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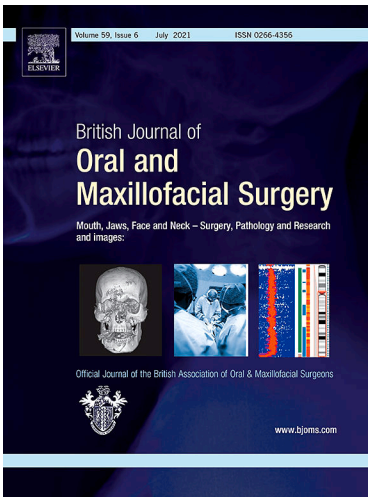

Review

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Balancing the Scales of Safety: The Criminal Laws Impact on Patient Safety and Error Reduction

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Abstract

The chance of death from medical error within the hospital setting is 33,000 times greater than dying in an aircraft crash. Despite patient safety being central to healthcare delivery across the world, medical errors and patient harm remain prevalent. This review evaluates the role of criminal law in regulating healthcare across England and Wales using prior legal case studies and focusing on the offence of Gross Negligence Manslaughter (GNM). It further examines the extent to which the law promotes patient safety to fatal errors in healthcare. Medical negligence resulting in a patient's death invokes the more punitive criminal law. In the context of the legal framework in England and Wales, individuals, including medical professionals, who are found to have caused a fatality due to 'gross negligence' may potentially be subject to manslaughter charges. Healthcare delivery is complex as it involves high-risk environments and invariably working as part of a team. When things go wrong, it is rarely the result of an individual's error but rather a systemic failure. Human factors that may contribute to GNM include organisational influences such as trust targets and pressures to deliver results, unsafe supervision or inadequate staffing and preconditions for unsafe acts whereby clinicians fatigue whilst performing multiple roles simultaneously. A more just culture is warranted in response to the criminalisation of cases of healthcare malpractice, in particular those involving GNM where healthcare professionals would be able to learn without fear of retribution.

Keywords: Criminal Law, Gross Negligence Manslaughter, Human Factors, Medical Negligence.

Abbreviations: Crown Prosecution Service (CPS), Gross Negligence Manslaughter (GNM), Medical Practitioners Tribunal Service (MPTS).

Introduction

> *"In the airline industry, the risk of death is one in 10 million. If you go into a hospital, the risk of death from a medical error is one in 300."*[1]

The above comment was made by the Chief Medical Officer at the time, Sir Liam Donaldson, back in 2006 and warned that the odds of dying as a result of clinical error in a hospital were 33,000 times higher than those of dying in an air crash. No doubt that in the time since, whilst the odds in aviation are now even rarer (an average of one fatality for every 287 million passengers carried by UK operators)[1]the risk of death or serious harm from medical error has been reported as 12%.[2] Patient safety and preventable harm is the central goal for healthcare delivery around the world. Nonetheless, the persistence of preventable adverse events, errors, and healthcare-related risks continue to pose significant challenges to patient safety. In England and Wales, a legal framework exists that includes laws and regulations which proscribe patient harm to ensure the well-being of patients in healthcare settings. Civil law, via the tort of negligence, allows patients to seek

compensation if it can be proven that medical treatment received failed to meet a reasonable standard (a standard accepted by a body of medical practitioners and that can withstand logical scrutiny) and thus breached the duty of care to the patient, causing foreseeable injury or harm.[3] If a patient succeeds in legal action for negligence, they may be awarded financial compensation for the loss, injury or harm they have suffered. Unlike civil law, medical negligence resulting in a patient's death can be subject to punishment by the criminal law, via the offence of gross negligence manslaughter (GNM). In this review, we examine the role of criminal law in regulating healthcare in England and Wales with a particular focus on the offence of GNM and the extent to which criminal law promotes patient safety and minimises fatal errors in healthcare.

The Criminal Law: Gross Negligence Manslaughter

The criminal prosecution of healthcare professionals for unintentionally causing patient death has garnered significant global media coverage in recent decades. The criminal liability of a doctor whose negligence resulted in the death of their patient was played out on a global scale with the death of pop star Michael Jackson in 2009. Jackson, undergoing gruelling rehearsals for a new worldwide tour, had hired Dr Conrad Murray, a cardiologist to serve as his personal physician for the tour for a fee of $150,000 a month. Nearly every night, for two months before Mr. Jackson's death, Murray administered a surgical anaesthetic (propofol) to Jackson in his bedroom. On the fatal night, Murray administered propofol to Jackson and claimed he went to the restroom for a few minutes and when he returned to check on Jackson he was not breathing. Statements from expert witnesses pointed out that Murray's actions were an 'extreme departure from the standard of care' and further medical evidence argued that Murray's care of Jackson contained 17 egregious violations, defined as acts that posed a foreseeable danger to the patient's life.[2] It was stated that this constituted gross negligence and upon conviction of involuntary manslaughter, Murray was sentenced to (the maximum) penalty of four years imprisonment.[4]

Similarly, in the context of the legal framework in England and Wales, individuals, including medical professionals, who are found to have caused a fatality due to gross negligence may potentially be subject to manslaughter charges.[3] The right to life is protected by Article 2 of the European Convention of Human Rights, and in cases where life is taken either deliberately or negligently, the law must provide adequate investigation. There is a great significance attributed to harm and death and often it is the consequence of careless conduct, not carelessness alone that transforms an error into a crime.[5]

In fatal cases caused by inadvertent error, if a jury deems an individual's conduct to have been grossly negligent, this may result in a conviction for GNM. In the seminal case of R v Adamako,[5] Lord Mackay held that negligence is gross when it is so bad that it should be criminal:

> *"The essence of the matter, which is supremely a jury question, is whether having regard to the risk involved, the conduct of the defendant was so bad in all the circumstances as to amount in their judgment to a criminal act or omission."*[6]

Lord Mackay further set out criteria which purported to provide the 'true legal basis of involuntary manslaughter by breach of duty', (I) namely that there is a duty of care, (II) the duty was breached

and (III) that breach caused the death of the victim, (IV) lastly that a jury considers that breach of duty should be characterised as gross negligence and therefore as a crime.[7] Many academics have criticised the 'circular' logic upon which the fourth element of GNM relies,[7-9]namely that conduct is classified as 'criminal' not by reference to an explicit, objective standard of decision-making, but rather on whether a jury assesses or believes that a crime has been committed.[5] The circularity of the definition of the GNM offence was unsuccessfully challenged in R v Misra,[10] when two junior doctors, Misra and Srivastava, were convicted of GNM when they had failed to notice symptoms of infection in a patient who had undergone routine knee surgery. The direction had emphasised the importance of there being a serious risk of death, in the light of which the failure to respond appropriately might be characterized as truly exceptionally bad.[10]

This foreseeability element was confirmed by the Court of Appeal in R v Rose; when the appeal of an optometrist's conviction for GNM was granted.[5] Honey Rose was initially convicted after failing to sufficiently examine the back of a young patient's eye, which would have shown swelling of the optic nerve and alerted Rose to the possibility of papilledema.[11,12] The young boy later died. Leveson P. stated that there must have been a serious and obvious risk of death.[11,12] If there is such a risk, but the defendant was unaware of it at the time of the relevant (mis)conduct, regardless of why that might be, the defendant has no case to answer.[11,12] There are, therefore, now five elements which the prosecution must prove for a person to be guilty of an offence of manslaughter by gross negligence:

(a) the defendant owed an existing duty of care to the victim;

(b) the defendant negligently breached that duty of care;

(c) it was reasonably foreseeable that the breach of that duty gave rise to a serious and obvious risk of death;

(d) the breach of that duty caused the death of the victim;

(e) the circumstances of the breach were truly exceptionally bad and so reprehensible as to justify the conclusion that it amounted to gross negligence and required criminal sanction.[11,12]

Insertion of this additional element of foreseeability has been welcomed as clarifying the law on GNM, whilst others claim it has served to only further muddy the waters.

In addition to persisting uncertainty as to the type and range of negligent conduct that would be deemed 'gross negligence', sentences upon conviction for healthcare professionals have also increased in severity in recent decades.[7,9] Custodial sentences upon conviction are now more likely to ensue following the publication of updated sentencing guidelines for those convicted of GNM under English law in 2018. Thus, unlike in the past where doctors convicted of GNM would often receive a suspended custodial sentence, now upon conviction they will face a minimum two to four-year custodial sentence, with provision for this to be increased depending on the level of culpability involved.[13]

The rarity of such prosecutions may bring little consolation. The most recent research from Griffiths and Quick which examined 192 Crown Prosecution Service (CPS) cases for the period January 2007 to March 2018 identified twelve cases where healthcare professionals were charged with GNM (ten of whom were doctors) – just 6% of the cases investigated.[14,15]

Systemic Errors and scapegoating of individual doctors

> Society demands much of a doctor, and yet there is little or no consideration that we are flying without a safety harness, with fallible instrumentation, under variable weather conditions, with minimal ongoing retraining, frequent near misses, and most certainly without a parachute.[16]

As noted by the Williams Review, healthcare professionals 'go to work to alleviate suffering not to add to it. They work in complex, high-risk environments, invariably as part of a team, and when things go wrong it is rarely the result of one individual's error.'[17]Many incidents of fatal medical errors show a failure of the system rather than an individual, so does punishing one individual with the *'jackboots of the criminal law*'[17]make those systems any safer? Consider the case of specialist registrar Dr Mulheim who was convicted of gross negligence manslaughter after he mistakenly instructed a Dr Morton, a Senior House Officer to administer vincristine into the patient's spine, instead of intravenously. The mistake resulted in the death of an 18-year-old patient, Wayne Jowett who had been in remission from leukaemia. This was the 36th incident of a fatal injection of vincristine worldwide[19], and the Toft Inquiry found that, while the doctors involved had some culpability, the patient's death was a result of a series of system failures from the management of the hospital to the specification of the regime of chemotherapy.

Systemic errors also played a role in the widely publicised case of Dr Hadiza Bawa-Garba, a paediatric trainee doctor, who was convicted of gross negligence manslaughter after the death of six-year-old Jack Adcock from sepsis, and sentenced to 2-years' imprisonment (suspended).[20,21] Whilst the Court of Appeal unanimously rejected her appeal against conviction,[20-23] the Medical Practitioners Tribunal Service (MPTS) when examining Dr Bawa Garba's case in 2017,[20-23] acknowledged that the fatal error took place amongst wider systemic failings and shortcomings attributed to her were not deliberate or reckless. During the trial of Dr Bawa-Garba, it was also revealed that the Trust's Serious Incident Report following the incident identified ninety-three failures, only six of which were attributable to the doctor herself. These failures included poor training, particularly concerning overseas qualified doctors; staff shortages; long working hours leading to exhaustion and poor judgement; and a lack of adherence to appropriate clinical governance standards.[20-23] Herein lies the problem with the offence of GNM, criminal law typically seeks an individual to blame, but by contrast, healthcare professionals work in complex and high-risk environments where errors rarely occur as a result of individual failure. The legal system has consistently downplayed the significance of systemic failures, often deeming them to be 'only of peripheral evidence' at trial (statement made during the trial of Bawa Garba).[20-23] The criminal law offence of GNM which makes an individual to blame for a fatal error, does little to address the systemic errors and failings which contributed to the incident. Systemic failures should not be attributed to individuals with the test of law applied disproportionately. A review by the Department of Health on GNM in 2019 (Williams Review) called for the embedding of a more just culture in response to the criminalisation of cases of healthcare malpractice, in particular, those involving GNM where healthcare professionals would be able to learn *'without fear of retribution'*.[17]

The role of Human Factors

No one is immune to faults and a vigilant approach to pre-empting errors, and mitigating risks with appropriate working conditions for doctors together with cognitive support such as algorithms and communication aids can reduce errors in healthcare.[24] In the operating theatre for example, there is a propensity to more harm in comparison to other hospital settings. Systemic pressures include the dynamic operative environment often attracts high patient turnover, staff shortages, time constraints and site-specific procedures.[25] On the other hand, at the individual level, surgeons are often faced with the prospect of long hours, overbooked operating lists, cases running late and on-call commitments.[24-26] This can pave the way for medical errors and potentially GNM to occur. A root cause analysis is required to identify the reasons an event had occurred as often a doctor may be easy to assign blame to, but they are not the root cause of the harm that came about.[27]

The criminal justice system often fails to consider systemic issues in an informed way, particularly the human factors involved in complex medical decision-making. Until this is addressed an ethical dilemma will remain between individual blame and contributory systemic factors. Often it is easier to confer convictions against individual doctors for GNM than it is to effect legal accountability upon organisations.[28,29] Within medicine and surgery, blame and punishment do not help to improve patient safety. Rather, focus should be placed on the systems and processes that guide and support healthcare workers. A just culture will enable us to consider the wider systemic issues that may have culminated in medical error or GNM.[28]

Conclusion

Whilst the right to life protected by Article 2 rightly means that the law must both protect and investigate incidents in which life is lost (either deliberately, or negligently), arguably the public's best interests are served by fostering an open and learning safety culture within healthcare, rather than one that is punitive in nature. Patient safety necessitates the comprehensive recognition and identification of all factors (including systemic ones) leading to avoidable deaths, placing a higher priority on understanding these factors, rather than assigning blame to individual doctors.

Conflict of Interest

Nil

Ethics statement/confirmation of patient permission

Nil required

References

1. Civil Aviation Authority. Home [Internet]. [Accessed 2023 Oct 18]. Available from: https://www.caa.co.uk/consumers/guide-to-aviation/aviation-safety/

2. Panagioti M, Khan K, Keers RN, Abuzour A, Phipps D, Kontopantelis E, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: Systematic review and meta-analysis. BMJ. 2019;l4185. doi:10.1136/bmj.l4185

3. Bolam v Friern Hospital Management Committee [1957] 1 WLR 582; Bolitho v City & Hackney Health Authority [1998] AC 232.
4. The People of the State of California v. Conrad Robert Murray 2011; Lyons B. Medical manslaughter. Ir Med J. 2013 Jan;106(1):26-7.
5. Margaret Brazier and Amel Alghrani "Fatal Medical Malpractice and Criminal Liability" (2009) 25 Professional Negligence 51.
6. M. Brazier and N. Allen "Criminalizing Medical Malpractice" in C. Erin and S. Ost (Eds) The Criminal Justice System and Health Care (Oxford University Press, 2007).

7. LawTeacher. R v Adomako - 1995 [Internet]. November 2013. [Accessed 18 October 2023]; Available from: https://www.lawteacher.net/cases/r-v-adomako.php?vref=1.

8. J Herring, Criminal Law Cases and Materials (2010, OUP), 291-8; Law Commission, Involuntary Manslaughter (1996), 3.9.

9. M Brazier, N Allen, 'Criminalising Medical Malpractice' in C Erin, S Ost, The Criminal Justice System and Healthcare (2007, Oxford University Press), p21.

10. LawTeacher. R v Misra and Srivastava [Internet]. November 2013. [Accessed 18 October 2023]; Availablefrom: https://www.lawteacher.net/cases/r-v-misra-srivastava.php?vref=1.13.R v Sellu [2016] EWCA Crim 1716, p151.

11. R v Rose [2018] QB 328.

12. A Mullock, 'GNM and the Puzzling Implications of Negligent Ignorance: Rose v R [2017] EWCA Crim 1168' (2018) 26(2) Med LR 346, p352.

13. The Sentencing Council for England and Wales, Manslaughter: Definitive Guideline, effective 1 November 2018,

    www.sentencingcouncil.org.uk/wp-content/uploads/Manslaughter-definitive-guideline-Web.pdf(accessed 31 March 2020).

14. D. Griffiths and O. Quick 'Managing medical manslaughter cases: improving efficiency and transparency?' Law Research Paper Series 2019 https://www.bristol.ac.uk/media-library/sites/law/documents/BLRP%20No.%207%202019%20Quick%20et%20al%20-%20merged.pdf

15. Goodbody A. The Hamilton Review – some views from outside the room where it happened. AL Goodbody ; 2021.

16. S. Goldstein, Medical Director HCF "Penalties bear a cost" Sydney, Australia 2000 Rapid Response Jon Holbrook to "The criminalisation of fatal medical mistakes"(2003) 327 BMJ 1118-1119.

17. Department of Health and Social Care. Williams review into gross negligence manslaughter in healthcare [Internet]. GOV.UK; 2018 [cited 2023 Oct 18]. Available from https://www.gov.uk/government/publications/williams-review-into-gross-negligence-manslaughter-in-healthcare

18. Campbell C. Life's dominion: An argument about abortion, euthanasia, and individual freedom, Ronald Dworkin. New York: Alfred A. Knopf, 1993. 273 pp. Cambridge Quarterly of Healthcare Ethics. 1994;3(2):303–6. doi:10.1017/s0963180100005065

19. B. Toft, Department of Health External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, 4 January 2001.

20. Case P, Sharma G. Promoting public confidence in the medical profession: Learning from the case of dr. Bawa-Garba. Medical Law International. 2020;20(1):58–72. doi:10.1177/0968533220933788

21. Bawa-Garba v The General Medical Council [2016] EWCA Crim 1841.

22. Medical Practitioners Tribunal Service [Internet]. [Accessed: 2023 Oct 18]. Available from: https://www.mpts-uk.org/

23. Bamrah J, Mehta R. Back to blame. Sushruta Journal of Health Policy & Opinions. 2020;11(1):9–12. doi:10.38192/11.1.3

24. Bindra A, Sameera V, Rath G. Human errors and their prevention in Healthcare. Journal of Anaesthesiology Clinical Pharmacology. 2021;37(3):328. doi:10.4103/joacp.joacp_364_19

25. Brennan PA, Mitchell DA, Holmes S, Plint S, Parry D. Good people who try their best can have problems: Recognition of human factors and how to minimise error. British Journal of Oral and Maxillofacial Surgery. 2016;54(1):3–7. doi:10.1016/j.bjoms.2015.09.023

26. Brennan PA, Oeppen RS. The role of human factors in improving patient safety. Trends in Urology & Men's Health. 2022;13(3):30–3. doi:10.1002/tre.858

27. Brook OR, Kruskal JB, Eisenberg RL, Larson DB. Root cause analysis: Learning from adverse safety events. RadioGraphics. 2015;35(6):1655–67. doi:10.1148/rg.2015150067

28. Wolvaardt E. Blame does not keep patients safe. Community Eye HelathJournal . 2019;32(106).

29. Samanta A, Samanta J. Gross negligence manslaughter and doctors: Ethical concerns following the case of Dr Bawa-Garba. Journal of Medical Ethics. 2018;45(1):10–4. doi:10.1136/medethics-2018-104938