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Safety in Healthcare: The Pharmacy Legislative Framework and Patient Safety

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The evolution of the concept of "accident"

In the introduction to the book "Just Culture", Sidney Dekker[1] explains how the term "accident" is a relatively modern concept. He describes how, up until the scientific revolution of the 17th century, people believed that misfortune was underpinned by religious or superstitious influences, and that humans were powerless to intervene. By the 20th century, this view had matured, tending to see accidents as "meaningless coincidences of space and time", somewhat less judgemental than the religious view, but equally unhelpfully, human intervention was seen as impossible. A modern view sees accidents simply as failures to effectively manage risk. Safety scientists view accidents as entirely normal properties of complex sociotechnical systems.[2] It is from such a systems perspective that the authors consider the impact the current pharmacy legislative framework may have on patient safety, a key target of all healthcare organisations in the light of the recognition that healthcare-induced injury is one of the leading causes of death worldwide.[3]

Healthcare: A system of (complex sociotechnical) systems

A system can be defined as a set of interrelated (coupled) entities united in a joint purpose.[4] Entities include physical objects, technology, processes and relationships, as well as organisational constraints and indeed the legal and regulatory framework that underpins professional behaviour. When entities are tightly linked and inter-dependent (a relationship known as "coupling") changes can cascade rapidly through the system, causing a ripple effect that may only be felt at a distance from the point of change. Systems can be small (micro; perhaps a worker using a tool or technology), medium (meso; a healthcare example might be a surgical team) or large (macro; perhaps a hospital, or indeed the NHS as a whole[5]). Larger systems (certainly those seen in healthcare) tend to be sociotechnical in nature, reflecting the fact that a key feature of the system is the people within it (and their relationships with other entities, which increasingly include technological elements). It can also be appreciated that such large systems subsume many meso- and micro-systems, and the relationships between these need to be considered. In such complex systems, there

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[1] S. Dekker, *Just Culture* (2012).

[2] C. Perrow, *Normal accidents* (New York: Basic Books, 1984); S. D. Sagan, *The limits of safety: Organizations, accidents and nuclear weapons* (Princeton NJ: Princeton University Press, 1993).

[3] Institute of Medicine, "To err is human. Building a safer health system" [1999] National Academy Press, Washington DC; D. Berwick, *A promise to learn—a commitment to act* (National Advisory Group on the Safety of Patients in England, 2013) at *https://www.gov.uk/government/publications/berwick-review-into-patient-safety* [Accessed 17 January 2018]; R. Francis, *Report of the Mid Staffordshire NHS Foundation Trust Public Enquiry* (London: HMSO, 2013).

[4] J. Dul, R. Bruder, P. Buckle, P. Carayon, P. Falzon, W. S. Marras, J. R. Wilson and B. Van der Doelen, "A strategy for human factors/ergonomics: developing the discipline and profession" [2012] *Ergonomics* 55, 4, 377–395.

[5] S. Hignett, A. Lang, L. Pickup, C. Ives, M. Fray, C. McKeown, S. Tapley, M. Woodward and P. Bowie, "More Holes than Cheese. What prevents the delivery of effective, high quality, and safe healthcare in England?" [2018] *Ergonomics* 61, 1, 5–14.

are so many interactions between entities, with relationships often tightly coupled, that outcomes can be difficult to predict, a concept known as emergence. Safety is one such emergent property, making safety management highly complex.

Given the relationship between system performance and safety, the authors define safety (including patient safety) using this systems language: "[Safety is] the level of system performance required to keep the incidence of harm (and risk) as low as reasonably practicable." There are obvious issues (particularly from a legal perspective) with this definition, particularly in relation to defining an acceptably low level of risk. However, in terms of proactively improving patient safety, this is a far more usable definition than that those most commonly used in healthcare. While the term "safety" is frequently used in healthcare, it is infrequently defined, and where definitions exist, there is a lack of standardisation, which causes confusion. A common feature of such definitions is "prevention of medical error". This is problematic in two ways, first, because prevention of error is unachievable in complex sociotechnical systems, and focussing on error prevention inhibits resources from being used more effectively to develop resilient systems that can accommodate this inevitable error without compromising safety. Secondly, identifying error allocates blame, meaning that individual system "actors" bear the brunt of responsibility for adverse outcomes which are inevitably systems issues, with multiple interacting contributory factors. Increasingly often in healthcare, attribution of blame has attracted civil and indeed criminal proceedings, and the authors would contend that this trend of criminalising errors actively undermines the opportunity for genuine improvement of patient safety.

Just Culture and the "high reliability" dream

Functioning of complex sociotechnical systems needs effective safety management,[6] and this requires hazard identification, accurate risk estimation and active control measures. Reason[7] believes this is best supported by cultures which are: (i) *open to reporting;* (ii) *just;* and (iii) promote *learning* (and using this learning to visibly improve safety performance[8]). The safety performance pinnacle is considered to be the "high reliability organisation" ("HRO").[9] Weick and Sutcliffe[10] describe HRO characteristics as follows:

- Such organisations are pre-occupied with failure, constantly searching for small signals that may predict failure. They gather, analyse and review this data, linking it to outcomes, and establish critical monitoring measures for their own operational context.
- They reward open reporting, and use the date they collect to proactively manage future risk.
- They show reluctance to simplify interpretation of their data, socialising workers at all levels of the organisation to be curious about safety.
- HROs are sensitive to operations, meaning staff have good situational awareness.
- HROs are resilient. Errors occur, but are not disabling, and such organisations achieve this because they take a systems approach to safety management.

Interestingly, despite the risks involved (and the financial and personal costs associated with medical injury), healthcare organisations have not traditionally viewed themselves as HROs, and although there have been suggestions that adopting HRO frameworks might usefully support enhanced patient safety,

[6] S. Wilke, A. Majumdar and W.Y. Ochieng, "Airport surface operations: a holistic framework for operations modelling and risk management" [2014] *Safety Science* 63: 18–33.

[7] J. Reason, *Managing the risk of organisational accidents* (Aldershot: Ashgate, 1997).

[8] C. Burns, K. Mearns and P. McGeorge, "Explicit and implicit trust within safety culture" [2006] *Risk Analysis* 26(5): 1139–1150.

[9] A. Hopkins, "The problem of defining higher reliability organisations" 2017 *Working Paper 51*; National Research Centre for OHS Regulation at *http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.461.7777&rep=rep1&type=pdf* [Accessed 17 January 2018]; J. C. Le Coze, "Viva la diversité! High reliability organisation (HRO) and resilience engineering (RE)" [2016] *Safety Science* at *http://dx.doi.org/10.1016/j.ssci.2016.04.006* [accessed 17 January 2018].

[10] K. Weick and K. Sutcliffe, *Managing the unexpected: assuring high performance in an age of complexity* (San Francisco: Jossey-Bass, 2001).

there are significant barriers to achieving this. Perhaps the greatest of these is the absence of truly *Just Culture*, which is dependent upon open reporting.

Just culture

Leape[11] asserted "the greatest impediment to error prevention is … punish[ing] people for making mistakes" calling for non-punitive cultures. However, this fails to acknowledge some errors warrant individual accountability.[12] *Just Culture* recognises this, representing "a collective understanding of where the line is drawn between blameless and blameworthy actions". It reflects the systems thinking described above, recognising error is also an emergent property, but including room for individual accountability.[13] It is important to be clear that *Just Culture* does not mean no blame but rather fair blame. There is plenty of evidence in the medical literature to indicate that not all medical injury is the result of "normal accidents" of healthcare delivery, including significant UK cases, such as Harold Shipman[14] and Beverly Allitt.[15] This seems relatively straightforward and desirable, but the problems lie in implementation. "Drawing the line" is highly subjective, biased by the role of the decision-maker and, in healthcare, by medical hierarchy.[16] Delivering *Just Culture* is as complex as the system it serves.

The complexity of *Just Culture* resides in the flawed assumption that there is one "true story" in the narrative of an adverse event. The term "Just Culture" (note the upper case) is often used as shorthand to describe the structures in place within an organisation designed to deliver just culture. Such structures often include decision-making tools such as the "decision tree" used by the UK NHS.[17] This comprises four tests:

- **Deliberate harm test:**

  Was there "a conscious and deliberate breach of duty" and did this breach result in patient harm?

- **Physical and mental health test:**

  Was there any underlying health condition, and did this impact care in anyway? If yes, the contribution of this to the "harm" must be established.

- **Foresight test:**

  Were standard operating procedures/policies followed? Could the effects of any such violation have been reasonably predicted?

- **Substitution test:**

  Would a similarly qualified/experienced practitioner in the same circumstances have followed a similar course of action?

[11] L. L. Leape, "Errors in medicine" [2009] *Clinica Chimica Acta* 404(1): 2–5.

[12] S. Petschonek, J. Burlison, C. Cross, K. Martin, J. Laver, R. S. Landis and J. M. Hoffman, "Development of the Just Culture Assessment Tool (JCAT): measuring the perceptions of healthcare professionals in hospitals" [2013] *Journal of Patient Safety* 9(4): 190–197; S. Dekker and T. B. Hugh, "A just culture after Mid Staffordshire" [2014] *BMJ Quality & Safety* 23: 356–358.

[13] C. Burns, K. Mearns and P. McGeorge, "Explicit and implicit trust within safety culture" [2006] *Risk Analysis* 26(5): 1139–1150; R. M. Wachter and P. J. Provonost, "Balancing 'no blame' with accountability in patient safety" [2009] *New England Journal of Medicine* 31(14): 1401–1406.

[14] J. Smith, "The Shipman Enquiry. The final report" (2005) at *http://webarchive.nationalarchives.gov.uk/20090808160144/http://www.the-shipman-inquiry.org.uk/finalreport.asp* [accessed 17 January 2018].

[15] Department of Health, *The Allitt Inquiry (Clothier Report)* (Stationery Office Books, 1994).

[16] S. Dekker, *Just culture: balancing safety and accountability* 2nd edn (Farnham: Ashgate, 2012); B. J. Weiner, C. Hobgood and M. A. Lewis, "The meaning of justice in safety incident reporting" [2008] *Social Science and Medicine* 66: 403–413; T. von Thaden, M. Hoppes, Y. Li, N. Johnson and A. Schriver, "The perception of just culture across disciplines in healthcare" Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting 2006; San Francisco, HFES.

[17] P. G. Boysen, "Just culture: a foundation for balanced accountability and patient safety" [2013] *Oschner Journal* 13(3): 400–406.

The problem is that each of these tests requires someone to make a judgement call, and such a "judgement" is simply a social construction, no more than somebody's attribution. Here there are many similarities with the legal system: this "somebody" has both the power to decide what category an act falls into, and also to attach sanctions, sanctions which may have severe impact for the person being judged. The reason that there is not one "true story" of any event is that all those involved have a different perspective and understanding of the event. Rasmussen[18] captured this problem eloquently:

> "If we find ourselves asking 'how could they have been so negligent, so reckless, so irresponsible?', then this is not because the people in question were behaving bizarrely, it is because we have chosen the wrong frame of reference for understanding their behaviour."

This quote also succinctly captures the essence of truly just cultures: the idea is not to judge individuals for apparent safety failings, but to try and understand the context, what it was about the working environment that made it seem reasonable to those involved to undertake the course of action they selected. If it made sense to this worker, then it is likely to make sense to others working under similar conditions. Often the person empowered with "drawing the line" has no understanding of the pressures under which the work was being carried out, what Dekker15 refers to as the "messy, conflicted details of [the worker's] responsibilities". There are numerous potential flaws in all of the above tests, but there are three that are particularly worthy of highlighting. The first of these is hindsight bias. There is a wealth of evidence in the literature to indicate that the outcome significantly influences the opinion of those judging others' behaviour. The more serious the outcome, the more likely it is that the behaviour will be judged in a negative light. This makes the substitution test unreliable. Secondly, it is highly likely that the foresight test will reveal deviations and even violations of policies and procedures, and these are often then considered to be the root cause of the incident. This notion that following standard operating procedures leads to good outcomes, while deviations and violations underpin poor outcomes is simply not true. In recent years, there has been a shift, often referred to as a move from Safety I to Safety II.[19] Safety I involves analysis of comparatively rare adverse events. Safety II turns this around, acknowledging that most of the time healthcare outcomes are good. By exploring normal work in this way, the factors that underpin success can be identified. These sorts of studies reveal that procedural deviations and violations are part of normal work, and often reflect the adjustments that staff need to make on a day-to-day basis to deliver successful outcomes. This allows the weak points in the system to be identified, facilitating intelligent system re-design. The third issue is that patient harm is not necessarily a good marker of the safety status of a system. There can be endemic weaknesses in a healthcare system that sometimes lead to patient harm. All of these factors make achieving *Just Culture* very difficult, and innocent mistakes can be "constructed" to appear as negligent or wilful acts. How effectively *Just Culture* operates within an organisation is influenced by a combination of the legal and regulatory framework governing professional behaviour and the expectations of society and both of these can be particularly negative with respect to healthcare, particularly in relation to pharmacy practice.

Pharmacy regulatory framework

In general, healthcare "wrongs" are dealt with (in the UK) under a tort system, so civil liability rather than criminal liability. Legal action through this route may be pursued for a number of reasons, but one important aspect is that assigning blame (whether to an organisation or an individual) allows the release of financial compensation. Significantly though, the "zero tolerance" message contained within the Francis Report[20]

[18] Cited in S. Dekker, *Just culture: balancing safety and accountability*, 2nd edn (Farnham: Ashgate, 2012).
[19] J. Braithwaite, R. L. Wears and E. Hollnagel, "Resilient healthcare: turning patient safety on its head" [2015] *International Journal for Quality in Health Care* 1–3 at *https://academic.oup.com/intqhc/article/27/5/418/2357417* [accessed 17 January 2018].
[20] R. Francis, *Report of the Mid Staffordshire NHS Foundation Trust Public Enquiry* (London: HMSO, 2013).

has led to an increasing trend for criminal proceedings, and there have been changes in the legislation to support this. The Criminal Justice and Courts Act 2015 ss.20–25 set out a framework for a crime of "wilful neglect of a patient". This charge can be levied against an individual or a corporate body such as the NHS. Sanctions can include remedial orders and fines as well as the reputational damage for the organisation. The increasing penalties for such offences means that an organisation may feel it is "better" for an individual to be blamed for an adverse outcome. Even if this is not the case, the new legislation emphasise personal responsibility and, even in the case of corporate charges, there is a focus on individual liability, of identifying those considered "most guilty" in the case of extreme poor care.

In addition to the healthcare regulatory framework, there are additional concerns for practising pharmacists. Currently, the larger part of their work involves the supply of pharmaceutics, involving the process of dispensing. Dispensing is dealt with under a different regulatory framework: Medicines Act 1968 (partially repealed by the Human Medicines Regulations 2012[21]). Offences against ss.64 and 85 of this legislation are absolute offences, and due diligence is not considered a defence. Section 85 is concerned with the packaging and labelling of pharmaceutics, while s.64 concerns the medicinal product being of the nature or quality demanded by the purchaser. Essentially, this legislation means that an act which is recognised by all concerned as an innocent error made by an individual pharmacist can still be treated as a criminal offence. While prosecutions under this Act have been rare, they have occurred and, because the prosecutions have been a response to patient fatality, the initial charges in some of the cases were actually gross negligence manslaughter, rather the charges specified within the legislation. On appeal, these charges were generally reduced to offences against ss.64 and 85. One of the outcomes of these prosecutions was clarification of s.85. The legislation refers to the offence occurring "in the course of a business carried on by him", and this is now interpreted as meaning the retail pharmacy company, not the individual pharmacist.

The impact of legislation on Just Culture

The outcomes of criminalisation of healthcare errors are drastic. For the individual, these may include loss of liberty, financial penalties, fear, grief, guilt, depression, loss of job and even suicide. The impact is enormous, and Dekker refers to these staff as "the second victim" of the adverse event. There is evidence to indicate that many of the emotional responses are normal in the wake of any adverse event (including those not prosecuted), and recovery requires peer support which, in the event of a prosecution, is usually denied to the accused as colleagues are usually required to maintain a distance until after the trial. While these outcomes are tragic, the effect of prosecution can be even more severe with respect to future patient safety. The trial itself becomes rather less about "the truth" and more about trying to minimise what Dekker refers to as "the spiralling negative consequences of a trial". The events become a powerful driver of behaviour to all in the organisation or profession. Practice becomes much more defensive, rather than concentrating on delivering a high quality service, practitioners become much more focussed on limiting their own personal liability. Furthermore, staff are very unlikely to voluntarily report incidents and near-misses as they have seen that the behaviour considered to contribute to such performance failings may be punished. Without open reporting, there are no data on which to build a proactive risk management strategy.

Two of the high profile cases which resulted in pharmacist prosecutions are testament to this. The cases of Elizabeth Lee and Martin White show alarming similarity. Both "errors" involved selection of propranolol instead of prednisolone. Contributory factors included:

[21] Human Medicines Regulations 2012 (SI 2012/1916).

- shelves in both pharmacies arranged according to the World Health Organisation[22] recommendation that "drugs are arranged in alphabetical order of generic names"; and
- packages for both medicines were similar in appearance.

It was acknowledged that both pharmacists had impeccable records and both made errors that "any competent pharmacist could (and in all probability would) unintentionally make a number of times throughout their professional career". Both were punished rather than learning from the cases to (according to RPS President Martin Astbury[23]) put "measures in place so that one simple mistake can't lead to such devastating harm to patients and their families". Furthermore, it was suggested that awareness of these outcomes leads to a fear of the legislation which can be seen to have a significant impact on pharmacist behaviour.[24] Fear of the legislation may lead to pharmacists having reduced confidence in their ability to take sole responsibility for patient outcomes, which may undermine the enhanced future role envisaged for pharmacists.

The relationship between Just Culture and human factors/ergonomics: A mechanism for delivering improved patient safety

Just Culture is largely concerned with achieving the resilience and sensitivity to operations that are such an important feature of HROs. This supports a proactive risk management strategy. HROs generally implement such strategies by using a human factors/ergonomics approach. Human Factors is synonymous with the term "ergonomics", hence the abbreviation HFE. HFE approaches are useful because they share three fundamental characteristics. They:

- take a systems approach, as described at the beginning of this paper;
- are design-driven to support good performance and prevent poor outcomes rather than promoting safety by demanding behavioural modification of the actors within the system, processes, equipment etc;
- focus on dual outcomes of optimising system performance and improving human wellbeing.

In the UK, there have been initiatives to introduce HFE since 1990 after a change in legislation in 1986 when Crown Immunity from prosecution under the Health and Safety Act 1974[25] was removed. HFE input was used in 1980s–2000s for building design,[26] occupational health[27] and systems approaches to embed HFE as part of the organisational culture.[28]

In 2013, a Concordat was signed by 16 health care agencies in England (including professional regulators, inspection agencies and education providers) stating that "a wider understanding of Human Factors principles and practices will contribute significantly to improving the quality (effectiveness, experience and safety) of care for patients".[29] One of the initiatives to implement the Concordat was a series of HFE taster workshops in collaboration with the UK professional body for HFE (Chartered Institute of Ergonomics & Human Factors ("CIEHF")) to a wide range of NHS staff.

HFE can address many safety issues: it offers validated tools for modelling, re-designing and testing systems. While some of these require expert professional input, many are usable for less experienced

[22] See *http://apps.who.int/medicinedocs/en/d/Js7919e/7.10.3.html#Js7919e.7.10.3* [accessed 17 January 2018].

[23] See *https://www.chemistanddruggist.co.uk/news/lawyer-pharmacists-sentencing-shocking-and-wrong* [accessed 17 January 2018].

[24] H. Vosper and S. Hignett, "A review of Human Factors and patient safety education in pharmacy curricula: a UK undergraduate perspective with lessons for pharmacy education" [2017] *American Journal of Pharmacy Education* at *http://www.ajpe.org/doi/pdf/10.5688/ajpe6184* [accessed 17 January 2018].

[25] I. Seccombe, "Sickness Absence and Health at Work in the NHS" [1995] *Health Manpower Management* 21 (5): 6–11.

[26] P. Hilliar, "The DHSS Ergonomics Data Bank and the Design of Spaces in Hospitals" [1981] *Applied Ergonomics* 12 (4): 209–216.

[27] L. M. Straker, "Work-Associated Back Problems: Collaborative Solutions" [1990] *Occupational Medicine* 40: 75–79.

[28] S. Hignett, "Embedding Ergonomics in Hospital Culture: Top-down and Bottom-up Strategies" [2001] *Applied Ergonomics* 32:61–69.

[29] National Quality Board, "*Human Factors in Healthcare. A Concordat* (2013) at *http://www.england.nhs.uk/wp-content/uploads/2013/11/nqb-hum-factconcord.pdf*.

personnel.[30] Furthermore there are tools which allow staff to explore the "normal" working environment, allowing a Safety-II approach to be used to underpin risk management. The focus on the working environment, rather than the individual system actors, makes it much more likely that staff will feel safe in offering information that is useful to the organisation in terms of delivering safe and effective practice, including appropriate disclosure, making it less likely that legal action will be seen as a reasonable route to take.

[30] H. Vosper, S. Hignett and P. Bowie, "Twelve tips for embedding Human Factors and Ergonomics principles in healthcare education" [2017] *Medical Teacher* at *http://www.tandfonline.com/doi/full/10.1080/0142159X.2017.1387240* [accessed 17 January 2018].