

HEALTHCARE ADMINISTRATION EXPERT GROUP

REPORT DATED 7 AUGUST 2026

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List of Abbreviations

AAC	Advisory Appointments Committee
BSR	British Spine Registry
CCST	Certificate of Completion of Specialist Training
CEO	Chief Executive Officer
CESR	Certificate of Eligibility for Specialist Registration
CHI	Community Health Index
COPFS	Crown Office and Procurator Fiscal Service
CPD	Continuous Professional Development
CSBS	Clinical Standards Board for Scotland
DCC	Direct Clinical Care
DPA	Data Protection Act
EPR	Electronic Patient Records
EWTD	European Working Time Directive
GDPR	General Data Protection Regulation
GMC	General Medical Council
GP	General Practitioner
HCP	Healthcare Professional
HES	Hospital Episode Statistics
HIS	Healthcare Improvement Scotland
HSE	Health and Safety Executive
HSWA	Health and Safety at Work etc. Act 1974
ICO	Information Commissioner's Office
LoI	Letter of Instruction
MAC	Medical Advisory Committee
MDT	Multi-Disciplinary Team
MHRA	Medicine and Healthcare Products Regulatory Agency
MHSP	Maintaining High Professional Standards
M & M	Morbidity and Mortality
MPTS	Medical Practitioners Tribunal Service
MSN	Managed Service Network

NHS	National Health Service
NHSCR	National Health Service Central Register
NHS QIS	National Health Service Quality Improvement Service
NICE	National Institute for Health and Care Excellence
NICU	Neuro-Intensive Care Units
NMC	National Midwifery Council
NTN	National Training Numbers
PACS	Picture Archiving and Communication System
PASS	Patient Advice and Support Service
PHIN	Private Health Information Network
PMETB	Postgraduate Medical Education and Training Board
PPI	Public and Patient Involvement
PRSB	Professional Record Standards Body
PSA	Professional Standards Authority
PSV	Primary Source Verification
RO	Responsible Officer
SAER	Significant Adverse Event Review
SCOPME	Scottish Committee for Postgraduate Medical Education
SIGN	Scottish Intercollegiate Guidelines Network
SMC	Scottish Medicines Consortium
SOAR	Scottish Online Appraisal and Revalidation
SPA	Supporting Professional Activities
SpR	Standardised Specialist Registrar
SPSO	Scottish Public Services Ombudsman
SPSP	Scottish Patient Safety Programme
STA	Specialist Training Authority
StEIS	Strategic Executive Information System
UK	United Kingdom
VE	Voluntary Erasure
WHO	World Health Organization

As requested in the revised letter of instruction dated 16 June 2026, the matters to be addressed in this expert report are divided into the following parts:

Part A Your qualifications and background and approach to the report

Part B General

Part C Appointments

Part D Clinical Governance

Part E Healthcare Management

Part F Conclusions

Part A – Your qualifications and background and approach to the report

1. Please set out details of your qualifications, including your professional and/or academic experience. Please exhibit professional CVs with your report.

1.1 The Healthcare Administration Expert Group (HAEG) is comprised of Professor Anne-Maree Farrell (Edinburgh Law School), Dr Fay Gilder (University of Cambridge), and Professor Kieran Walshe (University of Manchester.) CVs of the members of the Group, detailing their qualifications, professional and academic experience have also been provided. [ELJ0003-00169]; [ELJ0003-00170]; [ELJ0003-00171]

2. Please set out in the report how you have gone about compiling it, including which sections have been allocated to each of the members of the expert group (if applicable) and why.

2.1 Professor Farrell and Dr Fay Gilder worked on preparing a full draft of the report. The report was then reviewed on several occasions by all three members of the Expert

Group, resulting in further revisions. Editing was also undertaken to enhance clarity and readability.

- 2.2 Where reference is made to the 'relevant period' in this report, it is intended to refer to the period from 1995 to 2015.
- 2.3 In response to the revised Letter of Instruction (LoI) dated 16 June 2026, the HAEG focused on identifying relevant general principles, policies and laws that would apply to registered doctors in the relevant period. This is on the basis that this would apply to consultant doctors across a range of specialties, including neurosurgery.
- 2.4 In relation to completing this report, the HAEG has predominantly relied on what might be described as high-level policy and regulatory documentation which are relevant to addressing the questions set out in the revised LoI dated 16 June 2026. As the Tribunal progresses, we anticipate that more evidence will be obtained about processes and practices which are relevant to these questions. The Expert Group would be happy to assess such evidence and provide a supplementary report in this regard, if it was considered to be of benefit to the Inquiry.
- 2.5 The HAEG has, to the best of our ability, set out the substance of all facts, materials and instructions which are material to the opinions expressed in the Report. Where appropriate, we have made clear which of the facts stated are within our knowledge, which are not and, to the extent that such facts are within our knowledge, we have certified them to be true.

Part B – General

3. **By way of broad context, what are/ were the key bodies having legal responsibility for the operation of NHS hospital care (with particular regard to the field of neurosurgery, with which the Inquiry is principally concerned) in Scotland? In particular:**
- (a) Please set out the broad respective responsibilities of these bodies and how these evolved since around 1995, including consideration of the broad impact of the devolution settlement on how these bodies operate.**
- (b) Please consider the broad remit and legal responsibilities of the following, insofar as you consider them to be relevant to your answer:**
- **Health boards;**
 - **Government, including the UK Government and the Scottish Executive/ Government since devolution, including but not limited to key figures within governmental structures such as the Chief Medical Officer for Scotland and ministers responsible for the delivery of health services in Scotland;**
 - **Regulatory bodies with responsibilities for the medical and associated professions, such as the General Medical Council;**
 - **Bodies with statutory/ regulatory responsibilities for safety, such as the Health and Safety Executive;**
 - **Bodies with statutory/ regulatory responsibilities for the improvement of services in the NHS, such as Healthcare Improvement Scotland or its predecessor bodies;**
 - **Bodies with statutory/ regulatory responsibilities for the improvement of training and education in the NHS, such as Public Services Delivery Scotland or its predecessor bodies (including NHS Education for Scotland) and universities or Royal Colleges; and**
 - **Other bodies with relevant legal responsibilities to play in this field.**

Devolution in Scotland and healthcare competence

- 3.1 In a devolved UK, it is important to distinguish between political and administrative devolution. In relation to the former, this involves a transfer of responsibility for health care to locally elected politicians in the devolved nations and is a relatively new phenomenon in constitutional terms. In contrast, administrative devolution in some

shape or form has long taken place in the UK's four nations, involving the separate administration of particular policy areas, such as healthcare, for example.¹ [ELJ0003-00022] By way of background, Scotland has long enjoyed a form of administrative devolution from Westminster and this was particularly notable in relation to the Scottish National Health Service (NHS). While England and Wales were under the control and direction of the UK Secretary of State for Health, for example, the Scottish NHS remained under the control of the Secretary of State for Scotland. In the 1970s, the Health Board structure was created in Scotland. Although in England, the NHS has operated a divide between purchasers of care and providers of health care, this does not exist in Scotland.² [ELJ0003-00050]

- 3.2 In 1999, the next major development took place which resulted in political devolution in Scotland. As a result of political devolution, many healthcare matters now come within the remit of Scottish Government, rather than Westminster. Healthcare matters that remain 'reserved' to Westminster include the regulation of health care professionals (HCPs), product safety and labelling, employment rights, and duties, as well as medicines and medical supplies and the standards for, and testing of, biological substances.³ [ELJ0003-00022] Post devolution, legislative control over the NHS in Scotland was transferred to the Scottish Parliament. The 'Scottish Executive' – later renamed the Scottish Government in 2007⁴ [ELJ0003-00006] – became directly accountable to the Scottish Parliament rather than the UK Parliament (i.e. Westminster) for the operational delivery and clinical quality of healthcare services.⁵

¹ Expert Report to the Infected Blood Inquiry, *Public Health and Administration*, August 2022, 31, available at: <[Expert Report to the Infected Blood Inquiry: Public Health and Administration](#)> accessed 21 July 2026.

² Scott Greer, 'Devolution and Health in the UK: Policy and Its Lessons Since 1998' (2016) 118(1) *British Medical Bulletin* 16, 19.

³ Expert Report to the Infected Blood Inquiry (n 3) 32.

⁴ BBC News, 'Scottish Executive Renames Itself', 3 September 2007, available at: <<http://news.bbc.co.uk/1/hi/scotland/6974798.stm>>, accessed 21 July 2026.

⁵ Health is a devolved responsibility of the Scottish Parliament under the *Scotland Act 1998*. The Act grants Scotland full legislative authority over all policy areas not explicitly 'reserved' to the UK

- 3.3 What is known as the Barnett formula is used by the UK Treasury to determine how much funding by way of an annual block grant is to be provided to Scotland to fund public services, such as healthcare. In 2024/25, for example, the Barnett block grant amounted to £45bn for Scotland.⁶ [ELJ0003-00014] Until political devolution took place in 1999, the Formula was used to determine the level of UK Government spending on public services in Scotland; since such time, it has been employed to set the budget for spending on public services by the Scottish Government. In essence, the Formula is organised on the basis of an annual block grant, which consists of a baseline allocation, plus an annual increment. Each year the baseline consists of the total block grant from the previous year. The increment reflects the change in spending in England; the extent to which the relevant English departmental programme is comparable with the services carried out by the devolved administration; and the proportion of the population in each devolved administration in relation to the appropriate one used for the UK Government's programmes.
- 3.4 Unlike the other devolved nations, Scotland does not receive needs-based adjustments on the basis of the Formula. This was on the grounds that it had been expected that over time that the application of the Formula would cause public services spending per person in Scotland to converge with levels in England, in what is known as the 'Barnett convergence'. This seems to have been a gradual process over time which has not been fully realised in practice. Calls for full 'fiscal autonomy' on the part of the Scottish government to address the financing of devolved public services, such as the NHS, have not as yet met with success.⁷ [ELJ0003-00162]

Parliament. Health is not listed as a reserved matter, see *Scotland Act 1998*, Schedule 5, for policy areas that are reserved to the UK government.

⁶ Aron Cheung et al, 'Barnett Formula', Institute of Government, 25 November 2020, last updated 25 November 2025, available at: <[Barnett formula | Institute for Government](#)> accessed 21 July 2026.

⁷ UK Parliament, Scottish Affairs Committee, 'The Financing of the Scottish Government', First Session of 2024-25, available at: <[The financing of the Scottish Government](#)> accessed 21 July 2026.

The Scottish government and the delivery of healthcare

3.5 As a result of political devolution in 1999 and over time, the Scottish Government has increasingly taken the initiative in relation to policy, institutional and regulatory matters touching on the delivery of healthcare in Scotland. In summary, healthcare is a major area of devolved competence in Scotland, and this is reflected in the prominence given to both in the organisation, policy, and legislative work of the Scottish Government. The Cabinet Secretary for Health and Care has political and statutory responsibility for healthcare, public health, and social care, and works with the Ministers for Community Care and Mental Wellbeing, Public Health, Sport, Alcohol and Drugs.⁸ [ELJ0003-00136] Specifically in relation to NHS Scotland, the Cabinet Secretary has overall responsibility for the performance, funding allocations, and strategic direction of the NHS in Scotland, with explicit legal power to issue binding directions to Health Boards regarding how they must exercise their functions.⁹

3.6 The Scottish Government ministerial team responsible for healthcare are in turn supported at senior management level by the Chief Executive for NHS Scotland and Director-General Health and Social Care, as well as the Chief Medical Officer (CMO).¹⁰ [ELJ0003-00137] The CMO acts as the senior medical advisor to the Scottish Government, Ministers, and policy teams. The CMO provides a vital clinical voice at the governmental level, issuing professional guidance, setting overarching public health strategy, and maintaining high professional standards across the medical workforce in Scotland.¹¹ [ELJ0003-00138]

⁸ Scottish Government, 'Cabinet Secretary for Health and Care', available at: <[Cabinet Secretary for Health and Care - gov.scot](https://www.gov.scot/cabinet-secretary-for-health-and-care)> accessed 21 July 2026.

⁹ *National Health Service (Scotland) Act 1978* (as amended), ss 1, 78.

¹⁰ See e.g. Scottish Government, 'Chief Executive of NHS Scotland and Director-General Health and Social Care', available at: <[Chief Executive of NHS Scotland and Director-General Health and Social Care - gov.scot](https://www.gov.scot/Chief-Executive-of-NHS-Scotland-and-Director-General-Health-and-Social-Care)> accessed 21 July 2026.

¹¹ Scottish Government, 'Chief Medical Officer Directorate', available at: <[Chief Medical Officer Directorate - gov.scot](https://www.gov.scot/Chief-Medical-Officer-Directorate)> accessed 21 July 2026.

Health Boards

3.7 Within the Scottish healthcare system, Health Boards are the operational cornerstone of the NHS. They have direct corporate legal responsibility for meeting the healthcare needs of their local populations, including the provision of primary medical services.¹² They also function as strategic governing entities, legally tasked with setting local clinical priorities, managing institutional financial risk and, crucially, monitoring the quality, delivery, and safety of its acute services (e.g. neurosurgery departments of the type established at Ninewells Hospital).

3.8 At the start of the relevant period, acute hospital care was fragmented and hospital management sat within NHS Trusts.¹³ Following political devolution, the then Scottish Executive enacted a major structural reform in 2004 which dissolved these separate NHS Trusts and unified all hospital services under a single, integrated 'territorial' Health Board model.¹⁴ As part of these reforms, Chief Executive Officers (CEO) of Health Boards were assigned statutory accountability for clinical governance.¹⁵ [ELJ0003-00143] [ELJ0003-00106] The Boards are responsible for the improvement of their population's health and for the delivery of frontline health care services. The Boards operate differently, meaning there is variation in their size, role, function and governance arrangements. There are currently fourteen geographically based Health Boards (which are further subdivided into Health and Social Care Partnerships), seven national non-geographic special health boards, and many small contractors for primary care services.¹⁶ [ELJ0003-00086]

¹² *National Health Service (Scotland) Act 1978* (as amended), ss 2, 2A-2D.

¹³ See *The Functions of Health Boards (Scotland) Order 1991*.

¹⁴ See *National Health Service Reform (Scotland) Act 2004*, s 1.

¹⁵ Scottish Office, *Clinical Governance*, Circular MEL(1998)75, 27 November 1998 (Edinburgh: Scottish Office), available at: <<https://www.publications.scot.nhs.uk/files/2000-29final.htm>>, accessed 21 July 2026; see more generally K Ritchie Susan Downie and J Warner, 'Clinical Governance: What Does It Mean for NHS Scotland?' 50(4) *Scottish Medical Journal* 147.

¹⁶ NHS Scotland, 'Organisations', available at: <<https://www.scot.nhs.uk/organisations/>> accessed 21 July 2026.

3.9 In terms of broader Scottish Government oversight, support, intervention and escalation frameworks operated in the relevant period to address underperforming Health Boards. Over time, this meant that there could be formal governmental intervention into a given Health Board's administration – ranging from Stage 1 'Support' to Stage 5 'Cabinet Secretary Intervention' – if there were severe, unresolved systemic failures in local clinical governance or financial management.¹⁷ [ELJ0003-00135] Specifically in relation to the management of doctors employed by Health Boards, they possessed local operational powers to suspend, restrict, or place doctors under clinical supervision, if patient safety concerns were validated. This was an internal administrative employment mechanism entirely separate from the GMC's formal fitness to practise procedures.¹⁸ [ELJ0003-00144]; [ELJ0003-00121]; [ELJ0003-00122]

Regulation of doctors

3.10 During the relevant period, the operational landscape of healthcare delivery in Scotland was governed by a number of external frameworks for professional accountability and workplace safety. While healthcare delivery was progressively devolved to the Scottish Parliament from 1999 onwards, professional medical regulation, as well as general health and safety enforcement, continued to operate on a UK-wide basis. This was

¹⁷ For the current version of the support and escalation Frameworks for NHS Scotland Health Boards, See Scottish Government, *NHS Scotland: Support and Intervention Framework*, June 2026, available at: <<https://www.gov.scot/publications/nhs-scotland-support-and-intervention-framework/>>, accessed 21 July 2026.

¹⁸ See e.g. Scottish Office, Department of Health, *Report of the Short-Life Working Group on Suspension of Medical and Dental Staff*, 6 April 1999, NHS Circular PCS(DD)1999/7, available at: <<https://www.publications.scot.nhs.uk/files/pcs1999-dd-07.pdf>>, accessed 21 July 2026, as well as later circulars, including Scottish Executive, Department of Health, *Report of Short-Life Working Group on Poorly Performing Doctors and Dentists in Training*, 6 August 2001, NHS Circular HDL (2001)60 Scottish Executive, Department of Health, *Report of Short-Life Working Group on Poorly Performing Doctors and Dentists in Training*, 6 August 2001, NHS Circular HDL (2001)60, available at: <[https://www.msg.scot.nhs.uk/wp-content/uploads/Circulars/HDL's/HDL%20Publications%20DD/HDL\(2001\)60.htm](https://www.msg.scot.nhs.uk/wp-content/uploads/Circulars/HDL's/HDL%20Publications%20DD/HDL(2001)60.htm)>, accessed 21 July 2026; Scottish Executive, Department of Health, *Discipline Procedures: Classification of Conduct*, 7 August 2001, NHS Circular: PCS(DD)2001/9, available at: <<https://www.publications.scot.nhs.uk/files/pcs2001-dd-9.pdf>>, accessed 21 July 2026.

primarily due to such matters being reserved to the UK Parliament under political devolution arrangements.

3.11 Within the context of this UK-wide approach, the General Medical Council (GMC) operates as the independent regulator of doctors.¹⁹ Its overarching purpose is to protect, promote, and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. During the relevant period, its core functions comprised the following:

3.11.1 The Medical Register: Maintaining the definitive, up-to-date register of qualified medical practitioners authorised to practice in the UK, including the Specialist Register for consultants (such as neurosurgeons).

3.11.2 Setting Standards: Defining the professional, ethical, and clinical behaviours expected of doctors, as set out in *Good Medical Practice* (first edition was published in 1995 and there have been several editions published to the present date).

3.11.3 Education and Training: Regulating the standards of undergraduate and postgraduate medical education and training.

3.11.4 Fitness to Practise: Investigating and adjudicating allegations where a doctor's fitness to practise was called into question due to misconduct, poor clinical performance, or ill-health.

¹⁹ See *Medical Act 1983*.

3.12 As noted previously, medical regulation was explicitly designated as a reserved matter under the Scotland Act 1998.²⁰ Consequently, the statutory powers of the GMC remain uniform across the UK. This has meant that Scottish Health Boards are required to adhere to the UK-wide regulatory framework for medical regulation, as overseen by the GMC. During the relevant period, the GMC's head office was based in London, but it later established a specific Scottish office to improve devolved stakeholder liaison in 2003.²¹ [ELJ0003-00046]

3.13 During the relevant period, the GMC also underwent a fundamental institutional cultural shift from one that was based on a reactive system of professional self-regulation to an accountability-driven model that centred explicitly on patient safety. This shift was accelerated as a result of a number of high-profile healthcare scandals, including that involving Harold Shipman.²² [ELJ0003-00153]; [ELJ0003-00015]; [ELJ0003-00159] Historically, the registration of doctors by the GMC was effectively granted for life unless a major fitness to practise failure was found to have occurred. However, this began to change when the GMC introduced the revalidation process in 2012.²³ [ELJ0003-00048] This required doctors to positively demonstrate every five years that they remained up-to-date and fit to practise, with supporting evidence drawing on clinical appraisals conducted within their place of employment. In the Scottish context, this would ordinarily take place within Health Boards who employ doctors.

²⁰ *Scotland Act 1998*, Sch 5, Part II, Regulation of Health Professions.

²¹ GMC, 'Our Work in Scotland 2025', available at: <[Our work in Scotland](#)> accessed 21 July 2026.

²² For an overview of the case of Dr Harold Shipman and the work of the Shipman Inquiry, see: <<https://www.the-shipman-inquiry.org.uk/>>, accessed 21 July 2026; see generally, CMO (England), *Good Doctors, Safer Patients* (Department of Health, 2006); UK Government, *Safeguarding Patients: The Government's response to the recommendations of the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries*, Presented to Parliament by the Secretary of State for Health by command of Her Majesty, February 2007, available at: <[Safeguarding Patients The Government's response to the recommendations of the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries CM 7015](#)> accessed 21 July 2026.

²³ GMC, 'Revalidation', available at: <[Revalidation - GMC](#)> accessed 21 July 2026.

Health and Safety Executive

- 3.14 The Health and Safety Executive (HSE) is the UK-wide statutory body responsible for the encouragement, regulation, and enforcement of workplace health, safety, and welfare pursuant to the Health and Safety at Work etc. Act 1974 (HSWA). As is the case with medical regulation, health and safety law is a reserved matter under current political devolution arrangements, with the HSE acting as the regulatory authority responsible for enforcement matters in order to ensure workplace safety within Scottish hospitals.²⁴ Under the HSWA, Scottish Health Boards are required to ensure, as far as it is reasonably practicable, the health, safety, and welfare of its staff, which would include their employed doctors. In addition, the Boards are required to ensure, so far as is reasonably practicable, that persons *not* in their employment (which explicitly includes hospital patients and visitors) are not exposed to risks to their health or safety.²⁵
- 3.15 In the relevant period, the HSE's preference was for matters of health and safety to be dealt with via internal disciplinary and enforcement structures within hospitals and/or Health Boards. This was largely on the grounds that it did not, in general, investigate matters of clinical judgement or matters relating directly to the quality of clinical care. Instead, the HSE restricted its interventions in healthcare settings to major 'non-clinical' structural risks impacting staff and patients alike. This included slip/trip hazards, anti-ligature environmental safety in mental healthcare settings, workplace violence, needle-stick/sharps injuries, hazardous chemical exposures, and mechanical failures (such as medical gas or hoist breakdowns). Incidents arising from substandard individual clinical techniques – such as surgical errors, or poor surgical decision-making – were referred to professional regulators (such as the GMC); or healthcare quality improvement bodies, rather than being positioned as criminal breaches of the HSWA.²⁶ [ELJ0003-00161]

²⁴ See *Scotland Act 1998*, Sch, 5, Part II, Head H1 (Health and Safety).

²⁵ See *Health and Safety at Work etc. Act 1974*, ss. 2 and 3.

²⁶ HSE Operational Circulars and published enforcement priorities regarding the healthcare sector (reaffirming the deferral of clinical judgment investigations to healthcare-specific oversight bodies), See

Healthcare quality assurance and service improvement in Scotland

- 3.16 During the relevant period, the statutory framework for healthcare quality and service improvement in Scotland underwent a significant evolution. Following political devolution in 1998, healthcare quality improvement became an entirely devolved matter. Over time, this led to a divergence in Scotland's approach from that adopted in England (e.g. Commission for Health Improvement, the Healthcare Commission, and the Care Quality Commission). As a result, the Scottish Government created new bodies and institutional arrangements to oversee clinical governance, as well as quality and safety standards, within Scottish Health Boards.
- 3.17 In 1998, the Scottish Executive published a circular which established a duty on the part of CEOs of Health Boards, making them directly accountable for the quality of care in their hospitals. Scottish health improvement bodies, including Healthcare Improvement Scotland (HIS) at a later stage (i.e. from 2011 onwards), were tasked with auditing how effectively Health Boards implemented their internal quality improvement governance systems.²⁷ [ELJ0003-00143] In 1999, the Scottish Executive also established the Clinical Standards Board for Scotland (CSBS), whose purpose was to develop and implement national clinical standards and run a system of external peer review across the NHS in Scotland.²⁸ In 2003, it was superseded by NHS Quality Improvement Scotland (NHS QIS) which was in operation until 2011, when it was then replaced by Healthcare Improvement Scotland (HIS). NHS QIS was formed by merging the CSBS with other bodies, including the Clinical Resource and Audit Group, and aimed to support, as well as monitor, the quality of clinical care provided by the NHS in Scotland.

e.g., UK Parliament, House of Commons, Select Committee on Health, Memorandum by the Health and Safety Executive (HSE) PPS 07), *Patient Safety*, 30 October 2008, available at: <<https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/1137/1137we08.htm>>, accessed 21 July 2026.

²⁷ Scottish Office Department of Health, *Clinical Governance*, (1998) (n 15).

²⁸ The CSBS was created as a Special Health Board pursuant to *The Clinical Standards Board for Scotland Order 1999*, pursuant to legislative powers under the *National Health Service (Scotland) Act 1978* (as amended).

It also set national standards, issued clinical guidelines, and conducted formal reviews of the performance of Health Boards.

3.18 In terms of a focus on driving quality improvements to enhance patient safety, the Scottish Patient Safety Programme (SPSP) was established in 2007 in order to promote patient safety initiatives in Scotland, as well as to address the problem of avoidable events causing harm to patients in healthcare settings. It represented the first time that a national quality improvement programme had been established to facilitate the safer delivery of healthcare in the UK context. Following on from its establishment in 2011, HIS also relied on the SPSP in its work to drive quality improvement in healthcare in Scotland.

3.19 In 2007, the Scottish Patient Safety Alliance was established through a partnership between the Scottish Government, NHS Scotland, the Royal Colleges and other professional bodies, the Scottish Consumer Council, and the Institute for Healthcare Improvement. One of the key activities of the Alliance was to extend patient safety initiatives across NHS Scotland, as part of the launch of the SPSP in 2007. The rollout of quality improvement initiatives as part of the SPSP extended across a range of specialties, covering acute adult care, mental healthcare, primary care, maternity and children, healthcare associated infections, medicines, and the delivery of community health care in areas such as dentistry, pharmacy, and district nursing.²⁹ [ELJ0003-00131]

3.20 In 2010, the Healthcare Quality Strategy for NHS Scotland [ELJ0003-00126] was published, which set out the approach to be taken for achieving an integrated vision of

²⁹ Scottish Government, Healthcare Quality and Improvement Directorate, *The Scottish Improvement Journey: A Nationwide Approach to Improvement*, 20 April 2018, available at: <<https://www.gov.scot/publications/scottish-improvement-journey-nationwide-approach-improvement-compiled-2016-17/pages/4/>> accessed 21 July 2026.

quality improvement for health and social care in Scotland. It identified key priorities, such as caring and compassionate staff and services; providing clear communication and explanation about conditions and treatment; fostering effective collaboration between clinicians, patients and others; creating a clean and safe care environment; and offering continuity of care and clinical excellence. As mentioned previously, HIS was established in 2011 and it continues to the present date. It took over the functions of the NHS QIS (and the independent healthcare functions of the Care Commission). It was given strengthened statutory powers to inspect hospitals, publish independent reports, and drive systemic quality improvements, with an explicit focus on patient safety and the effectiveness of local clinical governance. It now operates as the main body driving quality and safety in healthcare in Scotland,³⁰ [ELJ0003-00126] and draws on the Excellence in Care framework.³¹ [ELJ0003-00056] The Framework provides the foundation for promoting a culture of continuous improvement using a quality management systems approach. HIS is also responsible for conducting inspections of NHS hospitals, as well as the regulation of independent healthcare services across Scotland. HIS inspections are designed to give NHS boards a proactive, assertive way to report evidence; create a methodology for analysing NHS board evidence that can validate, risk assess and identify targets for inspection; and to monitor NHS board improvement plans.³² Scottish Ministers remain responsible and accountable to the Scottish Parliament for overall health and social care.³³ [ELJ0003-00085] [ELJ0003-00054]

³⁰ Scottish Government, Healthcare Quality and Improvement Directorate, *Healthcare Quality Strategy for NHS Scotland*, 10 May 2010, available at <<https://www.gov.scot/publications/healthcare-quality-strategy-nhsscotland/>> accessed 21 July 2026.

³¹ Note that the latest Excellence in Care Framework was updated in 2026; see HIS, *Excellence in Care*, available at: <[Excellence in Care Framework – Healthcare Improvement Scotland](#)> accessed 21 July 2026.

³² HIS, 'Improving Health and Care for Everyone' available at: <https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care.aspx> accessed 21 July 2026.

³³ See NHS Scotland, 'About NHS Scotland', available at: <<https://www.scot.nhs.uk/about-nhs-scotland/>>, accessed 21 July 2026; HIS, *Operating Framework: Healthcare Improvement Scotland and Scottish Government*, April 2026, available at: <<https://www.healthcareimprovementscotland.scot/wp-content/uploads/2026/05/Operating-Framework-HIS-SG-April-2026.pdf>>, accessed 21 July 2026.

3.21 On 1 October 2012, the Scottish Charter of Patient Rights and Responsibilities [ELJ0003-00013] was published, which sets out what patients are entitled to when they use NHS services and receive NHS care in Scotland, as well as what patients can do when their rights have not been respected in such circumstances.³⁴ The Charter is a mix of rights and responsibilities that currently exist under law, including what it is 'expected patients will do to help the NHS work effectively in Scotland and to help make sure it uses its resources responsibly.'³⁵ The information in the Charter is divided into a number of areas, including patients' rights in relation to accessing and being provided with NHS services in Scotland; rights to communication and being informed about one's healthcare and services, as well as being involved in decisions about them; rights to privacy and confidentiality and to the protection of one's personal health information; and the rights of patients to provide feedback and submit complaints about treatment or care in line with NHS Scotland's complaints procedure.³⁶ [ELJ0003-00139]

Medical education and training in Scotland

3.22 The quality of postgraduate medical training and education is intrinsically linked to patient safety, as doctors-in-training (junior doctors) must be appropriately supervised by consultants (including neurosurgeons) within clinical environments. Following the publication of the landmark Calman Report, a major structural transition occurred between 1995 and 1997. This dissolved the fragmented 'Senior House Officer' and 'Registrar' roles into a single, structured Specialist Registrar (SpR) grade, governed by a clear curriculum and the introduction of National Training Numbers (NTNs). The

³⁴ The Charter was established pursuant to *The Patient Rights (Scotland) Act 2011*.

³⁵ As set out in *The Patient Rights (Scotland) Act 2011*. Section 1(4) of the Act makes clear that nothing in the Charter gives rise to any new rights, imposes any new responsibilities, or alters in any way an existing right or responsibility.

³⁶ Scottish Government, 'Charter of Patient Rights and Responsibilities - Revised: June 2022', available at <[Supporting documents - Charter of patient rights and responsibilities - revised: June 2022 - gov.scot](#)> accessed 21 July 2026.

Medical Royal Colleges held primary authority over curriculum design, exams, and localised peer review inspections.³⁷ [ELJ0003-00060]

3.23 Prior to 2002, postgraduate medical education was decentralised and heavily peer-led, operating under the UK-wide Specialist Training Authority (STA).³⁸ Local delivery and funding were split between advisory committees, such as Scottish Committee for Postgraduate Medical Education (SCOPME) in Scotland, as well as individual regional postgraduate Deaneries within established medical schools. In 2002, NHS Education for Scotland (NES) was established as a Special Health Board. NES holds statutory responsibility across Scotland for the strategy, funding, and delivery of postgraduate medical education and training. NES works closely with the postgraduate medical Deans (within regional postgraduate deaneries) to manage training programs and allocate junior doctor rotations, as well as monitoring the training environment within hospital departments. Funding, regional administration, and the delivery of training are devolved to the NES. During the relevant period, mechanisms for monitoring the safety of training environments were strengthened in Scotland. For example, if a hospital department was found to have poor consultant supervision, inadequate clinical safety, or substandard governance, the Postgraduate Dean (via NES), and in conjunction with the GMC, held the power to withdraw junior doctor training accreditation and remove trainees from that hospital department. In turn, this had the potential to severely impact such department's operational capacity.³⁹ [ELJ0003-00044]

³⁷ *Hospital Doctors: Training for the Future: The Report of the Working Group on Specialist Medical Training*, NHS Executive, May 1995 [The Calman Report], available at: <<https://wellcomecollection.org/works/su27qdmr/items>>, accessed 21 July 2026.

³⁸ This was established pursuant to *The European Specialist Medical Qualifications Order 1995*.

³⁹ See GMC, 'How We Quality Assure Medical Schools and Postgraduate Training', available at: <<https://www.gmc-uk.org/education/how-we-quality-assure-education-and-training/medical-schools-and-postgraduate-training-organisations>>, accessed 21 July 2026.

3.24 In 2005, the Postgraduate Medical Education and Training Board (PMETB) was established, which was UK-wide in operation.⁴⁰ The PMETB was responsible for setting standards for postgraduate medical education and approving training posts. In 2010, the PMETB and its work was absorbed into the GMC, and this has continued to the present date. The GMC's work in this area involves publishing regular updates to what is known as *The Gold Guide*, which governs postgraduate specialty training management.⁴¹ [ELJ0003-00016] In Scotland, Medical Schools (including the University of Dundee, which is associated with Ninewells Hospital) hold statutory and academic responsibility under the Medical Act 1983 for undergraduate medical education and ensuring that clinical placements provide a safe and suitable learning environment for medical students.

3.25 Royal Colleges (including the Royal College of Surgeons of Edinburgh and the Royal College of Physicians and Surgeons of Glasgow) are independent professional bodies incorporated by Royal Charter, rather than operating as statutory regulators. They hold important formal responsibilities, including the following: they set the clinical curricula; design professional examinations; define standards for specialty training; and provide external expert representatives to participate in the quality management and formal approval visits of training departments, alongside Deaneries.⁴² [ELJ0003-00117]

4. **What key principles do, and have since 1995, governed effective policy making, decision-making and delivery of services in the NHS in relation to patient safety, treatment and care (with particular reference to the field of neurosurgery).**

⁴⁰ The PMETB was established pursuant to the *Health Care and Associated Professions (Superannuation and Medical Profession) Order 2003*.

⁴¹ See e.g. Conference of Postgraduate Medical Deans, *Gold Guide*, 10th edn, 7 August 2024, available at: <<https://www.copmed.org.uk/publications/gold-guide/gold-guide-10th-edition>>, accessed 21 July 2026.

⁴² See e.g., Royal College of Surgeons of Edinburgh, 'What We Do', available at: <<https://www.rcsed.ac.uk/the-college/what-we-do>>, accessed 21 July 2026; see generally Academy of Medical Royal Colleges, available at: <<https://www.aomrc.org.uk/>>, accessed 21 July 2026.

4.1 During the relevant period, the development of principles promoting patient safety, treatment and care came predominantly within the remit of peer regulation of doctors. This was particularly the case in the 1990s.⁴³ [ELJ0003-00067] This began to change as a result of a series of healthcare scandals,⁴⁴ [ELJ0003-00150] as well as a growing appreciation of the need for a more systematic, organisation-wide approach. This was underpinned by regulatory frameworks that were designed to guarantee standards of care and manage clinical risk,⁴⁵ [ELJ0003-00119] as well as to facilitate greater corporate accountability on the part of NHS Health Trusts/Boards, including in Scotland.⁴⁶ [ELJ0003-00087] Specifically, in the relevant period, key principles governing policy making, decision-making and delivery of services in the NHS in relation to patient safety, treatment and care in high-risk specialties, such as neurosurgery, should have included the following:

4.1.1 Corporate accountability for clinical performance (clinical governance):

In the late 1990s, the then Scottish Executive published formal guidelines on clinical governance processes, which were to apply to the NHS in Scotland. These guidelines emphasised that an NHS organisation's leadership was accountable for the clinical performance of its staff in corporate terms. Health Board executive teams could no longer treat surgical failures as isolated issues; instead, they had to build systems to monitor, audit, and investigate clinical outcomes. In the case of neurosurgery, for example, this meant that they could no longer treat surgical outcomes as a matter of individual clinical judgement;

⁴³ Rudolf Klein, 'The State and the Profession: The Politics of the Double Bed' (1990) 301 *BMJ* 700.

⁴⁴ Richard Smith, 'All Changed, Changed Utterly: British Medicine Will Be Transformed by the Bristol Case' (1998) 316 *BMJ* 1917.

⁴⁵ Ash Samanta and Jo Samanta, 'Regulation of the Medical Profession: Fantasy, Reality and Legality' (2004) 97(5) *J R Soc Med* 211.

⁴⁶ NHS Scotland, *Rebuilding our National Health Service: Guidance to NHS Chairs and Chief Executives for Implementing Our National Health A Plan for Action, A Plan for Change*, 2001, available at: <https://www.publications.scot.nhs.uk/files_legacy/sehd/publications/ronh/ronh.pdf>, accessed 21 July 2026.

rather, they were required to maintain functioning systems to audit, track, and scrutinise clinical performance data in the speciality.⁴⁷ [ELJ0003-00143]

4.1.2 Evidence-based practice and minimising variation of clinical care:

Decisions regarding patient treatment and care needed to be driven by robust scientific evidence, rather than localised custom or preference. This approach became embedded through the Scottish Intercollegiate Guidelines Network (SIGN) (established in 1993) and the Scottish Medicines Consortium (SMC) (established in 2001). In England, this was developed as a result of the creation of what was then known as the National Institute for Health and Care Excellence (NICE) (established in 1999).⁴⁸ [ELJ0003-00091] It should be noted that healthcare delivery and quality standards became fully devolved matters under the Scotland Act 1998. This meant that NICE guidelines/standards did not apply to the NHS in Scotland. Instead, the SIGN and the SMC were the key bodies responsible for the development of clinical guidelines and technology appraisals in Scotland. However, under formal inter-board agreements, NHS Scotland routinely reviewed and adopted specific NICE guidance to evaluate the safety of novel surgical techniques, for example. In the context of neurosurgery, this would have required that surgical pathways, patient selection criteria, and the adoption of novel operative techniques, would have been required to conform to national evidence-based guidelines and peer-reviewed protocols, so as to eliminate unauthorised or substandard variations in care.

⁴⁷ Scottish Office, *Clinical Governance*, (1998) (n 15).

⁴⁸ National Institute for Health and Care Excellence (NICE), 'History of NICE', available at: <<https://www.nice.org.uk/about-us/history-of-nice>>, accessed 21 July 2026.

4.1.3 Systematic risk management and adverse event auditing: Effective, high-quality healthcare service delivery relies on the principles of proactive risk identification and reactive learning from mistakes. During the relevant period, national expectations of best practice in this area evolved from informal and localised hospital/departmental discussions into structured, mandatory corporate processes. Healthcare organisations were expected to operate comprehensive risk registers and standardised incident reporting systems (which later materialised as software platforms like Datix). This took place on the basis of a perceived need to engage in both the standardisation and operationalisation of processes whereby ‘near misses’ and adverse outcomes in the delivery of healthcare could be systematically analysed to identify root causes, and the learning implemented to reduce the likelihood of such outcomes happening again.⁴⁹ [ELJ0003-00118]

4.1.4 A transition from a blame culture to an open and learning culture: This transition was heavily influenced by the findings of the Bristol Royal Infirmary Inquiry report, which was published in 2001, which recommended the elimination of a ‘blame culture’ when medical mistakes/errors occurred within the NHS.⁵⁰ [ELJ0003-00068] In the wake of the Report, the aim was to create an environment where all NHS staff could openly escalate concerns about an unsafe or underperforming colleague without fear of retaliation.⁵¹ [ELJ0003-00072]

⁴⁹ Note that there have been three editions of Royal College of Surgeons of England, *Good Surgical Practice* which were published in 2008, 2014 and 2025. The latest 2025 edition can be accessed at Royal College of Surgeons of England, *Good Surgical Practice*, March 2025, available at: <<https://www.rcseng.ac.uk/standards-and-research/good-surgical-practice/>>, accessed 21 July 2026.

⁵⁰ Learning from Bristol: The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995, CM 5207(I), July 2001, available at: <https://www.bristol-inquiry.org.uk/final_report/the_report.pdf>, accessed 21 July 2026.

⁵¹ See National Advisory Group on the Safety of Patients in England, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (2013) (Berwick Report), available at: <[Berwick review into patient safety - GOV.UK](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/231111/Berwick_review_into_patient_safety_-_GOV.UK.pdf)>, accessed 21 July 2026. The Berwick Report contributed to a shift within NHS England from a fear-based, target-driven, blame-oriented culture to a

4.1.5 Continuous quality improvement driven by data and evidence: The delivery of healthcare services became underpinned by the principles of continuous quality improvement science. This was accelerated by the Scottish Patient Safety Programme (SPSP) in 2008,⁵² [ELJ0003-00057] which promoted, supported, and accelerated the use of tools – such as the *WHO Surgical Safety Checklist*⁵³ [ELJ0003-00167] – in operating theatres to actively reduce harm, surgical site infections, and avoidable operative complications.

5. Please identify what broad principles have existed or ought to have existed over the relevant period through to the present day to seek to promote patient involvement in informing and shaping policy in the NHS in the areas of patient safety and the quality of patient care, with particular reference to the field of neurosurgery?

5.1 Patient involvement has transitioned from an historical, paternalistic medical model in the 1990s and into the early 2000s to a more active partnership framework, where patients and the public are now recognised as essential co-designers of safer healthcare delivery.⁵⁴ [ELJ0003-00111]; [ELJ0003-00058] In recent years, the broad principles described below have been established to promote patient involvement within Health Boards' patient safety and clinical quality structures:

learning-focused, transparent, system-improvement culture. Similar developments took place in Scotland.

⁵² HIS, *The Scottish Patient Safety Programme* (SPSP), available at:

<<https://www.healthcareimprovementscotland.scot/improving-care/scottish-patient-safety-programme/>>, accessed 21 July 2026.

⁵³ World Health Organization (WHO), 'Surgical Safety Checklist', available at:

<<https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery/tool-and-resources>>, accessed 21 July 2026.

⁵⁴ For relevant policy documents, see Scottish Executive, *Patient Focus and Public Involvement* (2001), available at:

<https://www.publications.scot.nhs.uk/files_legacy/sehd/publications/DC20011212PatFocus.pdf>, accessed 21 July 2026. Since it was established in 2011, Healthcare Improvement Scotland (HIS) has used the Scottish Government's National Standards for Community Engagement as the core benchmark for ensuring the public is involved in planning, designing, and improving health and social care services, see HIS, 'Engaging Communities', available at: <<https://www.healthcareimprovementscotland.scot/improving-care/engaging-communities/<>>, accessed 21 July 2026.

5.1.1 Patient-centred care: Enshrined in the core principle of ‘no decision about me, without me’, this dictates that clinical pathways, healthcare policy, and individual treatment plans must be configured around patient needs and preferences. In neurosurgery, for example, this would require that the patient’s voice be documented and integrated into daily medical practice, ensuring patients comprehend the high-risk versus benefit ratio, inherent in complex operative procedures.

5.1.2 Complaints and feedback as quality intelligence: Patient feedback and formal complaints are treated as important safety indicators, rather than institutional risks. This operates on the basis that a robustly managed complaint provides a direct metric of systemic or individual clinical underperformance, functioning as an early warning mechanism designed to mitigate future patient harm.⁵⁵ [ELJ0003-00013]

5.1.3 Independent patient advocacy and representation: To participate meaningfully within governance structures, patients, particularly those who have sustained harm as a consequence of medical treatment, must have unhindered access to independent support. This was formalised via bodies like the Patient Advice and Support Service (PASS) to ensure vulnerable patient voices achieve executive and organisational visibility.

5.1.4 Public and patient involvement (PPI) in governance: This requires Health Boards to embed patient and public representatives directly into committee structures tasked with policy formulation and safety oversight, a

⁵⁵ Note that in *The Patient Rights (Scotland) Act 2011*, it was established that patients had a right to provide feedback and escalate concerns regarding care and treatment received, which is set out in the *Charter of Patient Rights and Responsibilities* (published 2012), available at: <<https://www.gov.scot/publications/charter-patient-rights-responsibilities/pages/4/>>, accessed 21 July

mechanism progressively mandated in Scotland through Healthcare Improvement Scotland's Community Engagement directorate.

5.1.5 Open disclosure and institutional candour: Following an adverse event, the importance of patient involvement should extend to the investigation phase. Affected patients or their representatives have a right to be integrated into adverse event reviews, provided with transparent explanations of causative factors, and informed of implemented corrective actions.

5. 2 The GMC's *Good Medical Practice*, which was first published in 1995, stated that doctors must 'give patients the information they ask for or need about their condition, its treatment and prognosis and [they] must respond to complaints promptly.' In the 2001 and 2006 editions, [ELJ0003-00029]; [ELJ0003-00030] it was stated that an adequate clinical assessment must actively integrate 'the patient's views', alongside physical and history-taking examinations. The 2006 edition also introduced the concept of 'open communication', which required a prompt, open, and honest explanation by the doctor to the patient if an adverse clinical event occurred. The 2013 edition [ELJ0003-00031], codified 'patient-centred care' as a prerequisite for maintaining professional registration. It made clear that doctors must treat patients as individuals, respect their dignity, and support patients' choices regarding their own care. Doctors were explicitly barred from allowing their personal views or their own convenience to override a patient's autonomous treatment preferences. In addition, communication barriers were required to be actively accommodated by the doctor to ensure informed consent on the part of the patient.⁵⁶ [ELJ0003-00029]; [ELJ0003-00030]; [ELJ0003-00031]

⁵⁶ GMC, *Good Medical Practice*, 1995, 2001, 2006, 2013 editions, available at: <<https://www.gmc-uk.org/professional-standards/archived-professional-standards#good-medical-practice>>, accessed 21 July 2026.

Part C - Appointments

6. **What are the key objectives and principles involved in operating an effective system of appointment of consultant surgeons in the United Kingdom? How, if at all, have they changed since 1995?**

6.1 The appointment of a consultant doctor represents a critical risk management threshold for an NHS organisation. The system must ensure that any individual appointed possesses the necessary clinical competence, technical expertise, and professional suitability to practice independently at the highest tier of the hospital hierarchy. Across the UK, the operational mechanism for appointments has historically been underpinned by a combination of statutory regulation and national collective agreements. In Scotland, for example, this process is governed by the National Health Service (Appointment of Consultants) (Scotland) Regulations, alongside NHS staffing circulars.⁵⁷

6.2 The fundamental principles and objectives governing the appointment of NHS consultants have been in place since 1993 and have governed the consultant appointment process in Scotland since such time. The most recent update to such process took place in 2009 and includes the following:

6.2.1 The principle of merit and open competition: Vacancies must be advertised publicly to ensure a robust, fair, and transparent selection process, designed to attract the highest calibre of applicants.

6.2.2 The principle of independent, external assessment: To counteract local bias or institutional favouritism, appointment panels must feature mandatory external representation. This routinely requires an independent assessor

⁵⁷ *National Health Service (Appointment of Consultants) (Scotland) Regulations 1993.*

nominated directly by the relevant Medical Royal College (e.g., the Royal College of Surgeons of Edinburgh in the case of neurosurgeons) to formally validate that the candidate's clinical competencies match the requirements of the specific specialist consultant post.

6.2.3 The objective of statutory registration verification: A candidate cannot be legally appointed to a consultant post unless they possess active professional registration and are on the GMC's Specialist Register in the appropriate specialty (e.g., neurosurgery).

6.2.4 The principle of multi-disciplinary scrutiny: The selection panel must ensure diverse representation, typically comprising the Health Board's Medical Director (or their Deputy), the Clinical Director for the respective specialty, University/Academic representatives (for teaching hospital posts such as at Ninewells Hospital), another member of the hospital/Health Board executive team and a human resources specialist.

6.3 In terms of providing historical context, the system that was in operation at the start of the relevant period with regards to the appointment of NHS consultants was radically different. This was against a background where this appointment process took place in a decentralised administrative landscape in Scotland, and before political devolution occurred in the late 1990s. Key features of the consultant appointment processes that were in place at this time, included the following:

6.3.1 The 1995 appointment framework: At the start of the relevant period, NHS Tayside (then operating as the Dundee Teaching Hospitals NHS Trust) most likely would have constructed its consultant recruitment panel in the following way. It would have created an Advisory Appointments Committee

(AAC), which required that an independent external assessor be appointed from the relevant Royal College. In 1995, the GMC Specialist Register did not yet exist (it was introduced in January 1996), so this did not need to be checked in relation to a consultant appointment. Similarly, the Certificate of Completion of Specialist Training (CCST) appointment simply required that a doctor hold full registration with the GMC. The assessment of whether a candidate was qualified to be a 'specialist' consultant was left entirely to the local AAC panel and the Royal College assessor to check their credentials.⁵⁸

6.3.2 The structural and employment landscape: The unified NHS Tayside Health Board did not manage acute hospitals in 1995. Instead, hospital care was split into semi-autonomous, competing corporate entities.⁵⁹ Mr Eljamel's actual employer at the time was the Dundee Teaching Hospitals NHS Trust. The Tayside Health Board existed only as a purchaser of care, not the manager of the hospital or the employer of consultants. Under the pre-Calman era (pre-1995), the standardised Specialist Registrar (SpR) grade and National Training Numbers (NTNs) had not yet been rolled out (they began in December 1995). Postgraduate medical training was decentralised, managed loosely via individual University medical school deaneries and peer-led reviews.⁶⁰

6.3.3 Quality and clinical oversight frameworks: The requirement to implement clinical governance processes did not exist until the late 1990s in NHS Scotland. There was no statutory corporate accountability for clinical care. Instead, Health Boards were legally responsible for finances, building maintenance, and waiting times. Clinical quality was largely governed pursuant

⁵⁸ *The National Health Service (Appointment of Consultants) (Scotland) Regulations 1993.*

⁵⁹ *National Health Service and Community Care Act 1990.*

⁶⁰ *National Health Service and Community Care Act 1990* [establishing the NHS Trust system]; GMC, *The Specialist Register* [statutory verification protocols under the *Medical Act 1983*.]

to professional self-regulation, which essentially meant that doctors were trusted to monitor their own performance and peer review each other through informal, local clinical audits.

6.3.4 The lack of Scottish oversight bodies: At the start of the relevant period, there were few, if any, external oversight bodies, of consultant performance. SIGN was in its infancy (it was established in 1993) and had published no comprehensive neurosurgical guidelines at this time. In 2003, quality and safety in healthcare oversight and inspection bodies, such as NHS QIS, was established and it was not until 2011 that HIS took over its functions.

6.3.5 Pre-employment screening: Modern, centralised vetting systems, such as Disclosure Scotland were not in operation until 2002, with the Protecting Vulnerable Groups (PVG) Scheme being established in 2011.⁶¹ [ELJ0003-00113]; [ELJ0003-00114] Pre-employment checks relied on basic, manual verification of GMC registration status and paper reference letters sent between employers.

6.4 While the foundational pillars of open competition for the appointment of consultants and independent external peer review have remained constant, the institutional operational standards evolved significantly during the relevant period in the following ways. First, there was a shift away from subjective to objective competency assessment. Both prior to, and during the early part of, the relevant period, consultant interviews frequently relied predominantly on unstructured panel reviews of a candidate's curriculum vitae, as well as informal references. As the transition occurred to a more objective assessment

⁶¹ See Scottish Government, 'Disclosure Scotland', available at: <<https://www.mygov.scot/organisations/disclosure-scotland>>, accessed 21 July 2026; Scottish Government, 'PVG Scheme', available at: <<https://www.mygov.scot/pvg-scheme>>, accessed 21 July 2026.

took place, behaviour-based and competency-focused interviewing techniques were increasingly used to explicitly test clinical decision-making, leadership capability, communication skills, and whether there was a clear understanding of clinical governance frameworks. Following several high-profile cases of professional deception or unverified credentialing in the UK, the verification process also became much more regulated. In Scotland, for example, this included the introduction of mandatory Disclosure Scotland checks (and later the PVG scheme). Formalised, direct employer-to-employer reference checks replaced informal professional recommendations.

6.5 The NHS consultant contract was also modernised over time, which led to the introduction of the new consultant contract in Scotland in 2004. It fundamentally redefined how an appointment translates into daily hospital practice and a mandatory job planning process was also included in the contract. During the appointment phase, the system shifted from hiring a consultant with open-ended duties to explicitly negotiating a structured Job Plan consisting of a defined balance between Direct Clinical Care (DCC) and Supporting Professional Activities (SPA) (such as audit, research, and teaching).⁶² [ELJ0003-00124]; [ELJ0003-00166]

7. How ought the practising privileges of an NHS consultant surgeon to be determined and maintained? What principles ought to govern their grant and maintenance?

⁶² Scottish Executive, Health Department, Consultant Contract (Scotland) 2004, NHS Circular PCS(DD)2004/2, 30 March 2004, available at: <<https://www.publications.scot.nhs.uk/files/pcs2004-dd-02.pdf>>, accessed 21 July 2026; For an evaluation of the new consultant contract, see Sally Williams and James Buchan, *Assessing the new NHS Consultant Contract: A Something for Something Deal?* (The King's Fund, 2006), available at: <[Assessing the New NHS Consultant Contract: A something for something deal? - Sally Williams, James Buchan - 10 May 2006](#)>, accessed 21 July 2026.

- 7.1 Prior to the formal introduction of mandatory annual appraisals for medical consultants in 2002,⁶³ [ELJ0003-00120] there was no standardised, statutory, or contractually mandated mechanism within NHS Scotland for the maintenance of a consultant's practising privileges or clinical performance on an annual basis. The modern regulatory standard for assessing doctors' practising privileges now requires that maintenance of practising privileges must function as a continuous quality-assurance loop, rather than fixed at a particular moment in time in employment terms. As a result, a consultant 'ought' to maintain their right to practise only through the objective, annual verification of their localised clinical outcomes via the Scottish Online Appraisal and Revalidation (SOAR) framework. In 2012, this appraisal process was formally integrated into the mandatory and statutory five-year revalidation cycle, overseen by the organisation's RO.
- 7.2 Best practice dictates that any data driven variance in surgical performance must trigger an immediate, mandatory administrative and clinical review and a corresponding provisional restriction of those operating privileges to safeguard patient care. A consultant's right to practise is maintained through a strict, multi-layered system overseen by the Health Board's RO, typically the Executive Medical Director, and would likely include the following:

7.2.1 Mandatory annual appraisal: Consultants must complete a comprehensive annual appraisal via the SOAR. To maintain their privileges, the doctor must provide objective evidence across four core domains: (i) *clinical performance*: validated data on their caseload volumes, complications, and mortality rates; (ii) *quality improvement*: active participation in local, national, and international clinical audits; (iii) *significant events*: full transparency

⁶³ Scottish Executive, Department of Health, Collection of Information on the Treatment of NHS Scotland Patients By the Independent Healthcare Sector, Circular NHS HDL(2001) 56, 6 July 2001, available at: <<https://www.publications.scot.nhs.uk/files/hdl2001-56.htm>>, accessed 21 July 2026.

regarding any adverse events or "near misses" they were involved in; (iv) *feedback*: formal, anonymised 360-degree feedback collected from patients and multi-disciplinary colleagues (nurses, trainees, allied health professionals).

7.2.2 Medical revalidation: Every five years, the RO must make a formal recommendation to GMC as part of the medical revalidation processes. The RO can only recommend revalidation, which legally renews the doctor's license to practice, if the doctor has successfully passed all five consecutive annual appraisals and has no active fitness to practise investigations. There are two other outcomes of a medical revalidation recommendation which are 'deferral' and 'failure to engage', both of which are scrutinised by the GMC, with appropriate follow up actions taken.

7.2.3 Continuous job planning: Privileges are bound to an annual Job Plan review. This ensures that the consultant's clinical workload (e.g., the number of complex neurosurgical slots) matches their actual physical capacity, technical competencies, as well as the available support staff and necessary equipment in the hospital.

7.2.4 'Just culture' escalation trigger: Best practice mandates that if a consultant's clinical data triggers a statistical anomaly (e.g., in the case of a surgeon, a spike in surgical site infections or unexpected re-operations), an immediate, temporary restriction of practising privileges must be considered while an independent, non-adversarial, review takes place.

- 7.3 If a surgeon consultant operates on private patients, independent hospitals are required by the HIS to adhere to the following:

7.3.1 Medical Advisory Committees (MACs): Private hospitals must operate a MAC, or a dedicated Practising Privileges Committee. Privileges are not granted indefinitely; they are typically reviewed and formally renewed every one to two years.

7.3.2 The whole-practice appraisal mandate: Under current guidelines, a doctor cannot separate their private practice from their NHS work. To maintain private practising privileges, the consultant must present their unified NHS appraisal portfolio to the private provider's MAC. If a doctor is suspended, or under investigation in the NHS, their private practising privileges must be revoked immediately. The current state of communication between private and NHS providers is reliant both on self-declaration by the doctor and effective RO-to-RO communication between health organisations (whether public or private). It is not automated and is therefore not always reliable.

7.3.3 Independent practising privileges files: The private provider must independently verify and update their GMC specialist registration and ensure that they have a clean Certificate of Good Standing.

7.3.4 Continuous, specialised medical indemnity insurance: This needs to cover the actual high-risk procedures being performed (e.g., complex spinal or cranial neurosurgery).

7.3.5 Complication and readmission rates: This data should be provided for surgeries performed within the specific facilities where the consultant is in private practice.

8. In particular, how ought effective systems for the appointment of consultant surgeons to address the following issues:

- (a) the assessment or verification of foreign qualifications or surgical practices;
- (b) the assessment of the skill and competence of an applicant; and
- (c) the experience of an applicant for a consultant neurosurgeon post, insofar as that may have been gained beyond the geographical area to which the post being applied for relates?

8.1 The GMC regulates doctors through the medical registration process, which vets all international medical graduates. If doctors are not on the GMC Specialist Register, they cannot apply for a substantive (rather than locum) consultant job in the specialty for which they are registered (or any other specialty). Key principles for the appointment of consultant surgeons, including international and competency verification, should include the following:⁶⁴ [ELJ0003-00157]; [ELJ0003-00084]; [ELJ0003-00043]

8.1.1 The assessment and verification of foreign qualifications or surgical practices: In order to be appointed to the role of consultant, the applicant must be on the GMC Specialist Register. If they have qualified outside the UK, they need to go through the GMC's portfolio/Certificate of Eligibility for Specialist Registration (CESR) pathway. This will involve the following: (i) *Primary Source Verification (PSV)*: The regulatory system mandates direct, independent verification of medical degrees, specialist diplomas, and licenses directly from the issuing international University or Ministry of Health (historically managed

⁶⁴ This section draws on the following sources: *The National Health Service (Appointment of Consultants) Regulations 1996*; UK Department of Health, *The National Health Service (Appointment of Consultants) Regulations Good Practice Guidance*, January 2005, available at: <https://www.rcseng.ac.uk/-/media/files/rcs/standards-and-research/support-for-surgeons/nhs_aac20goodpractice_guidance.pdf>, accessed 21 July 2026; NHS Scotland, *Safer Pre-Employment Checking Frameworks and Statutory Advisory Appointments Committee Regulations*, March 2014, available at: <<https://www.staffgovernance.scot.nhs.uk/media/1412/safer-pre-and-post-employment-checks-in-nhsscotland-pin-policy-v2.pdf>> accessed 21 July 2026. GMC, 'Specialty Specific Guidance for Portfolio Pathway Applications', available at: <<https://www.gmc-uk.org/registration-and-licensing/join-our-registers/registration-applications/specialty-specific-guidance>>, accessed 21 July 2026.

via international credentialling services or directly by the national regulator, such as the GMC); (ii) *Statutory Equivalence Mapping*: Responsibility for assessing whether an international postgraduate training curriculum matches domestic standards is centralised at the national regulatory level via the GMC's portfolio/CESR process. For example, the hiring Health Board must verify that their preferred candidate has been formally granted entry to the national Specialist Register via this equivalence mechanism; and (iii) *International Certificates of Good Standing*: They must be collected from the medical regulatory bodies of every country where the candidate has previously held practising privileges to ensure there is no active, historical or pending disciplinary actions or clinical restrictions in place. These Certificates are submitted by the doctor applying for entry on to the GMC specialist register, as part of GMC portfolio/CESR process.

8.1.2 Assessment of the skill and competence of an applicant: The transition to independent consultant status requires definitive proof of technical mastery and safe clinical decision-making. The GMC equivalence process reviews all relevant data, inclusive of multi-dimensional, objective testing.

8.1.3 Assessment of experience gained beyond the local geographical area: Surgical experience gained in external jurisdictions or overseas healthcare systems cannot be assumed to translate seamlessly into local clinical environments without structural calibration. The appointing Health Board should ensure that there is an effective system in place to safeguard care quality through specific transitional mechanisms.

8.1.4 Unified whole-practice audit history: This is assessed by the GMC portfolio/CESR process. A consultant appointment committee is not required to

do this, as it is assumed that the consultant is on the GMC's Specialist Register. The candidate must present comprehensive clinical performance data and audit outcomes covering all their previous employments as part of this GMC process.

8.2 With respect to the consultant appointment committee, the following applies:

8.2.1 Structured competency-based interviewing: Panels are expected to use standardised, behaviour-based scenarios designed to explicitly evaluate clinical judgement; management of complications; understanding of clinical governance; and adherence to patient safety protocols. Local AAC application of this approach is variable.

8.2.2 Direct employer-to-employer reference verification: Written references must be cross-checked via direct verbal or secure electronic confirmation with the applicant's previous Clinical Directors or supervisors. These references must explicitly confirm day-to-day technical competence, operative safety, and multi-disciplinary communication style, rather than providing generalised character testimonials. This is usually done using a structured reference request form.

8.2.3 Operational context adaptation reviews: The selection process must evaluate the applicant's capability to practise within the specific administrative and regulatory context applicable to the local healthcare system. This includes assessing their familiarity with locally applicable regulations, specific national clinical guidelines (such as SIGN or NICE), domestic clinical governance processes, and risk-reporting software.

8.3 If a consultant appointment is made on a substantive (rather than a locum) basis, then Health Boards should ensure that there is a structured induction and supervised practice period. Best practice appointment frameworks usually require that a consultant arriving from another jurisdiction/country does not immediately enter an isolated, unmonitored on-call rota. The appointment ought to feature a contractually defined, formalised period of local orientation and initial peer oversight or mentorship so that their surgical practices can be benchmarked within the new clinical team.

9. **What inductions ought to be offered for newly appointed consultant neurosurgeons? What sorts of matters ought to be covered in such inductions and why?**

9.1 The induction process functions as a clinical risk management mechanism. It needs to orient the doctor to the local safety culture, operational workflows, and specific clinical governance systems of the hiring Health Board.⁶⁵ [ELJ0003-00118]; [ELJ0003-00038]; [ELJ0003-00109] To satisfy best practice standards, the induction ought to be structured into three distinct layers, covering specific administrative and clinical matters, which is set out in a formal documented induction programme: (i) *corporate induction*: focusing on the overarching statutory, legal, and employment obligations of the organisation; (ii) *clinical and departmental induction (surgical directorate level)*: focusing on the specific operational reality, clinical pathways, and human resources within the neurosurgical unit; and (iii) *operational 'buddying' and local mentorship*: a formal period where the new consultant is paired with an established local colleague to navigate localised clinical networks during their initial months of practice.

⁶⁵ The answer to this question draws on the following sources: Royal College of Surgeons (England), *Good Surgical Practice*, current as at March 2025, available at: <<https://www.rcseng.ac.uk/standards-and-research/good-surgical-practice/>>, accessed 21 July 2026; GMC, *Leadership and Management*, came into effect on 12 March 2012, updated 13 December 2024, available at: <https://www.gmc-uk.org/professional-standards/the-professional-standards/leadership-and-management>> accessed 21 July 2026; Scotland Deanery, 'Quality Management-Quality Improvement Framework', available at: <<https://www.scotlanddeanery.nhs.scot/quality/framework/>>, accessed 21 July 2026.

9.2 An effective neurosurgical induction would explicitly cover the following matters:

9.2.1 Clinical governance, adverse event reporting, and risk management:

Training should take place in relation to local adverse incident management systems (e.g., Datix), local duty of candour protocols, and the specific pathways for executing a Significant Adverse Event Review (SAER). It should also set out the hospital department's specific Morbidity and Mortality (M&M) meeting schedule and expectations. This is important because a new consultant must immediately know how to escalate a clinical 'near-miss' or adverse outcome. Informing the consultant about the local 'just culture' framework also supports and encourages transparent reporting from day one, and aims to prevent isolated practice.⁶⁶ [ELJ0003-00074]

9.2.2 Specialised MDT protocols and referral pathways: The precise operational pathways for specialised neurosurgical care should be made clear, including neuro-oncology, neuro-vascular (stroke/aneurysm), paediatric neurosurgery, and spinal trauma. This includes identifying the exact referral catchments, specialised neuroradiology review times, and what active links exist with neighbouring regional healthcare centres. This is important because neurosurgical outcomes depend heavily on the efficiency of wider multi-disciplinary healthcare networks. A consultant must understand local referral thresholds and multi-disciplinary team (MDT) operational rules to avoid dangerous delays in acute patient care or mismanaged elective oncology scheduling.

⁶⁶ In Scotland, the commitment to developing a 'just culture' is embedded in key HIS and NES documentation regarding learning from adverse events and enhancing patient safety, see e.g. NES, 'Restorative Just Culture Checklist' 22 November 2024, available at: <<https://learn.nes.nhs.scot/79398>>, accessed 21 July 2026.

9.2.3 Theatre environment, equipment, and Neuro-Intensive Care Units

(NICU): Direct orientation to the specific neurosurgical operating theatres should be provided, including localised technical equipment (e.g., specific intraoperative neuro-navigation software, surgical microscopes, ultrasonic aspirators, and neuromonitoring arrays). It should also cover the physical layout, staffing models, and admission/discharge criteria for the NICU or High Dependency Unit. This would be important because technical variations exist across different manufacturing brands, as well as hospital layouts. A neurosurgeon needs to have full operational familiarity with local theatre infrastructure *before* performing complex independent procedures so as to eliminate intraoperative friction or equipment errors.

9.2.4 Digital architecture: electronic patient records (EPR), PACS, and

auditing tools: Comprehensive technical training should be provided with respect to local EPR systems, prescribing software, the Picture Archiving and Communication System (PACS) for viewing neuro-imaging, and the national appraisal archiving system (e.g., SOAR in Scotland). This is important because modern clinical safety relies heavily on accurate, real-time data input and tracking. A consultant must be fully competent with local digital infrastructure so they can review critical pre-operative imaging safely, ensure accurate clinical coding, and maintain data continuity for subsequent surgical audits.

9.2.5 Transitional peer oversight and mentorship frameworks:

A formalised period of initial peer oversight should be provided. This includes assigning a designated senior consultant mentor; defining a transitional period where a colleague is easily accessible during high-risk, complex surgeries; and establishing an initial review interval (e.g., at 3 and at 6 months) to evaluate the new consultant's transition into the local on-call rota. This is important because

it provides a crucial safety layer, especially for consultants appointed from other jurisdictions/countries. It ensures that the surgeon's clinical adaptation is actively benchmarked and supported by the existing local clinical team, rather than leaving them to practise in isolation.

Part D – Clinical Governance

General

10. What is clinical governance?

10.1 Clinical Governance is the systematic framework through which NHS organisations are held continuously accountable for safeguarding high standards of care, maintaining patient safety, and driving quality improvement. Before the introduction of formal clinical governance processes, The responsibilities of NHS Health Boards/Trusts focused primarily on financial probity, waiting times, and physical infrastructure,⁶⁷ [ELJ0003-00020] while the actual quality of medical care was treated as a matter of responsibility for individual doctors.⁶⁸ Clinical governance fundamentally altered this by making clinical quality and patient safety a mandatory, corporate responsibility for the entire Health Board, from the CEO down to the ward floor. Clinical governance synthesises previously fragmented elements of hospital care into a single, auditable management system. In Scotland, clinical governance was formally legally introduced into the NHS in 1998, and the term was defined as 'corporate accountability for clinical performance'.⁶⁹ [ELJ0003-00143] [ELJ0003-00110]

⁶⁷ For an historical overview of how hospital boards operated in relation to managing quality and safety in the delivery of healthcare, as well as substandard practice on the part of doctors, see Marilyn Rosenthal, *The Incompetent Doctor: Behind Closed Doors* (Open University Press, 1995) Liam Donaldson, 'Doctors with Problems in an NHS Workforce' (1994) 308 *BMJ* 1277.

⁶⁸ On the issue of legal liability for clinical negligence of doctors, see Anne-Maree Farrell and Edward S Dove, *Law and Medical Ethics*, 12th edn, (Oxford University Press, 2023), Chapter 12.

⁶⁹ Scottish Executive, *Clinical Governance*, 1998 (n 15); Scottish Executive, Department of Health, *Clinical Governance*, Circular MEL(2000)29, 2 June 2000, available at: <<https://www.publications.scot.nhs.uk/files/2000-29final.htm>>, accessed 21 July 2026.

11. What is the difference (if any) between clinical governance, professional governance and corporate governance in the context of NHS hospital care?

11.1 Broadly speaking, corporate governance focuses on the organisational, financial, legal, and strategic integrity of the NHS Health Board/Trust. This is underpinned by corporate governance guidelines, legislation and relevant laws statutory public sector mandates and Treasury guidelines. Such governance also addresses financial solvency, capital projects, structural resource allocation, waiting-list/performance targets, business continuity, and compliance with employment law. The CEO and the Board of Directors are accountable for the overall viability and statutory compliance of the organisation. In 2018, the Scottish Government recognised the need to ensure that governance arrangements in NHS Scotland were fit for purpose. As a result, there was a review of best practice in healthcare governance, resulting in the first edition of Blueprint for Good Governance, which was published in 2019, with a second edition in 2022.⁷⁰ [ELJ0003-00112]

11.2 When reference is made to professional governance in the healthcare context, the focus is primarily on individual doctors (or other individual HCPs), their personal conduct, ethical behaviour, and core competencies. It is underpinned by independent UK-wide regulators, such as the GMC for doctors, or the Nursing and Midwifery Council (NMC) for nurses. These regulators enforce adherence to professional codes of conduct. In the case of the GMC, for example, this would usually involve reference to *Good Medical Practice*,⁷¹ as well as other professional guidelines, such as *Shared Decision Making and Consent*,⁷² [ELJ0003-00039] earlier versions of which were in

⁷⁰ Scottish Government, *NHS Scotland – Blueprint for Good Governance* <[NHS Scotland - blueprint for good governance: second edition - gov.scot](https://www.nhs.uk/blueprint-for-good-governance/)> accessed 21 July 2026.

⁷¹ GMC, *Good Medical Practice*, updated 13 December 2024, available at: <[Good medical practice - professional standards - GMC](https://www.gmc-uk.org/good-medical-practice/)> accessed 21 July 2026.

⁷² GMC, *Shared Decision Making and Consent*, updated 13 December 2024, available at: <[Decision making and consent - professional standards - GMC](https://www.gmc-uk.org/shared-decision-making-and-consent/)> accessed 21 July 2026.

operation in the relevant period. In the case of the GMC, the individual registered doctor would be expected to maintain their professional registration, working within their scope of practice, and keeping up to date with clinical advances in their field.

11.3 In relation to clinical governance – which involves the delivery of a high-quality health care system – the focus is on the systemic quality, safety, and performance of the clinical services delivered by the NHS organisation. The delivery of this system is underpinned by clinical guidelines, audit methodologies, risk management protocols, learning from incidents, and multi-disciplinary operational standards. The Executive Medical Director and Executive Chief Nurse hold a shared operational accountability, though ultimate statutory liability rests with the CEO and the Health Board.

12. Please provide a broad account of clinical governance and the principles associated with it, highlighting any key developments from around 1990 to the present day.

12.1 Since 1990, the structural evolution of clinical governance across the UK represents a significant shift in approach from largely unchallenged professional trust to one of transparent, statutory public accountability.⁷³ In what could be described as the pre-clinical governance era of the early to mid-1990s, following the introduction of the NHS internal market,⁷⁴ the UK government introduced a requirement for all doctors to participate in medical audits, which were defined as the systematic critical analysis of the quality of medical care. This built on a number of initiatives to measure and improve quality which had been introduced during the 1980s by some Royal Colleges and individual doctors. However, medical audit was found to be very variable in practice, with

⁷³ Questions of accountability are not just confined in healthcare, as was highlighted in scholarly works published in the relevant period, see more generally Michael Powers, *The Audit Society: H* (Oxford University Press, 1999); Onora O'Neill, *A Question of Trust* (Cambridge University Press, 2002).

⁷⁴ This was introduced via the *National Health Service and Community Care Act 1990*.

few healthcare providers having managed to establish effective programmes during this period, which covered the full range of medical specialties. It remained essentially the domain of medical staff, with little or no involvement of NHS managers or executive boards.⁷⁵ [ELJ0003-00011] As previously mentioned, questions of clinical quality were viewed as matters for professional self-regulation. Doctors were assumed to be competent by virtue of their qualifications and peer standing. While mechanisms such as clinical audits and postgraduate education existed, they were entirely voluntary, decentralised, and confidential, as well as isolated from executive hospital management. There was no systemic method for detecting failing clinicians or dysfunctional surgical departments, for example.⁷⁶ [ELJ0003-00065]; [ELJ0003-00019]

12.2 The period between 1997 and 2000 saw the emergence of more formal models of clinical governance. A key turning point occurred in the late 1990 and into the early 2000s, driven by several high-profile healthcare system failures, most notably highlighted in the Bristol Royal Infirmary Inquiry Report into paediatric cardiac surgery deaths, which was published in 2001. These failures demonstrated that professional self-regulation alone had proved insufficient to protect patients from harm. Other notable developments and publications in this period include landmark White Papers in Scotland and England, which formally introduced the term and concept of ‘clinical governance’: *Designed to Care* (Scotland),⁷⁷ [ELJ0003-00115] and *The New NHS: Modern.*

⁷⁵ Bristol Royal Infirmary (BRI), *BRI Inquiry Paper on Medical and Clinical Audit in the NHS* (BRI Inquiry Secretariat, September 1999), available at: <<https://www.uhbristol.nhs.uk/files/nhs-ubht/mcanhs.pdf>>, accessed 21 July 2026 [The purpose of this paper was to provide information on the wider context of medical and clinical audit in NHS hospitals during the period 1984-95, looking particularly at how attitudes, policy and practice changed over this period].

⁷⁶ See e.g. Donald Irvine, ‘Doctors in the UK: Their New Professionalism and Its Regulatory Framework’ (2001) 358 (9295) *Lancet: Public Health* 1807; Mary Dixon Woods et al, ‘Why is UK Medicine No Longer a Self-Regulating Profession? The Role of Scandals Involving “Bad Apple” Doctors’, (2011) 73(1) *Soc Sci Med* 1452.

⁷⁷ The Scottish Office, Department of Health, *Designed to Care Renewing the National Health Service in Scotland*, Cm 3811, December 1997, available at: <<https://assets.publishing.service.gov.uk/media/5a7ce91ae5274a2c9a484df0/scotnhs.pdf>>, accessed 21 July 2026.

Dependable (England/Wales).⁷⁸ [ELJ0003-00160] Both White Papers emphasised that quality must be given equal weight to financial metrics on the executive board agendas of NHS Health Boards/Trusts. In the Scottish context, how clinical governance was to be operationalised at local Health Board level was set out in a detailed circular published by the NHS in Scotland Management Executive in 1998. The circular made clear that the adoption of clinical governance and related processes were now mandatory for all Health Boards. As part of this, dedicated clinical governance committees were now required, which were to be directly accountable to executive boards.⁷⁹ [ELJ0003-00143]

12.3 Between 2000 and 2010, clinical governance transitioned from a largely theoretical concept into an explicitly policed operational reality. Key examples highlighting this development are set out below:

12.3.1 Creation of independent inspection bodies: External regulators were established to audit hospital governance frameworks. In Scotland, this began with NHS QIS in 2003, which set national clinical standards and conducted peer-led reviews of hospital compliance.

12.3.2 The 2004 consultant contract: As detailed in previous sections, the 2004 consultant contract formalised the importance of job planning for the first time, explicitly linking consultants' contracts to their clinical governance obligations, which included mandatory participation in clinical audits and continuous professional development.

⁷⁸ UK Government, Department of Health, *The New NHS: Modern. Dependable*, Cm 3807, December 1997, available at: <<https://assets.publishing.service.gov.uk/media/5a7c853740f0b62aff6c2405/newnhs.pdf>>, accessed 21 July 2026.

⁷⁹ Scottish Office, *Clinical Governance* (1998) (n 15).

12.3.3 Introduction of revalidation process This was first proposed in the early 2000s following the Bristol Royal Infirmary Inquiry and the Shipman Inquiry Reports.⁸⁰ [ELJ0003-00064] However, it took until 2012 for revalidation to be put into practice, following objections by the British Medical Association (BMA) and the GMC. The importance of developing a revalidation process involving doctors was also emphasised in the findings of the Francis Report, which was published in 2013. This Report highlighted how a corporate fixation on financial targets and waiting lists could lead to a catastrophic collapse in basic clinical safety.⁸¹ [ELJ0003-00104] [ELJ0003-00015] [ELJ0003-00101]

12.3.4 Introduction of professional appraisal processes for doctors: On 3 December 2012, the GMC introduced a statutory mechanism that formally tied clinical governance data directly to a doctor's legal license to practise. Every five years, a doctor practising in Scotland, for example, must be revalidated via local appraisal loops driven by the Scottish Online Appraisal Resource (SOAR) or regional equivalents.

12.3.5 Creation of bodies to enhance quality and safety in healthcare: Healthcare Improvement Scotland (HIS) was given statutory inspection powers over both NHS facilities and independent private clinics.⁸²

12.3.6 Duty of candour: A statutory duty of candour was introduced first in England, then in Scotland, which required open and honest disclosure to

⁸⁰ Donald Irvine, 'Patients, Professionalism, and Revalidation' (2005) 330 *BMJ* 1265.

⁸¹ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, 2013, (Francis Report), available at: <[Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry - GOV.UK](#)>, accessed 21 July 2026; see also CMO (England), *Good Doctors, Safer Patients* (Department of Health, 2006). For an overview, see Guidubaldo Querci della Rovere et al, 'Good Doctors: Safer Patients—the Chief Medical Officer's Prescription for Regulating Doctors' (2006) 99 (11) *J R Soc Med* 545.

⁸² See *Public Services Reform (Scotland) Act 2010*, Part 6, ss 108-110.

patients following an adverse event from an ethical guideline into a strict legal obligation (for further details, see the answer provided to Question 23 below).

13. What are the key objectives and features of successful clinical governance systems within NHS hospitals in the UK? What are the main pitfalls to be avoided or features which do not promote successful outcomes in the operation of such systems?

13.1 An effective clinical governance system requires an alignment of corporate culture, data infrastructure and clinical leadership. To understand how clinical governance operates on a daily basis within a hospital setting, it can be broken down into seven interconnected pillars, as described below.⁸³ [ELJ0003-00154]

13.1.1 Clinical audit: The systematic review of clinical care against explicit criteria or national benchmarks. A successful audit must be 'closed-loop', meaning if data reveals a deficiency in outcomes or compliance, a formal change in practice must be designed, implemented, and re-audited to ensure improvement. Included here is also organisational participation in relevant national quality audits, for example, the National Neurosurgical Audit Programme (NNAP) initiated in 2013, and which supports identification of variation of care across hospitals.⁸⁴ [ELJ0003-00010]

13.1.2 Risk management: The processes used to identify, assess, control, and minimise clinical risks to patients and staff. This relies on active reporting of near-misses and adverse incidents through tracking software (such

⁸³ For a useful overview of this issue, see THIS Institute, Elements of Quality and Safety Series, available at: <<https://www.thisinstitute.cam.ac.uk/elements/>>, accessed 21 July 2026.

⁸⁴ Note that the NNAP audit was only operationalised in England during the relevant period.

as Datix), maintaining an open corporate risk register, and investigating system failures using root-cause analysis rather than individual blame.

13.1.3 Patient and public involvement (PPI): Ensuring that feedback from patients, carers, and the wider public is actively integrated into the design, monitoring, and evaluation of clinical services. This includes analysing patient complaints and satisfaction surveys to identify systemic clinical vulnerabilities.

13.1.4 Clinical effectiveness and research: Ensuring that the therapies, surgical techniques, and clinical pathways deployed within the hospital are based on the best available scientific evidence. This pillar dictates that unproven or non-standard procedures cannot be introduced into routine practice without formal, independent clinical review and ethical sign-off.

13.1.5 Staff and professional development (CPD): Providing the necessary structure, funding, and time for healthcare professionals to continuously update their skills. It ensures that clinicians do not practice in a state of technical stagnation and that their continuing education directly reflects the specific needs of their clinical departments.

13.1.6 Information governance and management: Safeguarding patient data while simultaneously leveraging digital architecture (such as electronic patient records, prescribing software, and Picture Archiving and Communication System (PACS) imaging databases) to monitor clinical quality, track complication rates, and identify statistical performance anomalies early.

13.1.7 Staffing and staff management: Ensuring that clinical rotas possess the appropriate volume, skill mix, and multi-disciplinary

support required to execute procedures safely. This includes implementing rigorous pre-employment credentialing, annual Job Planning, and mandatory annual appraisals (such as the SOAR system) to verify a clinician's ongoing fitness to practice.

13.2 The main features of an effective clinical governance system include the following:

13.2.1 An authentic commitment and engagement in board level leadership:

Strong Executive Medical Director and Executive Nursing Director leadership and commitment, routine board discussions based on submission of a formal monthly report, and a board culture which promotes supportive challenge and where the wider board (including non-executive directors) can act as a critical friend.

13.2.2 A 'just culture' reporting environment: Successful systems use the 'just culture' framework, which aims to separate honest human error or technical complications from wilful negligence or misconduct. The approach is designed to support staff and patients by removing the fear of immediate punishment for accidental mistakes. Staff are encouraged to report near-misses and adverse events through incident reporting platforms (i.e., Datix). This gives the organisation real time reported data to enable responsive investigation, the outcomes of which support identifying and 'treating' systemic vulnerabilities to prevent the potential for harm or further harm.

13.2.3 Robust, data-driven morbidity and mortality loops: High-performing clinical directorates run regular, mandatory, and multi-disciplinary M & M meetings. Complications and deaths are systematically evaluated against national benchmarks (e.g., SIGN or NICE guidelines). The output enables

closed loop behaviour: if an audit reveals an unacceptably high infection rate or a recurring technical error, a formal change in clinical practice will be designed, implemented, and re-audited.

13.2.4 Clear 'ward-to-board' escalation pathways: There must be a direct, unblocked path for clinical risk data to travel from the event to the executive board. If a clinical team raises a formal concern regarding staffing shortages, equipment failure, or an individual colleague's competence, the governance framework must ensure that this data is evaluated, placed on the corporate risk register for visibility and addressed such that mitigations are enacted to reduce the risk to a level which is acceptable.

13.2.5 Achievement of clear and measurable parameters: In the early 2000s, a review by the National Audit Office (NAO) found that the structures and organisational arrangements to make clinical governance happen had been established in the corporate systems of most NHS trusts in England. It argued that clinical quality issues now had become more mainstream and there was greater or more explicit accountability of both doctors and managers for clinical performance. It found that the professional culture had also moved towards more open and collaborative ways of working. It concluded that key components of clinical governance – including clinical risk management, adverse incident reporting, better information for patients and use of information technology – were in place in most NHS trusts, but the practical commitment to each component within individual trusts varied widely; in some cases, there were other major barriers including a lack of resources, poor

training attendance and a culture that was not conducive to reporting risks.⁸⁵

[ELJ0003-00071]

13.3 The main pitfalls leading to ineffective systems of clinical governance include the following:

13.3.1 Tokenistic 'box-ticking' bureaucracy: The operational failure modes of clinical governance systems frequently stem from administrative gaps or organisational culture dysfunction: The most common failure occurs when clinical governance becomes a passive, administrative paper-chase. If annual appraisals, SOAR inputs, and job plans are completed merely to satisfy a regulatory checklist without active, qualitative cross-checking of the data, dangerous variances in clinical capability can remain undetected for years.

13.3.2 The 'clinical silo' and professional protectionism: In complex, highly specialised areas like neurosurgery, departments can develop insular 'silos', leading to what has been described as a 'club culture'. If non-specialist managers or general medical directors defer entirely to a senior clinician's reputation without independently reviewing raw outcome data, mortality rates, relevant national audit results or staff complaints, the governance system becomes blind to localised patterns of malpractice.⁸⁶ [ELJ0003-00021]

13.3.3 A punitive or 'blame' culture: If an institution responds to adverse event reports with immediate disciplinary action, finger-pointing, or public shaming,

⁸⁵ National Audit Office (NAO), *Achieving Improvements through Clinical Governance: A Progress Report on Implementation by NHS Trusts* (NAO, 2003), available at: <<https://www.nao.org.uk/reports/achieving-improvements-through-clinical-governance-a-progress-report-on-implementation-by-nhs-trusts/>>, accessed 21 July 2026.

⁸⁶ Clare Dyer, 'Bristol Inquiry Condemns Hospital's "Club Culture"' (2001) 323 *BMJ* 181.

the reporting system will fail. Staff will actively suppress information regarding complications, alter clinical charting, or conceal near-misses out of fear for their employment, driving clinical risk underground. This occurs where what might be called a 'fortress culture' exists, where there is an unwillingness to learn from elsewhere; there is a closed corporate and professional mindset; there is overconfidence in the organisation's reputation and standing; and there is a tendency to place blame elsewhere. In this type of working environment, staff often exhibit learned helplessness, and there is normalisation of the abnormal in terms of behaviours or actions.⁸⁷ [ELJ0003-00165]

13.3.4 Allowing a consultant to practise in an independent hospital without verifying their full unified NHS appraisal portfolio This is a fragmented oversight model. If a surgeon is under investigation or showing signs of clinical deterioration within the NHS, any failure to immediately communicate and suspend their private practising privileges represents a critical breakdown in system design.⁸⁸ [ELJ0003-00108]

Clinical governance processes

14. **Please explain the rationale behind, key objectives and main key features of successful systems which relate to the following:**
 - (a) **Professional governance within an NHS hospital environment, including but not limited to continued professional development, maintenance of technical surgical skills, peer oversight, re-validation and appraisal;**

⁸⁷ Kieran Walshe, *Inquiries: Learning from Failure in the NHS?* (Nuffield Trust, 2003), available at: <[Inquiries: learning from failure in the NHS? | Nuffield Trust](#)>, accessed 21 July 2026.

⁸⁸ This was a key recommendation of the Paterson Inquiry Report but has not been implemented to date, see Report of the Independent Inquiry into the Issues raised by Paterson, HC 31, 4 February 2020 (Paterson Report, (2020)), available at: <<https://assets.publishing.service.gov.uk/media/5e39484740f0b60917d658cb/issues-raised-by-paterson-independent-inquiry-report-print-ready.pdf>>, accessed 21 July 2026.

- (b) Whistleblowing for professional and other staff members within NHS hospitals relating to patient outcomes;**
- (c) Adverse incident or near miss review within NHS hospitals;**
- (d) Monitoring clinical outcomes in the field of neurosurgery;**
- (e) Clinical supervision of consultant surgeons within NHS hospitals; and**
- (f) Suspension of NHS consultant surgeons.**

Professional governance within an NHS hospital environment

14.1 The rationale underpinning professional governance in the NHS hospital environment is that individual clinical autonomy must be balanced with objective peer and regulatory accountability. Professional governance ensures that clinicians' knowledge, technical proficiency, and behaviour are continuously reviewed against national standards throughout their careers, rather than assuming lifelong competence based solely on their initial qualifications at the time of appointment. The key objectives of professional governance are to ensure that all practising clinicians remain fit to practise; to identify and remediate practice deterioration early; and to align individual clinical activities with statutory requirements for professional registration.

14.2 The main features of professional governance include the following:⁸⁹ [ELJ0003-00032]; [ELJ0003-00075]

14.2.1 Annual appraisal: [known as SOAR in Scotland] This should be a mandatory and structured review covering the GMC's core domains of *Good Medical Practice*. It requires a doctor to present a validated folder of their whole

⁸⁹ These main features draw on the following sources: *The Medical Profession (Responsible Officers) Regulations 2010*; *The Medical Profession (Responsible Officers) (Amendment) Regulations 2013*; GMC, *Good Medical Practice Framework for Appraisal and Revalidation*, effect March 2011, updated March 2013, available at: <[The Good medical practice framework for appraisal and revalidation](#)>, accessed 21 July 2026; NHS Education for Scotland (NES), *Scottish Online Appraisal Resource (SOAR) Quality Assurance Framework*, available at: <<https://www.appraisal.nes.scot.nhs.uk/what-is/appraisal/>>, accessed 21 July 2026.

practice (inclusive of NHS and non-NHS work), clinical data, personal audit loops, and multi-source 360-degree feedback from colleagues and patients.

14.2.2 Statutory medical revalidation: A formal regulatory cycle occurring every five years, where a designated RO evaluates the appraisal history and submits a recommendation to the GMC to maintain or defer the doctor's license to practise.

14.2.3 Continuous professional development (CPD) tracking: A formalised credit accumulation system set out by the Medical Royal Colleges and documented as part of annual appraisals, requiring doctors to actively participate in external and internal peer education, professional development and, where appropriate, technical skills updates.

Whistleblowing within NHS hospitals relating to patient outcomes

14.3 Institutional protectionism and hierarchies can inhibit reporting by staff members who observe suboptimal clinical practice or emerging patient safety risks. An established whistleblowing system can offer legally protected mechanisms for staff to raise patient safety risks and clinical performance concerns without fear of personal or professional reprisals. The key objectives of such a system are to eliminate the 'bystander effect' within clinical teams; to establish early warning indicators for systemic or individual failures; and to build an organisational culture that prioritises patient safety over institutional reputation. The main features of whistleblowing include the following:⁹⁰

[ELJ0003-00024]; [ELJ0003-00116]

⁹⁰ These identified main features draw on the following sources: *Public Interest Disclosure Act 1998* (c. 23) amending the *Employment Rights Act 1996*; Robert Francis QC, *Freedom to Speak Up: An Independent Review into Creating an Open and Honest Reporting Culture in the NHS* (February 2015) available at: <[The Report](#)>, accessed 21 July 2026; Scottish Public Services Ombudsman, *National Whistleblowing Standards*, available at: <<https://inwo.spsso.org.uk/national-whistleblowing-standards>>, accessed 21 July 2026.

14.3.1 Independent freedom for 'Speak Up' Guardians: Such individuals are designated, accessible individuals located outside direct line management and the executive hierarchy who can offer hospital staff confidential advice and safe escalation routes.

14.3.2 Anonymised and protected escalation channels: Clear policies aligned with public interest disclosure legislation which ensure full confidentiality and legal protection for whistleblowers.

14.3.3 Mandatory executive feedback loops: Structural tracking mechanisms that legally compel executive boards of Health Boards/Trusts to investigate whistleblower concerns, log the findings on the corporate risk register where appropriate, and provide transparent feedback to the person who raised concerns.

Adverse incident or near miss reviews within NHS hospitals

14.4 Every adverse clinical outcome or near miss provides data to identify healthcare system vulnerabilities or individual skill deficiencies. If the organisational response is known to focus purely on individual blame rather than systemic failures, the hospital loses the opportunity to prevent future harm, as there will be a reluctance on the part of staff to report the incident. The key objectives of developing an adverse event system within NHS hospitals is to systematically capture deviation from expected clinical care; to identify root causes rather than symptoms; and to execute proportionate and evidence-based practice modifications to prevent recurrence.⁹¹ [ELJ0003-00143]; [ELJ0003-00052]

⁹¹ See Scottish Office, *Clinical Governance* (1998) (n 15) which established mandatory adverse incident tracking; HIS, *Learning from adverse events through sharing and review: A national framework for Scotland* (originally issued 2013, updated regularly), available at:

14.5 The main features of an adverse event system in NHS hospitals should include the following:

14.5.1 Electronic adverse incident reporting (e.g., Datix): A standardised, hospital-wide platform allowing any staff member to flag an adverse incident, medication error, or operational near-miss immediately.

14.5.2 Significant adverse event reviews (SAER): A multidisciplinary, root cause analysis framework triggered automatically by specific clinical thresholds (such as an unexpected intraoperative death or a permanent neurological deficit). Crucially, the review panel must include external, objective clinicians to prevent local bias.

14.5.3 Triangulation with the professional/organisational duty of candour: A legal obligation to formally inform the patient or their family when an adverse event occurs, share the investigation findings transparently, and issue a meaningful apology (for further details, see the answer provided to Q23).

Monitoring clinical outcomes in the field of neurosurgery

14.6 Neurosurgery carries a high baseline risk of severe, irreversible patient harm. Because it is a highly specialised, low volume discipline, detecting an underperforming outlier requires specialised statistical tracking that distinguishes individual surgeon performance from broader case mix complexity. The objectives are to benchmark local surgical outcome rates against national and international standards; to provide statistical warning triggers for anomalous complication spikes; and to facilitate transparency

<<https://www.healthcareimprovementscotland.scot/wp-content/uploads/2025/02/A-national-framework-for-reviewing-and-learning-from-adverse-events-in-NHS-Scotland.pdf>>, accessed 21 July 2026.

regarding procedural volumes and survival metrics. The key features associated with successful monitoring of surgical outcomes, such as neurosurgery, include the following:

14.6.1 Risk-adjusted outcome modelling (e.g., NNAP metrics): Utilising specialised algorithms to adjust raw data based on patient age, pre-existing comorbidities, and the complexity of the underlying disease.

14.6.2 Statistical process control ('funnel plots'): Plotting procedural volumes against mortality or re-operation rates to visually track whether a surgeon or a unit sits within acceptable standard deviations, or if they have crossed statistical control limits into outlier territory.

14.6.3 Mandated registry interlocking: Automated data submission pathways linking the hospital's theatre tracking software directly to national specialty databases like the British Spinal Registry (BSR).

14.6.4 Collection and review of neurosurgical outcomes data: Although the National Neurosurgical Audit Programme (NNAP) was established by the Society of British Neurological Surgeons (SBNS) in 2013, it was restricted to English data networks. NHS Scotland never directly participated in the NNAP dashboard. Instead, Scottish clinical oversight was provided through the Managed Service Network (MSN) for Neurosurgery,⁹² [ELJ0003-00147]; [ELJ0003-00077] which sought to validate local outcomes using Scottish

⁹² See Society of British Neurological Surgeons (SBNS), *The National Neurosurgical Audit Programme (NNAP) Quality Improvement Framework* (launched 2013), available at: <<https://www.sbns.org.uk/nnap.html>>, accessed 21 July 2026; NHS England, *Everyone Counts: Planning for Patients 2013/14 - Consultant Outcomes Publication Initiative*, available at: <<https://www.england.nhs.uk/wp-content/uploads/2013/12/5yr-strat-plann-guid.pdf>>, accessed 21 July 2026; Managed Service Network for Neurosurgery, available at: <<https://www.msn-neuro.com/>>, accessed 21 July 2026.

Morbidity Records. Consequently, external cross-border data comparison between English and Scottish units (such as Ninewells Hospital in Dundee) was restricted during the relevant period, as there was no UK-wide audit programme in existence.

Clinical supervision of consultant surgeons within NHS hospitals

14.7 While a consultant is an independent medical practitioner, it must be understood that international knowledge and experience advance clinical practice over time, against a background where colleagues age, and surgical, as well as patient, complexity increases. Therefore, a system of professional boundaries and peer review must exist to ensure that complex or high-risk cases are validated by a broader clinical team, such as would take place through a Multi-Disciplinary Team (MDT). The key objectives in doing so are to eliminate isolated clinical practice; to ensure clinical practice is up-to-date; to remove variation of care; to promote collective multidisciplinary ownership of high-risk surgical plans; and to support transitional consultants or those returning to practice after a prolonged absence.⁹³ [ELJ0003-00118]; [ELJ0003-00038]

14.8 The key features of successful approaches that support oversight of individual doctors' practice include the following:⁹⁴ [ELJ0003-00079]

14.8.1 The use of MDTs: Their use is particularly important, particularly in the context of complex pathologies (such as neuro-oncology, spinal or neuro-

⁹³ Royal College of Surgeons (England), *Good Surgical Practice* (n 65).

GMC, *Leadership and management for all doctors*, in effect 12 March 2012, updated 13 December 2024) [Duties of clinical oversight and service delivery management], available at: <<https://www.gmc-uk.org/professional-standards/the-professional-standards/leadership-and-management>> accessed 21 July 2026.

⁹⁴ See e.g., for an overview, NHS England, *Multi-disciplinary Teams: Liaison and Diversion Manager and Practitioner Resources* (2019), available at: <<https://www.england.nhs.uk/wp-content/uploads/2020/01/Multidisciplinary-Teams.pdf>>, accessed 21 July 2026.

vascular cases). Attendance and presentation of cases that come within these areas at MDT meetings should be a pre-requisite for surgery, so that such cases can be subject to peer challenge, and collective sign-off at such meetings.

14.8.2 Dual-consultant operating for high-complexity index cases: Structural scheduling policies should require two fully qualified consultants for ultra-high-risk interventions.

14.8.3 Formal peer review and case notes audits: In cases where there are specific concerns, routine auditing of a consultant's outpatient letters, operative notes, and indications for surgery by an internal or external peer group, is indicated to ensure ongoing alignment with established practice guidelines.

14.8.4 Regular departmental and cross-departmental mortality and morbidity (M & M) meetings: M & M meetings are most effective when they include the wider clinical team, as well as being well structured and led to support safe discussion of each case; to ensure discussions are minuted; and that attendance is mandated.

Suspension of NHS consultant surgeons

14.9 When an individual doctor's practice poses an immediate or substantial threat to patient safety, the Health Board must have a rapid mechanism to remove that risk while a formal investigation is conducted. The main objectives in doing so are: to protect patients from immediate harm; to preserve the integrity of the clinical data and witnesses required for investigation; to support the clinician themselves (note that in most cases the harm is not intentional); and to maintain public trust in the Health Board. The main features of a

successful approach to dealing with this issue include the following:⁹⁵ [ELJ0003-00158]; [ELJ0003-00144]; [ELJ0003-00090]

14.9.1 Separation of immediate suspension from disciplinary action: The immediate deployment of exclusion from practice or temporary restriction of duties must be treated as a neutral act designed to manage risk, rather than an automatic assumption of guilt.

14.9.2 Adherence to standardised national human resource practices and frameworks: Adherence to a highly prescriptive, legally binding, framework that defines the roles of the Case Manager, the Case Investigator, and independent panel oversight.

14.9.3 Immediate external regulatory notification: Legally mandating that if a consultant is excluded or has their clinical practising privileges restricted due to safety or competence concerns, the Health Board must notify the medical regulator (e.g. GMC), neighbouring Health Boards, and private providers within a strict 24-to-48-hour window.

15. What are the main pitfalls to be avoided or features which do not promote successful outcomes in the operation of any such systems?

⁹⁵ This section draws on a range of sources: UK Department of Health, *Maintaining High Professional Standards in the Modern NHS* (MHPS) framework (2005) [Note: adopted in England but served as a UK-wide reference], available at: <https://www.elft.nhs.uk/sites/default/files/202201/mhps_policy.pdf>, accessed 21 July 2026; Scottish Office, Health Department, Report of the Short-Life Working Group on Suspension of Medical and Dental Staff, NHS Circular PCS(DD)1999/7, 6 April 1999, available at: <<https://www.publications.scot.nhs.uk/files/pcs1999-dd-07.pdf>>, accessed 21 July 2026; subsequent NHS disciplinary agreements, see e.g., NHS Workforce, *Management of Employee Capability Policy*, current, available at: <<https://workforce.nhs.scot/policies/capability-policy-overview/>>, accessed 21 July 2026.

15.1 The key features which do not promote successful outcomes in the operation of clinical governance systems include the following:

15.1.1 The 'conspiracy of tolerance' and deference to seniority: Elite clinical standing and institutional hierarchy can obscure systemic or individual failures with respect to quality and safety in healthcare settings.⁹⁶

15.1.2 The 'box-ticking' performance trap where appraisals are completed without qualitative verification: compliance patterns where qualitative input is substituted for checkbox administrative exercises.⁹⁷ [ELJ0003-00034]

15.1.3 A punitive culture that subdues reporting: Establishment of clear behavioural links between a punitive blame culture and the active suppression of medical error data.⁹⁸ [ELJ0003-00155]

15.1.4 Fragmented data architecture ('siloes information'): Fragmentation of complaints, audits, and clinical outcomes data across separate administrative silos prevents early risk identification.⁹⁹ [ELJ0003-00068]; [ELJ0003-00108]

16. Please highlight any key developments in relation to the approach to the successful institution and operation of any such systems which have occurred since 1995?

⁹⁶ Francis Report (2013) (n 81).

⁹⁷ GMC, *An Evaluation of the Introduction of Medical Revalidation in the UK* (UMbRELLA Report, 2018), available at: <<https://www.gmc-uk.org/about/what-we-do-and-why/data-and-research/research-and-insight-archive/evaluating-the-regulatory-impact-of-medical-revalidation>> accessed 21 July 2026.

⁹⁸ See e.g. UK Department of Health, *Organisation with a memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (TSO 2000), available at: <https://qi.elft.nhs.uk/wp-content/uploads/2026/02/r_02-an-organisation-with-a-memory-l-donaldson.pdf> accessed 21 July 2026.

⁹⁹ Learning from Bristol Report (2001) (n 50); Patterson Inquiry Report (2020), Recommendation No. 1 (n 88).

16.1 Key developments which contributed to the successful implementation and operation of clinical governance systems in the relevant period included the following: the shift from informal appraisal of doctors to mandated medical revalidation in 2012, which was, and continues to be, overseen by the GMC;¹⁰⁰ [ELJ0003-00048] the transition from paper documentation of adverse events/near misses to centralised electronic tracking platforms (such as Datix) in the 2000s;¹⁰¹ [ELJ0003-00002] the introduction of an independent national whistleblowing process (Scotland) (equivalent to speak-up guardians in England);¹⁰² [ELJ0003-00146] and the launch of the Society of British Neurological Surgeons, National Neurosurgical Audit Programme (NNAP) in 2013. Note that the NNAP benchmarks mortality outcomes and activity rates for neurosurgical units and individual consultants, drawing on Hospital Episode Statistics (HES) to ensure statistically valid comparisons of patient care but does not include Scottish neurosurgical data.¹⁰³ [ELJ0003-00147]

17. **To what extent is it or would it have been normal or beneficial for health boards (or similar bodies like health trusts) to institute, maintain and operate systems for monitoring clinical outcomes in the private practice of surgeons who also enjoy NHS practising privileges in hospitals under their management and control since 1995? What are the key objectives, principles and features of successful-for such systems/ what would they have been?**

¹⁰⁰ See GMC, 'Revalidation', available at: <<https://www.gmc-uk.org/registration-and-licensing/managing-your-registration/revalidation>>, accessed 21 July 2026.

¹⁰¹ Audit Scotland, *Overview of Scotland's Health and NHS Performance 2006/07*, 14 December 2007, available at: <<https://audit.scot/publications/overview-of-scotlands-health-and-nhs-performance-200607>>, accessed 21 July 2026.

¹⁰² Scottish Public Services Ombudsman, 'Independent National Whistleblowing Officer', available at: <<https://inwo.spsos.org.uk/>>, accessed 21 July 2026. The equivalent in England: 'Speak Up Guardians', see the report Francis, *Freedom to Speak Up Review* (n. 90).

¹⁰³ Society of British Neurological Surgeons, *National Neurosurgical Audit Programme (NNAP) Annual Reports* (2013, 2014). Note that the NNAP, which was first established in 2013, benchmarks mortality outcomes and activity rates for neurosurgical units and individual consultants. The programme utilizes Hospital Episode Statistics to ensure statistically valid comparisons of patient care, see British Neurological Surgeons, 'NNAP', available at: <<https://www.sbns.org.uk/nnap.html>>, accessed 21 July 2026.

17.1 Between 1995 and the introduction of statutory revalidation in late 2012, it was not normal practice for a Health Board to directly monitor, audit, or collect real-time data on the clinical outcomes of a surgeon's private practice, even if that surgeon held a full-time concurrent NHS contract within their facility. Under the 1995 NHS consultant contract framework, private practice and NHS practice operated as completely separate corporate and clinical entities. An NHS Trust's direct clinical governance jurisdiction ended at the organisational boundary of the NHS. Private healthcare providers (such as independent hospitals) operated under completely distinct regulatory regimes and issued their own independent 'practising privileges'. These providers utilised local Medical Advisory Committees (MACs) to oversee clinical standards. There was no automated, formal, or routine cross-sharing of complications, morbidity data, or surgical volumes between the private sector and the NHS. This strict separation created a significant vulnerability where an underperforming or dangerous surgeon could experience high complication rates or patient complaints within an independent private hospital without that data triggering any safety flags on their NHS Trust risk register, and vice versa.

17.2 Following the introduction of statutory medical revalidation in December 2012,¹⁰⁴ [ELJ0003-00042]; [ELJ0003-00032] the expectations for Health Boards changed significantly in the following key respects:

17.2.1 Mandatory whole-practice appraisal: A successful framework dictates that a Health Board, acting as the 'designated body' spearheaded by its RO,

¹⁰⁴ GMC, 'Effective Governance to Support Medical Revalidation', available at: <<https://www.gmc-uk.org/registration-and-licensing/employers-and-other-organisations/effective-clinical-governance-to-support-revalidation>>, accessed 21 July 2026; GMC, *Good Medical Practice: Framework for Appraisal and Revalidation* [Domain 1: Knowledge, Skills and Performance], available at: <<https://www.gmc-uk.org/-/media/gmc-site/registration-and-licensing/the-good-medical-practice-framework-for-appraisal-and-revalidation-55937137.pdf>>, accessed 21 July 2026.

compels the consultant to provide verified data from their private practice during their mandatory annual appraisal via platforms like SOAR.

17.2.2 Independent sector verification certificates: A consultant must secure a standard case load certificate from the registered manager or Medical Director of the private facility where they hold practicing privileges. This certificate must explicitly detail their volume of private procedures, logged adverse incidents (e.g., Datix entries), and any active or historical patient complaints.

17.2.3 Interlinked digital registries: Modern specialty registries, such as the BSR, allow consultants (including in Scotland) to upload surgical data regardless of whether the procedure took place in an NHS hospital or a private clinic/hospital. This creates a single, auditable record accessible during peer review. Mention should also be made of the Private Health Information Network (PHIN) which is a government-mandated, industry-certified, independent organisation which publishes information about the safety, quality and costs of private healthcare (although this occurred post the relevant period).¹⁰⁵
[ELJ0003-00008]; [ELJ0003-00097]

17.3 The main pitfalls and failures to avoid in relation to monitoring clinical outcomes:

17.3.1 Passive reliance on self-declaration: The most severe failure occurs when a Health Board passively relies on a clinician's signed self-declaration

¹⁰⁵ BMA / Independent Healthcare Provider Network (IHPN), *Medical Practitioners Assurance Framework (MPAF) for the Independent Sector* 2019, updated 2022 (established expectations for practising privilege validation and data-sharing), available at: <<https://www.ihpn.org.uk/report/medical-practitioners-assurance-framework-mpaf-refresh/>>, accessed 21 July 2026; see generally Private Health Information Network (PHIN), available at: <<https://www.phin.org.uk/>>, accessed 21 July 2026.

that they have 'no concerns or issues' to report from their private practice, without demanding verified, primary-source data from the independent facility.

17.3.2 The communication void during suspensions: A major governance failure may occur when a Health Board formally suspends a consultant or restricts their operative practice due to immediate patient safety concerns, but fails to issue an immediate notification to the responsible officers of neighbouring private facilities where that same surgeon has active practicing privileges. This leaves the surgeon free to continue operating on private patients despite being deemed unsafe by the NHS.

17.3.3 Fragmented information flows: Allowing private work data to remain strictly inside the doctor's personal appraisal portfolio rather than integrating its systemic risks (such as a high overall complication rate across both sectors) into the Health Board's overarching clinical oversight mechanisms.

Complaints and feedback

18. Why is it important for NHS hospitals to institute, maintain and operate systems for receiving and handling complaints and/ or feedback from patients (or representatives of those patients)?

18.1 Patient complaints and relatives/carers feedback systems provide a valuable data stream for clinical governance. Complaints act as an early-warning diagnostic tool for identifying behavioural issues, technical performance issues, and systemic communication breakdowns that staff might tolerate or normalise due to institutional hierarchies. The objectives of such systems are to provide a clear, transparent, and accessible path for patients to question their experience and outcomes of care; to de-escalate conflicts

through early local intervention; and to systematically capture, categorise, and convert patient distress into actionable clinical and where appropriate behavioural or team improvement loops.

19. **Please explain the reasons for, objectives and main key features of successful complaints or feedback systems within NHS hospitals. In particular, to what extent and how should such systems include features which:**
- (a) intimate to patients or their representatives what complaints or feedback systems are available to them and how they will work;**
 - (b) involve complainers in their operation;**
 - (c) take action arising from the outcome of any investigations undertaken; and**
 - (d) retain records of the processes involved in them and make them available to complainers or more widely; and why?**

19.1 Since the 1990s, NHS Scotland's approach to patient complaints policy, and its handling of complaints, has gone through several stages. In 1996, the first formalised NHS complaints procedure was introduced to establish a uniform approach for patients across Scotland. In 2005, the procedure was revised following independent reviews to make the system more patient-focused and less adversarial. The *NHS Quality Strategy*, published in 2010, set out the Scottish government's commitment to 'putting people at the heart of everything the health service does in providing safe, effective and person-centred care'.¹⁰⁶ [ELJ0003-00126] As part of this commitment, *The Patient Rights (Scotland) Act 2011* was adopted, which legally enshrined the rights of patients to give feedback, raise concerns, and make complaints. This legislation also established the Patient Advice and Support Service (PASS) to provide independent free advice and assistance to patients wishing to voice concerns.¹⁰⁷ [ELJ0003-00094] In the wake of the

¹⁰⁶ Scottish Government, Health and Social Care, *Healthcare Quality Strategy for NHS Scotland*, 10 May 2010, available at:

<<https://www.gov.scot/publications/healthcare-quality-strategy-nhsscotland/>>, accessed 21 July 2026.

¹⁰⁷ Patient Advice and Support Service (PASS), available at: <<https://pass-scotland.org.uk/>> accessed 21 July 2026.

2011 Act, a *Charter of Patient Rights and Responsibilities* was published in 2012,¹⁰⁸ [ELJ0003-00139] which sets out existing rights and responsibilities of people who use NHS services and receive NHS care in Scotland.¹⁰⁹ [ELJ0003-00128]

19.2 Secondary legislation was adopted to support the implementation of the Patient Rights Act which came into force on 1 April 2012,¹¹⁰ and a revised 'Can I Help You?' Good Practice Guidance on handling and learning from feedback and complaints was issued to NHS Health Boards in March 2012.¹¹¹ [ELJ0003-00127] This made the Boards directly responsible for the collection, monitoring and reporting of complaints received in relation to services they provide and places additional responsibility on Boards for the collection and monitoring of complaints received by their family health service providers. The aim was to focus on early and local resolution of complaints, as well as to ensure that learning from such complaints takes place and improvements are made where appropriate as soon as possible after the issue that gave rise to the complaint. Since 1996, Public Health Scotland has published annual data on complaints made to hospitals and community health services.¹¹² [ELJ0003-00100]

¹⁰⁸ Scottish Government, 'Charter of Patient Rights and Responsibilities', available at: <<https://www.gov.scot/publications/charter-patient-rights-responsibilities-revised-june-2022/>>, accessed 21 July 2026.

¹⁰⁹ Scottish Government, Health and Social Care, 'Can I Help You? Guidance for handling and learning from feedback, comments, concerns or complaints about NHS health care services', 29 March 2012, available at: <<https://www.gov.scot/publications/help-guidance-handling-learning-feedback-comments-concerns-complaints-nhs-health-care-services/>>, accessed 21 July 2026.

¹¹⁰ *Patient Rights (Complaints Procedure and Consequential Provisions) (Scotland) Regulations 2012* (Complaints Regulations) and the *Patient Rights (Feedback, Comments, Concerns and Complaints) (Scotland) Directions 2012* (Complaints Directions).

¹¹¹ Scottish Government, Chief Nursing Officer, Patients, Public and Health Professions Directorate, *Guidance on Handling and Learning from Feedback, Comments, Concerns and Complaints about NHS Health Care Services*, CEL 8 (2012) 28 March 2012, available at: <<https://www.publications.scot.nhs.uk/files/cel2012-08.pdf>>, accessed 21 July 2026.

¹¹² Public Health Scotland, 'National Data Sets', available at: <<https://publichealthscotland.scot/resources-and-tools/health-intelligence-and-data-management/national-data-catalogue/national-datasets/search-the-datasets/hospital-and-community-health-service-complaints-isd-s-40a/>>, accessed 21 July 2026.

19.3 The current *NHS Complaints Procedure* defines a complaint as: ‘any expression of dissatisfaction about our action or lack of action, or about the standard of service provided by us, or on our behalf.’ The complaint can be made in person, by phone, by email, or in writing. Anyone can make a complaint, and this can be done directly to the particular NHS service in question, or someone else can make the complaint on behalf of the patient, such as a relative, a carer, a friend or any other person chosen by the patient. There are also advocacy services, such as PASS, which can assist with making the complaint. There is a specified range of issues for which complaints can be submitted, including failure to provide a service; inadequate standard of service; lack of information and clarity; treatment by – or attitude of – a member of staff; operational and procedural issues; and a failure to follow the appropriate process. The complaint should ordinarily be submitted within 6 months of the specified event, or when the patient finds out they have a reason to complain, but no longer than 12 months after the event itself (this can be subject to review by the Scottish Public Services Ombudsman (SPSO)). There is a two-stage complaints procedure: stage one is focused on ‘early, local resolution’, which seeks to resolve the complaint within five working days. If the patient remains dissatisfied with the response received, then they may ask to proceed to stage two. The complaint may proceed directly to stage two if it is clear that it is complex or needs detailed investigation. The second stage complaint will be formally acknowledged within three working days, and a decision will be provided in no more than 20 working days, unless there is clearly a good reason for needing more time. Following receipt of the second stage decision, the complainant can ask the SPSO to consider it.¹¹³

[ELJ0003-00145]

¹¹³ NHS Education for Scotland, *NHS Scotland Complaints Handling Procedure Public Facing Model: Quick Guide*, available at: https://nes.scot.nhs.uk/media/x1wkngwf/20231031_nhs_complaints_procedure_public_quick_guide.pdf, accessed 21 July 2026; see also SPSO, *The NHS Scotland Complaints Handling Procedure*, Version 1.1, revised Jan 2021, available at: <https://www.spsos.org.uk/sites/spsos/files/csa/OriginalCHPs/NHSMCHPMarch2021.pdf> accessed 21 July 2026.

19.4 Published academic research examining NHS Scotland's approach to patient complaints has highlighted the gap between government/institutional policy and patient expectations regarding outcomes. Qualitative empirical research conducted in the mid-2000s found that patient complaints often resulted from a sense of feeling disempowered. Grievances included aspects of medical care, general care, not feeling fully informed, not including family members in the consent process and resourcing problems. Communication breakdown was also identified as one of the main reasons behind patient dissatisfaction.¹¹⁴ [ELJ0003-00129] Subsequent empirical research found that NHS responses to patient complaints rarely acknowledged the amount of detail or 'work' involved in making the complaint, with responses using strategies such as unintentionality or exceptionality to mitigate substandard experiences of care. There were also examples of what the authors described as the 'fauxpology' – a non-apology or false apology (e.g. I am sorry you feel) – which imputes the cause of distress to the subjective (and possibly misguided) impressions of patient complainants. In doing this, the responses sought to avoid blame or responsibility for the events that led to complaints, implying that complainants' feelings did not align with what they considered to be the 'facts'.¹¹⁵ From the doctors' perspective, published survey research showed that being the subject to NHS patient complaints procedures made them feel 'powerless and emotionally distressed', resulting in them 'experiencing negative feelings towards both those managing complaints and the complainants themselves. Many felt unsupported, fearful of the consequences and that the complaint was unfair'.¹¹⁶

¹¹⁴ Scottish Government, Health and Community Care, *A Study of Medical Negligence Claiming in Scotland*, 2012, authored by Frank Stephen, Angela Melville and Tammy Krause, available at: <<https://www.gov.scot/binaries/content/documents/govscot/publications/research-and-analysis/2012/06/study-medical-negligence-claiming-scotland/documents/study-medical-negligence-claiming-scotland/study-medical-negligence-claiming-scotland/govscot%3Adocument/00394482.pdf>>, accessed 21 July 2026.

¹¹⁵ May McCreddie et al, 'A Qualitative Study of National Health Service (NHS) Complaint-Responses' (2021) 21 *BMC Health Services Research* 696.

¹¹⁶ Tom Bourne et al, 'Doctors' Experiences and their Perception of the Most Stressful Aspects of Complaints Processes in the UK: An Analysis of Qualitative Survey Data' (2016) 6 *BMJ Open* e011711.

[ELJ0003-00004] In contrast, a review of patient complaint data from other jurisdictions highlighted the phenomenon of doctors who are ‘frequent flyers’ in terms of being the subject of patient complaints.¹¹⁷ [ELJ0003-00005]

19.5 From a healthcare systems perspective, patient complaints and relatives/carer feedback provide valuable data to inform the approach taken to clinical governance. Patient complaints have the potential to act as an early warning diagnostic tool for identifying behavioural issues, technical performance issues, and systemic communication breakdowns that doctors and other HCPs might tolerate or normalise due to institutional hierarchies. From a clinical governance perspective, the aim would be to design a transparent and accessible path for patients to question their experience and outcomes of care; to de-escalate conflicts through early local intervention; and to systematically capture, categorise, and convert patient distress into actionable clinical and where appropriate behavioural or team improvement loops.¹¹⁸ [ELJ0003-00052]

19.6 A successful, high-performing hospital-based complaints system relies on three key operational mechanisms:

19.6.1 Streamlined resolution pathway: In alignment with modern public service/ombudsman models, complaints are routed through a strict a staged framework (see paragraph 19.3 above).

¹¹⁷ Marie Bismark et al. ‘Identification of Doctors at Risk of Recurrent Complaints: A National Study of Healthcare Complaints in Australia’, (2013) 22 *BMJ Qual Saf* 540 [Note that 3% of Australia’s medical workforce accounted for 49% of complaints and 1% accounted for a quarter of complaints].

¹¹⁸ See generally, HIS, *Learning from Adverse Events through Sharing and Review: A National Framework for Scotland*, available at: <<https://www.healthcareimprovementscotland.scot/publications/a-national-framework-for-reviewing-and-learning-from-adverse-events-in-nhs-scotland-february-2025/>>, accessed 21 July 2026. Note also the Francis Inquiry (2013) (n 81), which highlighted how excluding the direct narratives of families caused the systemic minimisation of severe clinical failures and the Bristol Inquiry Report (2001) (n 99), which demonstrated that failing to bridge the gap between patient feedback and formal clinical practice restrictions directly results in preventable mortality.

19.6.2 Centralised data aggregation and coding: All incoming patient feedback, written complaints, and verbal concerns are expected to be registered on a single centralised digital architecture (such as Datix or InPhase) and complaints are expected to be cross-coded by the clinician's name, the specific procedure type (where relevant), and the clinical sub-directorate to enable automated trend analysis.

19.6.3 Independent advocacy: Providing patients with independent support mechanisms, such as PASS, to ensure that vulnerable or traumatised patients can present their concerns clearly and objectively.

19.7 Other beneficial features of a successful aspects of a high-performing hospital-based complaints system include the following:

19.7.1 Intimation and communication of available systems: Successful clinical governance systems actively publicise their feedback to patients and their representatives. This is achieved through physical signage across clinical areas; detailed information booklets distributed upon inpatient admission; and dedicated sections on the healthcare provider's public websites detailing clear, step-by-step guidance on how a complaint is processed.¹¹⁹ [ELJ0003-00052]; [ELJ0003-00078]; [ELJ0003-00151]

¹¹⁹ See e.g., HIS, *A National Framework for Reviewing and Learning from Adverse Events in NHS Scotland* (n 91); NHS England, *Serious Incident Framework: Supporting Learning to Prevent Recurrence*, 27 March 2015, available at: <[serious-incident-framework.pdf](#)>, accessed 21 July 2026; See the Strategic Executive Information System (StEIS) [NHS England's system for reporting and monitoring the progress of serious incident investigations], available at: <<https://www.england.nhs.uk/statistics/statistical-work-areas/patient-safety-data/overview-of-patient-safety-event-recording-systems/>>, accessed 21 July 2026.

19.7.2 Involvement of complainants in system operations: Modern clinical governance processes recognise that involving patient complainants at an early stage is highly beneficial and necessary for an accurate investigation. Patients and families possess critical factual details regarding timeline deviations, behavioural anomalies, and specific clinical statements that are rarely captured in official, retrospective medical notes.

19.7.3 Expected extent and mechanisms: Patient complainants should be integrated directly into the investigation process rather than treated as external observers, or even excluded from the process altogether. Operationally, this requires that, at the initiation of a formal investigation (Stage 2 under modern complaints procedures, see above), the designated investigator contacts the complainant directly to define the explicit parameters of the grievance, record their testimony, and map their expected outcomes. Successful complaint procedures also mandate that facilitated face-to-face resolution meetings are offered, where patient complainants can present their experiences of treatment and care directly to clinical managers and investigators. The rationale for this approach is that involving patients and their families is important because clinical notes are written retrospectively and may omit critical diagnostic timelines, behavioural changes, or explicit verbal assertions made by treating doctors and other HCPs. Involving the patient complainant and their families ensures that the investigation relies on a more rounded history, rather than a curated institutional record.

19.7.4 Taking action arising from investigation outcomes: A stage 2 investigation of a patient complaint should culminate in an explicit, auditable Action Plan. This plan should identify systemic or individual clinical failures, assign named corporate leads to execute remediation and specify firm

deadlines for completion. Crucially, complaints data must be integrated into the organisation's broader risk registers (e.g., Datix) and should directly inform the annual appraisals, job planning, and whole-practice evaluations of named doctors and other HCPs, where appropriate. If an investigation reveals direct threats to patient safety, the system must trigger immediate escalation routes to appraise and, where necessary, to restrict clinical duties or to initiate a formal capability review under standardised disciplinary frameworks.

20. What are the main pitfalls to be avoided or features which do not promote successful outcomes in the operation of such complaint and feedback systems?

20.1 The main pitfalls and features that promote unsuccessful outcomes in patient complaint and feedback systems:¹²⁰ [ELJ0003-00128]; [ELJ0003-00145]

20.1.1 Siloing: The most severe failure occurs when a hospital's complaints department operates in an administrative silo away from the Executive Medical Director's or Executive Chief Nurse's office, the litigation team, and clinical department heads. If a neurosurgeon accumulates multiple complaints regarding unexpected neurological deficits, for example, but these are handled as isolated events by administrative staff, then the aggregated clinical risk is likely to remain invisible.

20.1.2 Organisational defensiveness culture: When hospitals treat complaints as immediate reputational threats or legal liabilities, their responses become highly defensive, formulaic, and non-committal. This approach deepens patient

¹²⁰ The response to Q20 draws on the following sources: *The Scottish Public Services Ombudsman Act 2002* [establishes the legal basis for standardised public sector complaints monitoring in Scotland] Scottish Government, Health and Social Care *Can I Help You?* (n 109); SPSO, *NHS Scotland Model Complaints Handling Procedure* (n 113).

trauma, suppresses internal staff reflection, and forces patients and their families to escalate issues to external regulatory or legal bodies in an attempt to have their concerns addressed.

20.1.3 Passive deference to a doctor's personal narrative: When an administrative investigator receives a complex clinical complaint and simply asks the named doctor to self-certify what occurred, accepting their unvalidated account without independently auditing the operation notes, theatre records and nursing charts, the investigation fails to provide objective quality assurance.

20.1.4 Allowing unresolved staff retaliation: A system fails if frontline nursing or junior medical staff who witness clinical malpractice or technical errors are afraid to assist a patient with a complaint out of fear of professional bullying, marginalisation, or direct career retaliation from the senior doctor involved.

20.1.5 Adequate investigations, poor action planning and follow-up: Patient safety investigation is a skilled activity and requires appropriate resources. Without investment in resources and training to support investigations, action planning and follow up, the outcomes are likely to be flawed and erroneous and risk missing and remediating key elements that caused the original concern.

Part E - Healthcare management

Management of clinical practice

21. Please explain the main key objectives and features of successful systems which govern the following, as well as the main pitfalls to be avoided in the operation of such systems:

- (a) Referral of NHS patients for private treatment;
- (b) The operation and allocation of theatre lists for the scheduling of surgery and the allocation of surgeries to individual surgeons to perform, including but not limited to the allocation of surgeries to surgeons in training and the provision of adequate supervision;
- (c) The maintenance of an appropriate workload for consultant surgeons, including but not limited to the balancing of surgical commitments with teaching, research and private professional commitments;
- (d) The interaction and consultation between professionals involved in different fields of medical practice, including but not limited to the holding of and attendance at multidisciplinary meetings;
- (e) Training and supervision of neurosurgeons in training; and
- (f) The involvement of neurosurgical patients in research projects.

21.1 The main objectives and features of successful systems governing the management of clinical practice in identified areas, such as neurosurgery, as well as the main pitfalls to be avoided in the operation of such systems, are set out below.

Referral of NHS patients for private treatment

21.2 Successful referral systems operate clear administrative and operational boundaries between NHS and private treatment of patients. The key objectives in doing so are to ensure absolute clinical equity and transparency; to avoid (potential) conflicts of interest; and to prevent 'queue-jumping' where doctors utilise their NHS outpatient clinics to recruit patients for their private practice. For example, an NHS consultant should not be

actively suggesting or directing an NHS patient to their private practice during an NHS consultation. If a consultant is allowed to cross-refer an NHS patient directly to their own private list, then this facilitates the manipulation of NHS waiting times, as well as incentivising private financial gain for such consultants. This may also lead to ‘information black holes’, whereby there is a failure to track the long-term clinical complications arising from surgeries performed in private settings once the patient is re-admitted to acute NHS wards.¹²¹ [ELJ0003-00123]; [ELJ0003-00156]; [ELJ0003-00007]; [ELJ0003-00080]

Operation, allocation, and scheduling of theatre lists

21.3 This is often a matter of local custom and practice and is governed by local operational policies and procedures to maximise surgical efficiency and productivity. Trainee doctors are expected to be given roles and responsibility aligned to their training grade, experience and perceived competency. It is the responsibility of the surgical consultant to make a judgement on appropriate supervision, taking into account the above-mentioned matters. If the trainee doctor requires closer supervision or support with a case, then they should be able to raise that with the supervising consultant. If their concerns are not taken into account, then they should be able to escalate them through appropriate and structured hospital channels. This can prove to be difficult to achieve in practice, however, and it may turn on the culture of the surgical team, clinical directorate and medical education team support.¹²² [ELJ0003-00080] [ELJ0003-00081]

¹²¹ Scottish Executive, Department of Health, ‘New Consultants Contract’, 12 June 2002, available at: <https://www.publications.scot.nhs.uk/files_legacy/sehd/publications/DC20020612ConsContr.pdf> accessed 21 July 2026; UK Department of Health, *A Code of Conduct for Private Practice: Recommended Standards of Practice of NHS Consultants*, January 2004, available at: <<https://www.nhsemployers.org/system/files/2021-06/consultants-code-of-conduct-private-practice-guide.pdf>>; GMC, *Good Medical Practice*, [Duties regarding financial commercial arrangements and conflicts of interest], updated as at 13 December 2024, available at: <<https://www.gmc-uk.org/professional-standards/the-professional-standards/identifying-and-managing-conflicts-of-interest>> accessed 21 July 2026. See generally British Medical Association, ‘Setting up in Private Practice – Overview’, available at: <<https://www.bma.org.uk/advice-and-support/private-practice/setting-up-in-private-practice/setting-up-in-private-practice-overview>>, accessed 21 July 2026.

¹²² For an overview of work that has been done to improve operating theatre efficiency, see e.g. NHS England, available at: <[NHS England » Theatres, surgery and perioperative care](#)>, accessed 21 July

Maintenance of an appropriate consultant workload

21.4 The key objectives in managing consultant workload appropriately are to mitigate clinician fatigue, cognitive overload, and technical burnout; to ensure professional accountability across all facets of a whole-practice portfolio; and to guarantee that contracted NHS hours (direct clinical care) are not compromised by external professional activities.¹²³ The main features of successful systems for managing consultant workload include the following:

21.4.1 Statutory annual job planning: A mandatory contractual process that breaks down a consultant's weekly schedule into explicit programmed activities, typically differentiating between direct clinical care and supporting professional activities, such as research or teaching.

21.4.2 European Working Time Directive (EWTD) monitoring framework: This involves tracking on-call frequencies and consecutive working hours to prevent clinical performance deterioration from sleep deprivation. Notwithstanding Brexit, the EWTD was incorporated into UK law and the provisions are now incorporated into resident doctors' contracts. As such, it is still expected that all work beyond 48 hours is carefully evaluated by NHS management in conversation with the doctor, covering matters such as cognitive load and risk of poor performance due to excessive workload.

21.4.3 The whole practice job plan: This involves explicitly linking a consultant's declared private practice hours to their NHS job plan. It is in

2026; NHS England, 'Theatres and Perioperative Medicine', available at: [Theatres and Perioperative Medicine - Getting It Right First Time - GIRFT](#)>, accessed 21 July 2026.

¹²³ Scottish Executive Health Department, NHS Circular PCS(DD)2004/2: Consultant Contract (Scotland) 2004 [establishing the statutory infrastructure for PAs and mandatory job planning]. GMC, *Good Medical Practice* [Domain 4: Maintaining Trust - Managing a professional whole-practice portfolio].

addition to requiring formal NHS management sign-off to ensure a doctor's private practice does not conflict with emergency on-call rotas or scheduled NHS clinics.

21.5 The main pitfalls leading to unsuccessful systems for managing consultant workload include first, *passive administrative sign-off*, which involves treating annual job planning as a generic, unverified exercise where consultants' self-declared hours are accepted without comparison against actual theatre clock-ins or clinic discharge logs. Second, it involves *unmonitored multi-site practice*, which allows consultants to accumulate an excessive, uncoordinated, volume of private procedures outside their NHS job plan, leading to physical fatigue during acute NHS emergency shifts. Third, a *failure to review practice job plans on an annual basis*, which requires robust line management systems to be in place to ensure the appropriate conduct and assessment of consultants' practice job plans.

Interaction, consultation, and multidisciplinary team meetings

21.6 The main objectives of MDT meetings are to eliminate isolated and unmonitored clinical decision-making; to pool multidisciplinary clinical expertise for complex pathologies; and to establish a transparent consensus for high-risk surgical pathways. The main features of successful MDT systems include the following.¹²⁴ [ELJ0003-00140]; [ELJ0003-00053] First, there should be *mandatory disease-specific MDT portals* in which formal rules cover specialised pathologies (e.g., as neuro-oncology or complex skull-base tumours) and elective surgery cannot proceed without prior presentation and formal case discussion at an MDT panel. Second, there should be *quoracy and multi-professional*

¹²⁴ This section draws on the following resources: Scottish Intercollegiate Guidelines Network (SIGN), Scottish Intercollegiate Guidelines Network (SIGN), *Multi-disciplinary Cancer Care* <<https://www.sign.ac.uk/guidelines/>>; HIS, *Clinical Governance Standards*, updated 2026, Available at: <<https://www.healthcareimprovementscotland.scot/publications/clinical-governance-standards/>>, accessed 21 July 2026.

representation, whereby MDT meetings are only considered valid, if a predefined quorum of specialists is actively present (e.g., neuroradiologist, neuro-oncologist, neuropathologist, and lead neurosurgeon). Third, there is *automated digital outcome auditing*, which involves the mandatory recording of all MDT conclusions, minority opinions, and definitive surgical plans into a dedicated electronic tracker embedded directly within patients' permanent medical charts.

21.7 The main pitfalls leading to unsuccessful systems for MDT management include conducting a 'rubber-stamping' exercise, whereby a dominant or senior surgeon is able to intimidate the MDT panel, effectively bypassing peer challenge and forcing it to retroactively approve a pre-determined surgical plan. In addition, there is a failure to engage in attendance tracking, where there is no formal register kept of who attends MDT meetings, thus enabling consultants to claim peer consultation while practising in functional isolation. Finally, there may be an attempt to bypass the MDT process altogether. This can occur where there is no system to enforce pre-operative decision reviews by the MDT, or where cases which are done on a private basis are not subject to the MDT process.

Training and supervision of neurosurgeons in training

21.8 The HAEG do not have specific expertise in relation to the training of surgeons. However, in general terms, features of successful training schemes for surgeons include the following:

21.8.1 Joint Royal Colleges of Surgeons fellowship training (JCST) interface:

Aligning local departmental rotations with national curricula, utilising formalised workplace-based assessments and procedure-based assessments to

document manual progression.¹²⁵ [ELJ0003-00163]; [ELJ0003-00033];
[ELJ0003-00047] [ELJ0003-00066]

21.8.2 Named educational and clinical supervisors: Assigning every surgical trainee a named educational lead who is contractually allocated supported professional activity time within their job plan to review the trainee's e-portfolio (e.g., ISCP portfolio).¹²⁶ [ELJ0003-00063]

21.8.3 The escalation and feedback trigger: Clear hospital/departmental mechanisms which would enable a surgical trainee to confidentially report a supervisor who exhibits toxic behaviour, poor surgical technique, or a failure to provide safe, on-site intraoperative oversight.

21.9 The main pitfalls leading to poor training and supervision of surgeons in training include utilising trainees primarily to clear ward administration workloads, handle minor triage, or cover rota gaps at the expense of supervised theatre training time. This is in addition to allowing a surgical trainee to perform critical, high-risk stages of surgery without the named supervisor being physically present in the scrub room to intervene during a surgical crisis.

¹²⁵ The sources that were drawn on for this section include the following: The Postgraduate Medical Education and Training Board (PMETB) Standards. The PMETB was established in 2003 and operated until 2010, setting standards for medical education before it was then merged into the GMC. For an overview of the work undertaken by the PMETB during this period, see UK Parliament, House of Commons, Select Committee on Health, Memorandum by the Postgraduate Medical Education and Training Board, Modernising Medical Careers, available at: <https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/25/25we37.htm> accessed 21 July 2026. GMC, *Promoting Excellence: Standards for Medical Education and Training*, published 15 July 2015, in effect 1 January 2016, available at: https://www.gmc-uk.org/cdn/documents/promoting-excellence-standards-for-medical-education-and-training-2109_pdf-61939165.pdf, accessed 21 July 2026; GMC, *Promoting Excellence*, available at: <https://www.gmc-uk.org/education/standards-guidance-and-curricula/standards-and-outcomes/promoting-excellence>, accessed 21 July 2026. Joint Committee on Surgical Training (JCST), *Guidelines for Surgical Training*, available at: <https://www.iscp.ac.uk/home/jcst.aspx> accessed 21 July 2026.

¹²⁶ See Intercollegiate Surgical Curriculum Programme (ISCP), *Core Surgical Training Curriculum*, available at: <https://www.iscp.ac.uk/iscp/curriculum/core-surgical-training-curriculum/6-recording-progress-in-the-iscp-learning-portfolio/>, accessed 21 July 2026.

Involvement of neurosurgical patients in research projects

21.10 The HAEG do not have specific expertise in relation to the involvement of neurosurgical patients in research projects. However, in general terms, key features relevant to the conduct of clinical research projects involving neurosurgical patients would be in accordance with ethically principled and legally established approaches to the conduct of clinical research during the relevant period. The key objectives involved in the conduct of such research would be to uphold protect patient autonomy and safety during the conduct of the research; to ensure adherence to national and international clinical research laws and regulations; and to verify that the clinical research in question is driven by genuine ethical merit, rather than professional vanity or commercial influence.

21.11 The main features of successful systems for the conduct of medical research, including clinical trials:¹²⁷ [ELJ0003-00168]; [ELJ0003-00125]; [ELJ0003-00088]

21.11.1 Mandatory research ethics committee (REC) sign-off: There should be clear administrative barriers preventing the conduct of any clinical research, tissue removal, or experimental surgical modification from taking place without formal, independent approval from a suitably constituted REC.

21.11.2 The dual-signature informed consent process: A multi-stage, auditable, process requiring a distinct research information sheet, sufficient patient

¹²⁷ This section draws on the following sources: *The Medicines for Human Use (Clinical Trials) Regulations 2004*; World Medical Association, *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, adopted June 1964, updated 19 October 2024, <<https://www.wma.net/policies-post/wma-declaration-of-helsinki/>>; Scottish Executive, *Research Governance Framework for Health and Community Care*, 2nd edn, 2006 [first edition published in 2001], available at: <<https://www.cso.scot.nhs.uk/wp-content/uploads/2013/02/RGF-Second-Edition-February-06.pdf>>, accessed 21 July 2026; NHS Scotland, *UK Policy Framework for Health and Social Care Research*, v 3.2, 10 October 2017, available at: <<https://www.nhsresearchscotland.org.uk/uploads/tinymce/uk-policy-framework-health-social-care-research%20v1.1.pdf>>, accessed 21 July 2026.

reflection time, and a witnessed consent form detailing the precise boundaries of the clinical research/trial.

21.11.3 Centralised Health Board/NHS Trust research and development oversight: Ensuring that all active research clinical trials are authorised by the Health Board research and development office; officially catalogued on the Board's corporate research and development risk register; and automated monitoring of adverse clinical trials data.

21.12 The main pitfalls involved in the conduct of unsuccessful research projects include the following: (i) *bypassing REC approval to pursue innovative practice in research projects* allowing doctors, including surgeons, to introduce unauthorised technical modifications or unproven surgical techniques under the guise of innovative practice in order to bypass standard research ethics committee review channels; and (ii) *failing to address power asymmetries in patient-doctor interactions concerning research projects* allowing treating doctors, including surgeons, to use their dominant position of authority to pressure (potentially) anxious, high-risk patients into signing up for clinical research projects, including clinical trials, during an acute admission phase.

Disclosure obligations

22. **When things appear to have gone wrong in the NHS treatment or care of a patient or patients, in particular in the field of neurosurgery, in what circumstances would a health board (or similar body such as a health trust) expect to be informed? By whom would they expect to be so informed?**

22.1 There are various mechanisms by which Health Boards would be expected to receive information when things appear to have gone wrong in the treatment or care of patients,

including in the field of neurosurgery. Health Boards' executive boards (including the Medical Director and CEO) operate on an explicit tiered system of escalation. They do not expect to be personally notified of routine, minor clinical variations, but they would expect immediate notification of adverse events under the following defined circumstances:

22.1.1 Categorical severity thresholds (the sentinel events): Immediate notification should take place when an adverse event results in a patient's unexpected or avoidable death or their permanent or severe long-term disability (such as an un-consented complete spinal cord injury, paraplegia, or severe brain damage during a standard neurosurgical procedure), or a recognised 'never event' (e.g., wrong-site neurosurgery or a retained surgical instrument).

22.1.2 A statistical anomaly trigger: When routine, localised audit metrics or data extraction networks (such as the MSN for neurosurgery / Annual Review of Consultant Outcomes (ARCO) data profiles) detect a sudden, statistically significant, upward spike in a single consultant's 30-day postoperative mortality or re-operation rates. This would potentially signal that they have crossed national control boundaries into outlier territory.

22.1.3 Systemic or repetitive complications: When a cluster of similar near-misses, adverse events, or patient injuries occurs within the same hospital department or under the care of the same clinician over a shortened timeline, indicating that a local systemic risk or pattern of technical decline may be taking place.

22.1.4 Regulatory and institutional risk Indicators: The Health Board's executive board must be informed immediately if an external regulatory or training body (such as the GMC, the Postgraduate Medical Dean, or a Medical Royal College) raises formal, written concerns regarding a doctor's fitness to practise or threatens to withdraw training accreditation from the hospital department due to inadequate supervision or a toxic professional culture.

22.2 Corporate and clinical governance processes dictate that information must flow upward through specific, accountable individuals who act as formal gatekeepers. The notification mechanisms include the following:

22.2.1 The clinical director / lead for neurosurgery: The doctor who has direct management responsibility for the neurosurgical department. They hold a clear duty to immediately notify the Medical Director the moment a local M & M review, an informal peer concern, or a formal case review, confirm an exceptional clinical failure or an immediate threat to patient safety.

22.2.2 The general manager / service director for surgery: The non-clinical, operational manager who oversees the surgical directorate. They are responsible for monitoring administrative and operational data loops, and they must escalate issues to the executive team when departmental backlogs, high re-operation rates, or scheduling adjustments signal clinical or resource distress.

22.2.3 The risk management and complaints department leads: Administrative directors who oversee centralised electronic reporting infrastructure (such as Datix) and patient feedback repositories. They must inform the executive board when automated system analysis flags a critical cluster of adverse event

reports or significant patient complaints focused on a single doctor or a specific surgical team.

22.2.4 The individual consultant surgeon (self-reporting duty): Under GMC professional regulatory standards, the surgeon holds a personal/professional obligation to notify their Clinical Director and the Medical Director immediately following a serious intraoperative event or an unexpected patient death, ensuring that the local review process is initiated without delay.

22.2.5 The whistleblower channel: Frontline staff members, which include scrub nurses, theatre practitioners, anaesthetic technicians, and resident doctors, who bypass the established medical hierarchy to directly notify the executive board via independent guardians or confidential escalation routes when they witness substandard care significant technical incompetence that local department leads have failed to address.¹²⁸ [ELJ0003-00055]

23. What principles/ obligations of candour are or ought to be incumbent upon health boards (or other similar bodies such as health trusts) when things appear to have gone wrong in the treatment of NHS patients? How have these principles and obligations developed in the period since the start of the relevant period?

23.1 The rationale for the duty of candour is that there is openness and honesty when things go wrong in the provision of healthcare to patients.¹²⁹ [ELJ0003-00022] Prior to 1980, there was little in the way of a recognised legal duty of candour, and in the decade that followed, references to a need for candour in healthcare featured only occasionally and

¹²⁸ See HIS, 'How NHS Staff Can Raise Concerns', 21 July 2026, available at: <<https://www.healthcareimprovementscotland.scot/publications/how-nhs-staff-can-raise-concerns/>>, accessed 21 July 2026.

¹²⁹ The answer provided in this section draws on the Expert Report to the Infected Blood Inquiry (2022) (n 1), paras 36-38.

fleetingly when clinical negligence cases were brought.¹³⁰ [ELJ0003-00102] In 1990, the death of a child, Robbie Powell, as a result of a failure to diagnose and treat Addison's disease, and the subsequent post-death cover-up, revealed serious failures in this area.¹³¹ [ELJ0003-00003] The court ruling relating to this case made specific reference to the issues regarding the absence of a legal duty of candour at the time. It specified that, as the law stood, there was no duty for doctors to provide families with a truthful account of the circumstances surrounding a death due to negligence or even to refrain from deliberately falsifying records after the event.¹³² [ELJ0003-00095] In 1995, the GMC published its first edition of *Good Medical Practice*, outlining the standards of care patients should expect of doctors.¹³³ [ELJ0003-00045] Although it did not specifically mention a duty of candour, or provide any guidance on apologies, it did place a strong emphasis on trust and honesty, as guiding principles. Subsequent editions of *Good Medical Practice* made increasingly more explicit references to what doctors should do when things go wrong in this respect, which are described in more detail below.

23.2 In the early 1990s, the GMC relied upon what is known as the *Blue Book* (otherwise known as the *Professional Conduct and Discipline: Fitness to Practise Pamphlet*)¹³⁴ [ELJ0003-00027] [ELJ0003-00164] to determine the fitness to practise for their registrants. This guidance dealt with issues of misconduct, criminal offences and impairment, and provided some positive advice in certain areas of professional conduct.¹³⁵ [ELJ0003-00027] Although the *Blue Book* did not contain any guidance on

¹³⁰ Oliver Quick, 'Duties of Candour in Healthcare: The Truth, the Whole Truth, and Nothing but the Truth?' (2022) 30(2) *Medical Law Review* 324.

¹³¹ AvMA, (n.d.) *Robbie's Law*. available at: <[AvMA - Robbie's Law](#)> accessed 21 July 2026.

¹³² *Powell v the United Kingdom* (2000) 30 EHRR CD 362.

¹³³ GMC, 'Our History – Where We Started From', available at: <https://www.gmc-uk.org/about/who-we-are/our-history>, accessed 21 July 2026.

¹³⁴ GMC, 'Professional Conduct and Discipline: Fitness to Practise', (Spottiswoode Ballantyne Printers Lid, January 1993) available at: <<https://www.gosportpanel.independent.gov.uk/document-library/documents/hco005316/>>, accessed 21 July 2026; Unknown Author, 'GMC Launches New "Blue Book"', (1995) 311 BMJ 972 <<https://doi.org/10.1136/bmj.311.7011.972>> accessed 21 July 2026.

¹³⁵ GMC, 'Professional Conduct and Discipline: Fitness to Practise' (Spottiswoode Ballantyne Printers Lid, January 1993) 18-22, available at <<https://www.gosportpanel.independent.gov.uk/document-library/documents/HCO005316/>> accessed 21 July 2026.

a duty of candour, such as what to do when things went wrong in relation to care and treatment or apologies that could be given to patients, it did emphasise the importance of honesty in relation to the signing of medical certificates, financial transactions, advertising, and comment about professional colleagues. In 1998, the GMC amended its code of conduct, to include the following paragraph: 'If a patient under your care has suffered serious harm, through misadventure or for any other reason, you should act immediately to put matters right, if that is possible. You should explain fully to the patient what has happened and the likely long-and short-term effects. When appropriate you should offer an apology.'¹³⁶ [ELJ0003-00028] This version of the guidance was in effect until September 2001.

- 23.3 In 2001, GMC published an updated version of *Good Medical Practice*, where it stated: 'Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response. This will include an explanation of what has happened, and where appropriate, an apology.'¹³⁷ [ELJ0003-00029] In the 2006 version, it introduced a new section, entitled 'Being open and honest with patients if things go wrong' which broadened the duty to situations where the patient 'has suffered harm or distress'. It stated: 'If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects ... Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology. You must not

¹³⁶ GMC, *Good Medical Practice* (GMC, 1998) para 17 available at: <<https://www.gmc-uk.org/ethical-guidance/archived-ethical-guidance>>, accessed 21 July 2026.

¹³⁷ GMC, *Good Medical Practice* (GMC, 001) para 29, available at: <<https://www.gmc-uk.org/ethical-guidance/archived-ethical-guidance>>, accessed 21 July 2026.

allow a patient's complaint to affect adversely the care or treatment you provide or arrange.'¹³⁸ [ELJ0003-00030]

23.4 In 2013, the publication of the Francis Inquiry Report revealed a culture of fear and bullying in the Mid-Staffordshire NHS Foundation Trust in England, in which staff felt unable to report concerns and prevented from doing their jobs properly. It also referenced a culture of secrecy that was evident at a system level, in which the trust board distanced itself from these situations in its hospital and ignored its patients.¹³⁹ The Francis Inquiry prompted significant developments in this area, with the introduction of a statutory duty of candour for NHS organisations and the strengthening of the individual professional duty of candour. Having previously been minimal or non-existent, the regulatory space in which the duty of candour now exists requires that different individual and organisational duties are navigated and met. This marks a shift in focus away from the need for more regulation and towards improving the delivery of existing regulation that ensures healthcare professionals are open and honest with their patients when standards of care have fallen short of what should be expected.

23.5 The statutory organisational duty of candour is a legal duty which sets out how NHS organisations should tell those affected when things go wrong with care and treatment, and the actions that should be taken. There are different approaches taken in the UK's four nations to this statutory duty, and the circumstances in which this duty should be applied. Nevertheless, they broadly require that certain steps are taken when the relevant provisions are triggered, such as notifying the relevant parties when something

¹³⁸ GMC, *Good Medical Practice* (GMC, 2006) paras 30-31, available at: <<https://www.gmc-uk.org/ethical-guidance/archived-ethical-guidance>>, accessed 21 July 2026.

¹³⁹ The Francis Inquiry (2013), (n 81).

has gone wrong, offering an apology to those affected and incident reporting requirements.¹⁴⁰

23.6 Enforcement arrangements in relation to the statutory duty of candour differ between the UK's four nations.¹⁴¹ [ELJ0003-00012] In Scotland, initial non-statutory guidance was published in 2018, however, there was an update in March 2025, which focuses on the implementation of the legal duty of candour procedure for health, care, and social work services. The revised guidance draws on reviews of published annual reports, learning identified from the COVID-19 pandemic and other scenarios such as healthcare-associated infections and incidents involving multiple people, as well as extensive engagement and feedback from health, care and social work stakeholders. The revisions/updates focus on providing further clarity and guidance for those activating the duty and include the following: clarity on the benefit of the duty, particularly for care and independent healthcare providers; further guidance and signposting to training available at a national and/or local level; clarity on the differences between professional and organisational duty of candour; clarity on who the procedure applies to and when it should be activated. Several examples have been included based on learning from real world scenarios. Guidance on recording meetings has also been incorporated and further clarification has been offered as when the duty is activated, as well as when giving an apology should not be interpreted as being an admission of negligence.¹⁴² [ELJ0003-00133]

¹⁴⁰ In Scotland, this statutory duty is set out in *The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016* and *The Duty of Candour Procedure (Scotland) Regulations 2018*. The Regulations stipulate that an 'unintended or unexpected incident' fills the necessary criteria for the application of a duty of candour by organisations. In contrast, in England provisions for the statutory duty of candour are outlined in *The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014*, Regulation 20. It states that a 'notifiable safety event' meets the threshold for when this duty should be applied.

¹⁴¹ For an overview of the approach taken by the Care Quality Commission (CQC) to enforcement of the organisational duty of candour, see CQC, 'How We Regulate the Duty of Candour', guidance updated 30 June 2022, available at:

<<https://www.cqc.org.uk/guidance-regulation/providers/regulations-service-providers-and-managers/health-social-care-act/regulation-20/how-we-regulate>> accessed 21 July 2026.

¹⁴² Scottish Government, Chief Operating Officer, NHS Scotland Directorate, 'Organisational Duty of Candour: non-statutory guidance - revised March 2025: Executive summary', available at:

23.7 The individual professional duty of candour applies to all UK registered doctors.

Following the publication of the Francis Inquiry in 2013,¹⁴³ professional regulators, including the GMC, published a joint statement encouraging their registrants to be candid.¹⁴⁴ [ELJ0003-00026]; [ELJ0003-00092] It stated that every HCP must be open and honest with patients when something has gone wrong with their treatment or care which causes, or has the potential to cause, harm or distress. More specifically, it specified that HCPs must: (i) tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong, apologise and fully explain the short and long-term effects of what has happened, offering the appropriate remedy or support to put matters right, if possible; (ii) be open and honest with colleagues, employers and relevant organisations, taking part in reviews and investigations when requested; (iii) be open and honest with regulators, raising concerns where appropriate; and (iv) support and encourage each other to be open and honest and not stop someone from raising concerns.

23.8 The statement referred to in paragraph 23.7 above reflected the requirements of the professional individual duty of candour which was set out for doctors by the GMC in what was then the current version of *Good Medical Practice*, and which is still included in the current edition. It should be noted that a breach of this guidance could result in a concern being raised about an individual doctor's conduct to the GMC and in fitness to practise

<<https://www.gov.scot/publications/organisational-duty-candour-non-statutory-guidance-revised-march-2025/>>, accessed 21 July 2026.

¹⁴³ The Francis Inquiry (2013) (n 81).

¹⁴⁴ See General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland, Joint statement from the Chief Executives of statutory regulators of healthcare professionals. *Openness and Honesty: the Professional Duty of Candour*, 2014, available at: <<https://psni.org.uk/wp-content/uploads/2024/10/Joint-statement-on-the-professional-duty-of-candour-FINAL.pdf>> accessed 21 July 2026. See also NMC and GMC, *Openness and Honesty When Things Go Wrong: The Professional Duty of Candour*, 29 June 2015, updated 13 December 2024, available at:

<<https://www.gmc-uk.org/professional-standards/the-professional-standards/candour---openness-and-honesty-when-things-go-wrong>>, accessed on 21 July 2026.

proceedings.¹⁴⁵ [ELJ0003-00037] Anyone can raise a concern about a doctor's conduct to the GMC: members of the public, other doctors or colleagues, ROs, and doctors can even refer themselves. The most serious sanction that may be issued by the Medical Practitioners Tribunal Service (MPTS), which adjudicates on such matters, is the removal of the doctor in question from the medical register to stop them practising.¹⁴⁶ [ELJ0003-00035]

23.9 The Professional Standards Authority (PSA) also identified certain barriers to implementing the individual duty of candour in practice, in a report published in 2019.¹⁴⁷ [ELJ0003-00099] These barriers include toxic working environments where an organisation has a culture of blame or defensiveness; fear of litigation, disciplinary action, or of public and media perceptions and the associated impact on their careers; and heavy workloads which limit the time practitioners can spend with patients to have timely and meaningful discussions when problems have occurred. Additionally, the thresholds for individual and statutory duties of candour are not the same. This means there may be some instances in which the professional has a duty of candour as an individual, covering all situations where mistakes have been made, but that falls short of the threshold or an organisation's legal duty of candour, which may only apply in response to defined notifiable safety incidents. There is also some concern among HCPs that the statutory duty of candour has become a tick-box exercise, rather than a

¹⁴⁵ GMC, *Raising and Acting on Concerns about Patient Safety*, 12 March 2012, updated 13 December 2024, available at: <https://www.gmc-uk.org/professional-standards/the-professional-standards/raising-and-acting-on-concerns> accessed 21 July 2026.

¹⁴⁶ GMC and MPTS, *Sanctions Guidance* (General Medical Council, 2019), available at: https://www.mpts-uk.org/cdn/mpts-documents/05_-dc4198-sanctions-guidance--18th-november-2019_pdf-80152538.pdf accessed 21 July 2026.

¹⁴⁷ PSA, *Telling Patients the Truth When Something Goes Wrong: Evaluating the Progress of Professional Regulators in Embedding Professionals' Duty to Be candid to Patients*, January 2019, available at: <https://www.professionalstandards.org.uk/sites/default/files/attachments/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf>, accessed 21 July 2026.

genuine interest on the part of NHS organisations in being candid with patients about substandard healthcare practices.¹⁴⁸ [ELJ0003-00025]

23.10 In 2019, the PSA offered some insights regarding how the duty of candour can be encouraged. It proposed that professionals should be given education and training which covers the importance of candour and the communication skills which are needed to have difficult conversations with patients. The PSA suggested that a whole-of-sector response was necessary to improve workplace environments, increase engagement with frontline staff in order to listen to concerns, and to dedicate time for HCPs to be able to reflect on, discuss and review experiences with their peers. The PSA also emphasised that the delivery of candour and openness towards patients and families should not be thought of as simply a legal and professional obligation, but rather as a cultural and behavioural change that is embraced at all levels of an NHS organisation.¹⁴⁹ [ELJ0003-00049]

24. **When things appear to a health board (or other similar body such as a health trust) to have gone wrong in the treatment or care of an NHS patient or patients, in particular in the field of neurosurgery, what broad principles govern or ought to govern decisions relating to informing the following bodies:**

- (a) The patient concerned or the patient's representative;**
- (b) Regulatory authorities, such as the General Medical Council;**
- (c) Other bodies with responsibility for the maintenance of high standards of patient safety and care, such as the Health and Safety Executive, Healthcare Improvement Scotland, Public Services Delivery Scotland, Royal Colleges, the British Medical Association or their equivalents;**
- (d) Governmental authorities with responsibility for patient care and the operation of the national health service; and/ or**

¹⁴⁸ Simon Gardiner, Douglas Morrison and Simon Robinson, 'Integrity in Public Life: Reflections on a Duty of Candour' (2022) 24(2) *Public Integrity* 217.

¹⁴⁹ Dinah Godfree and Annie Sorbie, *The Duty of Candour in Scotland – What We Heard From Our 2021 Conference*, 2 November 2021, available at: <<https://www.professionalstandards.org.uk/news-and-blog/blog/detail/blog/2021/11/02/the-duty-of-candour-in-scotland-what-we-heard-from-our-2021-conference>>, accessed 21 July 2026.

(e)The police.

24.1 There is a range of broad principles that should govern the approach taken by Health Boards when things appear to have gone wrong in the treatment of NHS patients, (including in the field of neurosurgery). How those principles might be applied, and the decision-making approach that should be taken in relation to the following persons/bodies in these circumstances, are set out below.

The patient concerned or their representative

24.2 When clinical care results in unexpected or unintended harm, the relationship between the Health Board and the patient must be governed by an open disclosure model rather than institutional defensiveness. In the circumstances, the Board should be open and transparent with the patient, as well as acting in line with its statutory duty of candour, as appropriate. The decision to inform must not depend on whether the patient has filed a complaint or realised an error occurred. The moment an internal triage or review confirms a 'threshold event' (an incident resulting in death, permanent injury, or prolonged psychological harm), the patient should be proactively notified. This involves a formal face-to-face meeting within explicit timelines, the provision of a full and honest account of the known facts, an apology for the harm suffered, and a commitment to share the final written review (for further details, see the answer to Q23).

Notification to regulatory authorities

24.3 The governing principles that operate in this context are public protection, immediate risk mitigation, and threshold accountability. The Health Board's decision to notify the GMC must be triggered if a localised investigation, audit trail, or clinical performance review, reveal that a doctor's fitness to practise is seriously impaired due to technical incompetence, cognitive/physical health issues, or egregious behavioural misconduct. Crucially, if the Health Board implements an immediate local exclusion from practice or

places strict restrictions on a doctor's practising privileges due to clinical safety concerns, the GMC must be formally notified within a 48-hour window. The Board must not wait for a lengthy internal disciplinary investigation of the doctor to conclude before alerting the GMC. The RO of the Health Board plays a key role in this regard, in liaison with the GMC.¹⁵⁰ Each RO has a nominated GMC employer liaison advisor, from whom they can seek advice and support on potential referrals or other matters.¹⁵¹ [ELJ0003-00158]

Notifications to patient safety and professional bodies

24.4 Triggering notifications to patient safety and professional standards bodies shifts the focus from individual disciplinary action within a Health Board towards addressing systemic, national safeguards. Key bodies to be notified by the Health Board would include: (i) HIS, in relation to 'catastrophic' or major adverse events, via centralised data streams to ensure national oversight and cross-board learning; (ii) HSE, where there was a patient safety incident that was driven by structural estate failures, defective clinical machinery, or biological exposure hazards; (iii) Medical Royal Colleges / specialist associations, where localised peer review cannot determine the root cause of an anomalous spike in patient complications; in these circumstances, the Health Board could invite the relevant Royal College or a representative from the specialist association to provide an independent, external invited service review; and (iv) the BMA, which is the professional association and trade union for doctors. It should be noted though that the BMA is usually notified by its members, not by the Health Board itself, regarding the contractual and procedural execution of disciplinary or capability frameworks affecting

¹⁵⁰ *The Medical Profession (Responsible Officers) Regulations 2010* (SI 2010 No. 2841) and *The Medical Profession (Responsible Officers) (Amendment) Regulations 2013* (SI 2013 No. 591) [establishes the legal duties of the Medical Director/RO to report fitness to practise risks directly to the GMC].

¹⁵¹ See UK Department of Health, *Maintaining High Professional Standards in the Modern NHS* (MHPS) Framework (2005) [enacted in England but served as reference standard across the UK], available at: <https://webarchive.nationalarchives.gov.uk/ukgwa/20130123204228/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4103586> accessed 21 July 2026.

its members, rather than this operating as a clinical safety notification.¹⁵² [ELJ0003-00052]; [ELJ0003-00051]; [ELJ0003-00149]

Notification to governmental authorities

24.5 There are various circumstances in which governmental authorities may need to be notified about problems that may be occurring with respect to quality and safety at Health Boards. The Scottish Government, through its Health and Care Directorate, should maintain visibility over events that could destabilise public confidence or signal systemic operational failures. There may also be a need to notify the CMO, who is responsible for oversight of specific healthcare performance and safety matters, as well as HIS. Immediate alerts are required if an adverse event constitutes a ‘never event’, which may occur where a critical service area faces sudden closure due to clinical failure, or if a consultant is placed under formal suspension for major malpractice. This ensures that relevant governmental authorities can monitor corporate risk and assure the Scottish Parliament that appropriate intervention frameworks are active.¹⁵³

24.6 Clinical governance processes are entirely separate from the criminal law. A Health Board cannot use internal clinical reviews to shield or delay criminal investigations. If an adverse outcome review, whistleblower report, or clinical audit, reveals reasonable grounds to suspect that patient harm or death was the direct result of an alleged criminal act, then the Health Board should immediately suspend all internal administrative

¹⁵² See HIS, *Learning from Adverse Events through Sharing and Review* (n 91); HSE, *Reporting accidents and incidents at work: A brief guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)*, available at:

<<https://www.hse.gov.uk/pubns/indg453.htm>>, accessed 13 July 2026.

Society of British Neurological Surgeons (SBNS) / Royal College of Surgeons, ‘Invited Review Mechanism (IRM)’, available at: <[Invited Review Mechanism \(IRM\) — Royal College of Surgeons](#)>, accessed 21 July 2026.

¹⁵³ Note that CMO alerts in Scotland are managed via official Scottish Government circulars (CMO letters) and the UK-wide Central Alerting System, which is currently managed by the UK’s Medicines and Healthcare Products Regulatory Agency. They are usually published on relevant Scottish Government websites; see also *National Health Service (Scotland) Act 1978* (as amended) [which governs the overarching accountability pathways linking territorial health boards to Scottish Ministers].

procedures and contact Police Scotland. In a specialised neurosurgical context, this threshold includes evidence of deliberate physical assault, falsification of official medical records, operating under the influence of intoxicating substances, or clinical actions displaying gross negligence manslaughter (culpable homicide in Scotland).¹⁵⁴ [ELJ0003-00017]; [ELJ0003-00105] [ELJ0003-00069]

25. In particular, what role would a health board (or other similar body such as a health trust) be expected to have in circumstances where a medical practitioner was seeking to have their name removed from the GMC's medical register?

25.1 The term 'voluntary erasure' (VE) is used when a doctor applies to be removed from the GMC register.¹⁵⁵ Broadly speaking, a doctor cannot delete their name to evade a looming disciplinary or clinical performance investigation.¹⁵⁶ A Health Board, acting as the doctor's employer or 'designated body' under the direction of its RO / Medical Director, is legally and contractually expected to perform the following tasks. Upon receiving an application for VE, the GMC is legally mandated to formally contact the practitioner's current Health Board employer (and recent previous ones as well).¹⁵⁷ [ELJ0003-00040] The Health Board's RO must then complete a fitness to practise

¹⁵⁴ Crown Office and Procurator Fiscal Service (COPFS), *Work Related Deaths: A Protocol for Liaison*, updated 8 May 2025, available at: <<https://www.copfs.gov.uk/publications/work-related-deaths-a-protocol-for-liaison/>>, accessed 21 July 2026. Where a fatal accident occurs in a workplace, see generally *Inquiries into Fatal Accidents and Sudden Deaths etc. (Scotland) Act 2016*. For an overview of culpable homicide in healthcare settings, see - Report of the Task and Finish Group on context of the healthcare system in Scotland and Scottish law relating to culpable homicide: *Independent review of gross negligence manslaughter and culpable homicide*, June 2019, available at: <[report-of-the-task-and-finish-group-on-context-of-the-healthcare-system-in-scotland-and-sco-78716616.pdf](https://www.gmc-uk.org/cdn/documents/dc4316-guidance-on-making-decisions-on-voluntary-erasure-applications-and-advising-on-admin-25416412.pdf)>, accessed 21 July 2026; Jonathan Lilleker, 'Reforming Medical Manslaughter, the Scottish Way?' (2023) 87(3) *The Journal of Criminal Law* 161.

¹⁵⁵ The VE process is governed by *The General Medical Council (Voluntary Erasure and Restoration following Voluntary Erasure) Regulations 2004* (SI 2004 No. 2609) [also sets out the rules governing when the GMC Registrar must refuse voluntary erasure if an investigation is active or a complaint is outstanding].

¹⁵⁶ Note that there may be instances where a form of administrative erasure occurs, for example, where a doctor fails to pay their renewal fee for registration and is then removed from the register.

¹⁵⁷ GMC, *Voluntary Erasure: Guidance for the Employer Liaison Service and Responsible Officers*, September 2019, updated May 2025, available at: <<https://www.gmc-uk.org/cdn/documents/dc4316-guidance-on-making-decisions-on-voluntary-erasure-applications-and-advising-on-admin-25416412.pdf>> accessed 21 July 2026.

declaration (UD8 form). Via the RO, the Board is expected to provide transparent disclosure regarding the following: (i) whether the doctor is the subject of any active or pending local disciplinary procedures, capability reviews, or SAERs; (ii) whether there are any unresolved patient complaints, electronic adverse incident reports (Datix entries), or litigation claims naming the doctor; and (iii) whether any local restrictions, exclusions, or supervised operating mandates have been placed on their clinical practising privileges. In addition, the Health Board must formally indicate its position on the VE application. If concerns exist, then the Board has a clear governance duty to formally object to the VE of the doctor in question. It has a responsibility for advocating that the doctor remains on the register so that a full GMC fitness to practise investigation can proceed, if appropriate. If no such concerns exist, then the Health Board may support or remain neutral toward the VE application, if the retirement or departure of the doctor is standard and clear of clinical risk.¹⁵⁸

25.2 A successful VE system dictates that while localised employment disciplinary frameworks, embodied in *Maintaining High Professional Standards* (MHPS),¹⁵⁹ [ELJ0003-00076] may technically terminate because the individual is no longer an employee, clinical investigations into patient outcomes (SAER or look-back exercises) should continue to their logical conclusion. The Health Board remains obligated to compile its final clinical findings and submit them to the GMC, which should be retained on the doctor's file in case they attempt restoration to the medical register in the future. In short, it is important that a Health Board maintains jurisdiction over any clinical safety investigations that may be relevant to the VE application by the doctor in question.

¹⁵⁸ *The Medical Profession (Responsible Officers) Regulations 2010* (SI 2010 No. 2841) [establishes the ongoing statutory duty of the RO to cooperate with the GMC regarding a doctor's fitness to practise status].

¹⁵⁹ See NHS Employers, *Maintaining High Professional Standards and Appeal Panels*, updated 1 May 2024, available at: <https://www.nhsemployers.org/publications/maintaining-high-professional-standards-and-appeal-panels>, accessed 21 July 2026.

25.3 The GMC has detailed guidance for its case examiners on how to deal with applications for VE. Such applications should be referred to a lay and a medical case examiner in circumstances where is an investigation into an unresolved concern or information is received, including from the doctor applying, which may raise an issue of impaired fitness to practise. The guidance also makes clear that VE can be approved by case examiners, despite ongoing investigations, where they conclude it would be in the public interest to do so. If the case examiners fail to agree, then the VE application is referred to the GMC's Investigation Committee for determination. It should also be noted that case examiners can determine VE applications where a case involving the doctor in question has been referred to the MPTS, but the hearing has not yet started.¹⁶⁰ [ELJ0003-00040]

26. **How ought reflective learning to be incorporated into the policies and practices of health boards (or other similar bodies such as health trusts) and government in relation to the improvement of healthcare within the NHS (in particular in the field of neurosurgery), in response to things going wrong in this way?**

26.1 Reflective learning should be embedded as part of the way in which NHS organisations work, including Health Boards, rather than being an individualised, voluntary pursuit by doctors, as well as other HCPs. For Health Boards and the Scottish Government to translate clinical failures into actionable safety improvement, it has been suggested that the healthcare institutional environment must transition from a punitive 'blame culture' to a 'just culture' or a state of psychological safety for HCPs. In this regard, policies adopted by Health Boards must explicitly protect HCPs who engage in open and self-

¹⁶⁰ GMC, *Guidance on Making Decisions on Voluntary Erasure Applications and Advising on Administrative Erasure*, first published in September 2019, updated May 2025, available at: <<https://www.gmc-uk.org/cdn/documents/dc4316-guidance-on-making-decisions-on-voluntary-erasure-applications-and-advising-on-admin-25416412.pdf>>, accessed 21 July 2026.

critical retrospective analysis, in order to distinguish between honest human/system errors and reckless, deliberate malpractice.¹⁶¹

26.2 A high-performing clinical governance framework incorporates reflective learning through four formalised operational mechanisms:

26.2.1 Multi-Disciplinary Significant Adverse Event Reviews (SAERs): The primary mechanism for translating clinical failures into learning is the SAER. When a medical procedure goes wrong, in the case of neurosurgery for example, the review must follow national quality framework standards. The review should also be led by an independent facilitator external to the immediate clinical directorate in order to minimise defensive peer bias.

26.2.2 Human factors and systems engineering: principles should be employed that look beyond individual technical errors, identifying latent systemic flaws (such as inadequate theatre scheduling, fatigued teams, or broken communication channels).¹⁶²

26.2.3 Inter-disciplinary group reflective practice: Health Boards could mandate and allocate dedicated, protected time for regular, facilitated group reflective sessions across clinical boundaries (for example surgeons, anaesthetists, theatre and ward staff). These groups can review localised

¹⁶¹ See generally Sidney Dekker, *Just Culture: Restoring Trust and Accountability in Your Organization*, 3rd edn, (CRC Press, 2016).

¹⁶² See generally James Reason, *Human Error* (Cambridge University Press, 1991); Alan Merry and Warren Brookbanks, *Medicine, Errors and the Law*, 2nd edn, (Cambridge University Press, 2017) [NB: the first edition was authored by Alan Merry and Alexander McCall Smith and was published in 2001].

complication trends using external national peer benchmarks to avoid institutional insularity.¹⁶³ [ELJ0003-000134]

26.2.4 Standardised Datix action trackers and learning summaries: For every Stage 2 complaint or adverse event review, the system can generate a standardised Learning Summary, detailing what went wrong and what improvements must occur. These summaries can be uploaded to centralised risk software (such as Datix), utilising dedicated action trackers that prevent a file from closing until departmental managers submit verified primary evidence that the safety adjustments are complete. This requires dedicated personnel and time: in short, an organisational commitment to funding this system.

26.2.5 Individual appraisal and revalidation: Personal reflective learning remains a prerequisite for professional registration for doctors. Clinicians must continue to document their reflections on adverse outcomes, clinical audits, and complaints directly within their annual appraisal folders (such as the SOAR platform in Scotland), ensuring that their appraisers and medical directors can examine their insight, decision-making, behaviour and technical competency (where relevant) during mandatory contract reviews.¹⁶⁴

26.3 The Scottish Government, supported by the Health Directorate, should be responsible for ensuring reflective learning crosses regional boundaries. There are various ways in which this can potentially take place: First, under the national adverse event_notification

¹⁶³ Scottish Government / National Wellbeing Hub, *Reflective Practice Toolkit for Health and Social Care Teams in Scotland 2025* [detailing parameters for safe, resourced group reflection], available at: <https://wellbeinghub.scot/wp-content/uploads/2025/04/NWH_Reflective-Practice-Toolkit.pdf>, accessed 21 July 2026.

¹⁶⁴ GMC, *Good Medical Practice* [Domain 1: Knowledge, Skills and Performance - Duties regarding clinical reflection, audit participation, and adaptive learning], available at: <https://www.gmc-uk.org/professional-standards/the-professional-standards/good-medical-practice/domain-1-knowledge--skills-and-development>, accessed 21 July 2026.

system: managed under the auspices of (HIS), this digital framework standardises the aggregation of significant clinical failures nationwide.¹⁶⁵ [ELJ0003-00052] Scottish Government policy could mandate that anonymised data, thematic analyses, and structural lessons from localised neurosurgical failures are continuously fed into a national learning library. This ensures a safety warning generated in one health board immediately informs surgical protocols across all other tertiary units. Second, explicit links should be made to the statutory organisational duty of candour. Health Boards are now legally required to publish annual reports detailing not only the volume of unexpected patient harms but also the explicit, verifiable improvements and reflective adjustments implemented in response to those events.¹⁶⁶

26.4 There are two main ‘pitfalls’ to be avoided. The first one is a shift towards ‘institutional group think’. This occurs when group reflective practices operate in isolation, without external inputs or data verification. For example, if a surgical unit uses its own localised, substandard outcomes as its reflective benchmark, it inadvertently encourages poor thinking and normalises bad practice against a background of uncritical reflection. The second one involves treating reflection as a substitute for accountability. Reflective learning frameworks should never be subverted to act as a soft alternative to formal disciplinary, capability, or regulatory intervention. If a Health Board allows a doctor with an escalating track record of patient safety incidents or erratic behaviour to simply write a ‘reflective essay’ or express verbal remorse as a resolution, without executing formal practice restrictions, then the likelihood is that patient safety will continue to be compromised over time, with the potential for significant adverse consequences for patients and their families.

¹⁶⁵ HIS, *A National Framework for Reviewing and Learning from Adverse Events in NHS Scotland*, (n 91).

¹⁶⁶ *Health (Tobacco, Nicotine and Care and Treatment) (Scotland) Act 2016*, Part 2, [mandating the structural reporting and learning loops under the Organisational Duty of Candour Procedure].

27. **What are the principles and key practices that do and/ or should apply, broadly, to decision-making and practice to document management (including both accuracy and retention) by a health board, covering both administrative and medical records? Please consider the following in answering this question:**

(a) document creation, storage, access and retention; and

(b) how those principles and key practices have developed, identifying any significant changes that have occurred from the start of the relevant period to the present day.

27.1 Document or records management forms part of the organisation's functions related to governance and assurance. Activities involved in records management in the healthcare context include identifying, classifying, storing, securing, retrieving, tracking, archiving and destroying records. It is about knowing what information you hold, where it is and how long you are required to retain it, either in relation to business or regulatory/legislative requirements.¹⁶⁷ [ELJ0003-00132] During the relevant period (and beyond), there was an increasingly structured approach taken to what is called 'records management and retention'. This reflected in part political devolution leading to Scotland taking charge of healthcare and public health, as well as having to take account of legal developments in the areas of human rights, data protection and information governance more generally.

27.2 Prior to political devolution in the late 1990s, the Scottish Office, and specifically the NHS in Scotland Management Executive, issued guidance about record management and retention. For example, in 1993, a circular was issued providing guidance to then NHS Trusts/Health Boards in relation to the retention and destruction of patients' health

¹⁶⁷ Scottish Government, *Records Management Code of Practice for Health and Social Care*, published August 2024, section 2, para 29, available at: <<https://www.gov.scot/publications/records-management-code-practice-health-social-care/documents/>>, accessed 21 July 2026

records.¹⁶⁸ [ELJ0003-00142] In the covering letter to the guidance, reference was made to the following matters:

27.2.1 Definition of health records: ‘health records ... are those which relate to the physical or mental health of an identifiable individual which have been made by or on the advice of a health professional in connection with the care and treatment of that person or in connection with the organisation including microfilm, computer files, slides and specimens.’¹⁶⁹ [ELJ0003-00142]

27.2.2 Ownership of health records from public and private sectors: ‘All Health Board records, which include records relating to NHS patients treated in private sector clinics, are owned by the Secretary of State on behalf of the Crown and are subject to the provisions to the Public Records (Scotland) Act 1937 and may only be destroyed in accordance with the Disposal of Records (Scotland) Regulations 1992.’¹⁷⁰ [ELJ0003-00142]

27.2.3 Decision-making about retention of health records: ‘It will be a matter for Health Boards, Consultants, GPs [and related health professionals], and as appropriate NHS Trusts to decide which of their records should be retained for clinical or research purposes.’ At the end of the stated minimum retention periods, the records may be destroyed but that Health Boards are not obliged to do so.¹⁷¹ [ELJ0003-00142]

¹⁶⁸ Scottish Office, NHS in Scotland Management Executive, *Guidance for the Retention and Destruction of Health Records*, NHS MEL(1993) 152, available at: <<https://www.publications.scot.nhs.uk/files/1993-152a.pdf>>, accessed 21 July 2026.

¹⁶⁹ para 6, pp. 1-2.

¹⁷⁰ para 7, p. 2.

¹⁷¹ Appendix A, paras 2, 4.

27.3 In the same 1993 guidance, the time limits for maintaining different types of patient health records were specified as follows:¹⁷² [ELJ0003-00142]

27.3.1 General Hospital and Community Health Service Health Records: a minimum retention period of 6 years following the last recorded entry for a person 16 years or over, or for 3 years after death. The records need to be kept in their original form for the first 3 years and then may be microfilmed or transferred to other media for the remainder of the period.

27.3.2 Children and Young Adults Records: if the child/young person is less than 16 years on the date of admission, then the records should be retained until the person reaches 25 years of age, or 3 years after death if this is earlier.

27.3.3 Obstetric Records: should be retained for 25 years after the birth of the child.

27.3.4 Psychiatric Records: records with the *first* entry after 1 January 1961 should be retained for the lifetime of the patient, and 3 years after their death.

27.3.5 GP Records: should be sent to the appropriate Health Board on the death of a patient and retained for a period of 3 years. Different approaches may be needed depending on the age of the patient (child or young person, for example).

¹⁷² Appendix B, paras 1-8.

27.3.6 Records of Cancer Patients: records should be retained for the lifetime of patients and 3 years after their death. After this period, they can only be destroyed after consultation with the consultant in charge.

27.3.7 Records of Patients with Genetic Disorders: it is a matter for consultants in charge to consider retention of records beyond the minimum period of 6 years.

27.3.8 X-Rays: an integral part of the main health record and are therefore covered the minimum retention periods recommended in the guidance.

27.3.9 Cervical Smears: such records should be stored for 10 years and indefinitely for abnormal cases.

27.3.10 Histological specimens: blocks of tissue should be retained indefinitely and slides made from these specimens should be kept for 10-15 years, depending on available storage space.

27.4 In 2002, the *Freedom of Information (Scotland) Act 2002* was adopted, with the aim of making 'provision for the disclosure of information held by Scottish public authorities or by persons providing services for them; and for connected purposes.' All NHS organisations are public authorities under Schedule 1 of the Act, and therefore the records they create – Part 1 s 13(1) states that 'record' means anything in which information is recorded in any form – must be kept in accordance with the Act itself, as well as the *Public Records (Scotland) Act 2011* and the *Data Protection Act 2018*. Scottish Ministers and all NHS organisations are required under data protection and freedom of information laws to make arrangements for the safe keeping and eventual disposal of all types of records.

27.5 In Scotland, the *Records Management Code of Practice for Health and Social Care* [ELJ0003-00132] (current as at 2024), addresses the management of data, information, and records across organisations in order to promote consistency of approach and is based on current legal requirements and professional best practice. Its origins lay in the publication of in 2005, which was followed by subsequent version updates. In 2012, there was a significant update provided in the *Scottish Government Records Management: NHS Code of Practice*.¹⁷³ [ELJ0003-00132] The current Code of Practice is relevant to NHS Health Boards, and organisations who work with or under contract to them, to support the delivery of health care services across Scotland. It outlines records management best practice in relation to the creation, use, storage, management and disposal of data, information, and records (including, where appropriate, the archival preservation of vital and historically important records); providing guidance on the general legal obligations that apply to data, information and records within the health care sector; setting out recommendations for best practice to assist in fulfilling these obligations (e.g., adhering to information governance and cyber security standards; setting out recommended periods of retention for data, information and records held by organisations, regardless of the media on which they are held; indicating where further guidance on records management may be found; explaining the requirement to select, and transfer to a designated place of deposit, those records for archival preservation. Any organisation that processes health care data, information and records under the *Public Bodies (Joint Working) (Scotland) Act 2014* should use the Code of Practice, including subcontractors processing data, information and records on behalf of NHS Boards and contracted third party providers.¹⁷⁴ [ELJ0003-00132] The types of records with which the Code of Practice is concerned include, but are not limited to, paper, digital, email, scanned, audio/video recordings, photographs/medical imaging,

¹⁷³ Scottish Government, *Records Management: NHS Code of Practice* (2024) (n 167).

¹⁷⁴ Scottish Government, *Records Management Code of Practice* (2024) (n 167).

microform (microfiche/microfilm), instant messaging/SMS, social media posts, website content and (internet/intranet).

27.6 NHS Tayside (of which Ninewells Hospital is a part) has its own Governance Records Retention Schedule for Non-Clinical/Administrative Records.¹⁷⁵ [ELJ0003-00089] It states on the current version (2026), that the first version was published in January 2005. It also follows the *Records Management Code of Practice for Health and Social Care*. Specifically, it maintains a register of information assets, commonly known as an Information Asset Register. This contains details of the records (regardless of format) stored and maintained by NHS Tayside, including any risks associated with them and is subject to annual review. The development of departmental records management programmes must be carried out in preparation for information being introduced to the agreed NHS Tayside Corporate Repository – currently the Document Store. The programmes will include specific information about how the essential records of the department will be managed and will include retention periods and disposal arrangements that are relevant to that department's needs and the services and facilities available to it.

27.7 NHS Tayside also recognises the importance in records management in relation to the preservation of records, as well as the need for archiving, where appropriate. It sets out the minimum retention periods which should be adhered to in relation to different types of records, including corporate and administrative records. In terms of archiving, it uses facilities in agreement with the University of Dundee. It recognises that good practice suggests that non-active records should be transferred no later than 30 years from

¹⁷⁵ NHS Tayside, 'Governance Records Retention Schedule for Non-Clinical/Administrative Records', updated as at May 2026, version 5.4, available at: https://www.nhstaysidecdn.scot.nhs.uk/NHSTaysideWeb/idcplg?IdcService=GET_SECURE_FILE&dDocName=DOCS_016355&Rendition=web&RevisionSelectionMethod=LatestReleased&noSaveAs=1 accessed 21 July 2026.

creation of the record, with digital records being transferred within a shorter period. It points out that central archiving should be considered for clinical research sponsored by the University of Dundee/NHS Tayside and completed prior to 2008, which may have been archived locally in NHS or University departments before the designated facilities were put in place (Iron Mountain vendor/NHS Tayside Claverhouse off-site archive).

27.8 NHS Tayside has a policy for the destruction of confidential non-clinical and administrative records. A record of the destruction of records, showing their reference, description and date of destruction should be maintained and preserved by the Information Asset Owner with responsibility for holding records, so that the organisation is aware of those records that have been destroyed and are therefore no longer available. If a record due for destruction is known to be the subject of a request for information, or potential legal action, destruction should be delayed until disclosure has taken place or, if NHS Tayside has decided not to disclose the information, until the complaint and appeal provisions of the *Freedom of Information (Scotland) Act 2002* have been exhausted or the legal process completed.

27.9 NHS Tayside recognises that where a record is, or may reasonably be, relevant to a public inquiry, public investigation, audit, or has been made subject to a 'do not destroy' notice, legal hold, or similar instruction issued by a court, government body, or authorised authority, destruction of the record must be suspended immediately. This must stay in place until formal notification is received confirming that the inquiry, investigation, or legal hold has concluded and that normal retention and disposal arrangements may resume. If a record due for destruction is known to be the subject of a request for information, or potential legal action, destruction should be delayed until disclosure has taken place or, if NHS Tayside has decided not to disclose the information, until the complaint and appeal provisions of the *Freedom of Information (Scotland) Act 2002* have been exhausted or the legal process completed.

27.10 In Scotland, the minimum length of retention of general practitioner records is that they should be held for the lifetime of patients and 10 years after death (longer periods may apply where they be relevant to public inquiries, investigations, fatal accident inquiries. Electronic records should be kept in perpetuity.¹⁷⁶ [ELJ0003-00009] In relation to hospital records (other than non-specified secondary care records) should at a minimum be retained for 6 years after last entry or 3 years after a patient's death. Maternity records should be retained for a period of 25 years after the birth of the last child (or, in Scotland, until woman reaches age 50, whichever is longer'). For children and young people, they should be retained up until the patient reaches 25 years of age (or 26 years if an entry was made when the young person was 17 years of age; or 3 years after the death of the child or young person, whichever is sooner. Where a person has been assessed with a mental disorder, then it is 20 years after the date of the last contact between the patient and the mental health provider; or 3 years following the death of the patient if sooner and the patient died while in the care of the organisation.

27.11 In terms of the need for Health Boards to retain, rather than dispose of records, then account should also be taken of the *Inquiries Act 2005*, as well as *The Inquiry (Scotland) Rules 2007*. The Act aims to provide a comprehensive statutory framework for Scottish Ministers to set up formal, independent inquiries relating to particular events which have caused or have potential to cause public concern, or where there is public concern that particular events may have occurred. Scottish Government records management policy recognises that if an Inquiry is conducted, which covers healthcare organisations within Scotland, such as Health Boards, then they must take action to identify and protect records which may be relevant to the Inquiry. Although what is required can vary by

¹⁷⁶ BMA, 'Retention of Health Records', updated 29 December 2025, available at: <<https://www.bma.org.uk/advice-and-support/ethics/confidentiality-and-health-records/retention-of-health-records>>, accessed 21 July 2026.

Inquiry, Health Boards would need to consider what information may be relevant based on the terms of reference for the Inquiry. It is an offence to fail to provide evidence (which is held by the organisation) required by the Inquiry. Therefore, Health Boards must put in place the appropriate measures to ensure as far as reasonably possible that information and records are prevented from alteration or deletion and are easily retrievable should they be requested.¹⁷⁷ [ELJ0003-00132]

27.12 The Professional Record Standards Body (PRSB) was established in the UK in April 2013, and was officially registered as a community interest company in May 2013. It was founded by the Academy of Medical Royal Colleges to ensure consistent standards for health and social care records. This is done through the development of national standards for health and care records, working closely with people who use services, clinicians, and the teams who design and build digital systems. It is suggested that clear and consistent standards ‘help information flow safely across services, supporting better care, safer decisions, and more joined-up services for everyone.’¹⁷⁸ [ELJ0003-00098]

27.13 In terms of professional obligations on the part of doctors themselves, it is important that there is adherence to the GMC’s *Good Medical Practice*, which ‘makes clear that patients have a right to expect that their personal information will be treated as confidential. This guidance, which forms part of the professional standards, sets out the principles of confidentiality and respect for patients’ privacy that doctors are expected to understand and follow.’¹⁷⁹ [ELJ0003-00036] In addition, the GMC has produced specific guidance on the issue of confidentiality. As the GMC guidance makes clear, patient-doctor confidentiality is considered one of the cornerstones of medical practice, and

¹⁷⁷ Scottish Government, *Records Management Code of Practice* (2024) (n 167).

¹⁷⁸ Professional Record Standards Body, ‘About Us’, available at: <<https://theprsb.org/aboutus/>>, accessed 21 July 2026.

¹⁷⁹ GMC, *Confidentiality: Good Practice in Handling Patient Information*, 25 April 2017 updated 13 December 2024, available at: <<https://www.gmc-uk.org/professional-standards/the-professional-standards/confidentiality>> accessed 21 July 2026.

essential to the development of a relationship of trust between doctors and patients. The guidance also emphasises that the principles of confidentiality apply to all doctors, irrespective of their speciality. Patients should be able to expect that information about their health which they give in confidence will be kept confidential, unless there is a compelling reason that it should not. The guidance also sets out reference to relevant UK case law on issues which touch on aspects of medical confidentiality.

27.14 The GMC's guidance on confidentiality in patient-doctor interactions also makes clear that if a doctor is not sure how the law of confidentiality and data protection applies in a particular situation, then they may wish to consult what is known as a Caldicott Guardian. The term arose out of a report published in 1997, which made a number of recommendations for regulating the use and transfer of patient-identifiable information between NHS organisations, as well as between NHS organisations and non-NHS bodies. The report recognised the growing importance of information and records management as a core part of what health organisations should be doing in the context of information governance. While the report's focus was on the NHS in England, the recommendations and principles were adopted by the NHS in Scotland (with some exceptions). Key concepts, such as the information life-cycle, organisational responsibilities and operations were identified as an important part of the work of Caldicott Guardians in Scotland, in circumstances where there was a need to handle privacy breaches and security incidents relating to personal data. The work of Caldicott Guardians are informed by the following: Principle 1 - Justify the purpose(s) for using confidential information; Principle 2 - Only use it when absolutely necessary; Principle 3 - Use the minimum that is required; Principle 4 - Access should be on a strict need-to-know basis; Principle 5 - Everyone must understand his or her responsibilities; Principle 6 - Understand and comply with the law.¹⁸⁰ [ELJ0003-00130]

¹⁸⁰ Scottish Government, *NHS Scotland Caldicott Guardians: – Principles into Practice, Foundation Manual for NHS Scotland Caldicott Guardians*, June 2012, v. 2, available at:

28. What principles and general practices do and/ or should govern the ability that patients have or should have to seek the amendment or correction of their own medical records (including medical information relating to them held beyond their formal medical records)? Please comment on how those principles and practices have developed, identifying any significant changes that have taken place in the time period from the start of the relevant period.

28.1 Patients' ability, and indeed their rights, to amend or correct their own health records were evolving during the relevant period. This was predominantly attributable to developments in human rights law, as well as data protection laws, which increasingly recognised the importance of patients being able to access and review their health records, as well as to seek rectification of identified inaccuracies in such records. In the 1990s, for example, the NHS in Scotland Management Executive required Health Boards, and HCPs, to ensure compliance with changing data protection laws, taking account of the necessary legislative safeguards and exemptions. The Executive emphasised that Health Boards should also seek to accommodate informal access requests by patients to their health records, where possible. These legal and administrative developments were also taking place against a background of political devolution in Scotland, which took place from the late 1990s onwards.

28.2 What constitutes patients' health records could also be said to have changed over time in Scotland, in terms of their nature and scope. In 1993, 'health records' were defined as those which relate to patients' physical or mental health 'which have been made by

or on the advice of a health professional in connection with the care and treatment of that person or in connection with the organisation including microfilm, computer files, slides and specimens.’¹⁸¹ [ELJ0003-00142] In 2024, ‘health records’ were defined as consisting of ‘information and data relating to the physical or mental health or condition of an individual which have been made by or on behalf of a health professional in connection with the care of that individual’.¹⁸² [ELJ0003-00132] Nowadays, patients’ health records are expected to be ‘clear, accurate and legible’ and should be made at the same time as the events occur, or as soon as possible afterwards.¹⁸³ They should include relevant clinical findings, drugs investigations or treatments proposed, provided or prescribed, investigations or treatments proposed, information shared with patients, concerns or preferences expressed by patients concerning their ongoing care and communication support preferences.¹⁸⁴ Such records can comprise handwritten notes; computerised records; correspondence between HCPs; laboratory reports; imaging records, including x-rays; photographs; video and other recordings; and printouts from monitoring equipment.¹⁸⁵ [ELJ0003-00062]

28.3 By way of background, there was no central index of patients registered with a general practitioner when the NHS was established in 1948. In response to this in Scotland, the National Health Service Central Register (NHSCR) was set up in the early 1950s to create a central repository for basic demographic information to be used for healthcare purposes for people living in Scotland,¹⁸⁶ [ELJ0003-00083] including name, address, date of birth and gender. In the 1970s, what is known as the Community Health Index

¹⁸¹ Scottish Office, NHS in Scotland Management Executive, *Guidance for the Retention and Destruction of Health Records*, NHS MEL(1993) 152, para 6, pp. 1-2, available at: <<https://www.publications.scot.nhs.uk/files/1993-152a.pdf>>, accessed 21 July 2026.

¹⁸² Scottish Government, *Records Management Code of Practice* 2024 (n 167).

¹⁸³ GMC, *Good Medical Practice*, updated 13 December 2024, paras 69 – 71.

¹⁸⁴ para 70.

¹⁸⁵ For an overview of the GDPR, see Information Commissioner’s Office, ‘UK GDPR Guidance and Resources’, available at: <<https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/>> accessed 21 July 2026.

¹⁸⁶ National Records of Scotland, ‘NHS Central Register’, available at: <<https://www.nrscotland.gov.uk/statistics-and-data/nhs-central-register/#>> accessed 21 July 2026.

(CHI) was established, which draws on information provided by GP practices and other sources. In 1984, patients were granted statutory rights to access their computerised health records.

28.4 In 1990, the *Access to Health Records Act 1990* was adopted which gave patients a statutory right of access, with certain safeguards, to their manual health records made after 1 November 1991. In a circular published by the NHS in Scotland Management Executive in October 1991, it was stated that its purpose was to set out ‘the main provisions of the *Access to Health Records Act 1990* and the steps which Health Boards, NHS Trusts and health professionals within or contracted to the NHS, should take to ensure compliance with the Act when it comes into operation on 1 November 1991 ... [it] gives guidance on the procedures to be followed in allowing access to the records and in dealing with complaints.’¹⁸⁷ [ELJ0003-00141] The circular went on to state that: ‘neither of these Acts affects the duty of health boards, NHS Trusts, health professionals and all those employed in or contracted to the NHS to ensure the confidentiality of patients’ personal health records; the Chief Administrative Medical Officer or the nominated deputy will continue to have a responsibility for confidential issues, security and access to personal health information held by health boards. Nor are they intended to inhibit health professionals from giving informal access to patients who ask to see their records ...the Management Executive wishes to encourage voluntary informal access. Informal access will be in accordance with the principles and spirit of the Act and will have benefits for both patients and health professionals in that it will help to foster good relations between them and avoid the need for formal and time-consuming administrative processes. Health boards, if they have not already done so, will now wish to consider in discussion with local health professions the promotion of voluntary

¹⁸⁷ The Scottish Office, National Health Service in Scotland Management Executive, *Access to Health Records 1990*, NHS SOHHD No 1991(GEN) 27 (AC/S/22 7 October 1991), available at: <<https://www.publications.scot.nhs.uk/files/gen1991-27.pdf>>, accessed 21 July 2026.

informal access at the point of service as a part of the normal treatment and care of patients in the NHS.’¹⁸⁸ [ELJ0003-00141]

28.5 In the 1991 circular, it was also noted that certain exemptions to access would be in place. For example, ‘access can be withheld to the whole or part of a record where disclosure of the information might cause serious physical or mental harm to the individual or to any other person, or where there would be disclosure of information about an identifiable third party without the consent of that person. Access may also be withheld where a parent has applied for access to a child's health record, but where access is not considered to be in the child's best interests. A Health Board or NHS Trust must take advice from the responsible health professional before deciding whether to refuse or restrict access.’ In relation to any inaccuracies identified by the patients in the records: ‘they can ask for the record to be corrected. If there is a difference over the accuracy or completeness of what is contained in the record and the difference cannot be resolved the record should be noted accordingly. The patient should be given a copy of the correction or note free of charge.’¹⁸⁹ [ELJ0003-00141]

28.6 Data protection laws have now developed significantly since the *Access to Medical Records Act 1990* was passed. Living patients have a right to seek access to their health records pursuant to Subject Access Requests (SARs) as provided for under the General Data Protection Regulation (GDPR), further details of which are set out below. However, the rights set out under the 1990 Act continue to apply in relation to individuals seeking access to the health records of somebody who had died in Scotland, or anyone who has a claim resulting from the death.¹⁹⁰ A personal representative is the executor or administrator of the dead person's estate. The law allows the personal representative to

¹⁸⁸ paras 2 and 3, p. 1.

¹⁸⁹ paras 8 -9, p. 2.

¹⁹⁰ See *Access to Medical Records 1990*, s 3(1)(f).

see health records of the dead person's whose estate they represent, which were made after 1 November 1991. However, records are usually only kept for three years after someone's death. Even where access is permitted, the person will not be able to see certain types of information that could cause serious harm to your physical or mental health, or anyone else's; or to identify another person (except members of NHS staff who have treated the patient), unless that person gives their permission. In addition, no permission is given to view the records of someone who made it clear that they did not want other people reviewing their records after they had passed away.¹⁹¹ [ELJ0003-00082]

28.7 In 1998, the *Data Protection Act* (DPA) was adopted and became the UK's primary legislation regulating how personal information on living individuals could be obtained, used, and stored, including their health records. It was built on eight guiding principles with organisations, such as Health Boards, being legally required to ensure that patients personal data was processed fairly and lawfully; was obtained for specific and lawful purposes only; was adequate, relevant, and not excessive for its purpose; accurate and kept up to date; not kept for longer than necessary; processed in line with the rights of the individual; kept secure and protected against unauthorised access or loss; and were not transferred outside the European Economic Area without adequate data protection being in place.¹⁹²

28.8 The DPA 1998 was superseded by the DPA 2018, which was designed to ensure compliance with the GDPR.¹⁹³ The GDPR made some potentially significant changes,

¹⁹¹ NHS Mid Lothian, 'Access to Health Records 1990: Information Sheet', available at: <https://www.nhsllothian.scot/yourrights/wp-content/uploads/sites/7/2023/02/AHRA_AccessForm.pdf>, accessed 21 July 2026.

¹⁹² *Data Protection Act 1998*, s. 4 (now repealed).

¹⁹³ *Data Protection Act 2018*, c. 29. *Regulation (EU) 2016/679 (General Data Protection Regulation)*, OJ L 119, 04.05.2016; cor. OJ L 127, 23.5.2018. Please note also the recent adoption of *Data Use and Access Act 2025*, which amends but does not replace UK GDPR, the DPA 2018 and the *Privacy and*

including abolishing for subject access requests for data, such as health, and shortening the timescale for data controllers to respond SARs. Pursuant to Article 16 GDPR, patients have a right to ask for changes to be made to their health records, where they are inaccurate or incomplete. Data controllers with responsibility for processing health records, must ensure that they take reasonable steps to ensure that the data in health records is accurate and make rectification, if necessary. What constitutes reasonable steps will depend on the circumstances, but should include the arguments and evidence provided by patients. If clinical opinions turn out to be incorrect after further investigation, this does not mean that it would be considered inaccurate data nor does it mean that clinicians need to remove such opinions from patients' health records. However, patients may be permitted to add a note to the records to indicate that they do not agree with the particular clinical opinion in question. Where clinicians refuse patient requests for a rectification of their medical records, then they need to explain their reasons to such patients and inform them of their rights to complain to the Information Commissioner's Office (ICO) and to seek judicial remedies.¹⁹⁴ [ELJ0003-00061] Data protection legislation provides people with information rights over the health and social care data processed about them.¹⁹⁵ [ELJ0003-00132]

Part F – Conclusions

29. **Please highlight any limitations on your ability to compile your report, based on the material provided or available to you, including (where relevant) materials relating to the matters you have been asked to address in your report which you would suggest that the Inquiry should recover to assist with its investigations.**

Electronic Communications Regulations (PECR). The focus of this 2025 Act is on the management of digital information.

¹⁹⁴ For an overview, see Information Commissioner's Office, 'Right to Rectification', available at: <<https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/individual-rights/individual-rights/right-to-rectification/>> accessed 21 July 2026.

¹⁹⁵ See also Scottish Government, *Records Management Code of Practice* (2024) (n 167).

29.1 The expert group has undertaken a review of documentation that sets out high-level principles, policy and regulation relating to the questions set out in the revised Lol dated 16 June 2026. Once the Inquiry has obtained further evidence in relation to the matters set out in the revised Lol, in particular how they were applied in practice during the relevant period, then the expert group would be happy to provide a supplemental report providing more detailed answers.

30. **Please set out any particular matters relating to the field of health administration/ management which appear to you to be relevant to the Inquiry's Terms of Reference or List of Issues, which you think should be brought to the Inquiry's attention and/ or you think the Inquiry should investigate further.**

30.1 See above.

31. **Are there any other matters or areas which are covered by the Inquiry's Terms of Reference or provisional List of Issues on which other areas of expertise would be able to provide relevant and helpful evidence, in your view? Please explain how any other area of expertise could assist the Inquiry and which issues evidence from any such field of expertise would be able to contribute to resolving (beyond those matters already raised with existing expert groups, as set out in the letters of instruction for the experts in neurosurgery and medical ethics, copies of which are attached to this letter).**

31.1 Not applicable.

Statement of Truth

We confirm that we have made clear which facts and matters referred to in this report are within our own knowledge and which are not. Those that are within our own knowledge we confirm to be true.

We understand our duty to provide independent evidence and have complied with that duty in the provision of this report. The opinions we have expressed represent our true and complete professional opinions on the matters to which they refer.



CAT C

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PROFESSOR ANNE-MAREE FARRELL



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