Patient safety learning for healthcare improvement: considering the "system context" in medico-legal cases?

Paul Bowie[1-3], Alistair Ross[1], Thomas Purchase[4], Duncan McNab[1], Helen Hughes[5], Lauren Donovan[4] and Andrew Carson-Stevens[4]

[1]NHS Education for Scotland, Edinburgh, UK
[2]School of Health, Science and Wellbeing, Staffordshire University, Stafford, UK
[3]School of Health and Wellbeing, University of Glasgow, Glasgow, UK
[4]Division of Population Medicine, School of Medicine, University of Cardiff, Cardiff, UK
[5]Patient Safety Learning, https://www.patientsafetylearning.org/

Contact Details:

Prof Paul Bowie
Programme Director
NHS Education for Scotland
2 Central Quay
Glasgow, UK
G3 8BW
Email: paul.bowie@nhs.scot

SUMMARY

Patient safety incidents occur across all healthcare settings worldwide. Patients, families and carers can be physically and psychologically traumatised and often experience additional and prolonged harms due to lack of apology, openness and transparency. Healthcare professionals can also be emotionally impacted and subject to embarrassment, guilt, complaints, regulatory investigations and medico-legal action. Despite significant healthcare policy and professional attention, evidence of related learning and successful risk reductions at all levels are severely limited.

In this article, rather than focussing on the individual 'failings' of professionals, we take a Human Factors systems perspective in explaining how and why highly complex systems generally fail. We introduce a series of Systems Thinking principles for potentially guiding more meaningful discussions and learning from when things go wrong in highly complex sociotechnical systems, such as much of healthcare. We suggest to the medico-legal community whether a debate is needed around the need for judiciary, expert witnesses, regulators and legal professionals to be better informed in the Human Factors 'systems approach' to patient safety investigations as part of the medico-legal process.

Introduction

Published evidence suggests that harm arising from patient safety incidents is experienced by over 10% of patients across a range of medical care settings, with 50% estimated to be 'preventable' [1]. In general medical practice, specifically, it is reported that between 2-3% of consultations may result in a safety incident, with 1 in 25 of those incidents resulting in severe harm [2]. Given over 320 million such consultations occur annually in the United Kingdom (UK), this is undeniably a serious public health issue which places a substantive burden on already stretched national health services.

Although clinicians and healthcare organisations have a professional and statutory duty of candour toward their patients, families and carers, requiring them to be honest when care has gone wrong and openly disclosing safety incidents [3], patients subject to such events in the hospital setting report a lack of openness and support from clinicians and health services [4]. Where patients pursue claims of medical malpractice litigation, it is well-documented that the process is protracted, stressful and unpredictable [5], having a significant psychological impact on patients, families and carers [6]. This prompted the UK Government in 2021 to announce a review of medical negligence with a view to replace it with an alternative system [6].

Crucially, the current litigation process is misaligned with patients' needs following a healthcare-related harm, with patients (plaintiffs) often having several motives for bringing a negligence claim beyond that of financial compensation, including seeking an explanation, an apology and ensuring the events do not recur [7]. Claimant advice from NHS Resolution (the operating name for the NHS Litigation Authority) clearly states that such aims will not be resolved through this medico-legal process [8].

In the midst of this, the medical practitioners (so-called 'second victims' [9]) involved in the care of patients report feeling powerless, emotionally distressed and unsupported during the complaints process, with fear of the consequences and potential medical litigation [10]. There are repeated observations that such processes are embedded in a 'blame culture' which can lead to defensive practice and exacerbate any lack of transparency, to the detriment of safety improvement efforts [10-11].

In this article, we will provide a modern Human Factors (Box 1) and safety science [12] take for the medico-legal community on how and why complex healthcare systems generally fail. Further, we highlight how some healthcare bodies and organisations are finally recognising the need to move to 'systems thinking' as a concept and method for more meaningful learning from adverse events, despite this first being proposed over two decades ago [13]. If this is the expectation and way forward for patient safety learning in health systems, how does this 'fit' within the medico-legal context?

Box 1. About Human Factors

The International Ergonomics Association defines Human Factors (also known as Ergonomics) as: '*the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance.*' [14]

Why Complex Healthcare Systems Generally Fail

Everyday modern healthcare delivery takes place within safety-critical, highly complex systems [15]. In such systems there are many interacting components (e.g. patients, health professionals, tasks, work procedures, equipment, physical and social environments). These internal system components and their inter-relationships are also influenced by external factors (e.g. regulation, media, and disease outbreaks). Interactions, system constraints and often competing goals drive multiple system outcomes, wanted and unwanted alike; discrete events like patient safety incidents are properties of system complexity (we say 'emergent') and thus are notoriously difficult to predict and/or control. [16]

Acknowledging this context when attempting to explain 'scientifically' how and why serious patient safety incidents, resulting in death and severe disability arise, can seem improbable, perhaps disingenuous, and even cruelly outrageous to some. Either because people 'fail to understand' the complexity of events or because the facts of systems may seem to be absolving professional and organisational responsibility for avoidable harm to patients. This is especially so when compared with the completely misconceived and unattainable 'zero tolerance' culture or 'culture of perfection' whereby healthcare professionals are held accountable for any observed deviation from perfect care. [17]

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The modern safety science position, running contrary to the 'perfection model', is likely at odds with many of the assumptions and approaches embedded within the medicolegal and broader judicial systems which are essentially adversarial (and need to assign, or otherwise, fault, blame, culpability and liability - whether personal or organisational). This search for attributable cause is highly problematic; the following propositions are upheld by almost all safety scientists and professional ergonomists working in healthcare:

- Modern healthcare is arguably the most complex, dynamic work endeavour that has ever existed, and requires considerable human expertise to function effectively and safely;

- Patient safety is an *emergent* property of healthcare systems – event histories are seldom, if ever, causal, that is reliant upon single actions, technical faults, or isolated processes. Indeed, they most often cross professional and organisational boundaries whereby no single function 'owns' responsibility;

- Work systems are unavoidably hazardous (there are elements and processes introducing risk that cannot ever be fully eliminated) requiring by necessity the creation of multiple defences. Many of these are not well-designed, evolve over time, vary in applicability depending on system conditions, and require dynamic adjustment by staff to be in any way effective;

- When unwanted outcomes inevitably occur (in technical system terms we call these 'normal'[18]) they are predominantly underpinned by multiple proximal, intermediate and distal factors from across the healthcare system. Further, adaptive actions that are necessary to deal with variable inputs, capacity issues and multiple concurrent goals are often observed in both events and in safe care ('non-events'). For example, consulting for back pain over the telephone to free up time for examination of high risk patients, which turns out later to lead to a delayed diagnosis of something serious;

- Humans are the most flexible element of complex socio-technical systems, although some tasks and areas of work are more controlled and prescribed than others (generally, medical professionals legitimately practice with more autonomy, accept the need to take calculated risks in the best interests of patients, and are less reliant on checklists and standard protocols than nurses).

Often, there are (and need to be) 'multiple paths to success' in dynamic environments. This positive variation, sometimes referred to as positive deviance, comes with some risks but is absolutely vital for care to proceed at all. It is problematic that with hindsight, after something has gone wrong, actions are often held against unrealistic demands, unrealistic standards of optimal care for all, or evidence-based guidelines that fail to take into account intractable problems in their implementation into everyday practice [19]. Evidence suggests that this need to adapt to pressure, capacity issues and complexity is increasing [20], but this is yet to be reflected in examination of harm events, with the importance of context being consistently underplayed.

Systems Thinking and Learning

We now posit and briefly describe the importance of 12 evidence-based Systems Thinking concepts that can be considered in support of more meaningful healthcare safety policy, learning and improvement. We advocate that the 12 principles, when considered together, can positively influence the mindset and practice of anyone at any level working in healthcare safety practice, education, and policy. We then consider the potential for conflict between the modern safety science approach to learning from patient safety incidents and the approach and goals of related medico-legal cases.

1. **Prioritise the Needs of all People Involved**
   - As previously discussed, the needs of patients following a healthcare-associated harm, in additional to potentially seeking financial compensation, are unlikely to be met through a process of medical litigation [6-7]. Over the last few decades, strides have been made in the right direction with the development of programmes aiming to foster a person-centred approach when handling patient safety events at an institutional level.
   - One such alternative model to the current adversarial medical litigation system in the United States is the Disclosure, Apology and Offer (DA&O) program, which emphasises honest communication with families, promotes transparency and strengthens links between liability systems and patient safety [21]. Similarly, communication-and-resolution programs (CRPS) encourage hospitals and insurers to

proactively meet patient needs, utilise harms investigations to improve patient safety and offer compensation, with patients reporting positive experiences of this approach [22]. These programmes help maintain a positive therapeutic relationship between patients and healthcare providers and better meet their additional aims.

- In a tertiary hospital in Singapore, a dispute resolution system successfully addressed both patient dissatisfaction and the provider's perspectives through a process of open disclosure and early engagement to resolve claims prior to legal action being required [23] (Lim 2022), reducing the need for medico-legal litigation.

- A further alternative is the Restorative Justice approach adopted in New Zealand in response to a high-profile surgical mesh scandal [24]. This involves hearing and responding to the stories of survivors of this event and applying a restorative approach to listen and understand the lived experiences of those affected by surgical mesh harm to inform reparative action and prevent future harm.

- For doctors and others, emotional support should also be a priority following involvement (direct and indirect) involvement in serious patient safety incidents. Physicians have suggested organisational procedures around such events and complaints should be more transparent and time-limited, with additional staff support provided throughout [10].

2. **Avoid Inappropriately Apportioning Blame and Liability**

- Direct and indirect blaming are a well-established problem in healthcare organisations, and efforts to learn from and prevent patient safety incidents are hampered directly by this issue [25]. Learning should be holistically focused on improving care in the round, that is optimising the system from which the event emerged- not solely on the actions or inactions ('human errors') of people directly or indirectly involved. There is a fundamental attribution bias [26], observed over many decades, towards 'human action causes' even when taken in the most difficult of circumstances. This argument is notwithstanding clinical negligence or similar egregious behaviours which do exist and should obviously be reported and dealt with promptly using the appropriate organisational, regulatory or criminal authorities. These are actually the expectations that prove the rule - the great

majority of safety incidents can largely be understood only by considering complex care needs, processes and outcomes, rather than through trying to identify who the 'bad actors' are;

- It is basically unscientific to say 'error' causes patient safety incidents. Where events occur, errors can often be observed as precursors (error given event). But this probability is not transposable to observing the event given the error. The association is a function of both. Those who study everyday work (non-events) observe errors (and 'violations', or workarounds) all the time. It is actually a hallmark of good organisations that they detect and manage this variability without events and harm occurring (this refers to the area of complex systems theory around organisational resilience or 'Safety-II' [27]). The fact that there are some actions which in hindsight might be evidence of less-than-optimal care should be the start of the learning response and system improvement process, not the end point. A good systems analysis will often illuminate multiple actions that create safety through everyday adaptive performance because of, for example, the sub-optimal design, resourcing issues and conflicting goals that are inherent modern care delivery.

3. Safety is a Shared Responsibility of all Systems Actors

- Patient safety incidents are impacted by the decisions and actions of everyone across the care system [28]. Healthcare safety in general and safety incidents specifically are a shared responsibility of all 'system actors' from those at the sharp-~~epnd~~end of practice to managers, leaders, executives, board members, and policymakers and all the way up to elected politicians. Too often, however, is it those at the sharp-end who bear most, or all of the responsibility, for 'fixing problems' but without the full power, influence or resource necessary to support their endeavours. A counter argument is that system actors have a shared but not equal responsibility e.g. those in leadership positions (whether organisational, system or political) have more authority and therefore more responsibility for failures to act. Regardless, all people at all levels have their own roles to play in supporting learning and improvement in general, as well as when specific incidents or groups of similar incidents are highlighted.

4. **Safety Incidents are Influenced by Multiple Interacting Systemic Factors**

- Patient safety issues in highly complex care systems are the result of multiple, interacting contributory factors from across the system [29]. This thinking is the cornerstone of modern safety science and forms the basis of both the human factors and the systems approach to understanding complex safety issues.

- Drivers for important health and care outcomes such as patient safety or workforce wellbeing are distributed throughout systems. Improvement is therefore necessarily dependent on consideration of interactions, for example, where implementation of a device, procedure or training programme in one area may have unintended consequences elsewhere (or at a different time point).

- This modern way of thinking about highly complex system interactions and related outcomes often challenges and conflicts with, for example, the central risk management and clinical governance ideas of 'root cause' and 'root cause analysis' [30-31]. These are reductive 'find and fix' solutions that were adopted into health care after arising in relation to highly specified and controlled manufacturing processes, where it is more possible to isolate component failures as a means to optimise outputs.

5. **Non-linearity has profound implications for risk and safety**

- Non-linearity means predicting single/discrete events or incidents is very difficult if not impossible. Highly safety-aware organisations deal in patterns and look at safety, efficiency, quality, satisfaction and wellbeing as intertwined. Care should be taken to see events as predicable after-the-fact. If we really want to avoid similar incidents in future (i.e. have risk management and prevention goals), then at very least, all the outcomes that were achieved (or otherwise) in a shift or episode of care, including for all patients who received good care, should be part of the description of any given 'incident'.

6. **It's 'Up and Out' not 'Down and In'**

- Whilst it is difficult in resource terms, there is a consistent failure in any event review, investigation or management process [32] to consider the wider system

context and external environment (e.g. factors of policy, funding, procurement, politics). System latencies and defences are inextricably linked to influences, that may take time to impact at the front line, but include regulation, commissioning and funding, technological advances and procurement, demographic and epidemiological changes; educational provision, etc. We can only learn meaningfully about quality and safety issues if we look at performance influencing factors over, above and around the staff involved in the care – and over a sufficient period of time.

7. **Seek Multiple Perspectives**

- Recognise that different people, in different roles, with different information and goals, will have different perspectives on a given situation. In seeking these multiple perspectives [29], when warranted, aim to explore the experiences and views of all people (e.g. clinical, administrative, ancillary, managerial, staff, patients and carers) who work within the system of specific interest (e.g. test results management processes). This is important to better understand the functioning of the work system and change implementation issues when analysing previous safety occurrences, designing and applying change ideas, and then monitoring and evaluating the change(s).

8. **Consider both the Situation and the Context**

- When reflecting on events it is important to identify, explore and understand both the situation and contextual factors involved [34]:
  - *Situational factors* refer to the 'factual and discoverable' evidence of the circumstances at the time such as: the patient or client's condition or situation; the complexity of tasks involved and related time pressures; staffing levels and mix of staff ; individual, team or organisational roles, responsibilities and objectives; availability and functioning of tools and equipment; the design, relevance and usability of work procedures (e.g. protocols, guidelines or checklists); local cultural and other organisational issues (e.g. how things are done here; targets to be met); or relevant external factors (e.g. national policies or regulations).

- *Contextual factors* refer to the meaning given to a situation by those involved and the beliefs they hold about it e.g. what people believe was expected of them and what they believe to be true about the event in question. By its nature, defining context can involve speculation and trying to attribute meaning to people's intentions and behaviours – which is not available as factual evidence of motivations or behaviours

9. Explore Proxies for Human Work

- We should recognise that 'work-as-done' (WAD; i.e. the frontline reality) is often different to how 'work-is-imagined' (WAI) by mangers and policymakers and when it is enshrined in formal policies and procedures [29, 34]. The learning and improvement goal is to close the gap between WAD and WAI. There are further proxies such as 'work as disclosed' and 'wok as experienced'. With hindsight, when reviewing adverse events professional performance should be assessed against WAI rather than WAD – the logic being that it is virtually impossible for WAI to adequately reflect, specify or accurately represent all potential system conditions.

10. Examine Multiple Outcomes

- In healthcare, professionals continually must balance competing goals [29, 34]. One example of this is the Efficiency-Thoroughness-Trade-Off (ETTO). Professionals may want to be thorough (for example, a GP may wish to review the notes for every prescription they sign) but they need to be efficient (and sign prescriptions added to the patient record so that repeat issues are allowed) to ensure they have time for other clinical duties. Other trade-offs include focusing on long term versus short term outcomes, or on patient preference/ satisfaction versus financial outcomes etc.
- In resource-pressured situations, various high priority outcomes may covary and/or be negatively associated with each. The goal should be to achieve the best possible compound outcome for all patients or service users; this principle is similar to achieving risk levels that are 'as low as reasonably practicable'; systems should be optimised so that outcomes are balanced and are 'as positive as reasonable achievable'.

11. Consider Local Rationality

- As part of learning responses to safety incidents, it is critically important to explore people's 'Local Rationality' [34] i.e. their understanding at the time decisions were made including their work, personal and team goals and the system conditions the faced (e.g. demand, capacity, constraints and resource availability).

- It is a principle of Human Factors that only the people who do the job can fully understand its demands and constraints. Promote a restorative 'Just Culture' [24]. Do not seek to punish staff for actions that are in-keeping with their resources, experience and training. Instead understand what happened, support those involved and improve work systems by design to reduce the risk of recurrence.

- Keep in mind that issues perceived as 'negligence', 'incompetence' and similar are managed through other organisational processes.

12. Recommendations Should Largely Focus on Systemic Improvement

- In terms of meaningful patient safety learning, taking a Human Factors systems perspective acknowledges that a full spectrum of risk minimisation interventions should be considered to reduce the chance of harm events re-occurring. The temptation and practice in healthcare is typically to concentrate on frontline professionals when it comes to making improvement recommendations. Often these are weak, passive and vague and are focused at the person-level [30, 35-37]. For example: 'refresher training is clearly required'; 'the doctor needs to be more cautious next time'; 'the team should re-design the clinical protocol'; 'the theatre team need to use the checklist at all times'; and 'communication and teamworking should be improved'.

- The evidence is overwhelming that these types of low-level risk control interventions have very limited implementation success, and even where they do, they are not strong enough 'barriers' to reduce or prevent the risk of re-occurrence of unwanted outcomes.

- From the systems perspective, and in terms of having a greater risk improvement impact, the answer is much more likely to lie in targeting the 'design of equipment, interfaces and tasks, the environment within which work takes place, or the

management system and organisational arrangements that create the culture and conditions for work'.

Discussion

Blamism, Systems Thinking and Learning

Medico-legal proceedings are inherently directed at "human error", since the law of negligence is fault based and seeks redress for harms caused where a duty of care has breached [38]. Indeed, applying the *Bolam* test [39], the failure to meet the standard of an "*ordinary skilled man exercising and professing to have that special skill*" apportions blame to an individual.

From the Systems Thinking perspective, the person-level focus on 'human or medical error' is anti-systemic, alogical, self-defeating and contributes directly and indirectly to the ongoing counter-productive culture of 'blamism' that is deeply embedded in many areas of healthcare [9, 10, 12]. The frequent, incorrect use, misuse and abuse of the term 'human error' and related codes for action ('unsafe act', 'omission', 'rule violation' etc) are hugely problematic. While these terms are in general use in society, and particularly the media, as the quick and easy off-the-shelf (frequently incorrect) explanation for high-profile safety incidents, healthcare education, policy and practice around event learning has to do better.

The applicability of the *Bolam* test to medico-legal cases has been scrutinised on various fronts, notwithstanding its implied paternalism and purported deference to the medical sphere [40]. Furthermore, the *Bolam* test is much more easily utilised in a case of individual practice than in an abstract analysis of a complex system. However, this consequent preference towards the traditional individual tort type claim fails to adequately address systemic factors in adverse events [41]. Systems Thinking represents a radically different way of considering the nature of complex care system performance and so this may challenge our own assumptions and approaches about how we currently learn and improve – it may therefore take time to both learn about and embrace these concepts, but also to 'unlearn' how we think care problems and incidents come about and can be improved. Question: to what extent do the judiciary, expert witnesses and medico-legal profession

acknowledge the science of safety occurrences, taking into account in mitigation the complex contexts and situations, and inadequately designed work practices, technologies, built environments and policy regulations that significantly influence professional practices?

'Capturing learning' and 'sharing learning' are terms and agreed goals that are widely used and promoted by multiple stakeholders in the global patient safety domain. In the medico-legal world improving patient safety through sharing learning is also viewed as a key objective. But what do we mean by 'learning' in this context? Yes, we can 'learn' about 'measurement and quantification' of incident types, including medico-legal cases, and the development of related taxonomies. We can learn from the quality of related investigations and the effectiveness or otherwise of their recommendations for improvement in healthcare organisations and public inquiries. We can also argue that all stakeholder groups, including the medico-legal community, could be drawing on the growing number of academically rigorous research studies of patient safety incidents to get a handle on the frequency, burden and availability of healthcare-associated harm.

However, an agreed definition and shared understanding appear to elude us all in the healthcare policy, practice and educational landscapes, as well as in the medico-legal domain. How can we monitor and provide tangible evidence of demonstrable learning to enhance patient safety and the sharing of related outputs when it is unclear to most what this entails? Additionally, expectations around how society expects healthcare organisations to learn and improve from specific well-known 'wicked problems' [42] are arguably unrealistic and need to be reframed to adequately recognise the sheer complexity at play. If we focus on four common, and randomly chosen examples of such recurring problems:

1. Patient falls;
2. Suicides in healthcare facilities;
3. Medication incidents;
4. Misdiagnoses leading to the death of patients

The expectation is that organisations identify, review, learn and make recommendations for improvement to 'solve' these hugely complex issues. But these issues are regularly experienced in all modern healthcare systems worldwide and have been for decades. How can we expect a single healthcare organisation with very limited workforce capability in the evaluation and (re-)design of highly complex, interacting work systems to resolve this issue in any meaningful way given the lack of purposeful progress nationally and globally? As a comparison, this is directly equivalent to expecting the local district general hospital to innovate a novel treatment for a highly complex clinical condition affecting patients worldwide – this would typically involve millions of pounds in research grant funding and multi-national clinical trials over numerous years before regulatory approval for the intervention that, even then, is unlikely to fully benefit all afflicted patients. A key question here is: to what extent is this type of situational context known or acknowledged both as part of the medico-legal process and in healthcare policy circles?

Conclusion

It is widely acknowledged in modern safety science that things going wrong in highly complex healthcare systems is 'technically normal' [18], however unpalatable that may seem to many. Arriving at a conclusive understanding of how and why a serious patient safety incident has occurred in these types of systems is a 'social construction' i.e. a consensus on what happened and why that is reached by those undertaking the review or investigation, rather than a fully factual 'truth' [43].

The journey to this destination largely involves dealing with the collection, and analysis of complex, sometimes contradictory, (often) qualitative data and therefore the subjective interpretation of this information as 'evidence of causality' is potentially problematic. This can lead to individuals being held 'accountable' through the medico-legal route for the imperfections of healthcare system designs and the 'unknowable unknowns' that are emergent characteristics of such complex systems. The question remains, therefore, in terms of more meaningful patient safety learning and accountability, and justice for all concerned: should we be considering the 'system context' in medico-legal cases? And if we do, how might we approach this? What legislative and procedural changes would we need?

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