inspections of health and social care providers in England*, 23 October 2018, Health Expectations 2019;22:245-253 https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/hex.12849#:~:text=CQC%20involved%20service%20users%20in%20their%20inspections%20as,to%20service%20users%20who%20contributed%20to%20these%20activities. [downloaded 28 March 2024]

(c) They concluded that:

> *The encounters between CQC, individual and collective voices seemed to be somewhat transactional, organized directly to serve CQC functions and processes but not to build enduring relationships with local service user groups. There was a lack of transparency about how voice was incorporated into the inspection and rating process, and once people had shared their experiences with CQC, the engagement came to an end. Developing relationships that exist beyond an inspection and outside the inspection cycle would create opportunities for mutual and ongoing sharing of information, which could be used to help assess risk and build detailed profiles of providers so at the point of inspection, teams have more service user data to draw upon, and are better placed to engage in more focused and appropriate service user involvement during inspections.*

(d) In June 2021 CQC published a new strategy[164] which was said to have been developed with valuable contributions from the public service providers and partners. One of its themes was that regulation needed to be driven by people's needs and experiences, focusing on what was important to them and their communities. It acknowledged that people needed to see how their voice could make a difference, and that therefore CQC would seek to make it easier for people to give feedback and to find more and better ways to gather experiences, particularly from those disadvantaged sections of the community who were not often heard. Then in 2023 the Commission published a new public engagement strategy.[165] This referred to a new improved online feedback service, the NHS Patient Survey, administered by CQC, and a review of their handling of reports of concerns.

(e) With regard to staff, healthcare professionals are involved in a number of ways. CQC employs national clinical advisers but also maintains relationships with the medical and nursing representative bodies and Royal Colleges, with some of which CQC undertakes joint working.[166] The suggestion of nominated Board members representing professions was not taken up. Staff are almost invariably given opportunities for frank engagement with inspectors during inspections.

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[164] CQC, *A new strategy for the changing world of health and social care*, 26 May 2021, https://www.cqc.org.uk/sites/default/files/Our_strategy_from_2021.pdf [downloaded 28 March 2024]

[165] CQC, *Our plan for working with the public,* June 2023, https://www.cqc.org.uk/publications/public-engagement-strategy/2023-2026 . For previous engagement strategies published in 2015 and 2017 see https://webarchive.nationalarchives.gov.uk/ukgwa/20170310072332/http://www.cqc.org.uk/content/our-plan-engaging-public-our-work-2015-16 ; https://www.cqc.org.uk/sites/default/files/20171017_CQC_PublicEngage_2017_FINAL%20web.pdf [both accessed 28 March 2024]

[166] https://www.cqc.org.uk/guidance-providers/all-services/how-cqc-works-royal-colleges

(f) Current guidance,[167] which is under review, encourages healthcare staff to raise concerns within their own organisation but, if this has been tried, or if they feel unable to do this, then to contact CQC with their concern. The guidance encourages staff to raise concerns openly as it is easier to follow them up, but allows information to be received anonymously. I note that no undertaking is offered to give feedback to the informant as to what has been done with their information. Surprisingly, the guide omits any mention of the role of FTSU Guardians, or the National Guardian, although CQC hosts the latter.

(g) According to CQC's annual report for 2021-2022[168] it received 17,937 whistleblowing enquiries during the year. However the majority of these (80%) were about adult social care, and only 15% were about hospitals. The previous year CQC had received 15,829 whistleblowing enquiries (compared with 10,988 the previous year) of which 85% related to adult social care and 12% to hospital services.[169] The overall increase in contacts could be interpreted as caused by staff accepting more readily that contacting CQC would result in action, and the low proportion of reported hospital concerns could be attributed to a greater effectiveness of local channels for concerns. On the other hand, these figures need to be read with the NHS Staff Survey results which suggest a lack of faith in any effective action being taken on reported concerns. It is likely, in my view, that CQC could do more to involve staff and the valuable information they hold in its regulatory activity and to provide them with meaningful feedback about the action taken on that information.

8.11.2 *Recommendation 62 recommended that Monitor should incorporate patient and public involvement into its structures*

It is not clear to me what steps were taken by Monitor in this regard, but NHS England promotes such involvement in the way it works. In 2021 it published a five year patient and public involvement strategy an aim of which was to ensure that a diverse range of patients and the public and their representative organisations are involved in influencing their work programmes.[170] NHS England also hosts the NHS Assembly, a body of some 50 members who include people with lived experience of healthcare and leaders of patient representative organisations, as well as professional leaders in healthcare.[171]

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[167] CQC, *Raising a concern with CQC – a quick guide for health and care staff about whistleblowing*, 9 June 2023, https://www.cqc.org.uk/contact-us/report-concern/report-concern-if-you-are-member-staff [page last updated 9 June 2023; accessed 28 March 2024]; https://www.cqc.org.uk/sites/default/files/2023-06/20200420_Whistleblowing_quick_guide_final_update_amended.pdf [downloaded 28 March 2024]

[168] CQC, *Annual report and accounts 2021-22*, 6 July 2023, HC 1665 https://www.cqc.org.uk/publications/annual-report-and-accounts-202122 [downloaded 28 March 2024]

[169] CQC, *Annual report and accounts 2020-21*, 20 January 2022 HC1009 https://www.cqc.org.uk/publications/major-reports/cqc-annual-report-accounts-ara-2020-2021 [downloaded 28 March 2024]

[170] NHS England *Accelerated Access Collaborative Patient and Public Involvement Strategy 2021-26* https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2022/06/Accelerated-Access-Collaborative-patient-and-public-involvement-strategy.pdf [downloaded 27 February 2024]

[171] https://www.longtermplan.nhs.uk/nhs-assembly/

8.12 Trust applications for Foundation Trust status

8.12.1 *Recommendations 63, 65, 66, 67, 68, 69, 70, 71, 72, are effectively obsolete*

I believe that the pressure to turn remaining NHS Trusts into Foundation Trusts has eased if not ceased altogether: it does not receive a mention in the NHS operational planning guidance for 2014/15 to 2018/19.[172] In 2016 Monitor and the Trust Development Authority were merged into NHS Improvement.

8.13 Definition of regulatory and oversight functions

8.13.1 *Recommendation 73 suggested DH and CQC should regularly review their understanding of their separate roles*

As stated in the Schedule this is said to be part of the regular accountability processes which certainly include regular meetings between ministers, senior officials and the CQC leadership. I conclude that this recommendation is implemented.

8.14 Foundation Trust Governors

8.14.1 *Recommendation 74, 75, 76 concerned the need for guidance for NHS Foundation Trust governors and on communication with the public to obtain and be informed by their views*

(a) There is guidance available for Foundation Trust governors, but it is quite difficult to follow. The basic guide available via NHS England's website[173] was published in 2013 by Monitor. In 2022, instead of producing entirely new guidance to reflect to different landscape of the NHS now prevailing the NHS England webpage[174] advises governors on their duties with regard to that, but by reference to the old 2013 guide. There does not appear to have been any updating by either the DHSC or NHS England of the original 2013 guidance before 2022. NHS Providers, however, offer a variety of guidance which has appeared at a variety of dates [see below]. The response to the consultation leading to the 2022 guidance made this revealing observation:[175]

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[172] https://www.england.nhs.uk/publication/everyone-counts-planning-for-patients-201415-201819/ For access to all planning guidance to date see https://www.england.nhs.uk/operational-planning-and-contracting/ For a contemporaneous commentary on this see Collin *The Foundation Trust Model – death by a thousand cuts* 15 February 2016 The King's Fund https://www.kingsfund.org.uk/insight-and-analysis/blogs/foundation-trust-model [downloaded 26 February 2024]

[173] https://www.england.nhs.uk/long-read/addendum-to-your-statutory-duties-reference-guide-for-nhs-foundation-trust-governors/

[174] Also downloadable as a pdf file: NHS England *Addendum to Your statutory duties – reference guide for NHS foundation trust governors - System working and collaboration: role of foundation trust councils of governors* 27 October 2022 Publication reference PR2077 https://www.england.nhs.uk/wp-content/uploads/2022/10/B2077-addendum-to-your-statutory-duties-reference-guide-for-nhs-foundation-trust-governors-october-22 .pdf [downloaded 27 February 2024]

[175] NHS England *Response to NHS England governance consultations* 27 October 2022 PR2078, page 7 §18 https://www.england.nhs.uk/long-read/developing-trust-governance-consultation-response/

Some responses disagreed with the descriptions of the statutory duties themselves, notably the duty to hold non-executives to account for the performance of the board (these were not in scope for the consultation). Foundation trust governors were introduced in 2004, with the latest guide for governors published in 2012. How they undertake their role has likely evolved over nearly two decades and there may be variation across the sector in how different governors and councils carry out their role. We will consider this in further work.

(b) This supports my admittedly distant impression that there has been considerable variability between Trusts with regard to the functioning of the board of governors.

8.14.2 *Recommendations 77, 78 recommended a review of the training and support available to governors to enhance their independence*

NHS Providers offers training for governors branded as "*Governwell*".[176] This offers a range of resources, including guides on topics, newsletters and an induction toolkit. I have not examined the quality of this offering. A Panel for advising governors was set up in 2013 to answer questions about whether a trust has failed or is failing to act in line with its constitution or chapter 5 of the NHS Act 2006[177]. It was also tasked with determining governor election challenges. It has a formal process, requiring more than half the governors board to agree to a referral. Its 2014/2015 report stated that in the preceding year it had received 12 enquiries, none of which fulfilled the requirements of the Act. I could find no evidence of any later report or indeed of subsequent activity. If this body still exists it had a much narrower function than I have envisaged in my recommendation, but in fairness it may be that Governwell does provide wider support than this Panel.

[176] https://nhsproviders.org/development-offer/governwell/what-is-governwell

[177] NHS Act 2006 section 39A

8.15 Fit and proper person test for directors

8.15.1 *Recommendations 79, 80, 81, 82, 83, 84, 85, 86, 218, 219, 220, 221 recommended the introduction of a fit and proper person test for directors, which should include a requirement to comply which a prescribed code of conduct for directors. Serious misconduct or incompetence as a director should also be grounds for disqualification from being appointed to such a post. I also recommended the development of codes of conduct and consideration of regulation of managers*

(a) The relevant fitness requirement was enacted as regulation 5 of the CQC (Regulated Activities) Regulations 2014. Unless an individual satisfies all its conditions service provider must not appoint or have them in place as a director. The conditions include a requirement to have the necessary qualifications, competence and skills and also that "*the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity*."[178]

(b) While this was a complete implementation of the recommendation with regard to the modification of the fit and proper person test, it has proved difficult to enforce these requirements effectively in practice. In particular it is often challenging for organisations either to obtain relevant information from previous employers or to investigate disputed concerns sufficiently. In 2019 the Kark Review[179] concluded that the regulation did not ensure that directors were fit and proper persons or stop unfit persons "*moving around the system*". It pointed out that there were no criteria for competence, there was no central database or other accessible history of each director, the quality of information available was very variable, and there were considerable difficulties investigating conduct occurring at an organisation.

[178] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 SI 2936 reg 5(3)(d)

[179] Kark and Russell, *A review of the Fit and Proper Person Test* https://assets.publishing.service.gov.uk/media/5c937b7e40f0b633f5bfd89c/kark-review-on-the-fit-and-proper-persons-test.pdf [downloaded 28 February 2024]

(c) Among the Kark recommendations was a suggestion that a Health Director's Standards Council should be created with the power to suspend or disbar directors for serious misconduct. As had been the case with my suggestions for regulation, this recommendation was not accepted by the Secretary of State, but was referred to Baroness Harding, then Chair of NHS Improvement, as part of her consideration of the NHS workforce implementation plan. In the 2020/21 People Plan it was stated that NHS England and NHS Improvement had completed the engagement exercise commissioned by the DHSC in response to the Kark review, and were working with the Department to finalise a response to the review's recommendations, which was to be published "*shortly*".[180]

(d) That response[181] to the Kark review took until 2023 to be produced. It is a framework setting out in considerable detail how an assessment of fitness should be conducted. For example, in considering character organisations are required to consider employment tribunal judgements relevant to the appointee's history, settlement agreements relating to the dismissal and departure from any healthcare service, adherence to the Nolan principles, adverse findings or settlements in civil proceedings, and whether they have been disciplined previously. The framework also lists factors relevant to whether there has been serious misconduct, including bullying, harassment, disregard of appropriate governance standards, and repeated tolerance of poor practice.

(e) Assessment of competence is to be guided by NHS England's Leadership Competency Framework, and detailed and informative references should be obtained using a template provided. The NHS Electronic Staff Record is to be enhanced to include and maintain information relevant to this assessment. This Framework was published on 28 February 2024[182] and has six domains:

- *Driving high-quality and sustainable outcomes*
- *Setting strategy and delivering long-term transformation*
- *Promoting equality and inclusion, and reducing health and workforce inequalities*
- *Providing robust governance and assurance*
- *Creating a compassionate, just and positive culture*
- *Building a trusted relationship with partners and communities.*

(f) A Board Member Appraisal Framework is promised for the autumn of 2024.

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[180] NHS *We are the NHS: People Plan for 2020/2021 – action for us all.* July 2020 Publishing approval reference 0067 page 30 https://www.england.nhs.uk/wp-content/uploads/2020/07/We-Are-The-NHS-Action-For-All-Of-Us-FINAL-March-21.pdf [[downloaded 28 February 2024]

[181] NHS England *Fit and Proper Person Test Framework for board members* 2 August 2023 Publication reference PRN00238 https://www.england.nhs.uk/wp-content/uploads/2024/01/PRN00238i-kark-implementation-fit-and-proper-person-test-framework-v1.1.pdf [downloaded 28 February 2024]

[182] NHS England *NHS leadership competency framework for board members* 28 February 2024 https://www.england.nhs.uk/wp-content/uploads/2020/07/We-Are-The-NHS-Action-For-All-Of-Us-FINAL-March-21.pdf [downloaded 28 February 2024

(g) The Framework also describes the role of the CQC. This is not to investigate an individual's fitness themselves, but to consider whether the organisation's processes of assessment are, in a term favoured in the NHS, "*robust*" and whether a decision taken is reasonable. If they are not satisfied then they can take regulatory action.

(h) It can be seen, therefore, that while the Framework is a considerable improvement on what went before, the Kark recommendation of a regulatory body to suspend or disbar directors has not been adopted. As a result the Framework arguably does not overcome the serious practical challenges in investigating allegations of misconduct occurring in a separate employing organisation.

(i) Implementation of my recommendation for a code of conduct for directors was recently reviewed on behalf of the House of Commons Health and Social Care Select Committee by its independent expert panel.[183] They concluded that:

> *The publication of the Framework is a significant step forward that will help clarify what good practice looks like for board members.*

They considered on the evidence they received that there were "*useful*" guidelines and frameworks to draw upon in regard to conduct, ethics and standards for senior leaders. However, they noted a disparity between what the Governments stated it had delivered and the perception of some stakeholders, which suggested to them there were issues about enforcement and lack of investment in training. In particular they considered that the Framework did not fully meet that part of my recommendation referring to a code of conduct, ethics and professional standards, and means of ensuring compliance and enforcement. The Professional Standards Authority, which had produced professional standards for members of NHS Boards and commissioning bodies in 2013 at the Government's request, told the Panel that they did not think the recommendation had been fully implemented: their Standards had not been aimed at managers below board level, and there had been no progress towards any form of statutory scheme. They feared their Standards had fallen out of use and in effect had not been implemented.[184]

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[183] HSCSC, *Expert Panel: Evaluation of the Government's progress on meeting patient safety recommendations*, 19 March 2024, HC 362 page 16 https://committees.parliament.uk/publications/44002/documents/217961/default/ [downloaded 23 March 2024]. I am a member of the core panel of independent experts, but stood back from this inquiry in view of my authorship of some of the recommendations being examined, including in this area.

[184] PSA, *Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England*, November 2013 https://www.professionalstandards.org.uk/docs/default-source/publications/standards/standards-for-members-of-nhs-boards-and-ccgs-2013.pdf?sfvrsn=d5f77f20_2 [downloaded 23 March 2024]

(j) For the record I should make it clear that I saw the recommendation for a code of conduct as focussing on senior management and leadership and Board level or its equivalent, rather than lower positions in organisations. While a case could be made for spreading a similar requirement throughout an organisation, I felt that the important place to start would be at the senior level. To that extent, therefore, I would respectfully disagree with the PSA view. However, I agree that such steps as may have been taken to ensure enforcement of the code have been ineffective. My suggestion of using the Fit and Proper Person Test has been tried, but as demonstrated by the Kark review, this has not been successful. I consider the time has now come to consider seriously some form of statutory regulation.

(k) The effect of the developments described is or should be that an individual who does not have the required character or competence, or has a history of serious misconduct faces removal or barring from a director's position. The circumstances in which that is likely to happen are as of today clearer than they were when regulation 5 was introduced, through guidance and the Framework, and an understanding of the requirements to be a director are more readily available through training. There is, or can be expected to be, a better system of sharing relevant information about directors through the Electronic Staff Record. It has yet to be established that it is now any easier to enforce this regulation in practice. I remain doubtful.

8.16 Health and Safety Executive

8.16.1 *Recommendations 87 to 90*

These concern the Health and Safety Executive and unless asked to do so I shall refrain from commenting on them.

8.17 Risk management

8.17.1 *Recommendations 91, 92 concerned the introduction and incentivisation for proper risk management standards*

(a) As stated in the schedule the NHSLA, now NHSR, has moved away from assessment against risk management standards and focuses more on outcomes. Likewise risk management as a concept has increasingly been subsumed into the area of clinical governance.

(b) NHS has in recent years focused on seeking to encourage improvement in safety in maternity services, unsurprisingly given the enormous cost in litigation claims in that area. In 2017 NHSR started a Maternity Incentive Scheme since when it has set participants 10 safety actions to perform for which they are given the incentive of a reduction in their indemnity contribution. In the past, two of those actions have concerned having appropriate workforce planning in place and a third compliance with the Saving Babies Lives Care Bundle.[185] The scheme works on the basis of self-assessment, and a 2020 evaluation[186] recognised that recent examples of poor governance from trusts meant that further action was required. However the self-assessed results are subjected to "*external validation*" by NHSR on three of the 10 actions and "sense checked with CQC" before the results are finalised. The 2020 evaluation found that in 2019 117 out of 130 trusts had certified they had achieved all 10 actions; providers highlighted benefits of the scheme including an improvement in safety culture, in board engagement in maternity issues, funding for additional maternity posts and a positive influence on multi-disciplinary working. The guidance for the 2024 scheme has just been published.[187] This requires Trusts to meet standards for their obstetric medical, anaesthetic medical, neonatal medical, and neonatal nursing workforce standards. For example Trust Boards are required to formally record compliance with BAPM nursing staffing standards using the Neonatal Nursing Workforce Calculator. An 18 month evaluation process was started in 2023.[188]

8.17.2 *Recommendation 93 suggested the NHSLA should produce guidance on staffing levels*

NHSLA has not done this, and the Government has not required it to do so. However, as described above, NHSR has adopted the workforce guidance of other organisations into its maternity (and perinatal) incentive scheme. More general staffing guidance is produced by NHS England; see my commentary on the recommendations of the Clothier inquiry [above].

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[185] NHSR, *Maternity Incentive Scheme (MIS) Year 6*, 2 March 2024, https://resolution.nhs.uk/wp-content/uploads/2024/04/MIS-Year-6-Summary-for-Trusts-2-March-2024.pdf [downloaded 12 April 2024]

[186] NHSR, *Maternity incentive scheme – an interim evaluation*, April 2020 https://resolution.nhs.uk/wp-content/uploads/2020/05/Maternity-Incentive-Scheme.pdf [downloaded 12 April 2024]

[187] NHSR, *Maternity (and perinatal) Incentive Scheme Year Six*, 26 March 2024 https://resolution.nhs.uk/wp-content/uploads/2024/04/MIS-Year-6-guidance.pdf [downloaded 12 April 2024]

[188] https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-trusts/maternity-incentive-scheme/ [updated 10 April 2024, accessed 12 April 2024]

8.17.3 *Recommendation 94 suggested that NHSLA should retain a running record and database of the evidence reviewed in claims*

Recently, with my support, NHSR and GIRFT [Getting It Right First Time, a programme of NHS England, led by Professor Tim Briggs] published a guide on learning from litigation claims.[189] It sets out a process whereby NHSR claims handlers can feed back learning points to the Trusts concerned., which, if implemented effectively, should meet this recommendation.

8.17.4 *Recommendation 95 and 96 suggested that NHSLA should make its assessments of trusts available to CQC, and its risk management reports in relation to Trusts participating in its indemnity scheme*

The Government's response suggest that these recommendations have been implemented but, if relevant, evidence should be sought of how these points are put into practice. NHSR intends to publish the results for each Trust of the Maternity Incentive Scheme, and there is an appeal process for those dissatisfied with the information to be published.

8.18 Patient safety functions

8.18.1 *Recommendation 97 to 104 concerned various aspects of the work of the National Patient Safety Agency which were considered in more detail in Chapter 17 of my report*

By the time my report was published the National Patient Safety Agency was closed and its functions were merged into the NHS Commissioning Board [NHS England] in 2012. A summary of how NHS England handles issues of patient safety can be found on their website, and aspects have been discussed above.[190]

8.18.2 *Recommendation 105 was that the consideration be given to whether use of incident reports could enhance consideration of the hospital mortality rate*

(a) This arose out of my finding that the NPSA was unaware of the Hospital Standardised Mortality Rate but did receive incident reports about hospital deaths. It seemed to me that examination of actual cases could help explain the statistics. Changes in expectations made since have gone well beyond this recommendation but appear to have been variably implemented by different organisations.

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[189] GIRFT-NHSR *Learning from Litigation Claims* May 2021 [downloaded 28 February 2024] https://gettingitrightfirsttime.co.uk/wp-content/uploads/2021/05/Best-practice-in-claims-learning-FINAL.pdf [

[190] https://www.england.nhs.uk/patient-safety/the-nhs-patient-safety-strategy/

(b) In 2016 CQC reviewed the way in which trusts investigated hospital deaths and concluded that opportunities for learning were being missed. Their report[191] observed that there was no single framework for NHS Trusts setting out what they need to do to maximise the learning from deaths that maybe the result of problems in care. The review was unable to identify any Trust that could demonstrate good practice across all aspects of identifying, reviewing and investigating deaths and ensuring that learning was implemented.

(c) Trust boards have a major role in ensuring that there is a just learning culture within their organisations, and that opportunities to learn are maximised with improvements in care clearly evidenced. In addition, they need to make sure they keep all deaths in care under review, share learning and act on recommendations both within and beyond their trust.

(d) One of their recommendations was that leaders of national oversight bodies with the Royal Colleges and families develop a single framework on learning from deaths. Another was that NHS Digital and NHS Improvement assess how they could facilitate reliable and timely systems so information about a death became available to all providers involved in the patient's care and that a standard set of information on patients who have died could be collected and analysed. Finally it was recommended that provider boards should ensure:

- *Patients who have died under their care are properly identified;*
- *Case records of all patients who have died are screened to identify concerns and possible areas for improvement and the outcome documented;*
- *Staff and families/carers are proactively supported to express concerns about the care given to patients who have died;*
- *Appropriately trained staff are employed to conduct investigation;.*
- *Where serious concerns about a death are expressed, a low threshold should be set for commissioning an external investigation;*
- *Investigations are conducted in a timely fashion, recognising that complex cases may require longer than 60 days;*
- *Families and carers are involved in investigations to the extent that they wish;*

[191] CQC *Learning, Candour and Accountability – a review of the way NHS Trusts review and investigate the deaths of patients in England* December 2016 https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf [downloaded 28 February 2024]

- *Learning from reviews and investigations is effectively disseminated across their organisation, and with other organisations where appropriate;*

- *Information on deaths, investigations and learning is regularly reviewed at board level, acted upon and reported in annual Quality Accounts;*

- *That particular attention is paid to patients with a learning disability or mental health condition.*

(e) The Royal College of Physicians at the same time started a national review of mortality case records, completed in 2019, which developed a Structured Judgement Review [SJR] process to review care received by patients who had died.[192]

(f) In 2017 the National Quality Board published national guidance on learning from deaths.[193] This commended the Structured Judgment Review process and offered training in the process. The guidance set out clear criteria for deaths which should be subject to a structured case note review. At a minimum, providers should require reviews of (emphasis as in the original]:

i. *all deaths where **bereaved families and carers, or staff, have raised a significant concern about the quality of care provision**;*

ii. *all in-patient, out-patient and community patient deaths of those with **learning disabilities** ….*

iii. *all deaths in a **service specialty, particular diagnosis or treatment group where an 'alarm' has been raised** with the provider through whatever means (for example via a Summary Hospital-level Mortality Indicator or other elevated mortality alert, concerns raised by audit work, concerns raised by the CQC or another regulator)*

iv. *all deaths in areas where people are **not expected to die**, for example in relevant elective procedures;*

v. *deaths where **learning will inform the provider's existing or planned improvement work**,…*

vi. ***a further sample of other deaths** that do not fit the identified categories so that providers can take an overview of where learning and improvement is needed most overall. This does not have to be a random*

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[192] For details see https://www.rcplondon.ac.uk/projects/national-mortality-case-record-review-programme

[193] NQB *National Guidance on Learning from Deaths* March 2017 1st edition https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf [downloaded 28 February 2024]

sample and could use practical sampling strategies such as taking a selection of deaths from each weekday.

(g) CQC reviewed the implementation of this guidance in 2019 and found that while good progress was being made by some hospital trusts *"failure to embrace an open and learning culture may be holding organisations back from making the required changes at the pace needed."* [194]

(h) A recent paper[195] on structured case note review used at a district general hospital concluded that:

The SCNR process is a tool that can identify poor systems and practice that otherwise pass unnoticed.

8.19 Hospital Associated Infection management

8.19.1 *Recommendations 106-108 concern arrangements for sharing information across hospitals about infections*

(a) NICE issued quality standards in relation to the control of hospital acquired infections in 2016.[196] Since 2017 provider trusts have been required to provide information about patients contracting one of the most common hospital associated infections, *clostridium difficile*, and also gram-negative bloodstream infections.

(b) The NHS Standard Contract has included increasingly detailed quality requirements to minimise infection rates since at least 2013.[197] In 2022 DHSC issued a detailed statutory Code of Practice[198] on infection prevention and control; it also brought together a compendium of relevant guidance. This includes requirements for keeping and analysing data at Board level. The Code also emphasises the need for an exchange of information between primary and hospital care settings. A national point prevalence survey has been conducted

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[194] CQC *Signs of progress on learning from deaths - but a more open learning culture is needed across the NHS to drive further improvement* 18 March 2019 Press release https://www.cqc.org.uk/news/releases/signs-progress-learning-deaths-more-open-learning-culture-needed-across-nhs-drive [accessed 28 February 2024]

[195] Gallegos et al, *A review of deaths in surgery using the structured judgement case note review process* June 2023 The Bulletin of the Royal College of Surgeons of England, vol 105 issue 4 203-207 https://publishing.rcseng.ac.uk/doi/epdf/10.1308/rcsbull.2023.71 [downloaded 28 February 2024]

[196] NICE *Healthcare-associated infections* 11 February 2016 QS113 https://www.nice.org.uk/guidance/qs113/resources/healthcareassociated-infections-pdf-75545296430533

[197] NHS England, *Minimising Clostridioides difficile and Gram-negative bloodstream infections* May 2023 Version 1 PR 00150 https://www.england.nhs.uk/wp-content/uploads/2021/08/PRN00150-NHS-Standard-Contract-202324-Minimising-Clostridioides-difficile-and-Gram-negative-bloodstream-infect-1.pdf [Accessed 29 February 2024] See *NHS Standard Contract 2023/24 Service Conditions (Full Length)* § SC21 Infection Prevention and Control and Staff Vaccination, version 1 March 2023 https://www.england.nhs.uk/wp-content/uploads/2023/04/03-nhs-standard-contract-fl-scs-2324.pdf [accessed 29 February 2024] and for all versions of the contract from 2013 to date https://www.england.nhs.uk/nhs-standard-contract/

[198] DHSC *Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance* 13 December 2022 https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance/health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance#appendix-e-regulations-extract

annually on healthcare associated infections since 2016 with a view to supporting surveillance and training.[199]

(c) However there is cause for concern at the system's ability to detect and treat sepsis. A very recent report in the Health Service Journal suggests that *"major progress in sepsis care during the previous decade has been significantly reversed"* and reported that in 31 inquests in the last five years coroners have warned of systemic issues.[200]

8.20 Management of large scale failures

8.20.1 *Recommendation 122 and 138 made suggestions of measures that needed to be in place to manage large scale failure of clinical services and the need for the National Quality Board to have primary responsibility but for commissioners to have plans for responding to this sort of failure*

(a) The changes referred to in the Schedule addressed how the regulators should address failure through the "*special measures*" regime. This may have provided a framework within which large scale provider failure could be managed but not much about how this would be used. In March 2013 Monitor produced guidance[201] on ensuring continuity of care services in the event of financial failure, but so far as I can discern this did not address serious failures in quality and safety. The NHS Oversight Framework now contains the basis on which support and intervention is provided by NHS England and ICBs in the event of serious concerns arising – see the next section.

(b) For further discussion see a commentary[202] on the failure regime shortly after my report and Professor Sir Chris Ham's Kings Fund article on the topic.[203]

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[199] UK Health Security Agency *Point Prevalence Survey on Healthcare Associated Infections, Antimicrobial Use and Antimicrobial Stewardship in England Protocol, 2023* contains the results since 2016 https://www.gov.uk/guidance/point-prevalence-survey-on-hcai-amu-and-ams-in-england

[200] Townsend, *Over 30 sepsis deaths linked to 'systemic' failings, investigation reveals* 27 February 2024 Health Service Journal https://www.hsj.co.uk/patient-safety/over-30-sepsis-deaths-linked-to-systemic-failings-investigation-reveals/7036636.article [downloaded 1 March 2024]

[201] Monitor, *Guidance for commissioners on ensuring the continuity of health care services* 28 March 2013 https://www.england.nhs.uk/wp-content/uploads/2021/01/ToPublishFinalCRSGuidance28March13.pdf [accessed 29 February 2024]

[202] Imison, *The NHS failure regime: what have we learnt so far?* 2 May 2013 The King's Fund https://www.kingsfund.org.uk/insight-and-analysis/blogs/nhs-failure-regime-what-have-we-learnt-so-far [accessed 29 February 2024]

[203] Ham, *A system response to provider failure: does Greater Manchester point to a different future?* 13 October 2017 The King's Fund https://www.kingsfund.org.uk/insight-and-analysis/blogs/system-response-provider-failure-does-greater-manc[dhester-point-to-different-future [downloaded 29 February 2024]

8.21 Commissioning and performance oversight for standards

8.21.1 *Recommendations 123 to 144 concerned the enhanced role I envisaged commissioners and performance managers having in ensuring that the services they commissioned and oversaw were provided to the appropriate standards and for them to monitor the quality and safety of provision as well as undertake procurement*

At the time of the events on which I reported commissioning of NHS hospital services was carried out by Primary Care Trusts. I found that while they had a theoretical duty to monitor the quality of commissioned services it was less than clear what this involved and was the subject to constant change in expectations. In any event effective monitoring was largely absent in the case of this Trust.[204] By the time I reported the system had been changed by the creation of NHS England, with its regional offices and Clinical Commissioning Groups (CCGs), intended to be led by local general practitioners, taking over the functions of Primary Care Trusts, in many cases with fewer staff and loss of corporate memory. More recently the system has changed again with the introduction of Integrated Care Boards in place of CCGs and subsequent NHS Oversight Framework.[205] I am not clear that, whatever the organisation responsible for commissioning, performance of the duty to monitor quality and safety has changed significantly. My impression is that the principal safeguard in this regard is the Care Quality Commission with performance management oversight provided by NHS England, via its regional offices. While concerns about safety are mentioned in the Framework, I observe that they appear not to be emphasised as a priority over other areas of concern.

Healthwatch and local scrutiny

8.21.2 *Recommendations 145 to 150 included suggested improvements to the roles of local scrutiny committees and Healthwatch*

At the time of my report Healthwatch had recently succeeded to Patient and Public Involvement Forums [PPIF] and Local Involvement Networks [LiNKs]. No forum involving local patients had detected the very significant dissatisfaction of some patients and their families, and I felt changes were needed to increase the chances of such concerns being picked up. My recommendations have only been implemented in part:

(a) The Government rejected the proposal that local Healthwatch should have a consistent structure throughout the country; instead it is a service which is commissioned by local authorities who put contracts out to tender, resulting in

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[204] See chapter 7 §7.38 et seq of my report.

[205] The current oversight framework is the *NHS Oversight Framework* 27 June 2022 https://www.england.nhs.uk/wp-content/uploads/2021/01/ToPublishFinalCRSGuidance28March13.pdf [downloaded 29 February 2024] refers to a "greater emphasis on system performance and quality of care outcomes" [§11] and to ICBs "assessing delivery against these domains [in the Framework]" and liaising with NHS England about action to be taken over "concerns" with it being the responsibility for "a material concern with regard to quality or safety" to be shared between ICS and Trusts [see page 14],. These can lead to the provision of "enhanced direct oversight" and/or "mandated support" [§37]

different arrangements throughout the country, causing, in my view considerable public confusion about their role and significance.

(b) The Government also rejected the proposal that the funds allocated by the DHSC for local Healthwatch should be ringfenced, with local authorities, to which these funds are paid, being obliged to hand them over to their local Healthwatch. Instead and inevitably, funding has been steadily reduced to many local Healthwatch as local authority budgets have come under increasing financial pressure. Healthwatch England has recently reported[206] that the budget for the Healthwatch network is now 43% of what it was in 2013/14 in real terms and that local authorities often top slice Healthwatch budgets because of their own financial pressures. Some authorities are unable to award tenders as no viable Healthwatch is willing to deliver a service on the funding offered.

(c) The transparency promised in the Government's response has not occurred in practice: Healthwatch England, which tries to track local Healthwatch funding, has enormous difficulty in identifying how much of the funding issued by DHSC actually arrives at local Healthwatch, and I suspect that DHSC does not really know much more either.

(d) With regard to training, Healthwatch England does provide training for local Healthwatch and other forms of support.

(e) I regret to say that I am unable to say whether there have been improvements in the resourcing and performance of local scrutiny committees, but could investigate this is asked to do so.

8.22 Medical education and training

I do not believe that progress on recommendations 153 to 161 on this topic is an issue likely to assist the Inquiry, save to note that I believe that considerable progress has been made on the part of the GMC in ensuring that organisations hosting medical trainees are suitable and safe places for such training to take place.[207] They have published training standards expected of all schools.[208] The GMC National Training Survey, started in 2014, is designed to detect cultural issues affecting trainees. The sanction available in the event of concerns being raised is for GMC to withdraw training accreditation which results in trainees having to be transferred elsewhere. While this is rarely done, the possibility is a serious incentive to providers to maintain proper standards. The GMC now publishes

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[206] Healthwatch England, *Local Healthwatch funding 2023-24 – A precarious future for patient engagement*, 28 February 2024, https://www.healthwatch.co.uk/report/2024-02-28/local-healthwatch-funding-2023-24 [downloaded 12 May 2024]

[207] For the GMC's responses to my recommendations, and those of the Berwick, Cavendish and Clwyd/Hart reviews see https://www.gmc-uk.org/-/media/documents/final-francis-public-response_pdf-51728757.pdf 2013 ; https://www.gmc-uk.org/-/media/documents/gmc-update-on-francis-recommendations---final_pdf-53738187.pdf 2013; https://www.gmc-uk.org/-/media/documents/gmc-12-month-update-on-francis-recommendations---final-web-copy_pdf-55890404.pdf 2014 ; https://www.gmc-uk.org/-/media/documents/francis-18-month-update-annex_pdf-58194194.pdf October 2014.

[208] GMC, *Promoting excellence: standards for medical education and training* 15 July 2015 https://www.gmc-uk.org/-/media/documents/promoting-excellence-standards-for-medical-education-and-training-2109_pdf-61939165.pdf [downloaded 2 March 2024]

quality assurance reports on all medical schools.[209] It also publishes annual reports on the state of medical education and practice in the UK. The 2023 report paints a grim picture of working conditions for trainee doctors.[210]

8.22.1 *Recommendations 170 to 171 addressed suggested changes in membership of Health Education England and Local Education and Training Boards, and qualifications which do not require further comment*

8.22.2 *Recommendation 172 suggested that consideration be given to introduction of a common English language proficiency requirement for all those providing healthcare*

As the Schedule points out requirements are in place for this with regard to doctors. For other staff:

(a) The Nursing and Midwifery Council Code of Conduct requires registered nurses to be able communicate clearly and effectively in English[211] and published a consultation on its English Language standards in August 2022.[212] To be registered as a nurse or midwife a person must be able to show that they know enough English to practice safely and effectively in that role to the standard of level C1 of the common European Framework of Reference for Languages (CEFR).[213]

(b) Occupations regulated by the Health and Care Professions Council are required, if English is not their first language, to self-certify proficiency, supported by evidence by proof of a completed test with shows they meet the minimum standards required for their profession.[214] The HCPC has recently closed a consultation on proposals to strengthen their requirements.[215] This has met with a mixed response from NHS Providers.[216] Applicants for a health and care worker visa are required to prove their knowledge of English to level B1 on the CEFR scale, unless a national of specified, English speaking, countries.[217]

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[209] See https://www.gmc-uk.org/education/how-we-quality-assure-medical-education-and-training/evidence-data-and-intelligence/proactive-quality-assurance-published-documents for these reports.

[210] See https://www.gmc-uk.org/about/what-we-do-and-why/data-and-research/the-state-of-medical-education-and-practice-in-the-uk [accessed 2 March 2024]

[211] NMC The Code - *Professional standards of practice and behaviour for nurses, midwives, and nursing associates* §7.5 2018 https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf [downloaded 2 March 2024]

[212] NMC, *English Language Standards Consultation - A report by BritainThinks on behalf of The Nursing and Midwifery Council* August 2022 https://www.nmc.org.uk/globalassets/sitedocuments/english-language/britain-thinks-report.pdf [accessed 2 March 2024]

[213] This requirement was inserted in the regulations in 2015: see The Nursing and Midwifery Order 2001 SI 252 Article 9(ba) NMC unofficial consolidated text effective from 24 March 2022 . https://www.nmc.org.uk/globalassets/sitedocuments/ftp_information/old-archived-guidance/the-nursing-and-midwifery-order-2001-consolidated-text.pdf?_t_id=rYSMkpZPgM-vDKRimNjqiQ%3d%3d&_t_uuid=6mdQiB5ySxSD_QTBLsbGOA&_t_q=nursing+order&_t_tags=language%3aen%2csiteid%3ad6891695-0234-463b-bf74-1bfb02644b38%2candquerymatch&_t_hit.id=NMC_Web_Models_Media_DocumentFile/_85bd73f3-0f17-4e89-ba2e-6d01138d98f8&_t_hit.pos=4 ; *Guidance on registration language requirements* updated June 2023 https://www.nmc.org.uk/globalassets/sitedocuments/registration/language-requirements-guidance.pdf

[214] See https://www.hcpc-uk.org/news-and-events/news/2022/statement-on-english-language-proficiency-requirements-for-internationally-trained-health-and-care-professionals/ [accessed 2 March 2024]

[215] https://www.hcpc-uk.org/news-and-events/consultations/2023/consultation-on-english-language-proficiency/ [accessed on 2 March 2024] The consultation closed on 19 January 2024

[216] https://www.nhsemployers.org/news/nhs-employers-responds-hcpc-english-language-proficiency-consultation 23 January 2024 [accessed 2 March 2024]

[217] See https://www.gov.uk/health-care-worker-visa/knowledge-of-english

8.23 Openness, transparency and candour

8.23.1 *Recommendations 173 to 184 were detailed proposals for the introduction of a statutory duty of candour on organisations, and a duty to be open and honest in all communications about the service*

(a) As noted above recommendations for such a duty had been made by the Bristol Inquiry but not implemented. It was my view that the events at the Mid Staffordshire NHS Foundation Trust demonstrated beyond argument the need for such a duty. As indicated in the Schedule the Government reflected at least the theory of these recommendations by introducing a duty of candour into the Health and Social Care (Regulated Activities) Regulations.[218]

(b) The requirements of openness and honesty in all communications were included in the NHS Constitution:

(i) Patients were told they had a right to

> *… an open and transparent relationship with the organisation providing your care. You must be told about any safety incident relating to your care which, in the opinion of a healthcare professional, has caused, or could still cause, significant harm or death. You must be given the facts, an apology, and any reasonable support you need.*

(ii) The NHS pledged to promote supportive and open culture that help staff do their job.

(iii) Staff were under a duty to be honest and truthful in applying for a job and in carrying it out, and to "aim" to be

> *open with patients, their families, carers or representatives, including if anything goes wrong; welcoming and listening to feedback and addressing concerns promptly and in a spirit of co-operation*

and to

> *contribute to a climate where the truth can be heard, the reporting of, and learning from errors is encouraged and colleagues are supported when errors are made.*

[218] Regulation 2

(c) The CQC issues guidance on the statutory duty candour,[219] the compliance with which it regulates. It points out that the duty arises when an incident which has occurred during the provision of a regulated activity, is unintended or unexpected and has or might result in death, severe or moderate harm to the patient. Even if one of these criteria is not present there is an overarching duty to be open and transparent. The duty is triggered by an incident, not its outcome. CQC has also endorsed guidance for patients prepared and published by Action against Medical Accidents [AVMA].[220]

(d) Although I have been unable to find an analysis showing the total number of enforcement actions taken by CQC in relation to the duty of candour – and their list of prosecutions to date does not explicitly list any for a breach of this regulation. However CQC is prepared to take action in some cases:

(i) It was reported in February 2019 that for the first time it had issued a fixed penalty notice for a failure to apologise to the family of a baby boy within a reasonable period.[221]

(ii) In October the same year it issued 13 such notices to a different trust for failing to apologise to patients within a reasonable time. [222]

(iii) In July 2021 it reported issuing 2 more such notices against a different Trust for failing to provide the family of a person who died after complications in childbirth with an account of the incident or offer an apology.[223]

(e) While the Government accepted the recommendations with regard to the organisational duty of candour in principle, it did not implement anything which gives the patient a remedy for a breach of that obligation affecting them individually.

(f) The Government declined to create offences in relation to individual healthcare professionals for providing misleading information to patients, obstructing others in the performance of their statutory duties of candour and openness, or making dishonest statements to commissioners or regulators, on the ground that such matters were sufficiently covered by the powers of professional regulators.

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[219] GMC *Regulation 20 – duty of candour* updated 30 June 2022 https://www.cqc.org.uk/sites/default/files/2022-12/20220722-duty-of-candour-pdf-version-FINAL-2.pdf [downloaded 2 March 2024]

[220] AVMA *The Duty of Candour* 26 June 2023 https://www.avma.org.uk/wp-content/uploads/Duty-of-candour.pdf

[221] https://www.pinsentmasons.com/out-law/news/care-quality-commission-issues-first-duty-of-candour-breach-fine

[222] https://www.cqc.org.uk/news/releases/trust-fined-failures-complying-duty-candour-regulation [accessed 2 March 2024]

[223] https://www.cqc.org.uk/news/releases/doncaster-bassetlaw-teaching-hospitals-nhs-foundation-trust-fined-failures-complying

(g) However, the Government did make the provision of misleading prescribed information by a prescribed publicly funded healthcare provider, and if knowingly involved, their directors, an offence, subject to a defence of due diligence.[224] The information prescribed by regulation is currently specified data on clinical outcomes, complaints, waiting times and maternity services, which is required to be submitted by providers to the National Health and Social Care Information Centre,[225] and also information in published Quality Accounts. On conviction, in addition to a fine, or on conviction on indictment up to 2 years imprisonment, the court may make a remedial order requiring the provider to remedy the misleading conduct, any matter appearing to the court to have resulted from the conduct and any deficiency in the management of information in policies systems or practices of which the conduct appears to be an indication. The court may also order a publicity order requiring the provider to publicise the conviction, sentence and remedial order.[226]

(h) Following the inquiry into the case of Elizabeth Dixon the Government again supported the concept of openness and transparency, as part of a just and learning culture as contributing to patient safety. Their response[227] pointed to the Patient Safety Strategy, the work of the CQC, and the promotion by NHS Resolution of that culture.

(i) There is mounting evidence that the duty of candour is not being complied with consistently, effectively or in some cases at all. The recent All-Party Parliamentary Group's report on birth trauma[228] after reviewing multiple distressing accounts of women's experience of maternity services concluded that

> *It is clear that the statutory duty of candour, introduced in the wake of the Francis report, is not being applied effectively*

(j) On 6 December 2023 the Government announced[229] a review of the duty of candour in response to recent critical reports with a view to establishing the extent to which the policy and its design are appropriate for the system, the extent to which the policy is honoured, monitored and enforced, and to what extent it has met its objectives.

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[224] Care Act 2014 section 92; The False and Misleading Information (Specified Care Providers and Specified Information) Regulations 2015 SI 988 as amended [downloaded 3 March 2024]

[225] Now merged into NHS Digital, which in turn has been merged into NHS England with effect from 1 February 2023: https://www.england.nhs.uk/2023/02/nhs-digital-and-nhs-england-complete-merger/

[226] Care Act 2014 section 93

[227] DHSC, Policy Paper. *Government response to the findings of the independent investigation into the death of Elizabeth Dixon*, 11 May 2023, https://www.gov.uk/government/publications/government-response-to-the-investigation-into-the-death-of-elizabeth-dixon/government-response-to-the-findings-of-the-independent-investigation-into-the-death-of-elizabeth-dixon [downloaded 28 March 2024]; for the report see https://assets.publishing.service.gov.uk/media/5fbf9792e90e077edf1127f0/The_life_and_death_of_Elizabeth_Dixon_a_catalyst_for_change_accessible.pdf [downloaded 28 March 2024]

[228] Listen to Mums: Ending the Postcode Lottery on Perinatal Care, A report of The All-Party Parliamentary Group on Birth Trauma, 13 May 2024, https://www.theo-clarke.org.uk/birth-trauma [downloaded 14 May 2024]

[229] https://questions-statements.parliament.uk/written-statements/detail/2023-12-06/hcws100 ; https://www.gov.uk/government/publications/duty-of-candour-review-terms-of-reference/duty-of-candour-review-terms-of-reference 6 December 2023

(k) Allegations still emerge suggesting that "*gagging*" clauses and non-disclosure agreements are still inhibiting some from "speaking up". I have commented elsewhere on the absence, to date, of regulation for health service managers.

(l) In conclusion, the duties of openness, transparency and candour have been clear and applicable throughout the NHS since before 2015. The requirements of candour have been set out in well publicised regulations, guidance and other reports and statements. In spite of that, there have been a number of unfortunate incidents which suggest that these requirements have and are not consistently complied with.

8.24 Recruitment, training and leadership or nurses and healthcare support workers

8.24.1 Recommendations 185 to 213 made detailed recommendations with regard to the recruitment, training, leadership and standing of nurses and healthcare support workers.

I made these recommendations because I found that serious deficiencies in all these aspects had made a significant contribution to the unacceptable standard of service provided to too many patients at Stafford Hospital.

8.24.2 Recommendations 185, 196, 198 sought to ensure that at all stages of their careers the proper practical values of nursing, including compassion were reinforced.

In 2012, in response to the first Mid Staffordshire report, the then Chief Nursing Officer, Jane Cummings, and DH's Director of Nursing, Viv Bennett, launched a campaign to promote the "*6 Cs*" in nursing: care, compassion, competence, communication, courage and commitment. Implementation plans for a three year strategy were promised by March 2013.[230] Annual reports on progress were published and at the end of the period a new framework for nursing and care staff was published.[231] This offered ten "*aspirational*" commitments designed to close what were admitted to be "*three gaps*" identified in NHS England's strategy *Five Year Forward View*:[232] in health and wellbeing, care and quality, and funding and efficiency. Since then there have been many

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[230] DH, NHS Commissioning Board, *Compassion in Practice – Nursing, Midwifery and Care Staff: Our vision and* Strategy. 4 December 2012 https://www.england.nhs.uk/wp-content/uploads/2012/12/compassion-in-practice.pdf [downloaded 4 March 2024] ; NHS England *Care Compassion Competence Communication Courage* Commitment 23 November 2013 https://www.england.nhs.uk/wp-content/uploads/2016/05/cip-one-year-on.pdf [downloaded 4 March 2024]; NHS England, *Compassion in Practice – 2 years on* 24 November 2014 https://www.england.nhs.uk/wp-content/uploads/2016/05/cip-two-years-on.pdf [downloaded 4 March 2024] See also NHS England, *Compassion in Practice – Evidencing the Impact* May 2016 https://www.england.nhs.uk/wp-content/uploads/2016/05/cip-yr-3.pdf [downloaded 4 March 2024]

[231] *Leading Change – Adding Value – a framework for nursing midwifery and care staff* May 2016 https://www.england.nhs.uk/wp-content/uploads/2016/05/nursing-framework.pdf . For a recent exhaustive review of the literature on compassion and how to achieve it see Malenfant et al, *Compassion in healthcare: an updated scoping review of the literature*, 2022 BMC Palliative Care (2022) 21:80 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9116004/pdf/12904_2022_Article_942.pdf [downloaded 4 March 2024]

[232] 24 October 2014 https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf [accessed 4 March 2024]

interventions designed to ensure sharing of good nursing practice, appropriate training, and research to appraise the effect of the strategy.[233]

8.24.3 Recommendation 186 proposed a review by NMC of training standards.

NMC have conducted a number of such reviews since 2014.[234] The first group of standards ["*Platform 1 – being an accountable professional*"] stated that:

> *Registered nurses act in the best interests of people, putting them first and providing nursing care that is person-centred, safe and compassionate. They act professionally at all times and use their knowledge and experience to make evidence-based decisions about care. They communicate effectively, are role models for others, and are accountable for their actions. Registered nurses continually reflect on their practice and keep abreast of new and emerging developments in nursing, health and care.*

It is fair to observe that this succinctly summarised the requirements I was looking for.

8.24.4 Recommendations 187, 188 suggested measures to ensure candidates for a nursing career had the necessary aptitude, values and attitude

(a) These measures included:

(i) a requirement of three months' work care experience under the direct supervision of a registered nurse as an entry level requirement. As noted in the Schedule, the Government proposed a pilot scheme, but there was criticism from the RCN that the recommendation failed to acknowledge practical experience already on offer. However they agreed there was a need to improve the consistency and quality of some practice placement experiences.[235] This may not be the place to debate the merit of my recommendation, but my intention was to ensure that aspiring nurses tested themselves with real life experience of care in a practical setting before embarking on training for a career for which they might not find they were suited. It does not appear that any such requirement has been introduced.[236]

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[233] For a 2019 article on this topic see Garratt, *How the Leading Change, Adding Value framework enables nursing, midwifery and care staff to transform practice* 10 October 2019 2019 BJN issue 18 https://www.britishjournalofnursing.com/content/regulars/how-the-leading-change-adding-value-framework-enables-nursing-midwifery-and-care-staff-to-transform-practice [downloaded 4 March 2024].

[234] NMC *standards framework for nursing and midwifery education* 17 May 2018, updated 25 April 2023 https://www.nmc.org.uk/globalassets/sitedocuments/standards/2023-pre-reg-standards/new-vi/standards-framework-for-nursing-and-midwifery-education.pdf ; NMC *Future nurse – Standards of proficiency for registered* nurses 17 May 2018 https://www.nmc.org.uk/globalassets/sitedocuments/education-standards/future-nurse-proficiencies.pdf ; NMC, *Review of minimum education and training standards in nursing and midwifery – desk based research* September 2021 https://www.nmc.org.uk/globalassets/sitedocuments/education-programme/education-programme-standards-research-sept-2021---harlow-consulting-evidence-review-report.pdf [all these accessed 4 March 2024]

[235] RCN *Mid Staffordshire NHS Foundation Trust Public Inquiry Report – Response of the Royal College of* Nursing Page 33 https://cdn.ps.emap.com/wp-content/uploads/sites/3/2013/07/RCN-response-to-Francis-Inquiry-Report.pdf

[236] See RCN, *Thinking about a career in nursing or midwifery?* 29 April 2019 https://www.rcn.org.uk/professional-development/become-a-nurse#becomeanurse [accessed 4 March 2024]

(ii) I also suggested an aptitude test. Currently the only candidates required to take such a test are internationally registered nurses and midwives.[237] In 2013 the NMC went to consultation[238] on an aptitude test for candidates seeking to register more than five years after obtaining a primary nursing qualification. However a brief examination of training standards documentation published since then suggests that no aptitude test as such has been introduced even for this group. Instead there is a requirement either to take a competence test, or to undertake a return to practice programme. However approved education institutions must comply with specified standards, which include a requirement to confirm on entry to their programme that students d*emonstrate "values in accordance with the [NMC] Code"*.[239]

(b) While an aptitude test is not the only way for aspiring nurses to find out whether this is a career for which they are suited, the only other way to find out is to be exposed to practical experience in caring for patients. While practical training is offered as part of nurse training, it would surely be prudent for the commitment to this vocation was tested before students and train providers alike were committed to each other.

8.24.5 Recommendation 189 - accreditation

This has been implemented in part, in that the NMC accredits education establishments and courses which meet its requirements and standards. However, to my knowledge there is no common examination or assessment.

8.24.6 Recommendation 190: training standards

The NMC sets out training standards,[240] and NHS England promotes its 6 Cs programmes. Health Education England offers certain training modules through universities, for example a three-month module for registered nurses considering a move to general practice nursing, and a "*blended learning nursing degree*" was launched in 2020 to attract those unable to take a conventional nursing training route.[241]

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[237] https://www.nmc.org.uk/globalassets/sitedocuments/registration/overseas/eu-aptitude-test-2021-information-booklet.pdf ; https://www.nmc.org.uk/news/news-and-updates/toc21-materials-published/ 17 March 2021 [both accessed 4 March 2024]

[238] NMC *Report on consultation findings on the introduction of guidance to cover individuals who apply to register qualifications awarded more than five years previously* 5 February 2014 https://www.nmc.org.uk/globalassets/sitedocuments/consultations/2014/report-on-the-five-year-rule-consultation.pdf

[239] NMC, *Applying for registration more than five years after qualifying – standards and guidance,* Updated 12 April 2024, *https://www.nmc.org.uk/globalassets/sitedocuments/registration/registering-more-than-five-years-after-qualifying.pdf* [downloaded 11 May 2024];

NMC, *Standards for return to practice programmes*, 20 May 2019, newly published 25 April 2023, https://www.nmc.org.uk/globalassets/sitedocuments/standards/2024/standards-for-return-to-practice-programmes.pdf [downloaded 11 May 2024]

[240] NMC, *Standards framework for nursing and midwifery education*, 17 May 2018, updated 25 April 2023. https://www.nmc.org.uk/globalassets/sitedocuments/standards/2023-pre-reg-standards/new-vi/standards-framework-for-nursing-and-midwifery-education.pdf [downloaded 12 April 2024]

[241] https://www.hee.nhs.uk/our-work/blended-learning/blended-learning-adult-nursing [accessed 4 March 2024]

8.24.7 Recommendations 190, 191, 192, 193, 194 232 – responsible officers and revalidation

These recommendations suggested organisations should have a responsible officer and/or employment liaison officer for nursing and a revalidation scheme similar to the requirements for registered doctors. NMC set up such a scheme with effect from April 2016.[242] NMC has stated that while preparation for the scheme was already under way, the Mid-Staffordshire report acted as a catalyst for the timing of the introduction of the scheme.[243] The process requires the support of a "*confirmer*" who has to check whether the requirements have been met. This is similar to one of the roles a medical responsible officer has, but does not entirely mirror their responsibilities. NMC does give guidance on how employers should appraise nurses. An evaluation after the first cycle of revalidation found what to me appear to be marginal benefits in terms of encouragement to self-reflect and to consider the NMC Code, and of responsiveness to patient needs. Some of these benefits appeared not to have been sustained, but there has been no further independent evaluation since 2019.

8.24.8 Recommendations 195 recommended that ward nurse managers should be able to devote their time to supervision as opposed to office or direct caring duties.

NHS Improvement published a handbook for ward managers in October 2018.[244] A literature review article in 2019 suggested that development towards this recommendation had ceased.[245]

8.24.9 Recommendations 197, 201, 202, 203, 204, 205, 206 sought to promote the nursing voice and authority at all levels of leadership.

(a) While some progress has been made within the NHS, and leadership development is promoted by among other organisations, the Florence Nightingale Foundation, my recommendation about the organisation of the RCN did not find favour with them.

(b) I believe it remains the case that the nursing profession lacks the equivalent recognition accorded to the medical profession either nationally or locally.

8.24.10 Recommendation 199 recommended that every patient should have a key nurse.

My observation is that this has not been implemented with any consistency.

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[242] See https://www.nmc.org.uk/revalidation/overview/what-is-revalidation/ for details [accessed 4 March 2024]

[243] Ipsos Mori, *Evaluation of revalidation for nurses and midwives – year three report*. July 2019, NMC https://www.nmc.org.uk/globalassets/sitedocuments/annual_reports_and_accounts/revalidationreports/ipsos-mori-revalidation-evaluation-report-year-3.pdf [downloaded 12 April 2024]

[244] https://www.readkong.com/page/the-ward-leader-s-handbook-october-2018-6129590

[245] Regan et al, *Progress on the introduction of supervisory ward manager roles since the Francis report recommendations* 2 June 2019 BJN Vol 28 Issue 11. The article also comments on some of the other nursing recommendations. https://clok.uclan.ac.uk/28942/1/28942%20Supervisory%20ward%20manager.pdf

[accessed 4 March 2024: subscription required for download.]

8.25 Healthcare support workers

8.25.1 Recommendations 209 to 213

(a) The Government rejected recommendation 209 suggesting healthcare support workers [HCSWs] should be regulated by registration, but instead commissioned the Cavendish Review to examine what could be done to ensure that the 1.3 million unregistered, unregulated NHS staff treated service users with care and compassion. Camilla Cavendish was required to complete the review in 14 weeks. She proposed[246] the introduction of a Care Certificate based on common training standards across the system, linking the training with nurse training. She said:

> *it makes no sense to teach nursing students and assistants the practical elements of fundamental care in different languages and separate silos. Airlines learned years ago that the most junior staff are crucial to passenger safety, and adjusted their training accordingly. The same must be done for patient safety. To build the workforce of the future, there is a big opportunity for employers to try and define a golden thread of values and competences that should be common to workers in both health and social care*

(b) She considered it crucial that the system enabled employers to remove with ease staff who were not caring or competent. The Care Certificate was introduced in 2015 and is still in place.[247] Its use is encouraged by the CQC as a means of providers meeting their obligations to induct, support and train their staff appropriately.[248] The Care Certificate has recently been reviewed and is being developed as a Level 2 qualification to provide a route to career progression in adult social care.[249] This is due to be launched in June 2024.[250]

(c) An independent expert review on behalf of the House of Commons Health and Social Care Select Committee has examined progress on induction training; they were not reassured by the evidence presented to them that induction training was to be implemented uniformly across providers: the resourcing for this was not specified, and there was in fact no evidence of funding enabling staff to take up this training.[251]

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[246] Cavendish, *The Cavendish Review, An Independent Review into Healthcare Assistances and Support Workers in the NHS and social care settings*, July 2013, https://assets.publishing.service.gov.uk/media/5a7b9df6e5274a7202e18537/Cavendish_Review.pdf [downloaded 23 March 2024]

[247] See https://www.hee.nhs.uk/our-work/care-certificate [accessed 23 March 2024]

[248] https://www.cqc.org.uk/guidance-providers/our-position-care-certificate [page updated 5 December 2023] [accessed 24 March 2024]

[249] https://www.cqc.org.uk/guidance-providers/our-position-care-certificate [accessed 23 March 2024]

[250] https://www.skillsforcare.org.uk/Developing-your-workforce/Care-Certificate/Care-Certificate.aspx [accessed 23 March 2024]

[251] HSCSC, *Expert Panel: Evaluation of the Government's progress on meeting patient safety recommendations* page 49, 19 March 2024, HC 362 https://committees.parliament.uk/publications/44002/documents/217961/default/ [downloaded 23 March 2024] I am a member of this Panel but took no part in this evaluation.

(d) However, in 2019 a new category of registered practitioner was introduced: nursing associates.[252] This role is designed to "*bridge the gap*" between HCSWs and registered nurses to deliver hands on care. The qualification is a Nursing Associate Foundation degree awarded by an NMC approved provider, which is intended to equip them to "*perform more complex and significant tasks than a healthcare assistant but not the same as a registered nurse.*" The role could also be considered as a step towards a career as a registered nurse. This development is a response to the critical shortage of nursing and care staff,[253] but has not been universally welcomed.[254] In any event it is not a move which addressed what I perceived to be a need for regulation of HCSWs.

8.25.2 Recommendation 210 proposed a code of conduct for HCSWs

This was accepted and a code was developed by SkillsforCare and Skills for Health. The code is not legally binding,[255] but HSCWs are now required to obtain the qualification of the Care Certificate. I am unable to say if employers apply the code consistently. As part of its response to the urgent need to recruit more staff in September 2019 NHS England launched a support programme for HSCWs which seeks to assist them develop their careers.[256]

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[252] See https://www.nmc.org.uk/education/becoming-a-nurse-midwife-nursing-associate/becoming-a-nursing-associate/ [accessed 4 March 2024]

[253] https://www.nhsemployers.org/publications/using-nursing-associate-roles-nhs . For a recent overview of how this role was developed and the position today see Peate, *The registered nursing associate – an overview*, 2 March 2023, BJN Vol 32 Issue 6 https://www.britishjournalofnursing.com/content/nursing-associates/the-registered-nursing-associate-an-overview/ [accessed 4 March 2024]

[254] Launder, *Why nursing associated are splitting opinion*, 1 October 2019 Nursing in Practice https://www.nursinginpractice.com/latest-news/why-nursing-associates-are-splitting-opinion/ [accessed 4 March 2024]

[255] In Scotland a mandatory induction process and code of conduct is in place: https://www.nes.scot.nhs.uk/our-work/healthcare-support-workers-hcsws/ [accessed 4 March 2024]

[256] See https://www.england.nhs.uk/nursingmidwifery/healthcare-support-worker-programme/ [accessed 4 March 2024]

8.26 Leadership training and standards

8.26.1 Recommendations 214 to 221

(a) The essence of these recommendations has been addressed above in connection with the fit and proper person requirements. Recommendation 214 proposed there should be an NHS Leadership Staff College. I envisaged this being similar in methodology to the College of Policing which conducts intensive residential courses at which leadership potential is assessed and supportive networks of peers are developed. The NHS Leadership Academy is a largely online resource albeit one running a wide variety of courses.[257] Inspired by the late Professor Aidan Halligan and under the auspices of University College London, what was described as an NHS Staff College[258] was started in 2010 and developed a second campus in Liverpool in 2013. In 2016 it became independent of the university and became a charity called The Staff College.[259] I remain of the view that the Leadership Academy, as developed, while offering many useful training programmes for leaders at many levels, is not a sufficient substitute for a Staff College of the type pioneered by Professor Halligan.

(b) I would regard recommendations 215, 216, 217 as having been implemented by way of the copious guidance for healthcare leaders produced by the NHS Academy, NHS England and the CQC, among others.

8.27 Role of professional regulators

8.27.1 Recommendations 222, 223, 224, 225, 226, 227, 228, 230, 231, 233, 234, 235

(a) In these recommendations I sought to remedy certain regulatory deficiencies as I saw them:

(i) The absence of investigations by professional regulators of systemic failures associated with regulated professionals, as opposed to focussing solely on complaints against named individuals.

(ii) Creation of a facility for complaints to be determined jointly – or at least coordinated - when they arose out of incidents involving professionals regulated by different bodies.

(iii) Inadequate information available to the public about the functions of various regulators

[257] See https://www.leadershipacademy.nhs.uk for details of what is offered.

[258] I should declare as an interest the award by the College of an honorary fellowship in 2014.

[259] See https://www.staffcollege.org for details of its history and work.

(iv) Inefficient processing of cases interfering with internal disciplinary processes.

(b) The first and second of these concerns have not, in my view, been addressed. All healthcare professional regulators operate under their own separate regulations and regime, which give them no effective power to look at the systemic implications of concerns raised with them, still less to undertake joint processed with other professional regulators. Improvements have been made with regard to collaboration with the CQC, but joint investigations and processes may require legislation to permit them.

(c) The information available to the public about regulators' functions can be judged for its adequacy by examining their websites. I think it is unlikely that an inexperienced member of the public would easily understand the limitations of each regulator.

(d) I believe that the NMC has improved its efficiency which may impact favourably on the last concern mentioned above.

8.28 Caring for the elderly

8.28.1 Recommendations 236 to 243

These recommendations were designed specifically to address concerns I had found with regard to the care of the elderly and therefore may have limited relevance to this Inquiry. However some may have a wider application:

8.28.2 Recommendation 236 – information re lead clinician

(a) It might be thought that every inpatient should know who their senior clinician is, usually a consultant, and who, at any one time, is ultimately responsible for their care. Shortly after my report, the Academy of Medical Royal Colleges [AMRC] published guidance[260] on this topic. It stated among other things:

(i) A patient's entire stay in hospital should be coordinated and caring, effective and efficient with an individual named clinician – the Responsible Consultant/Clinician – taking overall responsibility while retaining the principles of multidisciplinary working;

(ii) Ensuring that every patient knows who the Responsible Consultant/Clinician… is and also who is directly available to provide information about their care – the Named Nurse;

[260] AMRC, *Guidance for Taking Responsibility: Accountable Clinicians and Informed Patients.* June 2014 https://www.aomrc.org.uk/wp-content/uploads/2016/05/Taking_Responsibility_Accountable_Clinicians_0614.pdf [downloaded 5 March 2024]

(b) While the context of the recommendation was the care of adult inpatients, clearly in the case of children, their parents should know at all times who is the clinician responsible for the care of their child.

(c) The guidance pointed out that the concept depended on clear accountability and communication. It gave detailed practical methods of ensuring both these were achieved. Among its recommendations was the display of the relevant information where it needs to be, i.e. at the bedside for patients or visitors. The extent to which this has happened in practice, particularly under the pressures of the pandemic and short staffing is open to question. While many hospitals equip their beds with noticeboards for this purpose, from personal observation they are not always used. However, guidance issued by the Medical Defence Union in 2023 appeared to assume the AMRC guidance was still applicable to practice.[261]

(d) I note that the Ockenden Review later made a similar recommendation with regard to maternity services at Shrewsbury and Telford NHSFT [recommendation LaFL: 23 in the Schedule]

(e) The Government took the opportunity to go further than my recommendation by stating that all older vulnerable people, starting with the over-75s would have a named accountable clinician for out of hospital care, and that this would be incorporated into the GP contract.[262]

8.28.3 Recommendation 237 – teamwork

Teamwork is valuable throughout all forms of hospital care, and it is fair to say that this is promoted much more clearly in NHS guidance today. However, it is a breakdown in effective teamwork which may often lie behind failures in patient care.

8.28.4 Recommendation 242 drew attention to the importance of the proper oversight of the administration of medication.

NHS England has brought together the requirements in this regard in its guidance.[263] Unfortunately the cost to patients and the public purse of medication error continues unabated.[264]

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[261] Mein, *Delegation and accountability in the healthcare team*, 30 September 2023 https://www.themdu.com/guidance-and-advice/latest-updates-and-advice/delegation-and-accountability-in-the-healthcare-team [downloaded 5 March 2024]

[262] See announcement https://www.gov.uk/government/news/new-era-for-patients-and-nhs-as-government-accepts-recommendations-of-mid-staffordshire-inquiry

[263] See https://www.england.nhs.uk/long-read/medication-safety-management/ [accessed 4 March 2024]

[264] See https://resolution.nhs.uk/2023/03/30/learning-from-medication-errors/

8.29 Shared records and information - Recommendations 243 – 272

Many of these recommendations concerned the transparency and reliability of national level statistics and also Quality Accounts on which some comment has been made above. I offer specific comments here only on some of the other recommendations.

8.29.1 Recommendations 243, 244 – electronic shared records

(a) These recommendations proposed electronic patient records accessible to all staff needing access in relation to observations. Through a significant Government grant, and the work of NHS Digital, progress has been made with regard to electronic record systems to which staff and patients can have access. Progress was accelerated by the needs of the pandemic with the production of the NHS app. However the resources available in each Trust are variable.

(b) There are systems available whereby unusual or risky prescribing can be flagged in a hospital setting, and in at least some hospitals staff have access to current patient records on mobile phones. There have been concerns about data security, privacy and similar issues. NHS England reported in November 2023 that at least 90% of NHS Trusts now have electronic patient records.[265] The current strategy for digital transformation was published in June 2022.[266] There is a Connecting Care Records programme intending to allow sharing of records between different organisations with an expected completion date of March 2025.[267] NHS England has set up a National Record Locator to allow health and social care workers to access patient information shared by other organisations to support the direct care of the patient, with the support of £1.9 billion funding.[268]

8.29.2 Recommendation 245 – director responsible for information

This recommended that each Board should have a director responsible for information. This recommendation was supported in principle but left to individual Boards. NHS was to decide how information governance should be managed. I am unable to say what the prevailing practice is with regard to this. However NHS England does publish a Records Management Code of Practice, last updated in August 2023.[269] That states that records management should be recognised as a specific corporate responsibility with the lead responsibility being "*a designated member of staff with appropriate seniority*" which among other suggestions could be a staff member reporting directly to a board member.

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[265] https://digital.nhs.uk/news/2023/90-of-nhs-trusts-now-have-electronic-patient-records

[266] NHS England *A plan for digital health and social care* 29 June 2022 https://www.gov.uk/government/publications/a-plan-for-digital-health-and-social-care/a-plan-for-digital-health-and-social-care#summary

[267] https://digital.nhs.uk/services/connecting-care-records

[268] https://digital.nhs.uk/services/national-record-locator

[269] NHS England, *Records Management Code of Practice* August 2021, updated August 2023 https://transform.england.nhs.uk/media/documents/NHSE_Records_Management_CoP_2023_V5.pdf [downloaded 4 March 2024]

The Code requires each organisation to have an overall policy statement in this area which should be endorsed by the operational management team and the board. I conclude that this recommendation has not been implemented literally, although it may be said that the Code's requirements achieve the same objective.

8.30 Patient feedback

8.30.1 Recommendation 256

(a) This suggested that hospital patients should be followed up shortly after discharge in part as an opportunity to get feedback about the service. During the pandemic, in April 2020 all NHS Trusts were instructed that patients who were well enough should be discharged from acute beds as soon as possible. NHS England has published as a case study the introduction by one Trust of an "*innovative new wrap-around service*" to telephone all patients returning home within 24 hours by an Age UK representative.[270] Previous to the pandemic, in 2016 a "*discharge to assess*" model of discharge was adopted for patients no longer in need of acute care but who needed assessment of the care they needed in the community. A report in 2018 suggested that this was not always working, a finding supported by the CQC State of Care report for 2020/21.[271] DHSC published new statutory guidance on hospital discharge in January 2024.[272] Its detailed operational guidance appears to make no suggestion of post discharge follow-up direct with the patient from the ward. I conclude that this recommendation was not implemented.

(b) The discharge to assess model should in theory ensure that the patients post discharge needs are met, but there would not appear to be any opportunity for post discharge feedback included in any of the pathways.

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[270] https://www.england.nhs.uk/urgent-emergency-care/improving-hospital-discharge/case-studies/24hrs-post-discharge-phone-calls/ [accessed 4 March 2024]

[271] https://www.cqc.org.uk/publications/major-reports/soc202021_02d_discharging-patients [accessed 4 March 2024]

[272] https://www.gov.uk/government/publications/hospital-discharge-and-community-support-guidance/hospital-discharge-and-community-support-guidance#annex-a-discharge-to-assess---operational-process [accessed 4 March 2024]

8.31 Coroners and inquests

8.31.1 Recommendations 273 – 286 concerned the provision of information to coroners, the introduction of medical examiners, and the recruitment of assistant deputy coroners.

8.31.2 Recommendation 273 – information for coroner

One of the more concerning features of what happened at Stafford Hospital was a censoring of an adverse professional opinion which a member of the consultant staff wanted to offer to the coroner. I thought it essential that trusts should disclose all apparently relevant information to coroners in the case of reported deaths and allow the coroner to decide what use to make of it. Past reliance on voluntary disclosure has now been replaced by a statutory regime under which the coroner can order disclosure of any evidence, including the provision of a written statement and any documents relating to the matter relevant to the investigation.[273] The High Court has made it clear that the public interest in a full and appropriately detailed inquest fulfilled by disclosure to the coroner outweighs any public interest in non-disclosure to the public, which is a matter for the coroner to determine, not the witness or custodian of the documents.[274] The Chief Coroner has issued guidance.[275]

8.31.3 Recommendations 275 to 280 – medical examiners

While the 2009 Act contained the enabling provisions for the introduction of medical examiners, only a pilot scheme was in place at the time of my inquiry. A non-statutory, more widespread provision was not started until 2019, under the leadership of the National Medical Examiner, who issued good practice guidance in 2020.[276] The statutory scheme will finally be brought into force in September 2024.[277] The scheme will largely put in place a system envisaged at the time of my inquiry with one potentially important difference with regard to the examiners' independence. Whereas they were to be employed by local authorities, they will now be employed by NHS providers for the purpose of examining deaths in their care. They are enjoined to "*ensure that the independence of medical examiners is respected*", and examiners are instructed not to scrutinise cases where their independence may be questioned. It is and will remain part of the examiner's task to ask the bereaved family whether they have any concerns about the death or the circumstances surrounding it, the so-called "*Shipman question*".[278] I

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[273] Coroners and Justice Act 2009 section 32, Schedule 5 §1 in force with effect from 25 July 2013: SI 2013/1869 art 2(k). a power of search has not yet been brought into effect.

[274] *Worcester County Council and Worcestershire Safeguarding Children Board v HM Coroner for the County of Worcester* (2013) EWHC 1711 (QB). There is an exception relating to documents disclosure of which can only be ordered by the High Court: *The Secretary of State, R (on the application of) v HM Senior Coroner for Norfolk & Anor* [2016] EWHC 2279 (Admin) (28 September 2016)

[275] Chief Coroner, *Guidance No 44 – Disclosure* 13 September 2013 https://www.judiciary.uk/guidance-and-resources/guidance-no44-disclosure/ [accessed 4 March 2024]

[276] https://www.england.nhs.uk/wp-content/uploads/2020/08/National_Medical_Examiner_-_good_practice_guidelines.pdf [accessed 4 March 2024]

[277] For relevant material for the statutory scheme see https://www.gov.uk/government/publications/changes-to-the-death-certification-process/an-overview-of-the-death-certification-reforms [accessed 4 March 2024]; NHS England, *The National Medical Examiner Scheme*, https://www.england.nhs.uk/patient-safety/patient-safety-insight/national-medical-examiner-system/ [viewed 12 May 2024]

[278] NME guidance §5

remain concerned at whether the examiner's independence can be sufficiently protected in relation to their examination of the deaths of patients for whose care their employer has been responsible.

8.31.4 Recommendation 283 - prevention of future death letters

In accordance with this recommendation coroners often exercise their discretion to share "*Rule 43*" letters, now more properly called Prevention of Future Deaths letters [PFDs], issued where the coroner believes that actions should be taken to prevent a recurrence] with the CQC. Annual summaries of reports and response are available on the internet.[279]

8.32 DHSC Leadership

8.32.1 Recommendations 286 to 290 concern recommended changes at the DHSC

I doubt these recommendations require comment here.

[279] https://www.judiciary.uk/courts-and-tribunals/coroners-courts/reports-to-prevent-future-deaths/ [accessed 4 March 2024]

9. The Berwick Review into Patient Safety

This review was conducted by an internationally respected expert in health service management who, through his leadership of the International Health Institute based in Boston, promoted cultural solutions to healthcare service challenges. He was asked by the Government to review my recommendations and others

> *To distil for Government and the NHS the lessons learned and to specify the changes needed.*[280]

His approach was to draw overarching lessons and transform those into strategic policy aims, rather than to list specific measures of the type to be found in my recommendations. I do not consider the goals he described to have been inconsistent with my more specific focus. However, it might be said that he had the advantage for being able to take a broad view of the NHS as a whole, as opposed to my task which was to identify lessons and remedies arising for the system out of one NHS provider's failure. That being the case it is a challenging and perhaps sterile activity to attempt to analyse the extent to which his recommendations have or have not been implemented. Therefore, I shall limit myself to a few comments on his suggested approach.

9.1.1 Recommendation 1 – embracing learning to reduce patient harm

This was another way of expressing my message of the importance of putting the patient first. The Government's response in accepting this recommendation was in effect to refer to the actions being taken in response to my report. I consider that was appropriate and as such can be said to have been a policy implementation of the recommendation. That is not to say that the Government has succeeded in always putting patient safety ahead of targets and finance, but it has always been claimed that financial pressures should not be a justification for failing to protect patients from harm.

9.1.2 Recommendation 2 – Quality and safety to be first priority of NHS leaders

I have summarised in my consideration of the Mid-Staffordshire reports Government and NHS measures with regard to promoting quality and safety including expectations of leaders. I repeat my comments above under recommendation 1 and offer further comments below about training in safety under recommendations 5 and 6.

9.1.3 Recommendations 3, 8 – Empowering and involving patients and carers

(a) True patient involvement was at the heart of many of my recommendations including those concerning the provision of information, consent processes, and ensuring their informed and enabled presence at the tables where policy decisions are made, supported by organisations such as Healthwatch. While the Government and the NHS have consistently endorsed this concept, it has been a

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[280] Berwick, *A promise to learn – a commitment.to act* Executive summary page 4.

struggle to ensure it becomes a resilient reality. In particular I am not confident that the concept of a continuous and clear line of accountability at every stage of a patient's journey through the system has been achieved.

(b) I have already mentioned my doubts over the practical implementation of the suggestion that the responsible consultant's name should appear at the bedside, something which as the Schedule indicates, was mentioned in the context of this recommendation.

(c) Berwick emphasised in the context of this recommendation the need for a focus on staff welfare and appropriate career development. It is fair to say that recently NHS England has devoted much energy to this through the development of its People Plan, exemplified by the "NHS People Promise".[281] Again, however, the reality of the demand pressures and staff shortage do not make these aspirations easy to turn into reality.

(d) Berwick also recommended consideration of a national complaints system. I have already commented in the issues of the current system above.

9.1.4 Recommendation 4 – sufficient staffing

Berwick was anxious as I had been for the system to assure itself that sufficient staff were available to meet NHS needs now and in the future. He recommended very similar approaches to the ones I had advanced. I have commented above on this issue and therefore merely repeat that the system has in many areas not achieved or sought a consensus on a patient staff ratio, and demand is now such that it has become extremely challenging in some organisations to achieve a safe staffing level, whatever measures are relied on. There are regular reports of serous shortages in medical and nursing staff.

9.1.5 Recommendations 5, 6 – training in healthcare and patient safety sciences

(a) This is a more specific recommendation about training than contained in my report. In response to it, Health Education England commissioned a review of safety training and learning which published a report in March 2016.[282] The authors made 12 recommendations, including for a robust evaluation by HEE of education and training in patient safety, engagement of patient, carers and the public in designing such education and training, and support for lifelong learning. They thought it vital that all NHS leaders receive training in patient safety and that the principles of human factors and professionalism should be embedded in the training.

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[281] See https://www.england.nhs.uk/ournhspeople/online-version/lfaop/our-nhs-people-promise/the-promise/

[282] Williams, Pearson et al, *Improving Safety through Education and Training, Report by the Commission on Education and Training in Patient Safety*, HEE https://www.hee.nhs.uk/sites/default/files/documents/Improving%20safety%20through%20education%20and%20training.pdf [downloaded 5 March 2024]

(b) In July 2019 NHS England/NHS Improvement published a patient safety strategy.[283] Part of this involved the development of a common syllabus of patient safety open to all staff, building on existing courses and resources. Following on from the strategy a common patient safety syllabus was developed in 2021.[284]

(c) A recent assessment of the extent to which the system has embraces a safety culture of this type was undertaken by NHS England in 2022.[285] Its language suggests that up to that point good practice in safety learning and training was not consistently applied throughout the service. It pointed to the fact that in 2018 trusts were reported as being on average rated lower for safety. The CQC State of Care report 2022/3 reported that 15% of services were rated as inadequate, and 40% rated as either inadequate or requires improvement for safety, with a particular concern being expressed about maternity services.[286] This all suggests that despite multiple recommendations about safety culture and learning this remains a problem area.

9.1.6 Recommendation 7 – Transparency of data

A huge amount of data is available to the public through multiple sources. Whether, however, its interpretation is as accessible is open to question.

9.1.7 Recommendations 9, 10 – fully aligned regulation and oversight, and enforcement

(a) Berwick was keen to emphasise the need for regulation to be mainly supportive and not punitive. I agree. The CQC inspection regime is considered by some to be punitive rather than supportive, even though that has not been its intention.

(b) Likewise Berwick supported complete cooperation between regulators and oversight bodies, a standpoint with which I also agree. It is a principle universally recognised by the system and the organisations within it, supported by multiple memoranda of understanding and the like. However full coordination has been challenging in practice.

(c) He recommended an independent review of the "*structures and regulatory system*" by the end of 2017, with a view to redesignating CQC as a non-departmental public body accountable to Parliament rather than the Secretary of State, merging organisational regulators, and consideration of the effectiveness of public and community involvement measure such as

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[283] NHSE/I, *The NHS Patient Safety Strategy*, July 2019. https://www.england.nhs.uk/wp-content/uploads/2020/08/190708_Patient_Safety_Strategy_for_website_v4.pdf [downloaded 5 March 2024]

[284] NHS, *Curriculum Guidance for Delivering the NHS Patient Safety Syllabus*, November 2022 https://www.hee.nhs.uk/our-work/patient-safety

[285] NHS England, *Safety culture: learning from best practice*, 14 November 2022 PAR1760. https://www.england.nhs.uk/wp-content/uploads/2022/11/B1760-safety-culture-learning-from-best-practice.pdf [downloaded 5 March 2024]

[286] CQC, *The State of health care and adult social care in England 2022/23*, 19 October 2023 HC 1871 page 6, 42 https://www.cqc.org.uk/sites/default/files/2023-10/20231030_stateofcare2223_print.pdf [downloaded 5 March 2024]

Healthwatch and Health and Wellbeing Boards.[287] I am not immediately aware that any such review was commissioned, but some consolidation of functions has taken place, for example in the merger of the NHS Trust Development Authority and Monitor into NHS England. However, the system remains extremely complex, and from the point of view of provider leadership and management, burdensome, given the multiple reporting requirements.

(d) Berwick also recommended development of a means of permanent disqualification of directors if criminal conduct is proven. He was rightly concerned to see this form of action as being a last resort for extreme cases, but as I have described in addressing the Fit and Proper Person Test and its defects above, there is currently no such regulation of directors available, and I agree there should be.

[287] Berwick Report page 32

10. Freedom to Speak Up Review

I was asked by the Secretary of State to conduct this review into the treatment of whistleblowers in the NHS largely because of the volume of complaints of which he was made aware from NHS staff or former staff who claimed to have been treated extremely unfairly having raised legitimate concerns about safety or propriety in the service. I was not asked to investigate these cases as such but to examine the culture and the systems by which staff raising concerns were dealt with. As the report shows I was extremely concerned by what I learned. I proposed that at local level employers needed to have policies, leadership and culture which welcomed and supported staff raising their concerns as part of normal business. Part of that support should be in the form of a new concept, a Freedom to Speak Up Guardian, employed by the organisation to be a support for staff with concerns they believed were not being properly addressed. The Guardian had to be a person who had the confidence of the Chief Executive, the Board, and the staff, and to be given authority to go anywhere necessary in the organisation to seek a solution to the problems raised. At national level I recommended the creation of a post which was eventually called the National Freedom to Speak Up Guardian for the NHS to provide support and advice for the local guardian network and to review organisations' compliance with good practice.

I am pleased to say that virtually all my recommendations and principles were accepted by the Government and steps taken to implement them. Unfortunately, while I continue to believe the principles I have identified are the right ones, they are clearly not sufficient to allow staff freedom to speak up without the right leadership, sufficient staff and appropriate resources being in place. While there are many examples to choose from, I will cite the appalling story told in one of the latest reports about the Edenfield Centre run by Greater Manchester Mental Health NHS Foundation Trust,[288] where the events reported on all occurred well after the principles of this report – and indeed those described in many of the other reports considered here - should have been in place.

Without commenting separately on all the principles I will highlight some of them

10.1 Principles 1, 2: culture of safety

(a) As stated in the Schedule national level guidance was issued to boards and leaders. This was renewed in 2022.[289] CQC inspection of providers is likely to include a consideration of their freedom to speak up policies and

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[288] Shanley, *Independent Review of Greater Manchester Mental Health NHS Foundation Trust – Final Report* January 2024

[289] National Guardian, *National guidelines on Freedom to Speak Up training in the health sector in England* August 2019 https://www.cqc.org.uk/sites/default/files/20190812%20-%20National%20guidelines%20on%20Freedom%20to%20Speak%20Up%20training%20in%20the%20health%20sector%20in%20England.pdf NHS, *Freedom to Speak Up policy for the NHS*, version 2 PAR 1245i June 2022 https://www.england.nhs.uk/wp-content/uploads/2022/06/PAR1245i-NHS-freedom-to-speak-up-national-Policy-eBook.pdf ; NHS/National Guardian, *Freedom to Speak Up: A guide for leaders in the NHS and organisations delivering NHS services* PAR 1524ii June 2022 *https://www.england.nhs.uk/wp-content/uploads/2022/04/B1245_ii_NHS-freedom-to-speak-up-guide-eBook.pdf* ; NHS/National Guardian, Freedom to Speak Up a reflection and planning tool, June 2022 https://www.england.nhs.uk/wp-content/uploads/2022/04/B1245_iii_Freedom-to-speak-up-a-reflection-and-planning-tool.docx [all downloaded 5 March 2024]

implementation. Thus the "quality statements" against which it inspects leadership include:[290]

> *People and staff are encouraged and supported to raise concerns, they feel confident that they will be treated with compassion and understanding, and won't be blamed, or treated negatively if they do so.*
>
> *Raising concerns helps to proactively identify and manage risks before safety events happen.*

(b) Clearly the system does not work perfectly: CQC has recently had to review its own treatment of concerns raised with it by NHS staff, following an admitted deficiency in the way it dealt with issues raised with it.[291]

(c) Examination of the NHS Staff Survey[292] suggests that the desired culture is absent for too many employees. In the 2023 survey:

(i) 71.02% of respondents agreed that their immediate manager "*cared about their concerns*", leaving 28.98% who presumably did not agree.

(ii) 9.07% had experienced discrimination at work from managers or colleagues.

(iii) 62.31% feel safe to speak up about anything that concerns them – a slight improvement on the previous year.

(iv) 50.07% were confident that their organisation would address their concern.

(v) 71.28% would feel secure raising concerns about unsafe clinical practice.

(vi) 50.07% were confident their organisation would address their concern, a slight improvement on the previous year.

(vii) 10.17% said they had experienced harassment, bullying or abuse from managers [18.09% from other colleagues; 25.78% from patients/service users] in the last 12 months.

(viii) 51.86% of staff who had experienced harassment, bulling or abuse said they or a colleague had reported it.

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[290] CQC, *Single assessment framework – Key questions and quality statements* last updated 9 January 2024, https://www.cqc.org.uk/guidance-regulation/providers/assessment [downloaded 5 March 2024]

[291] Durairaj, *Listening, learning, responding to concerns*, 29 March, 20 September 2023 CQC https://www.cqc.org.uk/publications/listening-learning-responding-concerns/listening-learning-responding-concerns-phase-2-report [downloaded 5 March 2024]

[292] NHS Staff Survey 2023 national results [see above for online reference]

(ix) The 2022 survey reported that 0.8% had experienced at least one episode of violence from managers and 1.8% from colleagues in the previous 12 months. The 2023 report gave no figures for this owing to an issue with the data.

(x) 57.11% believed that in their team disagreements were dealt with constructively.

(xi) 33.19% had seen errors, near misses or incidents in the last month that could have hurt staff or patients; 59.45% said their organisation treated those involved fairly.

Many of these results showed a marginal improvement on the those reported in the previous survey, but when the negative implications are translated into the absolute numbers of the over 707,000 respondents who gave negative answers it is clear that there is a very high level of discontent among staff about their experiences at work.

(d) In its recent report the Expert Advisory Panel of the Health and Social Care Select Committee[293] have indicated that they consider that the FTSU recommendations are in the course of being implemented by way of the progress in setting up the FTSU guardian network and in publishing guidance, including the recent patient safety incident framework. However, they noted "*considerable variation*" in the roll-out and operation of guardians, and that some trusts have yet to implement the safety framework. The Panel noted the difficulty in finding evidence of measuring and reporting patient safety incidents. There was concern that non-executive directors do not always have the skills to challenge patient safety reports. However, the CQC's new assessment framework includes quality statements for learning culture and freedom to speak up which will be taken into account in the rating of providers.

(e) Given these serious problems, to some of which I will return below, I consider that Principles 1 and 2 can fairly be said to be works in progress. It is disappointing that better progress has not been achieved in the 9 years since the Freedom to Speak Up Review. It is, though, encouraging to see that there is a demonstrable willingness among staff to raise problematic concerns is evidenced by the fact that Freedom to Speak Up Guardians recorded over 25,000 cases in 2022/23, a 25% increase on the previous year.[294]

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[293] Expert Advisory Panel, *Evaluation of the Government's progress on meeting patient safety recommendations*, 22 March 2024, Health and Social Care Select Committee HC 362 https://committees.parliament.uk/work/8056/expert-panel-evaluation-of-governments-progress-on-meeting-patient-safety-recommendations/publications/reports-responses/ [downloaded 23 March 2024]. I am a member of the Expert Advisory Panel but stood down from this inquiry and took no part in it.

[294] https://nationalguardian.org.uk/learning-resources/speaking-up-data/ this web page also contains a spreadsheet for the current year to date.

10.2 Principle 3 – culture free from bullying

(a) As indicated in Schedule, all parts of the NHS are expected to do all in their power to eradicate bullying, intimidation and harassment. I anticipate that all NHS Employers will have policies which prohibit such behaviour under threat of disciplinary action should it occur. Unfortunately it is clear from the survey figures quoted above that such conduct is far too prevalent. For example, in the course of my writing this report, CQC have published a report on a well-known Trust, previously rated as "*Good*" at which, following an inspection late last year, has been downgraded to "*Inadequate*" for leadership.[295] Among other critical comments the report stated:

> *We met and spoke with a number of members of staff who came forward and recounted their experiences at the trust or recounted to them from fellow colleagues as they remained anxious to speak up. The majority of these were women in senior roles throughout the organisation. They talked of experiencing bullying, harassment (in its many forms), intimidation, disrespect, and misogyny. A number of these staff told us they had spoken up in the past but had felt unsupported by the process or the organisation. A number reported feeling let down by the speaking-up process when it was passed to others to resolve, and some talked of being embarrassed with colleagues; felt their confidentiality had been failed; and some talked of taking the tough decision to leave the organisation. Some staff reported that they would not speak up again due to their poor experience of previously doing this.*

(b) The steps referred to above include widespread injunctions against bullying. Nonetheless whatever measures are being taken to do not appear to be working throughout the system.

(c) I must emphasise that bullying behaviour does not merely affect the quality of the victim's experience of the workplace, it is a serious safety issue. Research suggests that bullying – or more broadly, incivility - has at least a temporary effect on the cognitive abilities not only of victims but those who witness such behaviour, and reduces their ability to attend to the task in hand.[296] This is in addition to the obvious disincentive of those bullied to speak up about their concerns.

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[295] CQC, *University Hospitals Birmingham NHS Foundation Trust Inspection Report* (8 March 2024) https://api.cqc.org.uk/public/v1/reports/c837b38b-36e2-4ac5-98b3-2e3c68c68107?20240308010509 [downloaded 8 March 2024]

[296] For resources on this subject see https://www.civilitysaveslives.com

10.3 Principle 4 – visible leadership

I considered that good leaders need to role model behaviour which welcomes the raising of concerns and openly accepts responsibility for things that have gone wrong, as a means of demonstrating that it is safe to be open about such things. Unfortunately I consider that this may be challenging for leaders in whom the system's culture instils fear that failure to achieve expected standards or targets may result in their dismissal.

10.4 Principle 5 valuing staff

This principle was intended to encourage employers to celebrate and recognise employees who had spoken up. Clearly this is difficult when a concern has been raised under conditions of anonymity, and I certainly found it difficult in the course of my review to acquire evidence of successful practice.

NHS Employers has guidance encouraging recognition of employees in appreciation of their efforts for the organisation.[297] NHS England has a staff recognition framework.[298] The National Guardian celebrates speaking up specifically and annually in a Speaking Up Month.[299] Therefore there is plenty of encouragement, but I agree that evidence of what local activity there is in this regard is sketchy.

10.5 Principle 6 – reflective practice

Reflective practice is encouraged for the professions it oversees by the Health and Care Professions Council.[300] Health Education England published a guide on "*transformative reflection*" in 2023,[301] likewise the General Medical Council in 2021 and the NMC in 2018.[302] Both GMC and NMC require evidence of reflection as part of the revalidation process. In a recent controversial case, the GMC was criticised for seeking disclosure of a registrants note prepared as part of their reflection. A policy has now been adopted that such notes will not be called for in connection with fitness to practice proceedings, but a court can order such disclosure if relevant in court proceedings.[303]

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[297] https://www.nhsemployers.org/articles/employee-recognition

[298] https://www.england.nhs.uk/long-read/staff-recognition-framework/

[299] https://nationalguardian.org.uk/2022/10/05/speak-up-month-2022/

[300] https://www.hcpc-uk.org/standards/meeting-our-standards/reflective-practice/

[301] https://www.hee.nhs.uk/our-work/enhancing-generalist-skills/enhance-learning-resources/handbook/cross-cutting-themes/transformative-reflection

[302] https://www.gmc-uk.org/-/media/documents/dc11703-pol-w-the-reflective-practioner-guidance-20210112_pdf-78479611.pdf ;

[303] GMC, *the reflective practitioner* 2021, https://www.gmc-uk.org/-/media/documents/dc11703-pol-w-the-reflective-practioner-guidance-20210112_pdf-78479611.pdf [downloaded 5 March 2024]

10.6 Principle 8 – investigations

(a) The Schedule suggests that the requirement for proportionate, fair and blame-free investigations to establish facts has been implemented. It is certainly the case that the policies and guidance referred to advocates just that. NHS policy published in response to my review in April 2016 stated:[304]

> *Where you have been unable to resolve the matter quickly (usually within a few days) with your line manager, we will carry out a proportionate investigation – using someone suitably independent (usually from a different part of the organisation) and properly trained – and we will reach a conclusion within a reasonable timescale…*
>
> *The investigation will be objective and evidence-based and will produce a report that focuses on identifying and rectifying any issues and learning lessons to prevent problems recurring.*

(b) A recent collection of recommendations from National Guardian case reviews states:[305]

> *Reasonable steps should be taken to respond to the issues raised by those who speak up in confidence. Matters should be investigated as fully as possible.*

(c) I am unaware of any reported data on the number of such investigations undertaken by registered healthcare providers, and I am not convinced that this principle is applied to all concerns raised by staff.

10.7 Principle 9: mediation and dispute resolution

While this was recommended by review and is supported by the National Guardian's guidance I am unaware of the use of these methods being reported, although there have certainly been a number of apparently intractable disputes.

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[304] NHSE/I, *Freedom to Speak Up: raising concerns (whistleblowing) policy for the* NHS April 2016 page 8 https://www.england.nhs.uk/wp-content/uploads/2021/03/freedom-to-speak-up-raising-concerns-policy-for-the-nhs-april-19.pdf [downloaded 5 March 2024]

[305] National Guardian, *Learning from case reviews*, December 2021 page 6 https://www.gmc-uk.org/-/media/documents/dc11703-pol-w-the-reflective-practioner-guidance-20210112_pdf-78479611.pdf [downloaded 5 March 2024]

10.8 Principle 11: support

As the material quoted in the schedule suggests there is a widespread requirement for clarity in organisations about where those who wish to raise concerns can go, and I believe that all NHS organisations are likely to have such a policy. What is less easy to discern is the degree of uniformity in the range of personnel to whom a whistleblower may refer. It may be restricted in practice in some places by the identity of those appointed to such roles. For example, I have received anecdotal evidence of NHS Trusts where the FTSU Guardian has also been a non-executive Board member. I regard that is presenting a conflict of interest which is likely to deter some employees from using that channel of communication.

10.9 Principle 12: support to find alternative employment

(a) In response to this recommendation pilot schemes were run in 2017, which offered support to 16 people who had left the service following raising concerns. One in three of them were successfully helped to retain or regain NHS employment. That was deemed a success, and in 2019 NHSE/I set up a Whistleblowers Support Scheme for staff who have suffered a detriment as a result of speaking up.[306] The scheme offered, where appropriate, help with transition from one employer to another, shadowing, work experience and work placement in a health and social care organisation. Understandably it was emphasised that the scheme was unable to guarantee an offer of suitable employment. One of the eligibility criteria was that the applicant had applied for suitable employment but had been unsuccessful. However, a review of that scheme found that people:

> *experienced challenges in moving forward in their professional and personal lives and required support with their health and well-being, career coaching and personal development.*

[306] https://www.longtermplan.nhs.uk/nhs-whistle-blower-support-scheme-to-roll-out-across-the-country/ 8 October 2019 NHS, *A guide to the Whistleblowers' Support Scheme*, March 2021 https://www.england.nhs.uk/wp-content/uploads/2021/03/whistleblowers-support-scheme-guide-update-march-2021.pdf [downloaded 5 March 2024]

(b) In 2022 the Scheme was changed to offer largely psychological support.[307] The scheme was clearly limited in size: it offered 10 places although 38 more people had applied. It did not then offer same sort of support as in the previous year with regard to introduction to work placements etc. An evaluation adjudged the scheme to be a success in raising the psychological scores of participants. However understandably negative feedback was received from those not accepted into the scheme, in particular because most had been unaware there was a limit on numbers. It is clearly very important that any limitations of a support scheme are made clear in advance to applicants: as a cohort they are likely to be particularly sensitised to rejection by their past experiences.

(c) At the time of writing this, the scheme is closed, but will reopen at some unspecified date to applications for a cohort in September 2024.[308]

(d) Therefore the scheme has moved away from its original intention of directly assisting employees who had suffered a detriment from raising concerns retain or regain NHS employment. It offers support to a very limited number of people, even though the numbers applying are in low double digits. This suggests there have been practical challenges in providing realistic practical help to those who have lost their job through victimisation to obtain alternative employment in the NHS. In my view there is a moral obligation on the part of the system to do whatever can be done to help them. I am not confident that is now in place.

10.10 Principle 12 – transparency

(a) As stated in the Schedule all prescribed bodies are required to report annually on whistleblowing disclosures made to them. I am unaware whether any administrative or regulatory requirement has been imposed on NHS providers to make similar reports.

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[307] NHS England, *Speaking Up Support Scheme evaluation report 2023*, 11 January 2024, https://www.england.nhs.uk/long-read/speaking-up-support-scheme-evaluation-report-2023/ [downloaded 26 March 2024]

[308] NHS England, Speaking *Up Support Scheme*, https://www.england.nhs.uk/ourwork/freedom-to-speak-up/speaking-up-support-scheme/ [accessed 26 March 2024]

(b) Settlements of claims for unfair or discriminatory dismissal have frequently been accompanied by confidentiality agreements, the terms of which have been interpreted as preventing the employee from raising public interest concerns about the employer. By law any provision in a contract between a worker and an employer which purports to preclude the worker from making a protected disclosure is void.[309] It has been made clear frequently and emphatically that agreements should not include such a term as explained in the Factsheet quoted in the Schedule. In 2018 the Solicitors Regulatory Authority issued a notice warning solicitors that they are professionally obliged not to take unfair advantage of another party when dealing with non-disclosure agreements and that the SRA was concerned to ensure that such agreements were not used to prevent reporting to regulators.

(c) In 2019 the then Secretary of State for Health stated that making a settlement agreement infringing an individual's right to speak up was completely inappropriate.[310] In the same year NHS Employers issued guidance[311] on settlement agreements which reinforced the requirement that:

> *Nothing in a settlement agreement should prevent a worker from speaking up, either before or after the agreement has been signed. Workers can and should speak up about any matter that may prevent an organisation from delivering high quality safe care. This includes, but is not limited to, matters related to patient safety, bullying, and harassment, and cultural issues that may affect quality of care or the wellbeing of workers.*

(d) Unfortunately, the clarity of the law and of this guidance has not prevented allegations being made of clauses being inserted into settlement agreements purporting to restrict the right to speak up. Thus in the same year the Government conducted a consultation on reforming the law on confidentiality in relation to this issue among others, and then pledged[312] legislation to ensure these clauses are not used to prevent a disclosure to regulated health and care professionals, to clarify the limitations on such clauses, to improve the availability of independent legal advice to individuals signing such an agreement and to provide guidance on drafting. No such legislation has been forthcoming to date.

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[309] Employment Rights Act 1996 section 43J [as inserted by the Public Interest Disclosure Act 1999 section 1]

[310] PA, *NHS non-disclosure agreements to end, vows Matt Hancock*, 27 April 2019 The Guardian https://www.theguardian.com/society/2019/apr/22/nhs-end-non-disclosure-agreements-vows-matt-hancock

[311] NHS Providers *The use of settlement agreements and confidentiality clauses* updated February 2019 https://www.nhsemployers.org/system/files/media/The-use-of-settlement-agreements-and-confidentiality-clauses_0.pdf [downloaded 5 March 2024]

[312] DBEIS, *Confidentiality Clauses, Response to the Government consultation on proposals to prevent misuse in situations of workplace harassment or discrimination*, July 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/818324/confidentiality-clause-consultation-govt-response.pdf [downloaded] 5 March 2024

10.11 Principle 14 – accountability

As implied in the Schedule, the Fit and Proper Person Test [considered in detail above] could be used as a form of accountability for suppression or discrimination against an NHS whistleblower. Evidence of this occurring is hard to obtain, but in one well publicised case a Chief Executive was suspended following adverse Tribunal findings but was still permitted to be employed as an acting chief executive elsewhere.[313] The Kark Review, considered above, set out eloquently the deficiencies in the Test which apply particularly strongly to misconduct relating to whistleblowing.

10.12 Principle 15 – regulatory action to protect whistleblowers

I was concerned that systems regulators in receipt of protected disclosures, and professional regulators receiving complaints possibly designed to silence or ruin whistleblowers, needed to do more to protect them. While there is much guidance addressed to those subject to regulation about their conduct, there is less with regard to the regulators themselves. Recently the CQC has had cause to review how it receives and treats whistleblowing information. While the report[314] refers to the fact that some informants will fear reprisals, I do not detect in this report any clear proposals with regard to what CQC will do to protect or reassure such persons.

10.13 Principle 18 – students and trainees

(a) I believe that the importance of speaking up and the freedom to do so are incorporated into training programmes for healthcare professional students. For example there is an HEE e-learning package available, but that does not mean in itself it is taken up by all for whom it is designed. I note that the programme is divided into a core programme for all workers, including volunteers, "*listen up*" aimed at line and middle managers, and "*follow up*" aimed at senior leaders at director level and above. This follows on from the National Guardian's training guidelines.[315]

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[313] Independent, *Health watchdog says lessons must be learned after NHS fraudster landed multiple top jobs* 19 December 2018 https://www.independent.co.uk/news/health/nhs-fraud-scandal-health-trust-whistleblower-job-appointment-ombudsman-report-a8689091.html [downloaded 5 March 2024]

[314] Duraig *Listening, learning, responding to concerns*_29 March 2023 updated 20 September 2023_CQC https://www.cqc.org.uk/publications/listening-learning-responding-concerns/5-reviewing-expectations-and-experiences-people-who-raise

[315] National Guardian, *National Guidelines on Freedom to Speak Up training in the health sector in England* August 2019 https://nationalguardian.org.uk/wp-content/uploads/2021/04/20190812-National-guidelines-on-FTSU-training.pdf [downloaded 6 March 2024]

(b) NHS England is seeking to consolidate training resources to make available for organisations cultural improvement tools by way of their IMPACT (Improving Patient Care Together) programme,[316] the components and resources of which would include programmes relating to supporting staff in an open culture. In theory CQC through its regulatory oversight of leadership in registered providers will assess their performance in relation to improving and maintaining the desired culture. However, it remains discretionary whether this resource is taken up by education providers or employers.

(c) GMC's training standards for medical schools and postgraduate training environments include a requirement that learners can demonstrate what is expected in GMC's *Good Medical Practice*. Organisations must demonstrate

> *a culture that allows learners and educators to raise concerns about patient safety …. Openly and safely without fear of adverse consequences… a culture that investigates and learns from mistakes, and responds to feedback from learners and educators on compliance with standards of patient safety and care…*[317]

(d) The NMC has similar requirements in its framework of standards for nursing and midwifery education.[318] Requirement 1.5 is that educators must

> *ensure students and educators understand how to raise concerns or complaints and are encouraged and supported to do so in line with local and national policies without fear of adverse consequences.*

(e) Therefore, while the methods of training may be discretionary, it is clear that educators and trainers will be assessed against these standards and expectations. I conclude that this Principle has been implemented.

10.13.2 Principle 20 – legal protection

(a) Victimisation of an applicant for healthcare employment on the grounds that they have made a protected disclosure is now unlawful, with effect from 23 May 2018.[319]. "*Applicant*" is defined in the Employment Rights Act 1996 section 49B. Therefore Action 20.1 has been taken.

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[316] For details see https://www.england.nhs.uk/nhsimpact/ [accessed 6 March 2024]

[317] GMC, *Promoting excellence – standards for medical training and education* R1.1-1.6 15 July 2015 https://www.gmc-uk.org/-/media/documents/promoting-excellence-standards-for-medical-education-and-training-2109_pdf-61939165.pdf [downloaded 6 March 2024] For an overview of all GMCs training requirements see https://www.gmc-uk.org/education/standards-guidance-and-curricula NMC

[318] NMC, *Standards framework for nursing and midwifery education* page 7, Requirements §1.5 (original 17 May 2018, newly published 23 April 2023) https://www.nmc.org.uk/globalassets/sitedocuments/standards/2023-pre-reg-standards/new-vi/standards-framework-for-nursing-and-midwifery-education.pdf

[319] The Employment Rights Act 1996 (NHS Recruitment – Protected Disclosure) Regulations 2018 SI 579

(b) With regard to the list of prescribed persons it is correct that the PHSO is not listed as a prescribed person, whereas the Ombudsmen for Scotland and Wales are,[320] but it should be noted that Public Health England no longer exists. Its functions were subsumed into the UK Health Security Agency [which is not a prescribed body] an executive agency of DHSC, and the Office for Health Improvement & Disparities, which is also part of DHSC. The UKHSA is now substituted for the PHE in the list of prescribed matters for which the Secretary of State for Health and Social Care is the prescribed person.[321]

(c) It is unlawful to victimise individuals working in the NHS making protected disclosure, if and only if they come within the extended definition of "*worker*" in the Employment Rights Act 1996 section 43K. This includes persons undertaking work experience provided pursuant to a training course or programme or with training for employment otherwise that under a contract of employment or by an educational establishment on a course run by that establishment. Some persons working in the NHS may come under this definition. Postgraduate trainees are employed by the NHS and therefore are protected in relation to discrimination by their employer, but not by any other healthcare agency. My report explained the issues around the exclusion of students/trainees from protection. As a sidenote Health Education England announced in 2016 that while it could not change the law, it was changing contractual arrangements to give postgraduate trainees analogous rights of protection against any discrimination by itself.[322]

(d) There remain serious issues around the efficacy of the legislative protection in this area for healthcare workers generally, due to the technical complexity of the legislation and the lack of equality of arms in pursuing claims. As evidence of the challenges, the BMA reported in July 2023 that, of the 46 cases involving public Interest disclosure disputes which were referred to their independent legal service providers during 2021, only four were assessed as having a greater than 50% chance of success.[323]

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[320] The full list of prescribed persons is at. https://www.gov.uk/government/publications/blowing-the-whistle-list-of-prescribed-people-and-bodies (updated 29 December 2023) The origin for the full list is challenging to find as the amendments to the original order have not been consolidated on line, but they are S.I. 2014/2418, amended by S.I. 2014/3294, 2015/1407, 2015/1682, 2015/1981, 2016/225, 2016/992, 2016/968, 2017/516, 2017/692, 2017/701, 2017/752, 2017/880, 2017/960, 2017/1064, 2017/1127, 2018/378, 2018/795, 2018/1237, 2018/1288, 2019/1341, 2020/2 and 2022/634.

[321] The Public Interest Disclosure (Prescribed Persons) (Amendment) Order 2022 SI 1064 Art 2(I)

[322] HEE, *guide for postgraduate trainees* (August 2016) https://www.hee.nhs.uk/sites/default/files/documents/Guide%20to%20extended%20whistleblowing%20protection%20for%20postgraduate%20trainees.pdf [downloaded 6 March 2024]

[323] BMA, *Legislative reforms and whistleblowing* (25 July 2023) https://www.bma.org.uk/advice-and-support/complaints-and-concerns/raising-concerns-and-whistleblowing/legislative-reforms-and-whistleblowing [downloaded 6 March 2024]

(e) The Government announced a review of the whistleblowing "*framework*" in 2023 with an expected conclusion by the end of that year.[324] I am unaware of any further announcement about this since then.

[324] https://www.gov.uk/government/publications/review-of-the-whistleblowing-framework/review-of-the-whistleblowing-framework-terms-of-reference [downloaded 6 March 2024]