Who Should We Blame for Healthcare Failings? Lessons from the French Tainted Blood Scandal

ABSTRACT

Many well-known cases of 'medical manslaughter' have shown that systemic issues play a significant role in contributing to fatal errors in healthcare institutions. The most prominent NHS scandal, Mid Staffordshire, demonstrated that wrongful prioritization of resources and shortage of staff had contributed to the death of between 400 to 1200 patients due to appalling care by nursing staff and doctors between 2005 and 2009. Following the scandal, the Trust was prosecuted and convicted of a criminal offence under the Health and Safety at Work Act 1974 in 2014 and 2015. In contrast, in a scandal of comparable scale across the Channel, 'the HIV-contaminated blood scandal', individual decision-makers were subject to criminal convictions. Learning from features of the French criminal process, and the aftermath of the 1980s French tainted blood scandal, this article argues that the criminal process can only be a useful response to healthcare systemic failings if higher-level decision-makers are also included in the scope of criminal liability when they have recklessly endangered patients. When no individual reckless fault is found on the part of decision-makers, corporate criminal liability is a suitable alternative to individual criminal liability, if it is focused on ensuring safety and offering justice to patients who have been harmed as a result of healthcare systemic failings.

KEYWORDS: Criminal Liability, Healthcare Scandals, Ill-treatment, Manslaughter, Systemic Failings, Wilful Neglect

I. INTRODUCTION

Until recently there was very limited literature concerning criminal liability for systemic failings in healthcare[1] despite evidence of serious systemic failings in NHS hospitals in the

[1]For a recent examination of medical errors and the regulation of patient safety, see O Quick, *Regulating Patient Safety: The End of Professional Dominance* (Cambridge University Press 2017); See also A Merry, W Brookbanks, *Errors, Medicine and the Law* (Cambridge University Press, 2nd edn, 2017); A Alghrani, M Brazier, AM Farrell, D Griffiths, N Allen, 'Healthcare scandals in the NHS: crime and punishment', (2010) 37(4) *Journal of Medical Ethics,* 230-232.

last decade.[2] The most prominent NHS scandal, Mid Staffordshire ('Mid-Staffs'), demonstrated that wrongful prioritization of resources and shortage of staff in the Mid-Staffordshire NHS Foundation Trust may have contributed to the death of between 400 to 1200 patients due to appalling care by nursing staff and doctors between 2005 and 2009, although these numbers have never been confirmed by the inquiries conducted into Mid Staffs.[3] There were instances of patients being left in soiled beds or unfed for hours, and generally staff members being unsympathetic, uncaring, and sometimes bullying towards patients.[4] Whilst staff had raised concerns about the poor care that was being delivered to patients, management had failed to act on those concerns over a period of three years.[5] A three-year police investigation which had begun in 2013 found that there was insufficient evidence to charge a single individual manager, doctor or nurse for any criminal offence for what had happened at Stafford Hospital.[6] But in 2014 and 2015, the Trust was prosecuted and convicted of a criminal offence under the Health and Safety at Work Act 1974 (HSWA).[7]

In some other well-known cases involving negligence in healthcare, however, individual healthcare professionals *were* subject to criminal prosecutions and sometimes convictions, whereas subsequent investigations in some instances had found that systemic issues had contributed to the fatal error.[8] The most recent example is that of Dr Bawa-Garba and Nurse Amaro, who were both convicted of gross negligence manslaughter in November 2015 for

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[2] See for instance D Campbell, 'Mid Staffs hospital scandal : the essential guide', *The Guardian*, 6 February 2013; N Bunyan, 'Morecambe Bay report exposes 'lethal mix' of failures that led to baby deaths', *The Guardian*, 3 March 2015 ; J Wise, 'Systemic failings in NHS contributed to death of Baby P', (2009) 338 *British Medical Journa*l.

[3] R. Francis QC, *Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005-March 2009*, Volume I, March 2010, 352.

[4]R Francis QC, above n3, 49, 52, 54.

[5] P Gooderham, B Toft, 'Involuntary automaticity and medical manslaughter', in D Griffiths, A Sanders (eds), *Medicine, Crime and Society* (Cambridge University Press 2013) 183.

[6]''No one to be prosecuted' over Mid-Staffs scandal'', *The Telegraph*, 1 March 2016.

[7]*R v Mid Staffordshire NHS Foundation Trust*, Sentencing Remarks of the Hon. Mr Justice Haddon-Cave, 28 April 2014.

[8] Some examples of 'medical manslaughter' convictions include the convictions of Dr Adomako, Drs Misra and Srivastava, Dr Garg, and more recently Dr Sellu and Dr Bawa-Garba. Dr Sellu was convicted and jailed for gross negligence manslaughter but his conviction was then quashed by appeal judges in 2016: C Dyer, 'Senior surgeon's conviction for manslaughter is quashed', (2016) 355 *British Medical Journal*; 'David Sellu trial : Doctor's conviction over patient's death quashed', *BBC News,* 15 November 2016, although it must be noted here that Dr Sellu worked in a private hospital ; see also *R v Adomako* [1994] 3 WLR 288, *R v Misra* ; *R v Srivastava* [2004] EWCA Crim 2375 ; *R v Garg (Sudhanshu)* [2012] EWCA Crim 2520; *R v Bawa-Garba* [2016] EWCA Crim 1841; P Gooderham, B Toft, 'Involuntary automaticity and medical manslaughter', in D Griffiths, A Sanders (eds), *Medicine, Crime and Society* (Cambridge University Press 2013) 183; M Brazier, A Alghrani. 'Fatal Medical Malpractice and Criminal Liability'(2009) 25(2) *Journal of Professional Negligence,* 51-67.

causing the death of a 6 year old boy with Down syndrome and were struck off the registers.[9] Following these convictions, the medical community expressed concerns that the systemic failings which led Dr Bawa-Garba and Nurse Amaro commit errors were ignored and overlooked.[10] These episodes demonstrate the damaging effect that the criminalization of healthcare negligence could have on patient safety if not used appropriately.[11] Individual healthcare professionals, being at higher risk of committing fatal or non-fatal errors, are becoming increasingly more vulnerable to criminal charges, and fearful of liability.[12] Criminalization of individual healthcare professionals in systemic failure cases may lead to undesirable outcomes, such as individual practitioners acting defensively for fear of legal repercussions, thereby further threatening patient safety.[13] However, it remains that victims' demands for justice and accountability must be addressed. The Gosport War Memorial Hospital disaster, which, between 1989 and 2000, saw up to 650 elderly patients die as a result of being given unnecessary lethal doses of opiate drugs, is another example of grave healthcare systemic failings where the criminal process was used but has so far failed to deliver justice to families and transparency to the public.[14] Whilst individual doctors and nurses seem to have become more vulnerable to criminal charges, key decision-makers, such as hospital managers, have so far not been subject to criminal prosecutions in cases involving healthcare systemic failings.

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[9]'Doctor and nurse given suspended jail terms over boy's negligence death', *The Guardian*, 14 December 2015; Following the Bawa-Garba case, Health and Social Care Secretary Jeremy Hunt ordered a review into manslaughter by gross negligence rulings in the NHS; see A Metthews-King, 'Bawa-Garba latest: Jeremy Hunt orders review into manslaughter by gross negligence rulings in the NHS', *The Independent,* 6 February 2018.

[10]H Agelholm, 'Dr Bawa-Garba: Doctors threaten to boycott their appraisals over treatment of trainee paediatrician'*, The Independent*, 1 February 2018.

[11]O Quick, above n1 at 108; A Samanta, J Samanta, 'Gross negligence manslaughter and doctors: ethical concerns following the case of Dr Bawa-Garba' (2018) 45(1) *Journal of Medical Ethics*, 3-7.

[12] It should be noted that an independent review is currently being conducted by Dame Clare Marx who was appointed by the General Medical Council (GMC) to help elucidate how gross negligence manslaughter is applied to medical practice, see https://www.gmc-uk.org/news/media-centre/media-centre-archive/dame-clare-marx-to-lead-medical-manslaughter-review.

[13]See for instance M Kazarian, D Griffiths, M Brazier, 'Criminal Responsibility for Medical Malpractice in France' (2011) 27(4) *Journal of Professional Negligence,* 188-199; M Brazier, N Allen, 'Criminalizing Medical Malpractice', in C Erin, S Ost (eds), *The Criminal Justice System and Health Care* (Oxford University Press 2007) 27; O Quick, O Quick, 'Medicine, mistakes and manslaughter: a criminal combination', *Cambridge Law Journal* (2010) Vol 69 Issue 1, 193, 202; D Archard, 'Criminalising Medical Negligence' in A Alghrani, S Ost and R Bennett (eds.) *The Criminal Law and Bioethical Conflict: Walking The Tightrop*e (Cambridge University Press 2012) 336; A Merry, W Brookbanks, above n1 at 2.

[14] Three separate police investigations were conducted, but no prosecutions followed; an inquiry was conducted into the scandal by the Gosport Independent Panel which published its report in June 2018, See *Gosport War Memorial Hospital: The report of the Gosport Independent Panel*, 20 June 2018, 37; *Gosport War Memorial Hospital: The report of the Gosport Independent Panel*, 20 June 2018, 322.

The ongoing public inquiry conducted into the UK tainted blood scandal which involved thousands of victims in the 1980s, aims to investigate the failings committed by UK authorities during the scandal in this country.[15] The UK tainted blood scandal has so far not led to any criminal prosecutions. Over three decades after the event, the scandal is still shrouded in secrecy, with victims remaining unsatisfied with such answers as they have received from the NHS and the government. Data on the UK blood scandal will now be reviewed by the new inquiry panel and a useful exploration of the failings in the UK scandal can only really be done effectively once the inquiry has made substantial progress and when its findings become available.

Across the Channel in France, the criminal law is known to have been used extensively in healthcare negligence cases, particularly when those have been heavily mediatized.[16] Such was the case in the French tainted blood scandal, '*Le scandale du sang contaminé*', which led to the contamination of over a thousand patients with HIV as a result of a number of failings by French authorities, thereby bearing remarkable similarities to the events and failures in the English tainted blood scandal. Following the French scandal, over 30 people including blood centre officials, doctors and ministers were prosecuted for criminal offences such as negligence and deception. Two senior officials were jailed for knowingly providing contaminated blood products to patients. In more recent healthcare scandals in France, the criminal law was also invoked as a way to ensure accountability and reparation to victims.[17]

Learning from the French experience, this paper explores where blame should lie and whether the criminal law can be of any use in cases involving healthcare systemic failings. In England, the academic debate has pointed out that the criminal law is ill-equipped to deal with most instances of healthcare negligence. Much criticism has been made of the gross negligence manslaughter (GNM) offence for being circular, unclear, and resulting in inconsistent convictions of healthcare professionals, and systemic issues in some individual

[15]P Walker, 'Full statutory inquiry to be held into tainted blood scandal', *The Guardian*, 3 November 2017; The inquiry's website can be found at https://www.infectedbloodinquiry.org.uk/about.

[16] M Kazarian, D Griffiths, M Brazier, above n13; AM Farrell and M Kazarian, 'The Role of the Criminal Law in Healthcare in France: Examining the HIV Blood Contamination Scandal' in D Griffiths and A Sanders (eds) *Medicine Crime and Society* (Cambridge University Press 2013) 265-279. Other healthcare scandals have seen the use of the criminal law in France more recently, see B Casassus, 'French Appeals Court Clears Scientists in Growth Hormone Scandal' *Science*, 5 May 2011; 'Breast Implants: PIP's Jean-Claude Mas Gets Jail Sentence', *BBC News*, 10 December 2013.

[17] *ibid.*

medical manslaughter convictions continue to be overlooked.[18] One question that has not yet been fully explored in the academic and policy debate is whether criminalizing key decision-makers could help in ensuring safety and bringing justice to victims in healthcare systemic failings cases.

This paper argues that prosecuting individual medical professionals who have not shown a reckless or deliberate level of culpability is unlikely to achieve safety. However, criminal liability should be imposed when decision-makers have made reckless or deliberate decisions which they knew could harm patients.[19] Currently, criminal offences used in the context of healthcare negligence in England and Wales do not allow key decision-makers to be included in the scope of liablity. The paper proposes that to achieve deterrence and safety, higher-level decision-makers should be included in the scope of criminal liability. Victims' demands for justice and transparency following healthcare scandals also require us to explore how victims could be given a stronger role in the criminal process, and some of the features of the French inquisitorial process offer a means of facilitating this that is worthy of consideration in other jurisdictions, thereby adding to the comparative law literature on the role of the criminal law in healthcare.[20] The paper further suggests that the criminalization of healthcare institutions may only be a suitable solution to addressing healthcare systemic failings if used in a way that will effectively ensure safety.[21] Finally the

[18] See above n8; This is not limited to doctors: Mrs Honey Rose, an optometrist, was also convicted of gross negligence manslaughter in July 2016, but appeal judges quashed the decision to convict her in July 2017, as the Court of Appeal decided that the defendant could not have reasonably foreseen an obvious and serious risk of death : *R v Honey Maria Rose* [2017] EWCA Crim 1168 ; See also 'Vincent Barker death : Optometrist Honey Rose conviction quashed', *BBC News*, 31 July 2017; O Quick, above n13; H Quirk, 'Sentencing white coat crime: the need for guidance in medical manslaughter cases', (2013) 11 *Criminal Law Review*, 871-888.

[19] All cases of healthcare failings analysed in this paper should be distinguished from those involving intentional wrongdoing, such as the recent criminal conviction of Dr Paterson for 17 counts of wounding with intent, for performing unnecessary and inappropriate operations on patients, which should always warrant the use of the criminal law. See A Topping, 'Breast surgeon Ian Paterson jailed for 15 years for carrying out needless operations', *The Guardian*, 31 May 2017.

[20] See for instance P Mistretta (ed.), *French law: from a Comparative Law Perspective: for an Overhaul of Medical Criminal Law?* (Institut Universitaire Varenne, Colloques et Essais, 2017).

[21] The offence of corporate manslaughter can be used in this context (see Corporate Manslaughter and Corporate Homicide Act 2007) but given the difficulties in proving corporate manslaughter on the part of a healthcare institution, as highlighted by C Wells in 'Medical Manslaughter: organisational liability', in D Griffiths, A Sanders (eds) above n8, 192-209, I suggest in this paper that where there is evidence that an individual decision-maker has made a deliberate decision which he/she knew would put patients at risk of injury or death, he/she should be punished of a criminal offence. I further argue that offences which punish breaches of the Health and Safety at Work Act 1974 are more helpful than corporate manslaughter when dealing with healthcare systemic failings if no individual fault has been found.

article argues that the criminal law *alone* cannot achieve healthcare safety, but other ways should be sought to prevent and address flawed systems in healthcare institutions.

This paper's critical analysis of the criminalization of individuals in systemic failure cases is especially timely in the England and Wales context because of the expansion of the criminal law since the enactment of the Criminal Justice and Courts Act 2015 (CJCA). This legislation has extended the offences of wilful neglect and ill-treatment, previously only applicable to instances of neglect of patients detained under the Mental Health Act 1983 or lacking mental capacity, to cover wilful neglect and ill-treatment of all patients in receipt of care.[22] Before 2015 negligence by healthcare professionals could only be subject to criminal prosecutions if it had caused the death of a patient under the common law offence of gross negligence manslaughter (GNM). However, charges of wilful neglect and ill-treatment can now be used to prosecute a care professional even when his/her conduct results in injury short of death. This article will consider whether this reform is a positive or negative development.

So far, English healthcare scandals or cases involving systemic failings have never been followed by the criminal prosecutions of key high-level individual decision-makers, and justice for the victims was not achieved in many of these cases in the UK. The Midstaffs scandal for instance, led to the criminal conviction of an NHS trust for causing the death of only 5 patients, out of an estimated few hundred victims. Victims of the UK tainted blood scandal never had access to justice and have only received *ex gratia* payments so far.[23] Yet, the evidence available on the Midstaffs scandal and UK tainted blood scandal suggests that these scandals feature similar types of failings as were found in the French tainted blood scandal, such as disorganization and regulatory gaps, a lack of transparency and openness within the institution, the management's failure to act when reports had been made of poor practice, and focusing on the wrong priorities. Evidence shows that a number of reckless failures and deliberate decisions resulting in harm to patients were, in part, caused by the prioritization of cost calculation over the safety of patients.[24] I argue that the deliberate

[22] Sections 20 and 21 Criminal Justice and Courts Act 2015.
[23] Rt Hon Lord Archer of Sandwell, Rt Hon Lord Archer of Sandwell QC, *Independent Public Inquiry Report on NHS Supplied Contaminated Blood and Blood Products*, 23 February 2009, from 73.
[24] Healthcare Commission, *Investigation into Mid Staffordshire NHS Foundation Trust*, Summary Report, March 2009, 9; R Francis QC, above n3, 4, 45, 51, 63, 65.

failure to protect the safety of patients when key decision-makers were aware of unsafe practices within the institutions amounts to at least reckless conduct, and should be subject to criminal liability. Other failures are more appropriately equated with incompetence and a lack of anticipation rather than deliberate or reckless conduct and should, therefore, not warrant the use of the criminal law. Lessons from the French criminal proceedings arising out of the tainted blood scandal are used here to suggest how the criminal process could effectively be used in England and Wales to respond to healthcare systemic failings and to achieve justice for victims of these scandals.

II. UNDERSTANDING THE FRENCH CRIMINAL PROCESS

This paper uses a qualitative and comparative methodology to reveal how lessons may be learnt from the French experience.[25] Whilst any general conclusions drawn from the case studied will only be hypothetical, they may well be informative in guiding policy in both law and healthcare, in France and England and other countries.[26] Further, the data that this paper utilises on the HIV-contaminated blood scandal in France include prosecution archives obtained from French courts and prosecution services that have investigated the role of individual directors and doctors in the blood supply organization during the relevant period.[27] This data has not yet been used in research conducted in England and Wales on the role of the criminal process in healthcare practice, and so it is believed that it will provide an important insight which has not previously been offered in the relevant literature on this subject.

In order to understand how lessons might be learnt from criminal proceedings arising out of the French tainted blood scandal, it is first important to note that there are significant differences in both substantive criminal law and criminal procedure in French and English law. In France, a wider range of criminal offences is available to criminalize negligent

[25] A Przeworski, H Teune, *The Logic of Comparative Social Inquiry* (Wiley Interscience, 1970), 32.
[26] A Lijphart, 'Comparative Politics and the Comparative Method', (1971) 65(3) *American Political Science Review*, 686.
[27] L Greilsamer, *Le procès du sang contaminé*, (Le Monde 1992) 21; M Lucas, *Transfusion Sanguine et SIDA en 1985, Chronologie des faits et des décisions pour ce qui concerne les hémophiles*, Inspection Générale des Affaires Sociales, Septembre 1991; Commission d'instruction de la CJR Arrêt portant renvoi devant la CJR, 17 juillet 1998, D6137; TGI de Paris, Ordonnance de transmission du dossier et des pièces à conviction au procureur général et de non lieu partiel, D20917.

conduct, including healthcare failings. Some of these offences do not always require proof of a gross degree of mental culpability - ordinary negligence suffices to fulfil the *mens rea* element of the offences in some circumstances.[28] This is the case for *homicide involontaire* (involuntary homicide) and *blessures involonvaires* (involuntary wounding). In contrast, the offence of *mise en danger délibérée* (deliberate endangerment) does require a reckless state of mind, but like the S20 CJCA offences, does not require any harm to ensue from the conduct.[29] *Mise en danger* can also be used as an aggravated circumstance of another criminal offence such as *homicide involontaire* if it is proven that conduct was reckless. The failure to rescue is also penalized in France under the offence of *non-assistance à personne en danger* (failure to rescue).[30] All of these offences may also be used against corporations. As will be explained below, these offences were all used to prosecute blood centre directors, civil servants, ministers and doctors in the three sets of proceedings arising out of the HIV-contaminated blood scandal in France.

Notwithstanding the wider range of criminal offences available in this context in French law, differences in criminal procedure are a more significant factor in explaining the wider use of the criminal law in healthcare negligence cases. In France, victims of crimes can become parties to the civil action (‘*parties civiles’)* in criminal proceedings conducted against an alleged offender.[31] A victim may, through this route, bring to the attention of the police and prosecution services, the alleged commission of an offence, by filing a criminal complaint against a named or unnamed person. If there is sufficient evidence that a criminal offence may have been committed, a criminal investigation is then launched and undertaken by an investigating judge with substantial means of investigation.[32] The cost of the investigations is borne by the state, and if the claim is successful, the *parties civiles* obtain civil compensation at the end of the criminal proceedings. The proceedings are thus more victim-oriented and victim-dependent, in that, in part, they rely on the victim’s role in bringing to light the commission of wrongful behavior.

[28]221-6 Code pénal ; 222-19 Code pénal.
[29]223-1 Code pénal.
[30]223-6 Code pénal.
[31]85 Code de procédure pénale.
[32] 92 to 190 Code de procédure pénale.

In England by comparison, it is difficult for victims to bring criminal proceedings against an alleged offender and legal aid cuts make civil claims even more difficult.[33] In criminal proceedings conducted either by the Crown Prosecution Service (CPS) or the HSE, victims in England do not have as active a role as in France, and may feel marginalized, albeit that research has demonstrated that the CPS does take victims' voices into account more than they used to.[34] The launch of a criminal investigation relies heavily on the willingness of prosecution services or the HSE to prosecute an alleged crime. As a consequence, many cases may not come to the attention of these prosecuting authorities because victims of these alleged crimes do not tend to play any considerable role in the launching of criminal investigations.[35]

In the French tainted blood scandal, victims had a central role in the prosecution of the defendants, at least in the first two sets of proceedings involvinig blood centre directors and civil servants. Notably, in the Mid-Staffs scandal, the two prosecutions brought against the Trust for health and safety offences were in part conducted following pressure from campaign groups and the findings of the independent inquiries which had brought the failings to light.[36] I argue later that these two prosecutions were unsatisfactory in providing justice for all the victims. As will be explained, the Trust was charged with a HSWA offence for the death of five victims, yet it was found that the Trust may have been responsible for the deaths of at least a few hundred victims. Ensuring that victims' voices were heard might have contributed to offering justice and transparency to more victims of the scandal.[37]

III. BLAMING INDIVIDUALS

[33]A Sanders, I Jones, 'The victim in court', in S Walklate (ed), *Handbook of Victims and Victimology* (Willan Publishing 2007) 283.
[34]A Sanders, 'Victims' Voices, Victims; Interests and Criminal Justice in the Healthcare Setting', in D Griffiths and A Sanders (Eds.), *Medicine, Crime and Society* (Cambridge University Press 2013) 82, 84-85; A Sanders, 'Victim Participation in Criminal Justice', (2002) 49/1 *Criminal Justice Matters*, 30-31.
[35]*Ibid.*
[36]'Midstaffordshire NHS Trust to face criminal charges over deaths', *The Guardian*, 15 October 2015.
[37] A Sanders, 'Victims' voices, victims' interests and criminal justice in the healthcare setting', above n33, 84, 96; A Bottoms, 'The 'duty to understand': what consequences for victims participation?', in A Bottoms, JV Roberts (eds), *Hearing the Victim: Adversarial Justice, Crime Victims, and the State* (Routledge 2011), 38; Dame H Reeves, P Dunn, 'The status of crime victims and witnesses in the twenty-first century', in A Bottoms, JV Roberts, above, 50-51.

Criminal proceedings arising out of the HIV-contaminated blood scandal in France have demonstrated that, in this episode at least,[38] the French criminal justice system favoured individual criminal liability over corporate liability. The episode led to three sets of criminal proceedings involving those said to be responsible for the contamination of blood products: blood officials, treating doctors and ministers. Prosecutions were brought on the basis that there had been failures: to achieve self-sufficiency in factor concentrates; set up donor screening and HIV-testing early enough; and heat-treat blood products soon enough. Doctors and health officials were also said to have knowingly supplied contaminated blood products to patients and failed to inform patients of the risk of contamination in blood products provided to them. As already noted, victims of the contamination had an active role in the proceedings, and it was victims' complaints which gave rise to the majority of criminal investigations being launched.[39]

At the end of the first set of criminal proceedings in 1992, the Director of the national blood centre, Michel Garretta and the Director of the Department of Research and Development in the national blood centre, Jean-Pierre Allain, were convicted of *tromperie*[40] and jailed. It was found that they had deceived the patients in knowingly supplying contaminated blood products to them.[41] The Director General of Health, Jacques Roux, and the Director of the National Health Laboratory, Robert Netter, were convicted of *non-assistance à personne en danger* for failing to protect patients from the risk of contamination.[42] In 1999, Laurent Fabius, Edmond Hervé and Georgina Dufoix, respectively the Prime Minister, Health Secretary and Social Affairs Minister between 1984 and 1986, were tried before the *Cour de*

[38]Although there are other episodes which support this argument.
See, for instance, criminal prosecutions in the Human Growth Hormone scandal: A Chrisafis, 'French doctors on trial for CJD deaths after hormone 'misuse', *The Guardian*, 7 February 2008, or more recently, the PIP breast implant scandal in France: K Willsher, 'French breast implant firm PIP's founder jailed', *The Guardian*, 10 December 2013.

[39]M Kazarian, *The Role of the Criminal Law and the Criminal Process in Healthcare Malpractice in France and England*, University of Manchester (PhD Thesis 2013) 123.

[40]*Tromperie sur les qualités substantielles d'un produit* is a type of deception offence in French criminal law. It criminalises deception related to the substantial qualities of a product and unlike English fraud offences, it also contains aspects of product liability offences: See L213-1 Code de la Consommation.

[41] L Greilsamer, above n26 at 304.

[42] Ibid; Crim. 22 juin 1994 in J Pradel (Dir.), *Sang et droit pénal: A propos du sang contaminé*, Travaux de l'Institut de Sciences Criminelles, vol XIV (Editions Cujas 1994) 173.

Justice de la République (CJR)[43] for *homicide involontaire* and *blessures involontaires*. Georgina Dufoix and Laurent Fabius were acquitted. Edmond Hervé was found guilty but given an absolute discharge, as it was decided that what he had been through as a result of the trial was punishment enough.[44] In 1993, the third set of proceedings began involving some of the same persons who had been prosecuted in 1992, and 26 other medical civil servants and treating doctors. They were all investigated by Marie-Odile Bertella-Geffroy[45] and prosecuted for different offences including *empoisonnement* (poisoning), *violences volontaires* (grievous bodily harm), *non-assistance à personneen danger* and *homicide involontaire*. Finally, in 2003, the third set of proceedings was referred to the *Cour de Cassation*[46] which discharged all the accused owing to the lack of a causal link.[47]

The outcome of these proceedings demonstrated the difficulty of bringing individuals to account for negligent (and even sometimes reckless) failures, notwithstanding that French criminal law includes a wider range of offences of negligence than English criminal law. The inadequacy of some of the criminal offences used in the proceedings (such as poisoning), to penalise this type of negligent conduct, and the difficulty in establishing evidence of causation for 'result' offences, explain the outcome of the proceedings. The only offence used which actually led to custodial sentences was not a 'negligence' offence, but a fraud offence: *tromperie*. The elements of the offence were easier to prove than those of a 'negligence' offence, as it only requires proof that there had been deception regarding the substantial qualities of a product. This offence is more widely used in relation to deception in the food industry and the use of the offence was highly criticised in the literature for being

[43] The *Cour de Justice de la République* deals with criminal liability of members of the Government in France. It was created during the blood scandal in order to try the executive on criminal grounds. It replaced the *Haute Cour de Justice*. O Beaud, *Le sang contaminé* (Presses Universitaires de France 1999) 3.
[44]See AM Farrell, M Kazarian, above n16.
[45]Marie-Odile Bertella-Geffroy was the *juge d'instruction* (investigating judge) who conducted criminal investigations in the third set of criminal proceedings arising out of the HIV-contaminated blood scandal in France.
[46]The *Cour de Cassation* is the highest court in the civil and criminal courts hierarchy. It deals with appeals lodged against lower criminal or civil courts, and looks at points of law only. It can quash or confirm a decision. When the lower court's judgement is quashed, another court of the same level in the hierarchy (tribunal or appeal court) will have to take into account the *Cour de Cassation*'s decision and follow it to make a final judgement. See https://www.courdecassation.fr/institution_1/presentation_2845/, accessed 16 December 2018.
[47]Crim 2 juill 1998, Bull Crim n211, JCP 1998 II 10132.

unsuitable in healthcare cases.[48] The blood contamination trials were perceived as 'show trials' through which the courts set an example and inappropriately singled out several decision-makers. The aim of the trials was to restore public trust and confidence in the public healthcare system.[49] However, for different reasons, both victims and accused saw the outcome of these proceedings as being unfair. The victims argued that justice had not been served as only two out of over thirty people went to jail. The accused felt that they had been used as scapegoats when they had been only one causative agent in the decision-making process. The general view of commentators and the wider public was that the proceedings had been unsuccessful in restoring public confidence in state institutions and in achieving justice for the victims.[50] In sum, the criminal proceedings in the blood episode demonstrated the criminal law's incapacity to adequately respond to healthcare scandals which involve systemic failure, even when there was unequivocal evidence of individual reckless conduct.

The criminal prosecutions focused on individual criminail liability which followed the blood episode in France were seen as unfair because, in 'scapegoating' those prosecuted, it appeared that prosecutors were seeking the 'convenient target'.[51] I suggest here that scapegoating individuals could undermine the usefulness of criminal investigations into systemic failings. Notably, the UK's Gosport hospital scandal also demonstrated that criminal investigations need to be conducted thoroughly and appropriately, and that focusing liability on one or a few individuals can be detrimental to finding out what happened. Although the Gosport report found that one doctor (Dr Barton) played a crucial role in the patients' deaths at the hospital, the Gosport panel concluded that the police's exclusive focus on one individual 'rogue doctor' was inappropriate as it had 'reinforced the perception that there were no systemic issues to be addressed'.[52] It is difficult to see how such an approach can

[48]See for instance JP Delmas Saint-Hilaire, 'Un crime d'empoisonnement: la double tromperie de l'Affaire du sang contaminé cessera-t-elle enfin ?' in J Pradel (Dir.), *Sang et droit pénal. A propos du sang contaminé*, Travaux de l'Institut de sciences criminelles de Poitiers (Edition Cujas 1995) 45.
[49]L Greilsamer, above n26 at 18.
[50]Ibid 204-205.
[51]G Mellema, 'Scapegoats', (2000) 19/3 *Crim. Just. Ethics*, 7; P Gooderham, No-one fully responsible: a 'collusion of anonymity' protecting health-care bodies from manslaughter charges?' (2011) 6/2 *Clinical Ethics*, 75.
[52] *Gosport War Memorial Hospital: The report of the Gosport Independent Panel*, 20 June 2018, 321, 323.

serve the goal of deterrence when underlying failings that could well also occur in other healthcare institutions are left unaddressed.[53]

I propose here that a vigilant approach to prosecuting individual medical professionals must be taken, especially given that it is easier to prosecute and/or convict medical professionals working in direct contact with patients than decision-makers. Following the expansion of the crime of wilful neglect under the CJCA, a care worker can now be criminally liable and face up to 5 years imprisonment if s/he wilfully neglects or ill-treats an individual under his/her care.[54] These offences are 'conduct' offences and do not actually require any result to ensue from the conduct.[55] This extension of the criminal law aimed to ensure greater accountability for negligent wrongdoing in healthcare: now any healthcare professional can potentially be held to account for wilful or reckless conduct (including acts and omissions) resulting either in death or injury. It also has the potential to address the unfairness that existed previously under the law related to 'moral luck', whereby a healthcare professional would escape any criminal liability provided that the patient's death was avoided.[56] Some unfairness remains, however, as the offence of gross negligence manslaughter requires a lower level of culpability (grossness) than the new offences, which require proof of (at least) reckless conduct on the part of the care professional. This is particularly problematic when the death of a patient was not only caused by one doctor's negligence, but also by failures in the healthcare system.

The liability under s.20(3) of the CJCA extends to any individuals who supervise or manage 'individuals providing such care' or are directors or similar officers of an organisation which provides such care. Thus, in theory, managers and/or hospital directors could also be liable for the offence. However, managers and directors cannot, under the Act be criminally liable for the wilful neglect or ill-treatment committed by a third party, *unless* they have aided or

[53] J Feinberg, 'The expressive function of punishment', in *Doing and Deserving: Essays in the Theory of Responsibility* (Princeton University Press 1970), 95-118; H Morris, 'Responsibility, Character and the Emotions', in F Schoeman (Ed.), *New Essays in Moral Psychology* (Cambridge University Press 1987) 220.
[54] s.20 (1), (2) Criminal Justice and Courts Act 2015.
[55] *Ibid*.
[56] *Ibid*; O Quick, above n1 at 116. Department of Health, Impact Assessment, Criminal Offence of ill-Treatment or Wilful Neglect, 10 June 2014, 13. On moral luck, see AF Merry, 'When Are Errors a Crime? - Lessons from New Zealand', in C Erin and S Ost (eds.) *The Criminal Justice System and Health Care* (Oxford University Press 2007) 67-97.

abeited the neglect or ill-treatment in question, or assisted or encouraged it.[57] The explanatory notes to the Act explicitly exclude liability for the acts or omissions of others.[58] The Act also provides that care providers (defined as a 'body corporate or unincorporated association which provides or arranges for the provision of' healthcare and social care) may also be criminally liable for the same offences under s.21 of the Act.[59] This means that, in cases of healthcare systemic failings where individuals have allegedly committed ill-treatment or wilful neglect, it will be possible to prosecute individual nurses, doctors, and other healthcare professionals, *or* the Trust for the same offences, or for HSWA offences. Consequently, 'higher-level' decision-makers may escape not only criminal, but also civil liability. This could well be counterproductive for the reporting of mistakes, near-misses and events, and for safety in general because those in direct contact with patients could be fearful of reporting mistakes to those in positions of authority who are then effectively shielded from criminal liability for wilful neglect or ill treatment unless they have played a direct role in such treatment.

IV. BLAMING INSTITUTIONS

In healthcare scandals in France, criminal liability against individual decision-makers tend to be favoured over corporate liability, although corporations can be prosecuted and convicted of the same criminal offences as individuals.[60] Indeed, no corporate prosecutions followed the French tainted blood scandal, because it was thought that individual criminal liability would better serve the victims' and the public's need for justice and accountability.

In England and Wales, NHS Trusts can be held criminally liable under both the Corporate Manslaughter and Corporate Homicide Act 2007 (CMCHA), and the HSWA. Under the CMCHA, a corporation is criminally liable 'if the way in which its activities are managed or organized: (a) causes a person's death and (b) amounts to a gross breach of a relevant duty

[57] K Laird, 'Filling a lacuna: The Care Worker and Care Provider Offences in the Criminal Justice and Courts Act 2015, (2016) 37 (1):1 *Statute Law Review*, 4.
[58]Criminal Justice and Courts Act 2015, Explanatory Notes, Schedule 4.
[59]S.21 Criminal Justice and Courts Act 2015.
[60] A Christafis, 'French doctors on trial for CJD deaths after hormone 'misuse'', *The Guardian*, 7/02/2008; 'Breast Implants: PIP's Jean-Claude Mas gets jail sentence', *BBC News*, 10/12/2013.

of care owed by the organisation to the deceased'.[61] The condition is that the way in which the corporation's activities are 'managed or organised by its senior management must be a substantial element in the breach'.[62] Section 1 (4) (b) indicates that 'a breach of a duty of care by an organisation is a "gross" breach if the conduct alleged to amount to a breach of that duty falls far below what can reasonably be expected of the organisation in the circumstances'.[63] Satisfying these requirements in the context of healthcare failures, especially proving causation, can be exceptionally burdensome. Since 2007, there has only been one (unsuccessful) criminal prosecution of an NHS Trust under the CMCH for the death of a patient.[64] It is argued that 'the Act is complex and the offence definition itself is full of ambiguities and interpretive uncertainty',[65] and 'the fragmented nature of the corporate NHS […] makes it difficult to apply elements of the offence contained in the Act to any one of the corporate bodies involved'.[66]

The HSWA has, however, been used to prosecute NHS Trusts for breaches of health and safety legislation. In the Mid Staffordshire scandal, two successful prosecutions were brought against the Trust by the HSE and related to the deaths of Lillian Tucker Gillian Astbury, Ivy Bunn, Edith Bourne and Patrick Daly, who all died at Stafford Hospital between 2005-2014. Thus, notwithstanding there being an estimated 400 to 1200 victims, the Trust was convicted of criminal charges for causing the deaths of just five victims. Notably, were this to have happened in France, more victims or their families would have been able to become *parties civiles* and bring civil claims in criminal proceedings against the institution for various offences, including individual and corporate 'negligence' offences.

The HSE prosecutions were based on Section 3(1) of the HSWA, which provides that 'it shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected

[61] S. 1(1) CMCHA.
[62] S. 1(3) CMCHA.
[63] S. 1(4) (b) CMCHA.
[64] *R v Dr Errol Cornish and Maidstone and Tunbridge Wells NHS Trust* [2016] EWHC 779 (QB).
[65] C Wells, 'Medical manslaughter-Organisational liability' in D Griffiths, A Sanders (Eds.), above n8 at 200.
[66] P Gooderham, above n50. In theory charges on the grounds of recklessly or intentionally causing harm could have been brought against individuals, but prosecution policy was that only the offence of gross negligence manslaughter was to be used in healthcare negligence cases, and establishing evidence of recklessly causing harm can be difficult. See O Quick, above n1; S. 20 Offences Against the Person Act 1861.

thereby are not thereby exposed to risks to their health or safety'.[67] Section 33 of the HSWA makes it a criminal offence to breach the duty stated under Section 3(1), with the aim of protecting the safety of the public within the particular institution. The 2010 Definitive Guideline on Corporate Manslaughter and Health and Safety Offences Causing Death provides that an appropriate fine against the institution could be no less than £100,000 and could 'be measured in hundreds of thousands of pounds or more'.[68]

On 28 April 2014, the Trust was sentenced to pay a fine of £200,000 by Mr Justice Haddon-Cave in Stafford Crown Court for causing the death of Mrs Astbury, and in 2015. It was sentenced by the same Court to a £500,000 fine for the deaths of Lilian Tucker, Ivy Bunn, Edith Bourne and Patrick Daly, which were all found to be 'wholly avoidable deaths' by the Court. The Trust had gone into administration in April 2014, and the Court recognised that it was in 'serious financial difficulty' in its 2014 judgment.[69] Thus any financial penalty imposed would likely have had a detrimental effect or no effect at all on the Trust. The Trust's counsel argued that the imposition of a mere nominal fine would not be justified, but he suggested that a fine in the region of £20,000 would be appropriate, claiming that 'the Trust had already learned its lessons and been punished enough in the past seven years'.[70] However, Mr Justice Haddon-Cave considered that 'a significant fine [was] called to reflect the gravity of the offence, the loss of a life and in order to send out a strong message to all organisations, public or private, responsible for the care and welfare of members of the public'. [71] In other words, the naming and shaming of the Trust was considered to achieve appropriate retribution. Whilst the fine of £400,000 was half that which was initially suggested by the magistrate because of the Trust's early guilty plea, the Trust was nevertheless unable to pay the fine. Mr Justice Haddon-Cave considered that 'if the fine [had] ultimately to be paid by the Department of Health itself, then sobeit', which is, in fact,

[67] S. 3(1) HSWA.
[68] 2010 Definitive Guideline on Corporate Manslaughter and Health and Safety Offences Causing Death.
[69] *R v Mid Staffordshire NHS Foundation Trust*, Sentencing Remarks of the Hon. Mr Justice Haddon-Cave, 28 April 2014, 12.
[70] *Ibid.*
[71] *Ibid.*

what eventually happened.[72] A similar approach was taken in relation to the sentence given to the Trust in the 2015 judgement.[73]

On the face of it, corporate liability, whether under the CMCHA or the HSWA, appears to be an attractive mechanism to achieve safety, and to avoid naming and shaming individuals who have been 'victims' of an unsafe system of work.[74] Because it is the institution itself that has failed to deliver safety, punishing the institution for breaching its health and safety duties would seem to be the most appropriate answer, and is surely necessary to ensure safety in the health environment, especially where there is no evidence of individual reckless or deliberate conduct. Yet, regarding the Mid-Staffordshire scandal, a number of criticisms can be raised concerning the outcome of the proceedings againt the Trust. I have already noted that, because the Trust was convicted of a HSWA criminal offence for the deaths of only five victims, only a small number of victims (or their families) received some form of justice. Moreover, effective deterrence may not have been achieved as there is no evidence that a fine is a powerful deterrent for a healthcare institution. Financial penalties against a corporation can only act as a deterrent if sufficiently substantial to discourage the institution from taking an unjustified risk.[75] Quick claims that 'the fact that trusts are unable to insure against the payment of criminal fines may be an important factor in terms of helping to incentivise compliance with safety standards'.[76] This was also the view taken by Mr Justice Haddon-Cave in the two judgments against the Mid Staffordshire Trust, who considered that a substantial fine was required in part to adequately reflect the grave and serious breach by the Trust of its health and safety obligations. However in cases such as this, the imposition of a large fine against a Trust which was already in serious financial difficulty could undermine patient safety even further, and evidence is lacking as to whether it has effectively deterred

[72] *Ibid* 13.
[73] *R (Health and Safety Executive) v Mid Staffordshire NHS Foundation Trust,* Sentencing Remarks of The Hon. Mr Justice Haddon-Cave, 16 December 2015.
[74] See for instance, C Wells, above n64 at 192-210; O Quick, above n13; N Allen, 'Medical or Managerial Manslaughter' in C Erin, S Ost (Eds.), *The Criminal Justice System and Health Care* (Oxford University Press 2007) 50-66; P Gooderham, above n50 at 68; A Merry, W Brookbanks, above n1, 386; B Fisse, J Braithwaite, 'The allocation of responsibility for corporate crime: Individualism, Collectivism and Accountability' (1988) 11 *Sydney Law Review* 468-513.
[75] JC Coffee, Jr., 'No Soul to Damn: No Body to Kick: An Unscandalized Inquiry into the Problem of Corporate Punishment', (1981) 79/3 *Michigan Law Review*, 386-459.
[76] O Quick, 'Patient safety and the problem and the potential of law', (2012) *Journal of Professional Negligence* 98.

other Trusts from committing similar reckless conduct, especially considering that the fine was eventually paid out of the 'public purse'.

V. LEARNING LESSONS

The preceeding analysis on criminal proceedings arising out of the French blood scandal highlighted that management had a considerable role in making decisions which would ultimately cause harm to patients who received contaminated blood. The failings for which key decision-makers in the French tainted blood scandal were prosecuted and convicted of criminal offences could be compared to failures in healthcare scandals in England which have not led to individual criminal charges.[77] Available evidence on the Midstaffs scandal also suggests that management had a crucial role in creating an unsafe healthcare environment, leading to multiple and avoidable deaths.[78] In some healthcare scandals, failings by those responsible reflect a complete disregard for patient safety, as seen in the French and English tainted blood scandals, and the Midstaffs scandal. The prioritization of finances over the protection of patients demonstrate a complete disregard for patient safety, whilst other failings demonstrate incompetence and human error.

Although the criminal law aims to perform important functions such as achieving justice and accountability which are surely vital following some instances of reckless or deliberate disregard for healthcare safety, there are many instances of healthcare failings which the criminal law cannot successfully address. I suggest here that the criminal law can only usefully respond to cases of reckless healthcare practice if it is ensured that all individuals who have committed at least reckless conduct are subject to criminal charges. As explained earlier, focusing liability on particular individuals, whilst overlooking the potential culpability of others, wider systemic issues and the inadequacy of regulatory mechanisms, is rarely helpful in addressing healthcare scandals that have occurred and deterring the occurrence of such scandals in the future. Overall, the analysis on the French tainted blood scandal indicates that in healthcare systemic failure cases, it is difficult to apply a 'one size fits all'

[77] M Kazarian, above n38 , 88-120.
[78] Healthcare Commission, above n23 at 9; R Francis QC, above n3 at 4.

approach for criminal liability, and each case needs to be treated individually. But decision-makers should not be immune to criminal charges.

Besides evaluating the role and success of the criminal process in addressing instances of healthcare failings, the evidence available on the French and English blood scandals, and the Midstaffs scandal, for instance, suggests that some healthcare failings can be prevented if the decision-making process is focused to a greater degree on patient safety. Government and decision-makers need to be motivated to be less keen to cut costs and to prioritise, instead, the improvement of healthcare safety and regulatory compliance. Further, failings could be prevented if a stronger reporting culture and greater transparency exists in healthcare institutions. Transparency is needed from and to management, amongst members of staff, and towards patients. The reporting of flaws in the treatment and care offered by healthcare institutions needs to be acted upon readily to avoid further failings, and whistleblowing should be strongly encouraged. Since human error is inevitable, when failings do occur, thorough and timely investigations should be conducted. Regulatory bodies should also have a decisive role in preserving healthcare safety, but as acknowledged in the relevant literature, regulatory mechanisms have sometimes failed to ensure proper healthcare safety.[79] Fitness to practice proceedings must also be used in a way which helps patient safety and serves the public interest. But recent examples have shown that this is not always achieved through the intervention of regulatory bodies. Following the Gosport Hospital disaster, Dr Barton was found guilty of serious professional misconduct by the GMC in 2010, but was allowed to keep her medical licence. This may be viewed as a potential threat to healthcare safety, following evidence found in the Gosport inquiry that Dr Barton's role in the scandal was quite influential. No other medical professional faced fitness to practice proceedings following the scandal, which could suggest that no other medical professional deserved to be blamed for misconduct, *or* that other individuals did have a role in prescribing dangerous doses of opioid drugs to patients at the Gosport War Memorial Hospital, but their role was overlooked. This limited use of disciplinary proceedings may indicate that GMC fitness to practice proceedings are not an 'appropriate sole mechanism' in

[79] See for instance AL Beaussier, D Demeritt, A Griffiths, H Rothstein, 'Accounting for failure: risk-based regulation and the problems of ensuring healthcare quality in the NHS', (2016) 18:3-4 *Health, Risk and Society*; and JM Chamberlain, 'Risk-based regulation and reforms to fitness to practise tribunals in the United Kingdom: Serving the public interest?', (2016) 18:5-6 *Health, Risk and Society*.

addressing cases of healthcare systemic failings.[80] As several authors have argued, the regulation of healthcare safety and quality must be seriously re-considered by policy-makers.[81]

VI. CONCLUDING REMARKS

As currently shaped, criminal liability, whether corporate or individual, is unable to respond adequately to many instances of healthcare failings. Criminal proceedings following the French tainted blood scandal have shown that the aim of deterrence regarding healthcare systemic failings is unlikely to be achieved when the defendant decision-maker's level of culpability was short of recklessness. However this article has demonstrated that in England and Wales, the *de facto* 'immunity' from criminal liability of healthcare decision-makers in cases involving healthcare systemic failings is unacceptable and should be reviewed. The French tainted blood scandal has shown that the multiplicity of contributing agents makes it difficult to fulfil evidentiary requirements in individual criminal offences, and scapegoating individuals who have not engaged in reckless or deliberate conduct might lead to unfair and unhelpful outcomes. Although fear of punishment could play a role in deterring wrongful conduct in the healthcare systemic context, this also has the potential to create defensive behaviour, and further undermine openness and transparency, especially if used against front-line staff who were not given the means to deliver safe care to patients, as demonstrated in the recent Bawa-Garba case. Overall, the deterrent effect of criminal punishment in healthcare scandals on its own cannot be said to be sufficient to ensure safety in healthcare state institutions.

Offences which punish breaches of health and safety legislation by healthcare institutions offer the most sensible response to episodes which have involved multiple victims, but the issue of whether financial penalties have any deterrent effect on public healthcare institutions remains insufficiently explored. What is more, imposing large fines on a publicly-

[80] *Gosport War Memorial Hospital: The report of the Gosport Independent Panel*, 20 June 2018, 76, 323.
[81] AL Beaussier, D Demeritt, A Griffiths, H Rothstein, above n79 at 218; JM Chamberlain, above n79 at 329; It should also be noted here that the French experience can teach us valuable lessons on the usefulness of no-fault compensation for medical accidents, see for instance S Taylor, *Medical Accident Liability and Redress in English and French Law* (Cambridge University Press 2015).

funded healthcare institution would be counter-productive in the achievement of patient safety.

The analysis of the French tainted blood scandal has highlighted the need to conduct thorough investigations into systemic failings cases, and to give victims a greater voice in finding out the truth about what went wrong, so that valuable lessons can be learnt to prevent healthcare failings. Criminal proceedings which mainly aim to punish are not always helpful in providing openness and transparency to victims, as they are not directed towards addressing the systemic failings which occurred in the institution. The need for blame and punishment should not be prioritized over finding out what went wrong and correcting mistakes to avoid further deaths or injury.

The new offences of wilful neglect and ill-treatment in England and Wales have the potential to provide greater fairness when it comes to prosecuting individual healthcare professionals, but they also have the potential to make individual healthcare professionals more vulnerable to criminal liability. By focusing on individual liability, people at the lower-levels of the decision-making process, or those who work in direct contact with patients and who are already at higher risk of committing fatal or non-fatal mistakes, would be targeted by criminal punishment, leaving senior managers, and hospital or Trust board directors protected from any form of punishment or liability. The new offences must therefore be used only to punish conduct which shows a high level of culpability, and the offence of gross negligence manslaughter will need to be reviewed to make sure that criminalization is imposed only when negligence has reached the required level of culpability, as consistent with the new offences of willful neglect and ill-treatment. Finally, we must reconsider how higher-level healthcare decision-makers should be included in the scope of criminal liability.