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Safety signals and near misses: exposing the design failures we can prevent

Joshua Clark ,[1] Oren Guttman,[2] Josje Kok[3]

[1]Institute for Healthcare Improvement, Boston, Massachusetts, USA
[2]Thomas Jefferson University, Philadelphia, Pennsylvania, USA
[3]Erasmus Universiteit Rotterdam Erasmus School of Health Policy and Management, Rotterdam, ZH, Netherlands

Correspondence to
Joshua Clark; jclark@ihi.org

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INTRODUCTION: HEALTHCARE MUST GET SERIOUS ABOUT PROACTIVE SYSTEM-LEVEL SAFETY

Healthcare continues to rely primarily on reactive safety—responding after harm occurs—rather than proactively identifying and addressing system weaknesses upstream. The purpose of this commentary is to argue that healthcare must treat near misses and early 'safety signals' as essential system-level intelligence and must build the infrastructure, processes and culture to learn from them at scale. We define proactive safety as the systematic identification, analysis and mitigation of risks before harm occurs, an approach widely used in other high-reliability industries but still underdeveloped in healthcare. We use the term 'safety signal' to refer to any observation—such as a near miss, workaround, recurrent interruption or unexpected system behaviour—that indicates a latent weakness in the system before patient harm occurs. Unlike traditional incident reports focused on actual harm, safety signals capture early warnings embedded in everyday clinical work. We acknowledge that definitions of a 'near miss' vary across healthcare systems and regulatory bodies, and in some systems, early-stage interceptions may already fall under the near-miss umbrella. Our use of 'safety-signal' is not meant as a replacement for existing terminology, but a conceptual extension intended to highlight earlier and often unrecognised indications of system vulnerability that are typically not captured or prioritised.

In high-reliability industries like commercial aviation, nuclear power and chemical manufacturing, near misses are treated with the gravity of actual failures. A plane that almost crashes, a valve that nearly ruptures or a reactor that just avoids meltdown—these are not minor incidents. They are urgent signals that trigger full investigations, systemic reviews and decisive action. There is much healthcare can learn from these industries, and at the same time, it is essential to recognise the contextual differences.[1] Most high-reliability sectors focus on standardisation and centralisation to help reduce uncertainty. By contrast, healthcare delivery is increasingly complex, and at times, chaotic, characterised by inherent variability and frequent unpredictability.[1] Patients differ, conditions and needs evolve and many processes cannot be completely standardised. Because of this intrinsic complexity, near misses in healthcare are especially valuable. They offer insights into potential failure points in an environment where outcomes are not easily controlled. Signalling, understanding and learning from them are therefore one of the most powerful ways to strengthen system resilience and keep our patients and clinicians safe.

Yet, too often, healthcare organisations normalise near misses, dismissing them as the cost of working in a complex—at times chaotic—domain, and citing a lack of resources to appropriately evaluate them and take necessary action. Research shows that under-reporting is common, and clinicians often perceive near misses as routine or not worth reporting, despite their learning value.[2] Regulators and other supervisory bodies have reinforced this mindset by focusing narrowly on compliance and measurable harms, diverting attention and resources away from deeper, systemic analysis. This tacit acceptance must end. It reflects deep cultural, operational and regulatory failures to recognise near misses for what they truly are: early warnings of system design weaknesses and our clearest opportunities to improve care and prevent harm.

In this commentary, we therefore make the case that healthcare—and its regulation—must move beyond its longstanding reliance on harm-based, retrospective safety models and instead embrace proactive system-level safety. Doing so requires elevating near misses and safety signals as core sources of intelligence, creating the organisational structures needed to analyse them and designing feedback mechanisms capable of converting these insights into meaningful system improvement. In what follows, we outline why this shift is urgently needed, what currently impedes it and how healthcare organisations and regulators can begin building the foundations of a truly proactive safety culture.

NEAR MISSES AND MISSED OPPORTUNITIES

The groundbreaking 1999 Institute of Medicine report, *To Err Is Human*, shocked the public and the healthcare industry by revealing that as many as 98 000 people die each year in the USA due to preventable medical errors.[3] In the decades since, more comprehensive data and global studies suggest the true number may be significantly higher. Yet despite this reality, the pace of change has been glacial. Every day, patients around the world suffer preventable harm or death, and many of these events are not fully investigated, learnt from or acted upon.[4]

Healthcare, like other high-risk industries, is exposed to abundant early warning signs, but the ability to consistently act on these signals remains uneven, and regulatory expectations often do not fully reinforce proactive learning. Near misses and safety signals are everywhere. These signals are the system's way of alerting us to risks. When we fail to

capture and respond to these signals, the conditions that cause harm remain unchanged. Tragedy, then, is not an accident; it is an inevitability.

In aviation, near misses prompt fleet-wide reviews. In nuclear energy, anomalies trigger system-wide alerts. In healthcare? The response is hardly as robust, not in breadth, nor in depth of response. This is not for lack of intent: healthcare has made substantial efforts to build reporting systems, promote transparency and strengthen just culture principles. But the gap between aspiration and practical reality remains wide.

Many healthcare systems around the world already have incident reporting systems intended to capture adverse events. However, research consistently shows that these systems often struggle to foster meaningful learning and improvement at the local and broader organisational levels.[5–8] Barriers such as perceived lack of psychological safety, the time required to report and limited feedback to reporters reduce engagement and inhibit learning loops.

Some countries have begun strengthening these systems—for example, England's National Health Service (NHS) has recently introduced the national Learn From Patient Safety Events system and Patient Safety Incident Response Framework, which explicitly promote a 'just culture' and emphasise system-level learning. While promising, these approaches remain relatively new and are still evolving.[9]

To illustrate what is possible: the US Federal Aviation Administration's voluntary Aviation Safety Reporting Program encourages reporting, including near misses and harm. Pilots, traffic controllers, crew members and others can submit reports on issues like air traffic procedures, maintenance, near collisions and airport conditions. These reports, if filed within 10 days, do not lead to disciplinary actions. National Aeronautics and Space Administration (NASA) acts as an independent third party that receives and analyses submissions, ensuring the programme effectively enhances aviation safety.

In healthcare, by contrast, reporting is often fragmented, can result in punitive action and frequently fails to produce meaningful system change. Empirical studies support this: for example, a recent analysis of 300 incident investigations found that investigations disproportionately focused on individual contributors and delivered only weak or medium-strength recommendation.[10] Studies also show that clinicians may fear blame or negative consequences when reporting, even in systems that formally promote a 'just culture'.[11–15]

It is important to openly acknowledge that most harm in healthcare is not caused by bad or ill-willing clinicians, but by poorly designed—or entirely undesigned—systems that make the probability of failure more likely. Underscoring that harm is rarely caused with intent is its frequency—more than 50% of clinicians are involved in a serious adverse event in their career.[16] As healthcare continues to become more complex, understanding and organising for this complexity become even more important. If complexity is not acknowledged and addressed through smarter design and stronger feedback systems, clinicians will become more vulnerable to failures that are beyond their control.[11] If we want to prevent harm, we must treat near misses as the urgent design failures they are, and use them to fuel learning and system change and to improve the resilience of these complex systems.

THE NEAR-MISS PARADOX IN HEALTHCARE

Healthcare has long emphasised the importance of being a learning industry. We emphasise 'just culture' and psychological safety to foster openness and learning. We promote 'Good Catch' programmes. But in practice, the structures needed to act on those safety principles are non-existent, or ineffective at best. How often do Good Catch reports result in sustainable system optimisation? Reporting systems remain clunky, time consuming and frustrating for frontline clinicians. And even when events are reported, they often fall into a black hole, triaged without feedback, follow-up or systemic response.[17]

Research reveals that clinicians rarely see the results of their efforts to report improvement opportunities, and in practice, reporting often feels more performative than purposeful, leading to frustration and future disengagement with improving safety.[18] Healthcare systems around the world remain trapped in a reactive safety model, focused on harm that has already occurred, rather than on the insights these events produce, or on the (just as) critical evaluation of when things go right.[19]

In high-risk industries, identification of near misses leads to a blueprint for prevention. In healthcare, these opportunities often go unreported or sit buried in underused databases. That healthcare celebrates identifying near misses, but fails to operationalise the learning and necessary action, is the paradox that weakens trust and the overall culture of the organisation.

A NECESSARY REORIENTATION OF REGULATORY FOCUS

One of the most persistent barriers to proactive safety in healthcare is the traditional orientation of regulators and other supervisory and accreditation bodies towards lagging indicators—measures that focus only on visible harm after it occurs.[20 21] This narrow lens has shaped how safety is defined, measured and managed across healthcare systems.

Safety is still predominantly framed as the absence of an adverse outcome, be they serious reportable events, hospital-acquired conditions, or mortality and morbidity scores.[19] When harm occurs, the event is labelled 'serious', whereas near misses or safety signals—those early indicators that allow harm to be averted—are seen as less urgent, if acknowledged at all. As a result, healthcare organisations are compelled to direct their limited resources towards compliance and incident investigation, while ignoring the more abundant, actionable signals that lie upstream.[8]

A further consequence of a harm-centric regulatory paradigm is that it crowds out alternative forms of safety intelligence. Approaches such as Learning from Excellence and other positive-deviance methods seek to systematically capture episodes where care goes exceptionally well, revealing the micro-adjustments, adaptations and resilient performance that keep patients safe despite system pressures.[20 21] Emerging evidence suggests that these approaches can strengthen staff morale and engagement in safety work, yet their system-level impact on learning and improvement remains uncertain.[22] Importantly, their adoption is often constrained by regulatory expectations that privilege the measurable, the adverse and the attributable. In such environments, learning from success is treated as optional rather than essential, despite its potential to enrich proactive safety intelligence.

This framing and focus reinforce the outdated logic of 'measure and fix',[23] which assumes that safety is a stable end state, rather than a dynamic process of adaptation in a complex system, that is, a moving target.[24 25] With such a regulatory focus, the system gets a pass if an adverse event did not happen, even if it nearly did multiple times in 1 week. The current focus does not account for the realities of clinical practice, where outcomes are shaped not just by individual decisions but by interdependent

systems, operating under conditions of uncertainty, time pressure and resource constraints. In such environments, the same set of conditions can produce different outcomes (eg, harm or no harm) based on chance, timing or minor variations in workflow. As Hollnagel and others have shown, complex systems behave probabilistically, not deterministically.[19] Yet, healthcare regulations and safety oversight continue to see errors as isolated failures of vigilance, rather than reflections of broader design weaknesses.

Worse still, regulatory scrutiny still (too) often focuses on individual culpability, using accountability tools such as withdrawal of license to practice to sanction if something goes wrong.[11] This reinforces a culture of blame that discourages reporting and learning and leaves little room for systemic understanding or contextual nuance. Clinicians are expected to perform flawlessly, but without the feedback loops, time or system support necessary to sustainably improve care. Organisations, meanwhile, are rewarded for luck, not for robust design or early risk detection.

This outcome bias also has an opportunity cost. By prioritising what has already gone wrong, we divert attention from what could still go right, if we intervene in time or redesign. We miss the chance to study and redesign the weak points in our systems before they harm someone. We ignore the human-centred work of making risks visible, errors more detectable and interventions more timely.

For regulators to genuinely foster safer care at scale, they must move beyond their current role as post-crisis auditors and become proactive stewards of learning systems. Encouragingly, Leistikow and Bal have highlighted promising examples of health and care regulators beginning to take on this expanded role.[26] This shift requires elevating near misses and safety signals as core safety intelligence—not peripheral data. It also demands a deeper sensitivity to the complexities and realities of daily operations,[27] recognising that safety emerges from how care is delivered in real time, not just from compliance with policy.

Regulators are uniquely positioned for broad impact. Much like the nervous system of the body, they can create a form of networked intelligence: connecting signals from across organisations, identifying patterns that no single institution could detect and amplifying not only what goes wrong but also what goes exceptionally well. At the same time, they can advance patient safety by holding organisations accountable not only for adverse outcomes but also for missed opportunities to learn and improve. By championing this shift, regulators can help cultivate a safety culture that is not only more proactive and adaptive but also more resilient and responsive to the complexities of modern healthcare.

FROM NEAR MISSES TO SAFETY SIGNALS

Healthcare often defines a near miss as an event that reached the patient, or nearly did, but caused no harm. To truly move upstream, we must expand our lens further to include proactive safety insights before an error even approaches the patient. Building on our introduction of proactive safety, we distinguish near misses from the broader category of 'safety signals', which capture earlier and more subtle indications of system vulnerability.

A safety signal is a recognition and interception of a failure point or necessary workaround before the risk affects care. For example, if a patient receives the wrong blood type but is unharmed, that could, by some definitions, be classified as a near miss. But if the error is caught before the blood is administered, that is a safety signal—evidence of a latent design weakness that has not yet reached the patient.

Both should be reported, but safety signals represent the earliest actionable opportunities for system learning, offering critical information about our system—often made visible through human-centred design principles—about how to make error more detectable, and preventable. These moments occur daily. They are the clearest windows into where design fails and humans succeed, in spite of the system. They must be prioritised and celebrated with feedback loops that clearly demonstrate to staff the impact of sharing their critical insight.

Today, most 'Good Catch' programmes celebrate staff getting in the way of harm before it reaches the patient. Although some programmes leverage these insights for broader learning, many remain primarily recognition-focused, limiting their impact on system redesign. Make no mistake, that is truly the ultimate demonstration of professionalism and the act needs to be acknowledged as such. However, recognition alone is insufficient. When near misses are treated primarily as individual acts of vigilance rather than signals of underlying design weaknesses, opportunities for proactive system redesign are lost. In the same way we think about the health of populations, beyond just any one patient, we have to ask a hard question about that 'Good

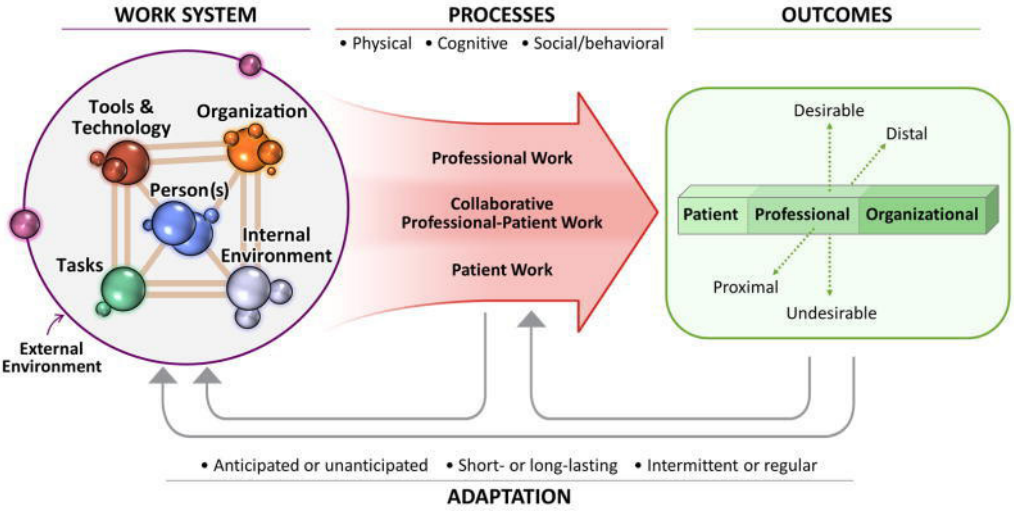

Figure 1 Systems Engineering Improving Patient Safety (SEIPS) model 2.0, designed by Holden and colleagues.[28]

Table 1 Recommendations for health systems

Health system strategy	Barriers/challenges	Enablers
Sourcing safety signals		
Set programme goals to encourage reporting of near misses or safety signals	► Culture of blame and fear of punitive consequences ► Perception that reporting does not lead to meaningful change	► Establish explicit just culture policies and leadership commitment ► Demonstrate clear link between reporting and system improvements
Implement or optimise reporting tools that are clinician-friendly, with an average entry time of less than 3 min	► Legacy systems with complex interfaces and lengthy entry requirements ► Poor integration with existing clinical workflows	► Apply human factors engineering to tool design ► Enable mobile access with auto-population from electronic health record (EHR)
Explore the use of artificial intelligence (AI) to reduce the time to report safety signals and to rapidly screen reports for systems improvement opportunities	► Implementation challenges and limited organisational capacity ► Concerns about algorithmic bias and insufficient evidence base	► Easily accessible and usable AI-enabled reporting platforms that ensure total time to report a safety signal or event is under 2 min ► Consider AI to help extract themes and trends from reports and unstructured clinical documentation
Analysing safety signals		
Ensure safety event triage teams have the capacity and tools to add value, not just process reports	► Report volume overwhelming triage capacity ► Lack of prioritisation criteria and decision-making authority	► Implement risk stratification algorithms for prioritisation ► Empower teams with resources, safety science training and clear roles for rapid triage and resolution of events
Establish cross-sectional teams, with capability to dissect work-systems and surface safety signals	► Safety teams have limited familiarity with systems engineering frameworks, like Systems Engineering Improving Patient Safety (SEIPS) ► Shortage of personnel trained in applied human factors ► Poor collaborative connection between clinical informatics and patient safety teams ► Production pressure limits ability to source 'work as done' solutions from Frontline teams	► Consider basic of understanding of human factors a core competency operational leaders ► Make it easy to leverage tools in triage and evaluation of events and safety signals to help identify systems issues.
Integrating safety signals		
Integrate safety signal analysis into regular daily clinical operations	► Organisational Structures silo quality and safety departments from integrating learnings into daily clinical operations ► Time constraints and lack of systems thinking skills	► Design learning into daily work via huddles and communications ► Support protected time for learning and cross-team analysis of systems issues
Track and evaluate solution creation	► Difficulty attributing improvements to specific reports ► Limited evaluation capacity and measurement expertise	► Recognise not only reporters but those who rapidly triaged and resolved the system issue ► Integrate recognition events and safety stories into communications and daily workflows
Feed-forward safety signals		
Establish clear feedback loops for reporters, leaders and system redesign teams to drive further learning and improvement cycles	► Fragmented communication channels and report volume overwhelming capacity ► Competing priorities that deprioritise feedback mechanisms	► Automate issue tracking and create tiered feedback protocols that close the loop across all levels ► Leverage daily huddles and standard feedback cadences to surface risks, celebrate fixes, and escalate issues quickly to problem solvers.
Celebrate improvements driven by reported events	► Difficult to coordinate celebratory events with Senior Leadership and staff who reported ► Staff availability to be celebrated (ie, production pressure) ► Lack of meeting infrastructure to celebrate staff across hospitals for 'system level improvement work'	► Recognise not only reporters but those who rapidly triaged and resolved the system issue ► Integrate recognition events and safety stories into communications and daily workflows

Catch'—namely, why did our system require a human to prevent that harm? What vulnerabilities enable the error pathway, and how might we redesign the process to surface and address safety signals earlier? It takes courage for leaders to ask those questions, but if we do, we can improve our systems and lower the probability of harm for many more patients in the future.

Table 2 Recommendations for regulatory organisations

Regulatory strategy	Barriers/challenges	Enablers
Expand oversight from a focus on lagging harm metrics to leading indicators, system-level metrics and narrative accounts of safety performance	► Preference for quantitative, easily auditable metrics ► Possible difficulty comparing across organisations	► Require reporting of proactive safety data as well as lessons learnt ► Develop guidance for different forms of reporting
Require organisations to demonstrate both harm prevention and harm anticipation	► Variable maturity of safety infrastructures across healthcare organisations ► Resistance to perceived 'new administrative burden'	► Embed proactive safety expectations into accreditation standards/inspection visits ► Provide clear guidance and tools for assessing everyday clinical practices ('work-as-done')
Incentivise and monitor proactive safety infrastructure and learning systems, to support continuous and proactive improvement	► Resource constraints and uneven adoption ► Difficulty verifying capability rather than paperwork	► Build regulator–academic partnerships ► Train inspectors in systems thinking and human factors to ensure evaluations reflect modern science
Convene cross-sector collaboration to bring safety science and systems thinking into healthcare and regulatory practices at scale	► Historically siloed safety efforts across systems and sectors ► Limited neutral convening bodies	► Establish multi-institution learning networks ► Promote pooled, (anonymised) data-sharing to reveal and learn from system patterns

A NEW STANDARD FOR PROACTIVE SAFETY

A proactive approach to manifesting safety does not happen without intentionality and design. It requires an infrastructure for doing clinical analysis and improvement work, starting with committed executive and senior leadership who partner and cross traditional organisational lines to collaborate (ie, digital/technology, clinical operations, quality and safety teams). As we shift towards true systems thinking, we must also shift how we measure successful system design.

One method that can help us frame our thinking about systems is the SEIPS model, or the Systems Engineering Improving Patient Safety model (figure 1).[28] This model looks holistically at the system as a series of not just contributors in isolation, but as a series of interactions that support a fuller picture of the complexity in human-centred design work. This model can be designed into the triage process for reported issues to help rapidly identify systems issues that should be prioritised for organisational follow-up and action. For example, rather than categorising an intercepted medication error as a 'staff lapse', SEIPS would prompt examination of interacting work system elements such as task complexity, technology usability, environmental distractions and staffing patterns.[28]

We propose a bold new standard: every health system should establish a formal programme to promote reporting and evaluation of near misses or safety signals. Not to inflate numbers, but to shift focus to learning early and often. These reported insights must lead to actionable design moments in healthcare, led by cross-sectional teams with capability and capacity to understand the work as performed by frontline staff and design solutions that are actionable and sustainable. System-level fixes should be prioritised, tracked, evaluated, celebrated and, perhaps most critically, shared. The most reliable health systems should be known not for their absence of harm, but for their abundance of learning.

In aviation, a near collision receives the same scrutiny as a crash. In nuclear energy, a failed warning sensor is treated as seriously as an actual alarm. In both, systems—not individuals—are the subject of investigation.

CALL TO ACTION: OPERATIONALISE PROACTIVE SAFETY NOW

We have actionable data. We have the tools and technology. Now we have an opportunity to come together with a shared commitment to move from reactive responses to proactive system design.

Healthcare has invested heavily in improving how organisations respond to serious safety events, from root cause analysis to Swarm huddles to comprehensive investigation protocols. While these advances represent important progress, we lack comparable focus on continuously evaluating systems and proactively designing them to mitigate harm before it occurs. Near-miss reports receive minimal follow-through. Safety signals identified by frontline staff languish unaddressed. Opportunities to learn from excellence go uncaptured.

If we are serious about achieving truly reliable and safe patient-centred care delivery, our industry needs a fundamental shift in focus from reactive to proactive. This shift starts by recognising safety signals, near misses and proactive safety reports, not as background noise, but as invaluable insights guiding us towards safer, more resilient healthcare practices.

In light of this opportunity, we have provided practical guidance for health systems (table 1) and regulatory organisations (table 2). Each table identifies key barriers and enablers. Because regulatory expectations strongly shape what organisations prioritise, a sustained shift towards proactive safety will require that regulators value and legitimise these upstream signals—not only traditional lagging harm metrics but also the contextual narratives that reveal how work is actually done. Given substantial variation across healthcare environments and regulatory regimes, these recommendations serve as overarching strategic guidance rather than system-specific implementation steps.

We do not need more evidence that near misses and safety signals matter. We need the healthcare industry to start acting like they do. The time for proactive safety is now.

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ORCID iD

Joshua Clark https://orcid.org/0009-0005-9576-1834

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