THE MODERN LAW REVIEW
Modern Law Review
DOI: 10.1111/1468-2230.70055

ARTICLE

Patient Safety and Organisational Accountability: Reassessing Criminal Liability Frameworks in Healthcare

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Serious harm in healthcare often results from systemic failures, yet criminal accountability remains largely addressed through homicide law, gross negligence manslaughter and health-and-safety offences, frameworks that emphasise individual culpability and are ill-suited to addressing organisational failings. The Corporate Manslaughter and Corporate Homicide Act 2007 was intended to redress this imbalance by prosecuting organisations for management failures causing death, yet its impact in healthcare remains limited: no NHS Trust has been convicted under this legislation. Persistent barriers, including proving an organisational 'gross breach', establishing causation across care systems and satisfying the senior-management requirement, have constrained its use. While cases such as Lucy Letby have sharpened public attention on professional wrongdoing and organisational oversight, the practical and normative questions raised by system-caused harm remain distinct. The Thirlwall Inquiry report provides an opportunity to reconsider whether the current legal architecture adequately addresses organisational responsibility. This article argues that although the Corporate Manslaughter and Corporate Homicide Act 2007 retains symbolic value, its practical limitations undermine its effectiveness in healthcare. It proposes reforms, including clarification of the senior-management requirement, closer integration of corporate liability with patient-safety governance mechanisms and enhanced use of remedial and publicity orders, to strengthen organisational accountability while preserving conditions for safe care.

INTRODUCTION

'Patient safety is the bedrock of a healthy NHS and social care system', the previous Health Secretary warned, adding that the service as it stands is 'broken'.[1] The scale of preventable harm underscores the point: in England,

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†Professor of Law, University of Liverpool. The authors thank Dr Paula Case and Dr Sarah Singh for their valuable comments on an earlier draft of this article and the two anonymous reviewers for their constructive feedback. An earlier version of this article was presented at the Socio-Legal Studies Association (SLSA) Annual Conference at the University of Liverpool. Thanks are extended to participants for their helpful feedback. The authors contributed equally to the development, research and writing of this article. Where no permalink is available all URLs last visited 9 July 2026.

1 Wes Streeting, 'Wes Streeting MP, Secretary of State for Health and Social Care, speech at Labour Party Conference 2024' 25 September 2024 at https://labour.org.uk/wes-streeting-speech-at-labour-party-conference-2024/ [https://perma.cc/ZZK5-7VZ2].

an estimated 237 million medication errors occur annually, contributing to over 1,700 deaths[2] and between 19,800-32,200 cases of significant avoidable harm.[3] How the law should respond to such risks, especially the role of criminal law, is therefore a question of both practical and constitutional importance.

A central difficulty lies in the mismatch between an individualised criminal doctrine, designed to punish individual wrongdoing and the reality that harm often arises within complex organisational systems. The law of homicide targets the most egregious intentional wrongdoing by an individual (for example Harold Shipman, Beverley Allitt and Lucy Letby), whereas gross negligence manslaughter addresses unintentional deaths caused by a gross breach of duty and, in practice, locates liability on the individual defendant, typically the clinician in the dock.[4]

In complex healthcare systems, empirical research in patient safety suggests that many serious adverse events arise not from isolated individual violations alone, but from the interaction between latent organisational conditions, such as staffing levels, supervision structures, protocols, information flows and safety culture and 'active failures' at the clinical front line.[5] This systems-oriented account of harm is well established in the patient safety literature and has been reflected in major national inquiries into healthcare failures.[6] That said, individual culpability remains an important part of the

2 John Illingworth and others, 'National State of Patient Safety 2022' (Imperial College London, Institute of Global Health Innovation, 2022) at https://www.imperial.ac.uk/media/imperial-college/institute-of-global-health-innovation/National-State-of-Patient-Safety-2022.pdf [https://perma.cc/G6UD-XZQ5] 13.

3 *ibid*.

4 Margaret Brazier and Amel Alghrani, 'Fatal medical malpractice and criminal liability' (2009) 25 *Journal of Professional Negligence* 51, 54.

5 See Richard Baker and Brian Hurwitz, 'Intentionally harmful violations and patient safety: The example of Harold Shipman' (2009) 102 *Journal of the Royal Society of Medicine* 223; Anthony Avery and others, 'Incidence, nature and causes of avoidable significant harm in primary care in England: retrospective case note review' (2021) 30 *BMJ Quality & Safety* 961; Abi Rimmer, 'Bawa-Garba case: When something goes wrong in healthcare there is never one person to blame' (BMJ, News, Voxpop, 8 December 2017) at https://www.bmj.com/content/359/bmj.j5721. The National Patient Safety Agency's Seven Steps to patient safety guide suggests, '[a]ll incidents are also linked to the system in which the individuals … [are] working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring.' NHS National Patient Safety Agency, 'Seven steps to patient safety' (The full reference guide, August 2004) at https://www.publichealth.hscni.net/sites/default/files/directorates/files/Seven%20steps%20to%20safety.pdf [https://perma.cc/77KU-G24W]. In the cases of *R* v *Adomako, R* v *Sullman, R* v *Holloway, R* v *Prentice* [1994] QB 302; *R* v *Sudhanshu Garg* [2012] EWCA Crim 2520; *R* v *Shahid Khan* (Manchester Crown Court, Sentencing Remarks of Mrs Justice Yip DBE) at https://www.judiciary.uk/wp-content/uploads/2020/11/KHAN-SENTENCING-REMARKS.pdf [https://perma.cc/VF8D-5W23] and *R* v *Bawa-Garba* [2016] EWCA Crim 1841, significant systemic failings, such as poor communication, inadequate protocols and staffing shortages, played a role in the adverse outcomes.

6 Mid Staffordshire NHS Foundation Trust Public Inquiry, *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* HC 947 (2013); Department of Health, *Learning not blaming. The government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation* Cm 9113 (July 2015).

accountability landscape, including in the relatively rare cases that lead to prosecution for gross negligence manslaughter. The difficulty, however, is that a liability framework focused primarily on individual fault risks obscuring the organisational context within which clinical decisions occur. As a result, systemic contributors to harm may remain insufficiently scrutinised, potentially encouraging forms of scapegoating and limiting opportunities for institutional learning. These concerns have also been linked to wider equity debates, including evidence suggesting that minority ethnic doctors may be disproportionately exposed to GNM investigations and proceedings.[7] This does not deny that some cases involve clear individual wrongdoing, as illustrated by prosecutions such as *R* v *Mamman*.[8] However, the existence of such cases does not displace the broader insight of patient safety research that serious harm in healthcare often emerges from the interaction between individual actions and the organisational environments within which those actions occur.

The Corporate Manslaughter and Corporate Homicide Act 2007 (2007 Act) was intended to correct that imbalance, shifting the focus of accountability away from isolated individual fault and towards organisations whose senior-management arrangements create or tolerate lethal risk.[9] In principle, the 2007 Act dispenses with the identification doctrine and instead asks whether 'the way' activities were 'managed or organised' by senior management constituted a substantial element of a gross breach causing death. In practice, the 2007 Act has not been the solution many hoped for.[10] The legislation was conceived largely with private-sector industrial disasters in mind, not with patient safety or quasi-public NHS bodies as the primary targets. Evidential hurdles around grossness, causation across diffuse systems and the senior-management link have proved formidable and no NHS Trust has been convicted to date, with attempts collapsing or giving way to health-and-safety routes.

Importantly, the 2007 Act potentially captures two conceptually distinct scenarios. The first involves cases where an identifiable individual perpetrator exists and the organisational failing lies in not preventing, detecting or responding adequately to that person's actions.[11] Although such cases are rare, they expose weaknesses in oversight, escalation pathways and governance cultures that may enable serious wrongdoing to persist. The second scenario involves deaths arising primarily from systemic or organisational deficiencies,

7 Amel Alghrani and Hannah Saad, 'Medical Manslaughter' in Elizabeth Chloe Romanis, Sabrina Germain and Jonathan Herring (eds), *Diverse Voices in Health Law and Ethics: Important Perspectives* (Bristol: Bristol University Press, 2025).

8 *R* v *Mamman* (Manchester Crown Court, 5 July 2022), discussed in Clare Dyer, 'Doctor jailed after patient dies from botched biopsy' (2022) 378 BMJ 1675.

9 James Gobert, 'The Corporate Manslaughter and Corporate Homicide Act 2007: Thirteen Years in the Making but Was It Worth the Wait?' (2008) 71 MLR 413, 418.

10 Victoria Roper, 'The Corporate Manslaughter and Corporate Homicide Act 2007 – A 10-Year Review' (2018) 82 JCL 48, 56; Simon Parsons, 'The Corporate Manslaughter and Corporate Homicide Act 2007 Ten Years On: Fit for Purpose?' (2018) 82 JCL 305, 308-309; *ibid* Gobert, *ibid* 427-428; Luke Price, 'Finding fault in organisations – reconceptualising the role of senior managers in corporate manslaughter' (2015) 35 *Legal Studies* 385, 390-407.

11 *R* v *Letby* [2024] EWCA Crim 1278.

such as those seen in *R* v *North East London NHS Foundation Trust*[12] (*North East London NHS Foundation Trust*), where harm stemmed not from a rogue actor but from entrenched failures in staffing, supervision, culture, information systems and resource allocation. While these scenarios raise markedly different theoretical and practical challenges, they both fall within the broad institutional obligation to prevent harm. Recognising this distinction allows the paper to clarify its own focus: organisational wrongdoing provides the principal lens through which we reassess the limits of existing criminal law, including the 2007 Act and consider how corporate liability could more effectively address system-caused patient harm.

This article argues that criminal accountability for patient deaths in healthcare is currently misaligned with how harm is produced in practice: an individual-centred criminal lens (through homicide and gross negligence manslaughter) struggles to capture system-caused harm in under-resourced environments and is even less equipped to address the organisational accountability questions raised when rare, intentional wrongdoing is enabled by governance failure. It contends that, although the 2007 Act was intended to bridge this gap, its design and enforcement record render it poorly adapted to complex NHS organisations; targeted, healthcare-specific reforms and tighter criminal-regulatory integration are therefore required to make organisational fault both provable and safety-productive.

The argument develops in three parts. The first part begins by examining the far more common problem of inadvertent clinical error arising within complex and often system-pressured healthcare environments. It then considers the criminal law's principal individual-centred response to patient deaths in such circumstances, namely the offence of gross negligence manslaughter and explains why offences structured around individual culpability are poorly suited to attributing responsibility for system-generated harm. The analysis then turns to the distinct category of intentional wrongdoing by healthcare professionals and considers the organisational failures that may enable or fail to detect such conduct. The second part examines the objectives, rationale and scope of the 2007 Act, considering its private-sector pedigree and the constraints caused by the senior-management and gross-breach requirements. It also explores why enforcement has faltered in the NHS, notwithstanding the 2007 Act's greater traction in other sectors. The third part then advances a measured reform agenda, proposing targeted doctrinal adjustments and integrated criminal-regulatory mechanisms that strengthen organisational accountability without undermining the conditions for safe, transparent and learning-oriented care.

12 Old Bailey, 9 June 2025 ('Sentencing Remarks', Central Criminal Court, Old Bailey, HHJ Richard Marks KC, 11 November 2025 at https://www.judiciary.uk/wp-content/uploads/2025/11/R-v-Benjamin-Aninakwa-and-NE-London-NHS-Foundation-Trust.pdf [https://perma.cc/PM48-VJWP]). See text to n 122 below.

INDIVIDUAL CRIMINAL LIABILITY AND SYSTEM-CAUSED HARM IN HEALTHCARE

This part examines the operation of criminal law in responding to patient deaths within healthcare institutions. It begins by distinguishing between two analytically distinct categories of harm. The first concerns deaths arising from inadvertent clinical error within complex and often system-pressured healthcare environments. The second involves the far rarer but deeply troubling cases of intentional wrongdoing by healthcare professionals. Although both categories may give rise to criminal liability, they raise markedly different questions regarding organisational responsibility, institutional oversight and the capacity of criminal law to address patient safety failures. In these latter cases, the relevant organisational failure does not lie in producing the clinical error itself, but in failing to detect warning signs, respond appropriately to concerns raised by colleagues, or intervene to restrict the individual concerned. Recognising this distinction is important because criminal law has historically focused on the culpability of individual actors, whereas many patient safety failures arise within complex organisational environments in which risk is shaped by broader institutional conditions.

System-pressured error and the limits of gross negligence manslaughter

When adverse patient safety incidents occur because of inadvertent error, the outcome cannot usually be attributed solely to the actions of a single individual. The National Patient Safety Agency's Seven Steps to Patient Safety guide emphasises that, '[a]ll incidents are also linked to the system in which the individuals … [are] working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring'.[13] Patient safety scholarship has long emphasised the systemic nature of healthcare risk. Reason's well known Swiss Cheese Model[14] illustrates how multiple factors contribute to the occurrence of an adverse outcome. Healthcare systems contain numerous defensive layers intended to prevent catastrophic harm, including protocols, supervision arrangements, training structures and communication systems. For example, in many hospitals where medicines are administered at unusual times or require specific monitoring, such drugs will be prescribed on a separate chart.[15] To safeguard against the occurrence of medication errors, procedures may be in place which mandate medication is double-checked when prepared and prior to administration to ensure the correct medication and dosage is administered.[16] In an ideal world each of

13 NHS National Patient Safety Agency, n 5 above.
14 James Reason, 'Human Error Models and Management' (2000) 320 BMJ 768, 769.
15 NHS National Patient Safety Agency, 'Safety in doses: medication safety incidents in the NHS' (The fourth report from the Patient Safety Observatory, 2007) at https://data.parliament.uk/DepositedPapers/Files/DEP2008-1788/DEP2008-1788.pdf [https://perma.cc/RTT5-2JEX] 34.
16 Alder Hey Children's NHS Foundation Trust, 'Medicines Management Code' (26 September 2023) at https://www.alderhey.nhs.uk/wp-content/uploads/2023/10/349-All-

these defensive layers and safeguards would remain intact, thus preventing a catastrophic event from occurring. In practice, as Reason's model depicts,[17] the safeguards are akin to slices of Swiss cheese, within the block of cheese, many holes exist representing active and latent failures. Catastrophic harm arises when those holes align, allowing an error to pass through every layer to cause patient injury or death.[18] Reason's well-known systems model illustrates this dynamic through the metaphor of a mosquito bite: treating the bite alone fails to prevent further attacks, meaningful prevention requires addressing the environmental conditions in which the mosquitoes breed.[19] Applied to healthcare, the analogy underscores the limitations of responses that focus exclusively on the actions of individual clinicians while neglecting the organisational conditions within which clinical errors occur.

Harm arising from negligent medical treatment is ordinarily addressed within the framework of civil liability. Negligence-based harm typically arises where a healthcare professional's conduct falls below the standard of care expected of a reasonably competent practitioner, a standard traditionally articulated through the *Bolam*[20] test and subsequently refined by the requirement of logical defensibility in *Bolitho and Others* v *City and Hackney Health Authority*.[21] In most cases, such failures remain matters for civil law and professional regulation. However, where negligence is considered sufficiently 'gross' and results in a patient's death, the conduct may cross the threshold into criminal liability through the offence of gross negligence manslaughter (GNM). The doctrinal contours of the offence, however, have long been regarded as uncertain.[22] As commentators have observed, the concept of 'grossness' provides limited analytical guidance and has been criticised as leaving the law of gross negligence manslaughter 'something of a dog's breakfast' and an example of the common law 'at its worst'.[23]

The modern formulation of the offence derives from the House of Lords decision in *R* v *Adomako*[24] which established that liability arises where a duty of care is owed to the deceased, that duty is breached, the breach causes death and the negligence is so gross as to justify criminal punishment, a determination ultimately left to the jury.[25] In the clinical context, this has come to require that the breach exposed the patient to a serious and obvious risk of death and represented a sufficiently grave departure from the standard of care expected of a reasonably competent practitioner to warrant criminal sanction.

Trust-policies-that-include-information-on-the-checking-of-medicines-when-they-are-being-administered-to-patients-and-any-associated-documents.pdf [https://perma.cc/CJ6S-GZBY].

17 Reason, n 14 above.
18 *ibid*.
19 *ibid*.
20 *Bolam* v *Friern Hospital Management Committee* [1957] 1 WLR 582.
21 *Bolitho and Others* v *City and Hackney Health Authority* [1998] AC 232.
22 Anne-Maree Farrell, Amel Alghrani and Melinee Kazarian, 'Gross Negligence Manslaughter in Healthcare: Time for a Restorative Justice Approach?' (2020) 28 *Medical Law Review* 526.
23 Anne Lodge, 'Gross Negligence Manslaughter on the Cusp: The Unprincipled Privileging of Harm over Culpability' (2017) 80 JCL 125.
24 *R* v *Adomako* [1995] 1 AC 171.
25 *ibid*.

Subsequent appellate decisions have refined the application of these elements. In *R* v *Rose*[26] the Court of Appeal clarified that the existence of a serious and obvious risk of death must be assessed objectively, but only by reference to the circumstances known to the defendant at the time of the alleged breach. As Mullock observed, what appears to follow from the judgment is that unless 'wilful blindness' is demonstrated, 'even the most truly, exceptionally bad negligence resulting in ignorance will excuse one suspected of GNM'.[27] In *R* v *Rudling*[28] the Court emphasised the objective professional standard expected of a reasonably competent practitioner when assessing breach of duty. More recently, *R* v *Broughton*[29] addressed the causation requirement, with the Court of Appeal quashing the conviction on the basis that the jury had not been properly directed on causation and that the medical evidence could not establish that earlier medical intervention would probably have prevented death.[30] GNM thus occupies a narrow doctrinal space within healthcare regulation: it captures the exceptional case of egregious individual culpability rather than the far more common patient safety failures that arise within complex organisational systems.

The limitations of this individualised framework become particularly apparent when the offence is applied to clinical practice, where patient harm frequently occurs within complex organisational environments rather than as the result of isolated professional misconduct. Several prosecutions involving healthcare professionals for GNM illustrate the tension between the criminal law's focus on individual culpability and the systemic conditions within which clinical errors often arise. The prosecutions of Drs Prentice and Sullman[31] for GNM followed the fatal intrathecal administration of vincristine to Wayne Jowett, a 16-year-old leukaemia patient. The error was well known to be invariably fatal and had been repeatedly reported across the NHS since the late 1960s. The factual matrix pointed to failures at multiple organisational levels: confusing storage and labelling of cytotoxics, inadequate protocols and checking procedures, deficient supervision of junior staff and a lack of training and experience in handling chemotherapy agents.[32] Although both clinicians were convicted at trial, their convictions were later quashed on appeal. Notably, meaningful reform followed not from the criminal process but from the external inquiry into Wayne Jowett's death[33] and the National Guidance on the Safe

26 *R* v *Rose* [2017] EWCA Crim 1168.
27 Alex Mullock, 'Gross Negligence (Medical) Manslaughter and the Puzzling Implications of Negligent Ignorance: *Rose v R* [2017] EWCA Crim 1168' (2018) 26 *Medical Law Review* 346, 354.
28 *R* v *Rudling* [2016] EWCA Crim 741.
29 *R* v *Broughton* [2020] EWCA Crim 1093.
30 For a commentary on this case, see Tony Storey, 'Causing Death by Failing to Seek Medical Help: *R v Broughton* [2020] EWCA Crim 1093' (2021) 85 JCL 62.
31 *R* v *Adomako, R* v *Sullman, R* v *Holloway, R* v *Prentice* n 5 above.
32 *ibid* at [328].
33 Brian Toft, 'External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, 4th January 2001' (Department of Health, 19 April 2001) at https://webarchive.nationalarchives.gov.uk/ukgwa/20040209163606/http://www.doh.gov.uk:80/qmcinquiry/ [https://perma.cc/M3SA-A58H].

Administration of Intrathecal Chemotherapy that followed.[34] As the Department of Health acknowledged in the aftermath of the case, 'it is too simplistic to assume that the problems lie only with poorly prepared doctors'.[35]

Similar issues arose in the prosecution in 2015 of Dr Hadiza Bawa-Garba for GNM following the death of six-year-old Jack Adcock.[36] Dr Bawa-Garba failed to recognise the early signs of sepsis and did not promptly administer antibiotics or seek senior review. When Jack later suffered a cardiac arrest, she mistakenly believed he was a different patient with a 'do not resuscitate' order and briefly halted CPR. Yet the circumstances in which these events occurred were far from straightforward. Evidence before the Medical Practitioners Tribunal Service revealed significant systematic failings including staff shortages and IT system failures that delayed critical test results.[37] An independent inquiry undertaken by the Trust,[38] identified widespread organisational deficiencies and resulted in more than seventy recommendations aimed at improving how acutely ill children were managed within the hospital. Despite these wider systemic failures, the criminal courts treated organisational factors as largely of peripheral relevance to the question of Dr Bawa-Garba's individual culpability for GNM.[39]

We argue that these cases highlight how a predominantly individualised criminal lens struggles to capture the structural and organisational conditions within which harm frequently arises. As a regulatory tool, GNM is therefore poorly equipped to address system-generated risk. By focusing on the actions of individual practitioners, it risks overlooking the causal architecture of healthcare harm, discourages openness and learning and, given concerns about the disproportionate investigation and prosecution of minority ethnic doctors, raises significant equity and fairness concerns.[40]

Rare, intentional wrongdoing and organisational accountability

While most patient safety incidents arise from inadvertent error within complex systems, a second category of cases involves deliberate wrongdoing by healthcare professionals. Although rare, such cases raise equally challenging

34 Department of Health, 'National Guidance on the safe administration of intrathecal chemotherapy' (Health service circular HSC 2001/022, 6 November 2001) at http://webarchive.nationalarchives.gov.uk/20121005045912/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004769 [https://perma.cc/5572-CHPL].

35 Department of Health, 'Safety First: A report for patients, clinicians and healthcare managers' at https://webarchive.nationalarchives.gov.uk/ukgwa/20130104224441/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064159.pdf.

36 *R* v *Bawa-Garba* [2016] EWCA Crim 1841 (*Bawa-Garba*).

37 *Hadiza Bawa-Garba* v *General Medical Council* [2018] EWCA Civ 1879 at [38].

38 University of Hospitals of Leicester NHS Trust, 'Investigation Report' at https://www.whatdotheyknow.com/request/460255/response/1128108/attach/2/FOI.SUI%20REPORT%20FOI%20Redacted.pdf?cookie_passthrough=1.

39 *Bawa-Garba* n 36 above.

40 Alghrani and Saad, n 7 above.

questions about organisational responsibility. As Merry observes, 'even when blame is justified, an undue focus on one individual often deflects attention from other important factors within the inherent complexity of modern healthcare'.[41] The case of Ian Paterson, a breast surgeon convicted of carrying out unnecessary operations on hundreds of patients, illustrates how deliberate wrongdoing can be enabled and prolonged by organisational failure.[42] Paterson was appointed in 1998 to Solihull Hospital, part of the Heart of England NHS Foundation Trust. Concerns about his surgical practices began to emerge several years later. Audits conducted by oncologists revealed unusually high numbers of patients requiring further procedures after purported mastectomies, while nurses raised concerns that Paterson was leaving breast tissue behind during operations.[43] Despite repeated warnings and internal reviews identifying serious concerns about his clinical practice, Paterson was allowed to continue performing unconventional surgical procedures for several years. He was eventually instructed to cease certain techniques in 2007, but only in 2011 was he excluded from practice. The subsequent independent inquiry concluded that safety checks and governance structures within the hospital were inadequate and had failed to prevent or detect his conduct, allowing Paterson to continue unsafe and unnecessary treatment which harmed patients.[44] As the Kennedy Review acknowledged:

> If lessons are to be learned, those seeking to learn them must get beyond focussing solely on the 'name and shame' approach, tempting and appealing as it may be. This is because when things go wrong…it is mistaken and naive to imagine that one person or group was solely responsible, with the corollary that blaming and shaming X or Y would make things right again, would solve everything. It would not…it is absolutely crucial to adopt an approach based on systems: to ask what was wrong with the systems of leadership and management in place in the Trust which allowed things to go wrong. That is the question. Once understood and answered, a better system can be put in place which will prevent things being repeated.[45]

In contrast to Prentice, Sullman and Bawa-Garba, the case of Paterson involved clearly intentional and serious wrongdoing, all of which was facilitated by organisational failings that continued for over a decade. Findings of the Report of the Independent Inquiry into the issues raised by Paterson concluded that checks and safeguards designed to ensure the safety of

41 Alan Merry and Warren Brookbanks, *Merry and McCall Smith's Errors, Medicine and the Law* (Cambridge: CUP, 2nd ed, 2017).

42 Clare Dyer 'Rogue surgeon Paterson is sentenced to 15 years after performing unnecessary operations' *BMJ* (News, 1 June 2017) at https://www.bmj.com/content/357/bmj.j2678.

43 *ibid*, 25.

44 Graham James, 'Report of the Independent Inquiry into the Issues raised by Paterson' HC 31 (4 February 2020) at https://assets.publishing.service.gov.uk/media/5e3947ed40f0b6090e0b446b/issues-raised-by-paterson-independent-inquiry-report-web-accessible.pdf [https://perma.cc/7P89-MSGB].

45 Ian Kennedy, 'Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice; Lessons to be Learned; and Recommendations' (December 2013) at https://coronerspatersoninvestigation.org/wp-content/uploads/2024/05/Kennedy-Report-Final.pdf [https://perma.cc/7G6S-VDL8] 19.

care at the hospital where Paterson practised were either inadequate or not effectively implemented, thereby allowing him to continue unsafe and unnecessary treatment.[46] Paterson's case illustrates how individual criminality may be intertwined with failures of supervision, escalation pathways and clinical governance.

Although cases of homicide committed by healthcare professionals are far rarer, involving a much higher level of deception, such cases similarly expose how structural conditions, gaps in oversight and misplaced trust can create opportunities for deliberate harm to be committed. Homicides committed by healthcare professionals provoke profound public concern, because they represent a fundamental betrayal, exploiting both the authority vested in clinicians and their privileged access to highly vulnerable patients and potentially lethal means. In Letby's case, it was her position as a 'professional nurse' that enabled her to 'repeatedly … harm babies on the unit without arousing suspicion for some time'.[47] The neonatal nurse was convicted for the murder of seven infants and the attempted murder of seven others.[48] In sentencing Letby to whole-life orders, Mr Justice Goss condemned her crimes as 'a cruel, calculated and cynical campaign of child murder involving the smallest and most vulnerable of children'.[49] An ongoing police investigation is examining potential corporate manslaughter liability at Letby's employing Trust, the Countess of Chester Hospital, with a particular focus on the actions and decisions of senior leadership.[50] This sits alongside investigations into possible gross negligence manslaughter charges against individual staff members.[51] Together, these inquiries seek to determine whether systemic failures in management and oversight contributed to the infant deaths, potentially giving rise to criminal liability at both organisational and individual levels.

Letby's case bears a striking resemblance to the case of Beverley Allitt, a paediatric nurse who, at the age of 31, was convicted of four counts of murder, three counts of attempted murder and six counts of grievous bodily harm with intent.[52] Allitt injected insulin and potassium chloride into her young patients while working on the children's ward of Grantham and Kesteven General Hospital. The sentencing judge described these as mur-

46 James, n 44 above.

47 *R* v *Letby* 'Sentencing Remarks', Manchester Crown Court, Mr Justice Goss, 21 August 2023 at https://www.judiciary.uk/wp-content/uploads/2023/08/LETBY-Sentencing-Remarks.pdf [https://perma.cc/XJ7T-9JUK] at [4].

48 An application to the Criminal Case Review Commission (CCRC) was made in 2025: Criminal Case Review Commission, 'Lucy Letby application received by Criminal Cases Review Commission' (Announcement, 4 February 2025) at https://ccrc.gov.uk/news/lucy-letby-application-received-by-criminal-cases-review-commission/ [https://perma.cc/S74A-DKN5]. The CCRC is an independent body set up under the Criminal Appeal Act 1995. It is responsible for independently reviewing suspected and alleged miscarriages of criminal justice in England, Wales and Northern Ireland. It is based in Birmingham and is funded by the Ministry of Justice.

49 n 47 above at [3].

50 Paul Burnell and Jonny Humphries, 'Manslaughter probe at Letby hospital expanded' *BBC News* 13 March 2025 at https://www.bbc.co.uk/news/articles/c4g94jzgl4eo [https://perma.cc/3WZ9-3UE2].

51 *ibid*.

52 *Re Allitt* [2007] EWHC 2845 (QB).

ders of 'young children whose lives were snuffed out almost before they had begun'.[53] The hospital was described as 'a place of danger, if not a killing field'.[54] Following her conviction, for which she received a minimum 30 year custodial sentence, a public inquiry chaired by Sir Cecil Clothier QC concluded 'a determined and secret criminal may defeat the best regulated organisation in the pursuit of his or her purpose'.[55] The report further noted: 'No measures can afford complete protection against a determined miscreant. The main lesson from our Inquiry and our principal recommendation is that the Grantham disaster should serve to heighten awareness in all those caring for children of the possibility of malevolent intervention as a cause of unexplained clinical events.'[56]

A mere seven years later, Dr Harold Shipman, a general practitioner, was convicted in 2000 for the murder of 15 patients while working as a junior hospital doctor in the 1970s and killed at least 215 patients over the course of his career.[57] Shipman's crimes targeted elderly patients, who were typically female and living alone. While initially killing opportunistically as a hospital doctor, Shipman later exploited the unmonitored autonomy of general practice, gaining easy access to controlled substances and unrestricted entry into patients' homes. His ability to falsify medical records and death certificates, combined with inadequate oversight, allowed him to kill undetected for decades. Shipman was sentenced to 15 concurrent terms of life imprisonment, but whilst in custody committed suicide. The Shipman Inquiry exposed widespread latent failures in medical regulation, drug control, death certification and coroner oversight, leading to subsequent reforms.[58] The Inquiry's conclusions were stark: 'The extent of Shipman's crimes was unprecedented, but the ability of a single doctor to act without scrutiny over a prolonged period exposed deep systemic failings'.[59] As Baker and Hurwitz argued, simply addressing these individual failures is insufficient.[60] Instead, a broader patient safety framework is needed, which includes recognising intentional violations, regarding Shipman's crimes as patient safety events, rather than relying solely on criminal or regulatory investigations. Rather, it is the shared responsibility of healthcare professionals and organisations to identify, report and learn from harmful violations, ensuring that systemic weaknesses do not enable similar abuses in the future.[61]

Thus, whilst some may hold that Paterson, Letby, Allitt and Shipman are aberrant 'one-off' sociopaths who happened to be healthcare professionals, this is dangerously complacent. Letby is now widely regarded as the UK's

53 *ibid*.
54 *ibid* at [44].
55 Sir Cecil Clothier, *Independent Inquiry Relating to Deaths and Injuries on the Children's Ward at Grantham and Kesteven General Hospital (The Allitt Inquiry)* (London: HMSO, 1994).
56 *ibid*.
57 Janet Smith, 'The Shipman Inquiry. Second Report: The Police Investigation of March 1998' Cm 5853 (July 2003) at https://assets.publishing.service.gov.uk/media/5a7ceaee40f0b65b3de0bf11/5853.pdf [https://perma.cc/QE5F-77HL].
58 *ibid*.
59 *ibid*.
60 Baker and Hurwitz, n 5 above.
61 *ibid*.

most prolific child serial killer and Shipman remains Britain's most prolific serial killer; treating them as mere outliers obscures the institutional conditions that enabled their crimes. These crimes also cast a long shadow, not only undermining public trust in healthcare professionals but also reinforcing the unsettling reality that systemic failures can enable even the most egregious abuses within medical settings. The Letby case has reignited these concerns, demonstrating that healthcare institutions remain vulnerable to individuals who exploit their position of trust and that regulatory safeguards and oversight mechanisms may still be inadequate in preventing such harm.

Organisational accountability and the limits of individual conviction

The Letby convictions highlight an important conceptual distinction between individual criminal liability and institutional accountability. Letby has been convicted of murder, resolving the question of her personal culpability (pending a CCRC appeal). However, the case has simultaneously exposed wider questions about the organisational environment within which those crimes occurred. Evidence disclosed during Letby's trial demonstrated that clinicians repeatedly raised concerns about unexplained collapses on the neonatal ward, yet these warnings were not acted upon. As early as 2015, Dr Stephen Brearey, lead consultant on the neonatal unit, formally raised concerns about Letby's association with unexplained deaths and sudden collapses, supported by his colleague Dr Ravi Jayaram. Despite these warnings, no decisive action was taken and Letby continued to work clinically.[62] More troubling still, staff who persisted in linking Letby to these deaths were instructed to apologise and, in some cases, required to participate in mediation with her.[63] Nearly three years elapsed between the first formal warnings and Letby's eventual arrest in July 2018.[64]

Following Letby's convictions, in 2024 the government commissioned the Thirlwall Inquiry, chaired by Lady Justice Thirlwall, to examine systemic failures in oversight, whistleblowing protections and managerial accountability at the Countess of Chester Hospital. Sir Duncan Nichol, the former chairman of the Countess of Chester Hospital, gave testimony to the Thirlwall Inquiry on how the hospital handled Letby's case and apologised for the 'unimaginable grief for the families whose babies died' and on multiple occasions said the hospital had 'failed' to keep babies safe in its care.[65] Although the Inquiry's recommendations will not be legally binding, they are likely to shape the evidential and policy landscape for any organisational charges and for regulatory

62 Judith Moritz, Jonathan Coffey and Michael Buchanan, 'Hospital bosses ignored months of doctors' warnings about Lucy Letby' *BBC News* 18 August 2023 at https://www.bbc.co.uk/news/uk-66120934 [https://perma.cc/UY2L-FLCD].

63 *ibid*.

64 *ibid*.

65 Thirlwall Inquiry, Transcript, 2 December 2024 at https://thirlwall.public-inquiry.uk/wp-content/uploads/2024/12/Thirlwall-Inquiry-2-December-2024.pdf [https://perma.cc/C49P-YQ58].

reform. Public inquiries have historically played an important role in the governance of the NHS. While they do not themselves impose legal liability, they often catalyse institutional change when their findings are taken forward by ministers, regulators and professional bodies. Their impact, however, remains uneven and contingent on political will and effective implementation.[66]

The policy question for this article is whether the current statutory and common-law tools are adequate for addressing harm caused by organisational failings within healthcare institutions, or whether targeted enhancements, especially to corporate liability are required. Whilst intentional harm and wrongdoing by healthcare professionals (Shipman, Allitt, Letby and Paterson) rightly attract criminal prosecution such cases sit at the margins of the wider patient safety problem. The reality is that most harm in healthcare arises not from deliberate wrongdoing but from failures within organisational systems, or from human error occurring within complex and resource-constrained environments.[67] The central challenge for law and policy is therefore how responsibility should be attributed where patient harm emerges from systemic organisational conditions, rather than from the conduct of a single culpable individual.

THE CORPORATE MANSLAUGHTER AND CORPORATE HOMICIDE ACT 2007

Objectives, rationale and legislative scope

Recent events in healthcare have renewed scrutiny of the institutional environments in which serious patient harm may occur. High-profile cases such as the convictions of Lucy Letby have prompted renewed public and legal attention to the question of whether organisational failures within healthcare institutions themselves may attract criminal accountability. Even where an individual offender has been subjected to the gravest criminal sanction, broader questions frequently remain regarding the organisational culture, governance structures and management decisions that may have enabled catastrophic harm.

The 2007 Act was enacted to address precisely this problem.[68] Prior to the 2007 Act, under the common law, successful prosecution of an organisation for manslaughter required proof that an individual who could be identified as the 'directing mind' of the company was personally guilty of gross negli-

66 See Kieran Walshe and Joan Higgins, 'The use and impact of inquiries in the NHS' (2002) 325 BMJ 895, and Graham P. Martin, Susanna Stanford and Mary Dixon-Woods, 'A decade after Francis: is the NHS safer and more open?' (2023) 380 BMJ 513 (both showing influence alongside a persistent 'implementation gap').

67 Sir David Dalton and Norman Williams, 'Building a Culture of Candour. A review of the threshold for the duty of candour and of the incentives for care organisations to be candid' (RCS, March 2014) at https://www.rcseng.ac.uk/-/media/files/rcs/library-and-publications/non-journal-publications/building-a-culture-of-candour.pdf [https://perma.cc/2H5U-3Q2C].

68 Corporate Manslaughter and Corporate Homicide Act 2007, Explanatory Notes, paras 9-14.

gence manslaughter.[69] This 'identification doctrine' was notoriously ill-suited to modern, complex organisations, where decision-making is diffuse.[70] While smaller companies sometimes faced prosecution, large corporations and public bodies effectively escaped liability.[71] As the Law Commission observed, prosecutions under the identification principle were almost impossible for complex entities: 'if responsibility … is not vested in a particular group or individual, it becomes almost impossible to identify the "directing mind"'.[72] Contemporary scholarship had already urged a pivot from 'medical' to 'managerial' manslaughter in cases of system-caused deaths in hospitals.[73] Allen argued that concentrating on clinicians masks organisational fault and that the identification doctrine rendered large NHS bodies difficult to prosecute.[74] Further, holding NHS Trusts accountable where unfit hospital systems contributed to errors being made, would likely be more effective in identifying errors and creating momentum for change, leading to patient safety gains.[75]

Following calls for reform after several high-profile disasters, the 2007 Act sought to overcome the barriers of the identification doctrine by creating a bespoke offence,[76] where liability would no longer be dependent on pinpointing a guilty individual but on whether the way an organisation's activities were managed or organised by senior management amounted to a 'gross breach' of a duty of care causing death.[77] In principle, this shifted the focus from individual culpability to systemic management failure, symbolically promising to redirect criminal law from scapegoating junior staff towards scrutinising corporate and institutional structures.

The legislative timing is notable. The 2007 Act was introduced at a moment when many contemporaneous reforms reflected a broadly neoliberal regulatory orientation that emphasised personal responsibility and individual blame.[78] Against that backdrop, creating a corporate offence that explicitly targeted organisational failings might appear anomalous. Yet this tension is partly explained by the reform's origins. The Law Commission's 1996 Report was not directed at healthcare, but at recurrent failures in high-risk sectors: construction, manufacturing and transport and at the difficulty of

69 Home Office, 'Reforming the Law on Involuntary Manslaughter: The Government's Proposals' (May 2000) at https://www.corporateaccountability.org.uk/dl/manslaughter/reform/archive/homeofficedraft2000.pdf [https://perma.cc/82FN-M9UG]13.
70 See *DPP* v *Kent and Sussex Contractors Ltd* [1944] KB 146.
71 Home Affairs and Work and Pensions Committees, Draft Corporate Manslaughter Bill: First Joint Report of Session 2005–06 (HC 540-I, 2005–06), 540.
72 Law Commission, *Legislating the Criminal Code: Involuntary Manslaughter* Law Com No 237 (1996), para 1.17.
73 Amel Alghrani and others, 'Healthcare scandals in the NHS: crime and punishment' (2011) 37 *Journal of Medical Ethics* 230; Oliver Quick, 'Medical manslaughter and expert evidence: the roles of context and character' in Danielle Griffiths and Andrew Sanders (eds), *Bioethics, Medicine and the Criminal Law, Vol II: Medicine, Crime and Society* (Cambridge: CUP, 2013) 101-116.
74 Neil Allen, 'Medical or Managerial Manslaughter' in Charles A. Erin and Suzanne Ost (eds), *The Criminal Justice System and Health Care* (Oxford: OUP, 2007) 53.
75 *ibid*.
76 Law Commission, *Criminal Law: Involuntary Manslaughter* Consultation Paper No 135 (1994).
77 Corporate Manslaughter and Corporate Homicide Act 2007, s 1: Explanatory Notes.
78 Emma Bell, *Criminal Justice and Neoliberalism* (Basingstoke: Palgrave Macmillan, 2011).

holding complex organisations to account under the identification doctrine.[79] Its stated rationale was threefold: first, widespread concern that it was wrong if the criminal law placed all the blame on junior employees while shielding employers who operated and profited from unsafe systems;[80] second, the persistent toll of preventable deaths in workplaces such as factories and building sites; and third, the rarity of corporate manslaughter prosecutions under the common law.[81] The reform was therefore envisaged with private and commercial entities in mind.[82] Improving patient safety within the NHS was not an explicitly articulated objective of the Law Commission's rationale.[83]

Introduction of the corporate manslaughter offence sought to ensure that there were 'effective laws in place to prosecute organisations where they have paid scant regard to the proper management of health and safety with fatal results.'[84] This raises a central tension in the application of the 2007 Act. NHS Trusts, as quasi-public bodies tasked with delivering universal healthcare in conditions of sustained resource constraint, sit uneasily within a legislative framework crafted primarily with profit-driven corporations in mind. Holding Trusts criminally liable for 'gross breaches' by senior management is conceptually possible, but politically and practically fraught. It was arguably not envisaged by the drafters that the principal battleground for the 2007 Act would be healthcare organisations rather than private corporations. Nevertheless, the extension of the 2007 Act to healthcare had clear symbolic and practical implications. For the first time, NHS bodies lost Crown immunity from prosecution they had enjoyed until 1990[85] and corporate manslaughter entered the arsenal of criminal law available to regulators in cases of fatal patient safety failings. Symbolically, this represented a decisive shift in acknowledging the systemic nature of many medical errors and in principle promised a framework through which unsafe practices, defective governance and dysfunctional institutional cultures could be exposed to criminal sanction. The theoretical deterrent effect was evident: Trusts and their senior leaders were expected to review policies, strengthen decision-making, improve communication and embed a culture of patient safety, lest criminal liability follow. Yet this promise has not been realised. Prosecutions of NHS Trusts under the 2007 Act have either collapsed or failed,[86] evidentiary thresholds have proven formidable and the ethical dilemmas of criminalising essential public

79 n 72 above.
80 *ibid*, para 1.10.
81 *ibid*. At the time of the Law Commission's report in 1996, only four prosecutions of a corporation for manslaughter had been brought in the history of English law, and in only one of these cases had a conviction resulted.
82 *ibid*, paras 1.10-1.13.
83 *ibid*; see Gobert, n 9 above.
84 Home Office, 'Draft Corporate Manslaughter Bill: response to first joint report of the Home Affairs and Work and Pensions Committees' (Policy paper, 8 March 2006) at https://www.gov.uk/government/publications/government-reply-to-the-first-joint-report-from-the-home-affairs-and-work-and-pensions-committees-2005-to-2006 [https://perma.cc/MBX9-YNT7] 1.
85 National Health Service and Community Care Act 1990, s 60(1).
86 See *R* v *Dr Errol Cornish and Maidstone and Tunbridge Wells NHS Trust* [2015] EWHC 2967 (QB).

bodies have become increasingly salient. Against this backdrop, the Countess of Chester investigation following the Letby murders represents a crucial test case: whether and under what conditions, the 2007 Act can genuinely deliver organisational accountability in healthcare.

Early enforcement and the shape of organisational fault

Introduction of the 2007 Act sought to ensure that companies and other organisations would be properly held to account for very serious failings which resulted in death.[87] Under the 2007 Act, an organisation is guilty 'if the way in which its activities are managed or organised, (a) causes a person's death, and (b) amounts to a gross breach of a relevant duty of care owed by the organisation to the deceased'.[88] The 2007 Act makes clear that liability arises only where 'the way in which its activities are managed or organised by its senior management is a substantial element in the breach'.[89] 'Gross breach' is defined as conduct 'falling far below what can reasonably be expected of the organisation in the circumstances'.[90] The 'relevant duty of care' embraces duties owed 'under the law of negligence' including those owed as employer, as an occupier of premises and 'in connection with the supply by the organisation of goods or services' among others.[91] 'Senior management' means persons who play 'significant roles' in 'the making of decisions about how the whole or a substantial part of [the organisation's] activities are to be managed or organised, or the actual managing or organising of the whole or a substantial part of those activities'.[92] In deciding grossness, the jury must consider the seriousness of the failure and the risk of death and may take into account 'attitudes, policies, systems or accepted practices within the organisation' that encouraged the failure or produced a tolerance of it as well as compliance with health and safety legislation.[93] Taken together, these provisions move beyond the old identification doctrine and focus the inquiry on systemic senior-management failings that substantially contribute to a gross breach causing death.

The 2007 Act's earliest convictions concerned elementary management failings in high-risk work settings. The first conviction arose in *R* v *Cotswold Geotechnical Holdings Ltd* when employee Alexander Wright was killed in September 2008 after a pit collapsed whilst he was taking soil samples.[94] Shortly afterwards, Northern Ireland's first conviction arose from the death of

87 CPS, 'Corporate Manslaughter' (Prosecution Guidance, 16 July 2018) at https://www.cps.gov.uk/legal-guidance/corporate-manslaughter [https://perma.cc/UB39-SE3R].
88 Corporate Manslaughter and Corporate Homicide Act 2007, s 1(1). The gross breach of duty need not be the sole nor the main cause, so long as it was an operating cause which made more than minimal contribution to the death *R* v *Hennigan* (1971) 3 All ER 133 and *R* v *Hughes* (2014) 1 Cr App R 6.
89 Corporate Manslaughter and Corporate Homicide Act 2007, s 1(3).
90 *ibid*, s 1(4)(b).
91 *ibid*, s 2(1).
92 *ibid*, s 1(4)(c).
93 *ibid*, ss 8(2)-(3).
94 *R* v *Cotswold Geotechnical Holdings Limited* [2011] WL 2649504.

Robert Wilson in 2010, when a large metal bin fell from the raised forks of a forklift and crushed him on a farm operated by JMW Farm Ltd. The forklift was being driven by a company director and the bin had not been properly secured to the forks.[95] HHJ Burgess emphasised that a 'simple, reasonable and effective' precaution would have prevented the death.[96] In *R* v *Lion Steel Equipment Ltd*[97] the company pleaded guilty to corporate manslaughter following an employee's fatal fall from a factory roof.[98] In 2016 *R* v *Sherwood Rise Ltd*[99] marked the first conviction against a care provider, after 86-year-old Ivy Atkin died at Autumn Grange care home from profound neglect. The director was also convicted of GNM and the manager of health and safety offences. More recently, in 2021, Aster Healthcare pled guilty to corporate manslaughter at Guildford Crown Court and was fined £1.04 million after 93-year-old Frances Norris, a resident with dementia, died from scalding when staff failed to control bathwater temperature.[100] These cases demonstrate the offence's traction where managerial responsibility and causation are relatively direct, and the relevant 'system' is bounded within a small organisation. The contrast with the NHS is stark: in complex, multi-layered public healthcare settings, mapping systemic fault to senior management decisions is far more challenging. To date there have been 40 prosecutions under the 2007 Act, resulting in 32 convictions, with the bulk arising in smaller, bounded organisations (for example care homes or small or medium-sized enterprises).[101] As Roper observes, the legislation represents 'a disappointing compromise; fewer prosecutions than predicted, unjustifiable inconsistency in sentencing, a continued lack of individual accountability and a prosecutory preoccupation with a limited range of defendant'.[102]

Effectiveness and limitations of the 2007 Act

With NHS Trusts theoretically exposed to prosecution, the 2007 Act was designed to elevate standards of governance by signalling that organisational failings causing death would attract criminal sanction. The offence was designed to prompt Trusts and senior staff to uphold very high standards through robust policies, sound decision-making, effective communication and a culture of risk assessment and accountability.[103] Yet no NHS Trust has ever

95 *R* v *JMW Farm Ltd* [2012] NICC 17.
96 *ibid*.
97 *R* v *Lion Steel Equipment Ltd* (Manchester Crown Court, 20 July 2012).
98 *ibid*.
99 *R* v *Sherwood Rise Ltd* (Nottingham Crown Court, 5 February 2016).
100 *R* v *Aster Healthcare Ltd* (Guildford Crown Court, October 2021).
101 Maya Sikand and Jordan Briggs, 'Criminal Law in Healthcare (Part 1): Corporate Manslaughter – Goodmayes Hospital, Lucy Letby and Beyond' (Doughty Street Chambers, 10 June 2025) at https://insights.doughtystreet.co.uk/post/102kdqw/criminal-law-in-healthcare-part-1-corporate-manslaughter-goodmayes-hospital [https://perma.cc/XAF2-58LQ].
102 Roper, n 10 above.
103 Alec Samuels, 'The Corporate Manslaughter and Corporate Homicide Act 2007: How Will It Affect the Medical World?' (2007) 75 Med Leg J 72, 77.

been successfully prosecuted, casting serious doubt on the 2007 Act's capacity to achieve its legislative purpose in healthcare. The offence sets a high threshold, requiring proof that 'the failings of senior management … formed a substantial element in the breach'.[104] Investigations are typically lengthy, resource-intensive and evidentially difficult. These challenges are magnified in large, decentralised organisations such as NHS Trusts, where accountability is diffuse and decision-making dispersed. The ongoing Grenfell Tower investigation underscores this difficulty.[105] The fire on 14 June 2017, caused by an electrical fault and fuelled by combustible cladding and insulation, killed 72 people and displaced hundreds more.[106] The final report of the Grenfell Inquiry (in September 2024) attributed the disaster to a cascade of systemic failings across manufacturers, contractors, regulators and government and concluded it was avoidable.[107] Yet despite this stark indictment, the criminal investigation is 'one of the largest and most complex ever undertaken' and the CPS does not expect charging decisions before the end of 2026.[108]

Application of the 2007 Act in healthcare has similarly proved problematic: causation, managerial oversight and organisational culture must be dissected with precision to show that a gross breach of duty by senior management was a substantial cause of death. Its utility in the NHS context has therefore remained largely theoretical. This was exemplified by the Maidstone and Tunbridge Wells NHS Trust outbreaks of *Clostridium difficile* in 2005-06, which led to formal investigations.[109] More than 500 patients were infected, with around 90 deaths in which *C. difficile* was, or was likely to have been, the main cause.[110] Despite grave systemic failings, no criminal charges were brought.[111] Legally, two points were decisive: first, the 2007 Act had not yet come into force;[112] secondly, even had it applied, conviction would have been improbable given causation difficulties in an elderly, co-morbid cohort and given the absence of evidence tying a gross organisational breach to senior management. Police likewise reported no evidence of gross negligence by

104 n 78 above.

105 Ministry of Housing, Communities and Local Government, Cabinet Office and Home Office, 'Grenfell Tower Inquiry Phase 2 Report: Government Response' (Policy paper, 4 September 2024) at https://www.gov.uk/government/publications/grenfell-tower-inquiry-phase-2-report-government-response [https://perma.cc/PPE5-3AUE].

106 *ibid*.

107 *ibid*.

108 Metropolitan Police, 'Investigation update: Investigation into Grenfell Tower tragedy' (News, 22 May 2024) at https://news.met.police.uk/news/investigation-into-grenfell-tower-tragedy-487374 [https://perma.cc/2SFY-42L5].

109 The Healthcare Commission, 'Investigation into outbreaks of Clostridium difficile at Maidstone and Tunbridge Wells NHS Trust, Executive summary' at https://www.whittington.nhs.uk/document.ashx?id=1169 [https://perma.cc/T5JZ-HZMK].

110 *ibid*.

111 'No one to be prosecuted over 90 c-difficile deaths at Kent hospitals' *The Times* 30 July 2008 at https://www.thetimes.com/article/no-one-to-be-prosecuted-over-90-c-difficile-deaths-at-kent-hospitals-tkg5ck77vtj.

112 Corporate Manslaughter and Corporate Homicide Act 2007, s 27(3) makes clear the act only applies to deaths that occur from the date the act came into force. Deaths which occurred prior to that time continue to be covered by the previous law on corporate manslaughter.

the Trust.[113] More broadly, the GMC's *Independent Review of Gross Negligence Manslaughter and Culpable Homicide* concluded that 'it is extremely difficult to prove a direct causal link between high-level policy decisions and the death of an individual patient so as to secure a corporate manslaughter conviction'.[114]

The first NHS body to be charged with corporate manslaughter under the 2007 Act arose in *R* v *Dr Errol Cornish and Maidstone and Tunbridge Wells NHS Trust*[115] (*Maidstone and Tunbridge Wells*). The case arose after the death of Frances Cappuccini, who suffered severe postpartum haemorrhage following a caesarean section at Tunbridge Wells Hospital on 9 October 2012 and died despite prolonged resuscitation. Dr Cornish, the attending consultant anaesthetist, was charged with gross negligence manslaughter. Pre-trial rulings required the Crown to specify the alleged 'senior management' tier and permitted reliance on earlier events to show knowledge and systemic failings, while confirming that the offence had to be made out at the time of death. At trial, the judge upheld a submission of no case to answer on the corporate manslaughter count: the evidence could not properly be left to the jury that the way in which senior management managed or organised the Trust's activities was a substantial element in a gross breach of a relevant duty of care that caused the death.[116] The GNM charge against Dr Cornish did not result in conviction. As the first NHS prosecution under the 2007 Act, the case illustrates the offence's systemic focus, the stringent grossness threshold and the necessity of a causative link between senior management arrangements and death. The case demonstrates the 2007 Act's structural limits: to convict an NHS body, the Crown must translate ward-level shortcomings into a gross, senior-management-shaped breach causing death, a framework that risks shifting attention 'back from systemic fault to individual fault'.[117]

Maidstone and Tunbridge Wells NHS Trust[118] provides rare judicial guidance on corporate manslaughter prosecutions against NHS bodies. The offence targets systemic management failures, not isolated clinical errors, which rarely suffice.[119] The statutory 'gross' breach threshold sets a high bar: conduct must fall far below reasonable expectations, with juries considering the seriousness of the failure, risk of death, compliance with health-and-safety standards, and organisational culture. As Coulson J noted, such cases are uncommon because the conduct must be 'so flagrant and so atrocious that it would consequently amount to a crime.'[120] Crucially, the Crown must prove that senior management's organisation or management of activities was a substantial element in the breach and that the breach caused the death. In this case, the judge

113 *ibid*.
114 General Medical Council, 'Independent review of gross negligence manslaughter and culpable homicide' (June 2019) at https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide—final-report_pd-78716610.pdf 32.
115 *R* v *Dr Errol Cornish and Maidstone and Tunbridge Wells NHS Trust* [2015] EWHC 2967 (QB).
116 *ibid*.
117 n 9 above.
118 n 115 above.
119 *ibid* at [87] and [92].
120 *ibid* at [9].

upheld a no-case-to-answer submission on corporate manslaughter because the evidence could not satisfy the senior-management and causation requirements. These elements, the systemic focus, grossness threshold and senior-management nexus, help explain the scarcity of NHS prosecutions under the 2007 Act.

The same structural difficulties are evident in the prosecution of *North East London NHS Foundation Trust* for corporate manslaughter and an offence contrary to section 3 of the Health and Safety at Work etc. Act 1974 (HSWA 1974) following the death of a detained patient at Goodmayes Hospital in 2015.[121] Over the preceding five months, the patient, Alice Figueiredo had 39 self-harm incidents and on 18 occasions obtained plastic bin liners on the ward; she ultimately suffocated using a bin bag left in a communal lavatory on Hepworth Ward.[122] In 2025, after a seven-month trial at the Old Bailey and prolonged jury deliberations,[123] the Trust was acquitted of corporate manslaughter (and the ward manager was acquitted of gross negligence manslaughter) but both were convicted of health and safety offences: the Trust under section 3(1) and section 33(1)(a) of the HSWA 1974 (failure to ensure the safety of non-employees) and the ward manager under section 7(1) (failure to take reasonable care). The facts alleged repeated access to means, observation/risk-assessment failures and escalation gaps could not be translated into proof that 'the way' senior management managed or organised activities was a substantial element of a gross breach that caused the death. By contrast, the HSWA 1974 route, which does not require grossness, a senior-management nexus, or causation of death, succeeded, illustrating why the 2007 Act's evidential architecture (organisational grossness, causation across diffuse systems and the senior-management limb) remains exceptionally demanding for complex NHS settings.

Commenting on the case, barristers Maya Sikand KC and Jordan Briggs emphasise the two persistent obstacles to applying the 2007 Act to NHS bodies: 'to-date, the NHS has never been convicted of corporate manslaughter. That may be because its organisation is too labyrinthine to identify "senior management", or because there is such sentimentality about the NHS that prosecutions are not brought'.[124] They add that in Ms Figueiredo's case the prosecution 'only got off the ground due to her parents' relentless investigatory work'[125] and note the family view that the case has 'moved the dial' alongside Roper's observation that 'public bodies, the police and the CPS will … see what can be learned' from the verdict.[126] These remarks reinforce

121 n 12 above. See also Alison Holt, 'Hospital and manager guilty over patient death' *BBC News* 15 June 2025 at https://www.bbc.co.uk/news/articles/cdd2l0rmrrdo [https://perma.cc/ZMT9-YWFH].

122 James Melley and Alison Holt, 'We quit our jobs, sold our home twice and spent 10 years fighting for the truth' *BBC News* 10 June 2025 at https://www.bbc.co.uk/news/articles/cdxn5d4dzrwo [https://perma.cc/5U9J-ZXH4].

123 The jury deliberated for 24 days, matching a joint record in British legal history before delivering its verdict.

124 n 102 above.

125 *ibid*.

126 *ibid*.

the doctrinal pinch points identified above, corporate manslaughter charges against large NHS organisations will remain exceptional in the absence of clear, causally probative evidence that senior-management arrangements were a substantial element of a gross breach that caused death.

Further charges of corporate manslaughter on the horizon?

The institutional questions raised by the Letby case continue, but now against the backdrop of fresh scrutiny of her convictions. On 4 February 2025 the Criminal Cases Review Commission confirmed it had received an application on Ms Letby's behalf seeking a review of all convictions from 2015-16 at the Countess of Chester Hospital (the Inquiry Chair has also recorded the application in rulings).[127] In parallel, police investigations into organisational liability have continued. The corporate-manslaughter probe, opened in October 2023, was expanded in March 2025 and on 1 July 2025 three former senior managers at the Trust were arrested on suspicion of GNM and bailed; detectives emphasised that 'both the corporate manslaughter and gross negligence manslaughter elements … are continuing'.[128]

Legally, a corporate manslaughter charge under the 2007 Act would still turn on proof that the way the Trust's activities were managed or organised by its senior management was a substantial element of a gross breach of a relevant duty of care that caused the deaths, an inquiry distinct from, though factually entangled with, the evidence used at Letby's trial. Whilst a future CCRC outcome could affect the factual matrix available to prosecutors; it does not determine the viability of a corporate case, which rises or falls on organisational grossness, causation across diffuse systems and the senior-management nexus. Whatever the conclusions of the Thirlwall Inquiry, they will not substitute for criminal proof but may shape the evidential landscape and regulatory response.[129]

A structural limitation: the senior-management limb in complex NHS organisations

The central difficulty is that the gateway to organisational fault remains person-centred: the Crown must prove that the way activities were managed or organised by senior management was a substantial element of a gross breach causing death.[130] The 2007 Act forces 'inquiry back onto the issue of identifiable individuals and the part they play in the organisation'.[131] Conse-

127 CCRC, n 48 above.
128 Countess of Chester Hospital NHS Foundation Trust, 'Statement in response to launch of Cheshire Police corporate manslaughter investigation' (Corporate information) at https://www.coch.nhs.uk/corporate-information/news/statement-in-response-to-cheshire-police-corporate-manslaughter-investigation.aspx [https://perma.cc/W7ES-KAXS].
129 Thirlwall Inquiry, n 65 above.
130 Corporate Manslaughter and Corporate Homicide Act 2007, s 1.
131 David Ormerod and Richard Taylor, 'The Corporate Manslaughter and Corporate Homicide Act 2007' (2008) 8 Crim LR 589, 590.

quently, the 2007 Act creates an artificial level of systemic accountability and acknowledgement of systemic flaws and despite organisational failings being acknowledged, the spotlight remains on individual failings. Attribution within large NHS bodies is particularly exacting due to their multi-site operations, matrix management structures and dense regulatory environments. It risks re-importing the individualisation problem the 2007 Act was meant to cure: the inquiry slides back from system design to who, precisely, at senior level can be said to have organised the relevant activity in a way that was grossly deficient and causative. Parliamentary scrutiny anticipated this scale bias. The Joint Committee on the Draft Corporate Manslaughter Bill warned that confining liability to senior-management failure would tend to capture small entities (where 'senior management' is coterminous with day-to-day control) while allowing large organisations to evade prosecution.[132] In advancing this criticism, the Committee reflected on the following example: where a person dies in a factory and investigation shows that there had been a very senior management failure that caused the death, which was the responsibility of the most senior people in that particular factory. If this factory were the only unit of business in a small company, the company would be liable. However, if the factory was one of ten owned by a company, it might not be prosecuted.[133]

That concern maps onto the NHS with thousands of senior and 'very senior' managers across Trusts: the evidential task is not merely to show serious failings, but to pinpoint the senior-management tier whose arrangements substantially constituted the breach and caused the death. NHS England reported in December 2023, that amongst NHS Trusts and other core organisations in England, there are 14,065 senior managers, out of that number 2,520 are deemed very senior managers.[134] Overwhelmingly, the successful targets of claims concerning corporate manslaughter have been small organisations with directors who are clearly identified as the controlling mind of the company.[135]

The courts have tried to soften the sharpest edge of this requirement. In *Maidstone and Tunbridge Wells NHS Trust*[136] Coulson J cautioned that 'it is not … helpful … to expect the CPS to delve deep into the labyrinthine management structures of any large NHS trust … to identify precisely who should have been doing what' and held that the prosecution need not name individuals but should instead 'identify the tier of management … the lowest level of the senior-management team within the trust that is culpable'.[137] That clarification lowers the pleading burden, but it does not resolve the proof problem: the Crown must still link that tier's arrangements to (i) a gross breach at organisational level and (ii) causation of death in a diffuse clinical system.

132 Home Affairs and Work and Pensions Committees, above n 71, 540.
133 House of Commons Home Affairs and Work and Pensions Committees, *Draft Corporate Manslaughter Bill* First Joint Report of Session 2005-06, HC 540-I (12 December 2005).
134 NHS, 'Managers and Senior Managers by grade, gender and ethnicity' (NHS Digital, Supplementary Information, 2024, Dec 2023) at https://digital.nhs.uk/supplementary-information/2024/managers-by-grade-gender-ethnicity-dec23 [https://perma.cc/V6CN-FZZA].
135 Steve Tombs and David Whyte, *The Corporate Criminal, Why Corporations Should Be Abolished* (London: Routledge, 2015) 498.
136 n 115 above.
137 *ibid*.

As the enforcement record shows, that is where NHS cases have repeatedly foundered. In short, the 2007 Act's senior-management filter, while conceptually aimed at systems, operates in practice as a demanding attribution test that is easier to satisfy in bounded, hierarchically simple organisations than in complex public healthcare settings. Until doctrine or evidential guidance is calibrated to reflect how healthcare risks are actually produced and governed, prosecutions of NHS Trusts will remain rare outliers rather than a routine mechanism of institutional accountability.

Sanctions and suitability: what if a trust is convicted?

Even if the senior-management and causation hurdles are overcome, a further difficulty arises: the remedial toolkit under the 2007 Act fits poorly with an essential public service that is already at breaking point.[138] An organisation that is guilty of corporate manslaughter is liable on conviction on indictment to a fine[139] and the court may also make remedial[140] and publicity orders.[141] Under the Sentencing Council's Corporate Manslaughter guideline and section 164 of the Criminal Justice Act 2003, courts can impose an unlimited fine 'sufficiently substantial to have a real economic impact'[142] yet are also told that, for public bodies, fines should 'normally be substantially reduced' where they would significantly impair service provision.[143] That produces a structural dilemma: a fine that bites risks diverting funds from front-line care; a discounted fine preserves services but weakens deterrence. We do not attempt a full economic analysis of Trust finances here but note that in the NHS a corporate manslaughter fine is typically paid from the same ring of public funds that finances care; boards commonly respond through cost-containment measures (vacancy freezes, deferred maintenance and service rationalisation), which risk safety-negative externalities. If the fine is discounted to protect services (as the guideline contemplates for public bodies), its marginal deterrent effect is correspondingly diluted. Either way, patients not decision-makers, bear the financial pain.

Whether substantial fines for Trusts send a clear message of deterrence remains uncertain. In many clinical negligence cases, NHS Trusts are frequently held to account and significant sums of damages are payable in the aftermath

138 Richard Griffith, 'Extending the scope of wilful neglect will result in paternalistic nursing care' (2013) 22 *British Journal of Nursing* 1190, 1191.
139 Corporate Manslaughter and Corporate Homicide Act 2007, s 1(6).
140 Corporate Manslaughter and Corporate Homicide Act 2007, s 9.
141 Corporate Manslaughter and Corporate Homicide Act 2007, s 10.
142 Sentencing Council, 'Health and Safety Offences, Corporate Manslaughter and Food Safety and Hygiene Offences' (1 February 2016) at https://sentencingcouncil.org.uk/guidelines/corporate-manslaughter/ [https://perma.cc/QF9N-FTCW].
143 *ibid*.

of tortious negligence claims.[144] Scholarship on the duty of candour[145] repeatedly questions the behavioural value of fining NHS bodies, arguing that openness is better achieved through culture, learning systems and proportionate enforcement rather than pecuniary penalties that drain care budgets.[146] As Quick warns, 'the relationship between legal duties and the safety of healthcare is complicated, relatively poorly understood and requires robust empirical health law research'.[147]

The 2007 Act's other disposals also have limits. Publicity orders add little in a system already saturated with statutory transparency (for example, CQC reports, duty of candour and inquiry publications) and can erode public trust without improving safety. Remedial orders are the most safety-congruent, but they often duplicate existing regulatory duties and lack guaranteed ring-fenced funding or independent assurance to ensure durable system change. Crucially, the 2007 Act creates no individual penalties (no imprisonment or director-disqualification route within the offence), so an entity-only conviction can be expressive rather than effective where managerial decision-making was central. The implication is straightforward. Even post-conviction, the 2007 Act's sanctions are ill-matched to the NHS: fines risk collateral harm or under-deterrence; publicity orders are largely symbolic; remedial orders need stronger design (ring-fenced investment, external monitoring, time-bound milestones) to translate culpability into patient-safety gains. This remedial misfit helps explain prosecutorial caution and underscores the case for the targeted reforms advanced in the following part.

All of which speaks to the broader question of whether criminal law is the right instrument to drive safety improvements in healthcare: it condemns and deters at the level of principle, but given evidential hurdles, entity-only sanctions and the risk that fines deplete care budgets it is a blunt tool for engineering system change, better deployed alongside (not instead of) targeted regulatory, remedial and governance interventions.

144 In 2023-24 £2.8 billion was paid out in compensation and associated costs on all NHS Resolution indemnity schemes for clinical negligence claims. NHS Resolution, 'NHS Resolution continues trend of resolving more cases without need for litigation' (23 July 2024) at https://resolution.nhs.uk/2024/07/23/nhs-resolution-continues-trend-of-resolving-more-cases-without-need-for-litigation/ [https://perma.cc/6VKJ-ZZ5B].

145 The creation of professional and statutory duties of candour has formalised the requirement for clinicians and healthcare organisations to be honest with patients and families when treatment has gone wrong: General Medical Council (GMC) and Nursing and Midwifery Council (NMC), 'Openness and Honesty When Things Go Wrong: The Professional Duty of Candour' (2015) at https://www.gmc-uk.org/professional-standards/the-professional-standards/candour—openness-and-honesty-when-things-go-wrong; The Health and Social Care Act 2008 (Regulated Activities) 2014, reg 20.

146 See for example Oliver Quick, who emphasises that sustained candour depends on organisational learning rather than punitive responses: Oliver Quick, 'Duties of Candour in Healthcare: The Truth, the Whole Truth and Nothing but the Truth' (2022) 30 *Medical Law Review* 324.

147 *ibid*.

RECOMMENDATIONS: SHIFTING FOCUS FROM INDIVIDUAL BLAME TO SYSTEMIC ACCOUNTABILITY IN HEALTHCARE

The present architecture under the 2007 Act makes it unduly hard to prove that senior-management arrangements were a substantial element of a gross breach that caused death in complex NHS systems. We argue that the following targeted reforms are modest, feasible and better aligned with how harm is produced in healthcare.

Clarify 'senior management' to reach safety-critical governance

Sections 1(3)-(4) of the 2007 Act sees liability turn on whether 'the way' an organisation's activities were managed or organised by its senior management was a substantial element of a gross breach that caused death. In large NHS bodies, however, responsibility for safety-critical functions: staffing establishment and escalation, incident response, clinical-risk governance and compliance with National Patient Safety Alerts is diffused across boards and their committees, divisional triumvirates and functional leads. The present definition in section 1(4)(c) ('persons who play significant roles in deciding or managing the whole or a substantial part of the organisation's activities') is too indeterminate to anchor attribution in this environment. As Coulson J recognised in *Maidstone and Tunbridge Wells NHS Trust*, the prosecution should not be required to identify named individuals within 'labyrinthine management structures' but it must be able to identify the culpable tier.[148] The statute, as drafted, does not make that task straightforward. A targeted textual amendment would resolve the problem while preserving the 2007 Act's systemic focus. We thus suggest the proposed replacement section.

Proposed text (new section 1(4)(c) of the 2007 Act):

> 'Senior management' means persons who play significant roles in (i) the making of decisions about how the whole or a substantial part of the organisation's activities are to be managed or organised, or (ii) the actual managing or organising of the whole or a substantial part of those activities; and includes the board and its committees, divisional leadership and persons exercising functional control over safety-critical systems, including staffing and escalation, incident management, clinical-risk governance and compliance with national patient-safety directives.

This formulation does three things. First, it operationalises Coulson J's tier-based approach: the Crown can plead and prove the lowest culpable tier (board/committee/division/functional lead) without reverting to the identification doctrine. Second, it improves evidential fit: the evidential inquiry could focus on board papers, risk registers, rota and escalation logs, local investigation and learning outputs produced under the Patient Safety Incident Response Framework (PSIRF), relevant findings and recommendations

148 n 115 above.

of the Health Services Safety Investigations Body (HSSIB) and compliance with patient-safety alerts. Such material speaks to system design and organisational oversight, rather than merely to error at the bedside. Third, it leaves the grossness and causation thresholds untouched: the jury must still be sure that the identified tier's arrangements were a substantial element of a gross breach that caused death (sections 1 and 8).

Doctrinally, the amendment aligns with the 2007 Act's explanatory materials, which emphasise management failings, and it respects the statute's public-function carve-outs (section 3 and Schedules). It does not criminalise high-level resource allocation per se; it targets operational safety governance. Concerns about over-breadth or chilling effects are met by the existing high bar for gross breach and the jury's structured evaluative task under section 8. Nor does the proposal duplicate the Health and Safety at Work etc. Act 1974: HSWA 1974 continues to regulate risk creation and management; the 2007 Act, as clarified, remains the forum for organisational homicide when the criminal threshold is crossed.

Implementation could be achieved by a short amending Bill. Pending legislation, prosecutorial guidance (and a Crown Prosecution Service (CPS)-Care Quality Commission (CQC)-Health and Safety Executive (HSE)-NHS England protocol) can adopt a tier-based pleading and proof model in healthcare cases, signalling to investigators and courts the evidential focus on safety-critical governance. In multi-death neonatal settings, for example, the clarified definition would direct fact-finders to staffing and escalation decisions, responses to early warning signals and board oversight of sentinel events, precisely the levers that determine whether latent hazards reach patients.

Give juries healthcare specific guidance on 'gross breach'

Section 8 of the 2007 Act permits the jury to consider the seriousness of the failure, the risk of death, compliance with health and safety law and organisational attitudes, policies, systems or accepted practices when deciding whether a breach was 'gross'. In healthcare cases however those generic prompts have proved too open-textured to steer fact-finders towards organisational safety governance (as opposed to individual error) and too non-specific to reflect how risk is actually created and controlled by NHS providers. The result is an evidential drift back to clinician conduct, the very individualisation the 2007 Act was designed to overcome. A narrow textual addition would retain flexibility while giving juries sector-salient anchors that point to system design and oversight rather than personal blame; insertion of a new healthcare clause in section 8 is needed, so that juries may assess organisational grossness using sector-salient indicators.

Proposed text (new section 8(4A) of the 2007 Act – Healthcare):

> In determining whether there was a gross breach in relation to healthcare activities, a jury may have regard to evidence of: (a) compliance with National Patient

Safety Alerts and 'never events' controls; (b) safe-staffing standards and escalation protocols; (c) implementation of PSIRF and responsiveness to HSSIB findings; (d) performance under the statutory duty of candour and whistleblowing protections; and (e) board-level oversight of safety metrics and risk registers.

This operationalises section 8 for healthcare without creating strict liability and directs fact-finders away from clinician-centric narratives towards system design and governance. The proposed factors direct investigators, prosecutors and juries towards concrete organisational evidence: board minutes, committee papers, rotas and escalation logs, safety-alert compliance records, local investigation and learning materials produced under the PSIRF, relevant findings and recommendations of the HSSIB and candour correspondence. Such material may illuminate how a Trust designed, governed and monitored patient safety, rather than merely what occurred at the bedside, keeping the focus on whether management arrangements created or tolerated a lethal risk. This also means in cluster cases (for example multiple neonatal deaths) the approach directs the fact-finder to the decisions that really determine risk: staffing and on-call cover, escalation of concerns, responses to early warning signals and board oversight, so the law can see and if appropriate punish, systemic failure rather than scapegoating an individual.

Calibrate sanctions to improve safety rather than drain care budgets

Reform could address the nature of remedies available following a successful prosecution. While sections 9 and 10 of the 2007 Act technically provide for remedial and publicity orders, these mechanisms remain under-utilised and sentencing practice continues to emphasise financial penalties as the primary sanction. In public healthcare settings, such as NHS Trusts, this approach is not only ill-suited but may be counterproductive, risking harm to patient care through resource depletion of already over-stretched resources. To address this, we propose that the Sentencing Council be mandated to develop specific sentencing guidelines for corporate manslaughter cases involving public healthcare bodies, with a view to ensuring that sanctions reflect the public interest and promote system-wide learning. In addition, we recommend that the 2007 Act be amended to prioritise the imposition of constructive remedies, such as mandatory organisational reviews, court-supervised improvement plans and expanded use of remedial orders, over financial penalties. These changes would not only preserve the original spirit of the Act, as envisaged by the Law Commission,[149] but would also enhance its practical effectiveness in promoting accountability, transparency and patient safety in complex institutional settings. One reform could be to mandate the Sentencing Council to produce a sector-specific annex for public healthcare defendants in corporate manslaughter cases, built around a remedial-first presumption. Courts should presume a remedial order as the principal disposal, with any fine sub-

149 n 72 above.

sidiary, unless the court gives reasons showing a monetary penalty will improve safety (not simply punish). Reasons must address service impact, the defendant's learning response and how any sanction will be translated into measurable safety gains. Publicity orders should be framed to support candour and learning (for example to publish the remedial plan, milestones and independent assurance reports), rather than to inflict reputational damage for its own sake. Targeted statutory amendments which would adopt light-touch drafting could be to adopt two short changes to the 2007 Act to embed safety-oriented dispositions.

Proposed text (new section 9A of the 2007 Act – Public healthcare defendants (remedial-first)):

> Where the offender is a public healthcare organisation, the court shall consider a remedial order as the primary disposal. A fine shall be imposed only where the court is satisfied and states reasons, that a financial penalty is necessary and proportionate to secure public protection and will not materially impair essential services.

Proposed text (new section 10A of the 2007 Act – Court-supervised improvement plans):

> A remedial order may require: (a) a court-approved improvement plan with ring-fenced funding for safety-critical measures; (b) appointment of an independent monitor reporting to the court and relevant regulators; (c) time-bound milestones and publication of quarterly progress; and (d) mechanisms for variation and sanction on non-compliance (including further financial penalties).

This better aligns with the purpose of the 2007 Act which, according to the Law Commission's rationale, was to reach organisational failings;[150] a remedial-first model turns conviction into system change (governance, staffing, escalation, alerts compliance), not a budgetary shock. It would also be evidentially more coherent as court-supervised plans tether the sanction to the same organisational evidence that proved liability (board minutes, risk registers, PSIRF/HSSIB) without collateral harm. Ring-fencing and independent monitoring protect patients from the perverse effects of blunt fines while preserving teeth (breach of order remains sanctionable). These changes would not only preserve the original spirit of the 2007 Act, as envisaged by the Law Commission,[151] but would also enhance its practical effectiveness in promoting accountability, transparency and patient safety in complex institutional settings.

Unlimited fines could be retained for egregious or recalcitrant Trusts (with a judicial safety-impact statement explaining why a fine will improve safety) and could pair entity sanctions with targeted individual accountability through existing routes (for example section 7 and section 37 of the HSWA 1974, Fit and Proper Person enforcement) where evidence supports

150 *ibid*, paras 8.20-8.23.
151 *ibid*.

it. A remedial-first framework delivers court-supervised, independently assured correction of safety-critical systems (staffing, escalation, incident response, compliance with National Patient Safety Alerts), ensuring that any conviction yields tangible gains in patient safety rather than an accounting entry in an already stretched NHS budget. To achieve this there could be a court practice direction or guideline tweak that where the offender is an NHS body, reasons must explain how any fine is expected to improve safety; in the absence of such reasoning, the court should prefer a remedial order with (i) ring-fenced spend on safety-critical fixes, (ii) an independent monitor reporting to the court and regulator, and (iii) time-bound milestones with public progress reports.

Entity liability could be paired with targeted HSWA 1974 section 7 and section 37 cases or Fit and Proper Person enforcement where individual managerial neglect is evidenced. This avoids the perverse effect of punitive fines on patient care while ensuring dispositions change systems.

Hardwire criminal regulatory integration

At present, criminal proceedings and regulatory action frequently run on different tracks, risking missed opportunities to convert criminal scrutiny into durable system change. We propose a formal CPS–HSE–CQC–NHS England protocol under which any decision to charge in a healthcare death/serious-harm case is accompanied by an Integrated Regulatory Improvement Plan (IRIP). The IRIP would set out immediate risk controls, time-bound milestones, board-level ownership, independent monitoring and transparent (but trial-safe) reporting, so that a criminal case catalyses, rather than substitutes for, organisational reform.

The protocol should be triggered consistently with the Department of Health and Social Care 2024 memorandum of understanding (engaged where there is 'reasonable suspicion' of criminality in the course of care),[152] with the CPS convening an IRIP board comprising the lead regulator (CQC or HSE), NHS England and the relevant Integrated Care Board, and drawing on HSSIB findings where appropriate. Information-sharing would use existing legal gateways and preserve fair-trial rights; the IRIP would be strictly remedial and without prejudice to criminal issues. On conviction, the IRIP should become the backbone of any remedial and publicity orders; on acquittal, regulators would retain and enforce the plan under their ordinary powers, ensuring system risks are reduced whatever the verdict.

152 Department of Health and Social Care, 'Investigating healthcare incidents where suspected criminal activity may have contributed to death or serious life-changing harm' (Guidance,17 December 2024) at https://www.gov.uk/government/publications/investigating-suspected-criminal-activity-in-healthcare-mou/investigating-healthcare-incidents-where-suspected-criminal-activity-may-have-contributed-to-death-or-serious-life-changing-harm-accessible-version [https://perma.cc/HBK4-YGK8].

When failures turn fatal: re-centring corporate manslaughter

As set out above, prosecutions for GNM retain a legitimate but tightly circumscribed role in healthcare. They should be confined to the genuinely exceptional case in which an individual's conduct departs so gravely from minimally competent practice and demonstrates such personal culpability, that criminal condemnation is warranted. However, where the evidential landscape points instead to organisationally generated risks (staffing deficits, inadequate supervision, unsafe protocols, flawed escalation pathways, poor information governance, or corrosive workplace cultures) the appropriate locus of accountability should shift away from the individual. In such cases, prosecutors should pursue organisational liability under the 2007 Act, or the HSWA 1974, supplemented by regulatory enforcement. This reserves GNM for truly egregious individual failings while directing system-caused harm towards the legal frameworks specifically designed to address structural and managerial culpability.

Operationally, the CPS could require before any GNM charge: (i) a systems-evidence dossier (staffing/rota and escalation logs, risk registers, safety-alert compliance, PSIRF/HSSIB outputs); (ii) an independent, specialty-matched expert panel addressing clinical and systems causation; (iii) a brief equality impact assessment and (iv) regulatory consultation (CQC/HSE, NHS England) mapping parallel remedies. Indicia for GNM should include conscious disregard of an obvious, life-threatening risk (*R* v *Adomako*);[153] repetition after explicit warning (*R* v *Misra and Srivastava*);[154] falsification/cover-up (*R* v *Garg*);[155] or gross abandonment of basic duties (*R* v *Adomako*),[156] not errors traceable to unsafe systems (*R* v *Prentice and Sullman*).[157] Where evidence is mixed, action should be sequenced: prosecutors should prioritise organisational enforcement and professional regulatory routes, turning to GNM only if later evidence squarely satisfies the exceptional-culpability threshold. The case of Letby shows individual liability will still be pursued where intent is proved; for unintentional deaths, this right-sizing aligns criminal law with systemic accountability, while preserving conditions for safe care.

Application of corporate manslaughter in circumstances of intentional wrongdoing

In circumstances involving healthcare professionals who have demonstrated high levels of dishonesty and intentionally caused harm such as in the case of Letby, the clarified test would pull the jury to board minutes, escalation logs, staffing rotas, National Patient Safety Alert compliance, PSIRF/HSSIB outputs and candour records, evidence capable of proving that

153 *R* v *Adomako, R* v *Sullman, R* v *Holloway, R* v *Prentice* n 5 above.
154 *R* v *Misra* [2005] 1 Cr App R 21.
155 *R* v *Sudhanshu Garg* n 5 above.
156 n 5 above.
157 *ibid*.

senior-management arrangements were a substantial element of any gross breach, rather than merely cataloguing ward-level error.

CONCLUSION

The first part of this article distinguished individual intentional wrongdoing: rare, intentional homicide (Shipman, Allitt, Letby) and the offence of GNM for unintentional patient fatalities and explained why focusing exclusively on an individual, whether for error or malice cannot by itself improve patient safety. Whilst criminal courts can resolve questions of individual culpability they cannot address the organisational and system faults and holes through which harm travels. It is here that the prosecution of NHS organisations for corporate manslaughter becomes necessary. Only organisational liability can meaningfully address the systemic drivers, failures of governance, supervision, escalation, information systems and safety culture that permit harm to occur. The second part examined the Corporate Manslaughter and Corporate Homicide Act 2007, its enforcement record and the doctrinal pinch points that have stymied prosecutions of NHS bodies, above all the senior-management attribution requirement, open-textured grossness guidance, demanding causation in diffuse systems and a sanctions toolkit that can misfit essential public providers. The third part subsequently set out a targeted reform programme designed to make organisational fault both provable and safety productive.

The article's original contribution is a coherent, sector-specific set of suggested reforms that: (a) clarifies 'senior management' to capture safety-critical governance (board/committee, divisional and functional leads); (b) adds healthcare-specific signposts in section 8 so that juries can evaluate organisational grossness using the evidence that actually governs risk (staffing, escalation, PSIRF/HSSIB responses, safety-alert compliance, candour and board oversight); (c) recalibrates sanctions through a remedial-first model (ring-fenced spend, independent monitoring, time-bound milestones), with fines as a reasoned backstop; (d) hard-wires criminal-regulatory integration via a CPS–HSE–CQC–NHS England protocol and an Integrated Regulatory Improvement Plan; and (e) ring-fences GNM through a charging presumption that reserves it for truly exceptional personal culpability, directing system-caused deaths to organisational routes. Collectively, these measures align proof with how harm is produced and governed in modern healthcare and ensure that any conviction yields system change, not merely an accounting entry. The reforms proposed here allow the law to see and to remedy organisational fault without undermining the conditions for safe care. They retain a criminal backstop for egregious cases while placing day-to-day emphasis where it belongs: on governance, learning and durable improvement.