Regulating Reliably: Building High-Reliability Regulators in Healthcare

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Regulation and regulators play a critical role in assuring the quality and safety of care, and undertake a range of influential activities. This includes setting appropriate standards of care; assessing and monitoring care actually being delivered within healthcare systems—often through intensive data collection and inspection; intervening when standards of care are suboptimal, with options ranging from supportive guidance to legal sanction; and, perhaps most fundamentally, determining whether organisations and practitioners can provide care in the first place, through licensing and registration. Healthcare organizations and practitioners are heavily scrutinised by an array of these external regulatory actors. In the English National Health Service (NHS), for instance, around 126 different oversight bodies have some role in assessing, monitoring and regulating patient safety.[1] Despite this—and indeed, likely in part due to this supervisory complexity[2]—disastrous care failures still happen with distressing regularity,[3,4] with healthcare regulators often identified as having missed or misunderstood the emerging signs of impending failure.[5] Moreover, regulators themselves can struggle to establish regulatory strategies, practices and cultures that enable effective regulation of increasingly complex and pressured health services,[6,7] leading to regulatory crises that threaten the legitimacy of, and trust in, the regulatory system itself.[8,9]

This situation poses an urgent set of questions. How can regulators, and the regulatory work that they do, be organized in ways that: enables close and attentive monitoring of the complex activities of delivering care; supports constructive, honest but appropriately challenging interactions with healthcare organizations and practitioners; and facilitates ongoing improvement and learning—both within healthcare organizations and regulators themselves? These are fundamental regulatory challenges, but they are similar to the safety and quality challenges faced within healthcare organizations themselves, and by organizations in many other safety-critical sectors.[10] They are also questions which have been engaged with by decades of organizational and social scientific research.

One of the most productive arenas of organizational research to engage with these questions has, over the past 40 years, explored the characteristics, systems and strategies that underpin organizational high-reliability in challenging settings, such as aircraft carrier flight decks.[11,12,13,14] These insights have been translated into studies of high-reliability organizing in healthcare,[15,16] and now inform the organizing principles of many leading approaches to quality and safety, including the US Joint Commission.[17] One useful synthesis of this work identifies a set of organizational and cultural characteristics that can underpin highly-reliable performance,[18,19] including a widespread preoccupation with failure, a heightened sensitivity to monitoring operational activities, a reluctance to simplify in the face of complexity, an enduring cultivation of and deference to expertise, and a deep commitment to organizational resilience (Box 1).

Box 1. Key characteristics of high-reliability organizing

Organizational and cultural characteristics of high-reliability organizing

The study of high-reliability organizations (HROs) was initiated in the 1980s and aimed to understand how organizations that operated in challenging, unforgiving and dynamic environments were able to maintain greater than expected levels of reliability.[11,13] These studies focused on settings such as aircraft carrier flight decks,[12] nuclear power plants[14] and air traffic control facilities.[23] Research into the organizational processes and cultural characteristics that underpin high-reliability organizing has developed over the past four decades, and a popular and widely applied framework developed by Weick and Sutcliffe[18,19] synthesises a set of foundational characteristics that underpin high-reliability organizing and has been popularised and applied in different settings, including healthcare. Some key aspects of these organizational and cultural characteristics can be summarised as follows:

- **Preoccupation with failure**
  Organizations foster a deep and widespread preoccupation with failure, in which people are encouraged and supported to notice and speak up about failures and mishaps, and these become the focus of more generalised efforts to understand and improve organizational systems and practices.

- **Sensitivity to operations**
  Organizations work to maintain a persistent sensitivity to operations, where people in all areas and at levels of the organization pay close attention to front line operational work, and work to build a clear and detailed picture of the status of those current activities and any problems that might be developing.

- **Reluctance to simplify**
  Organizations aim to foster a reluctance to simplify, in which people are encouraged to avoid simplistic answers to complex questions, to remain open novelty and surprise and to seek out divergent and diverse perspectives and viewpoints in an effort to maintain a detailed and nuanced picture of risk.

- **Deference to expertise**
  Organizations are structured to build deep expertise, and enable the most relevant knowledge to be brought to bear on a problem, encouraged by a widespread deference to expertise in which people defer to those with the greatest practical expertise and experience rather than those with the highest rank.

- **Commitment to resilience**
  Organizations aim to sustain a commitment to resilience by designing and maintaining organizational processes and systems that can identify, catch and bounce back from disruptions and failure and that can respond adaptively and flexibly to surprising, unexpected and unplanned events.

These characteristics of organizational high-reliability have been derived from—and are particularly relevant to—organizations that directly deliver and manage complex services, like hospitals or airlines. But they also resonate with the challenges faced by organizations that are responsible for regulating the delivery of complex services, too. Regulators may not be involved in the direct delivery of care services, but regulatory work involves engaging with, understanding, monitoring and intervening in these complex systems. And regulators are also, of course, organizations whose primary purpose is the systematic and reliable identification, analysis and management of risk.[20] Accordingly, models of organizational high-reliability offer a rich and expansive framework for exploring the creation of regulatory high-reliability, and provide insights into the organizing principles that may enable healthcare regulators to more effectively—and more reliably—govern the safety and quality of healthcare systems.

Towards principles of regulatory high-reliability

The core characteristics and practices of high-reliability organizing developed by Weick and Sutcliffe[18,19] can be elaborated and reoriented to reflect the supervisory challenges and oversight objectives of regulatory work, providing an initial set of organizing principles for regulatory high-reliability (Table 1). These principles illustrate the many ways that healthcare regulators might better support the attentive monitoring, constructive challenge and systemic improvement that is required to assure safety and quality across complex healthcare systems.

Preoccupation with risk

First, regulators need to develop a rigorous and sustained preoccupation with risk that is founded on a clear articulation and meticulous analysis of the adverse outcomes that regulators—and those they regulate—are seeking to avoid. High-reliability organizations develop sophisticated shared understandings[13] of the organizational outcomes they are continuously

Table 1. Principles and illustrative strategies and practices of regulatory high-reliability

Principles, strategies and practices of regulatory high-reliability	
Principles of regulatory high-reliability	**Illustrative strategies and practices**
1. Preoccupation with risk	a. *Define core risks of regulatory concern:* specify, describe and communicate the key risk outcomes and forms of harm that regulation is seeking to mitigate in each arena of healthcare. b. *Embed systemic risk analysis*: develop assessment and analysis processes that can build integrated and diagnostic pictures of risk, precursors and risk controls to target regulatory activity. c. *Organize collaborative inquiry around risk*: focus regulatory interactions, conversations and inquiry on exploring effectiveness of and capabilities for risk identification and management.
2. Sensitivity to practice	a. *Collect data on practical realities:* build data collection methods and prioritise sources of data that provide granular, close and detailed insight into the realities of organizing and delivery care. b. *Maintain close regulatory relationships:* establish structures and processes that enable regulators to build constructive relations and remain in close contact with those they are regulating. c. *Develop analytical methods that retain detail:* create analytical systems and methods that provide rich and detailed insight into the practical contexts of care organization and delivery.
3. Engaging with diversity	a. *Foster cultures of curiosity:* build shared practices, values and norms that encourage and seek out diverse viewpoints and experiences, and that value challenge, dissent and debate. b. *Create spaces to explore diverse perspectives*: establish organizational forums and structures that support and bring together divergent views, peripheral voices and diverse experiences. c. *Build methods to integrate diverse evidence*: develop processes and methods that acknowledge and synthesise diverse evidence and accommodate different forms of data and emerging signals.
4. Enabling of expertise	a. *Recognise and build specialist expertise*: create and support roles that develop specialist knowledge and expertise relevant to each aspect of the complex systems and practices being regulated. b. *Flexibly organize and apply expert knowledge*: institute processes and systems that enable the appropriate expertise to be identified, brought together and applied in each specific regulatory activity.

	c. *Nurture cultures that value expertise:* promote and enable expert collaboration and consultation, and build expert capabilities that align with knowledge and experience in the sectors being regulated.
5. Commitment to learning	a. *Enable constructively challenging conversations:* create the contexts and capabilities for conducting open, exploratory and learning-oriented conversations between regulators and regulated. b. *Synthesise and share practical insight*: provide system-wide synthesis and of practically-relevant insights into the risks, capabilities, strategies and opportunities across different sectors. c. *Continually examine and iterate regulatory processes*: develop and support competencies in, and systems for, continual reflection on and improvement of regulatory strategies, processes and practices.

working to avoid—and, importantly, the precursors and conditions that can lead to those outcomes,[18] and the risk controls that defend against them.[10,14,21] The terminology of risk is common in healthcare regulation, but is rarely translated into the structured and systematic exploration of specific risk outcomes, precursor events and risk controls that is a hallmark of high-reliability organizing. Healthcare regulators should define and focus on the risk outcomes that matter in each arena of care they regulate, and ensure that the people and organizations they regulate can effectively and consistently identify, understand, communicate, monitor and manage those risks.

Sensitivity to practice

Second, regulators need the capacity for close examination of and deep sensitivity to practice and the practical realities of care in the settings they regulate. A hallmark of high-reliability organizing is an intensive effort to pay close and relentless attention to the organizational front line, where the work gets done,[18] and avoid the broad abstractions, generalisations and summaries that can obscure those practical realities.[19,21,22] Regulators are often awash with data about those they regulate, but the more abstracted and summative this information, the less is revealed about the practical challenges, risks and capabilities in different areas of care. Diagnosing problems and supporting improvements necessarily requires nuanced and detailed understanding of how care is being organized and delivered in practice. Healthcare regulators

should privilege data collection and analysis methods that provide rich, granular and diagnostic insight into the practical realities of those they regulate.

Engaging with diversity

Third, regulators need to remain open to multiple perspectives and actively engage with diversity of experiences and evidence, to fully understand the quality and safety of care. A key characteristic of high-reliability organizing is a reluctance to rely on simplified or reductive explanations of complex phenomena,[18] and a commitment to seek out and engage with dissenting views, diverse experiences and divergent perspectives that may illuminate otherwise hidden issues.[13,14,21] Organizing and delivering care is an enormously complex endeavour, and regulators need to maintain an equally complex and multivocal narrative of care quality that acknowledges and integrates diverse experiences and data, including the qualitative insights from peripheral voices and professional intuitions that can contain the early—though often weak and fragile—signals of emerging risks. Healthcare regulators should seek out and synthesise diverse experiences and evidence by creating cultures that value dissent and challenge, spaces that accommodate a plurality of experience and evidence, and methods that encourage curiosity, openness and inquisitiveness.

Enabling of expertise

Fourth, regulators need to ensure that they draw extensively on and are consistently enabling of expertise and the array of specialist knowledge that is required to thoroughly understand healthcare systems and practices. One of the distinct markers of high-reliability organizing is a widespread but nuanced deference to expertise,[19] in which people with the greatest practical expertise and experience in an area are recognised, sought out and listened to—rather than simply deferring to those in positions of greatest authority.[14,22,23] A huge range of knowledge and expertise is needed to rigorously understand the quality and safety of care. This expertise comes

in many different forms spanning, for instance, from highly specialist clinical insight, to lived experience and expertise of patients, to expertise in safety management and quality improvement. Healthcare regulators should recognise and nurture all these forms of knowledge and expertise, and become adept at flexibly organizing, integrating and applying relevant expertise to each regulatory problem being addressed.

Commitment to learning

And fifth, regulators need to enact and demonstrate a deep commitment to learning, supporting both the learning efforts of those they regulate and within their own regulatory activities. High-reliability organizations commit considerable time and effort to orchestrating adaptive and resilient responses to unexpected events[19] and surprising disruptions.[18,22,24] Learning from moments of disruption and change—which encompasses both adverse incidents and innovative improvements—has long been central to healthcare quality and safety.[5,15] Regulators occupy a special place in healthcare, having both a wide view across the system and deep insights into specific arenas of practice, providing a unique vantage point to survey and steer the current landscape of learning opportunities, activities and challenges. Healthcare regulators should develop the organizational capabilities to encourage and support learning through open, constructive and challenging conversation; continuously synthesise and share the insights that the unique regulatory perspective affords; and enable learning in their own activities through ongoing reflection on regulatory practice and iterative tests of change.

Designing and organizing regulatory high-reliability

Regulation and regulators have critical roles to play in assuring the quality and safety of healthcare, and in maintaining public confidence and trust. Regulators occupy a uniquely privileged position, combining a wide-angle view across the system with deeply granular insights into specific places and practices. Our increasingly complex, innovative and pressured

healthcare systems need regulators with sophisticated and reliable capabilities to attentively monitor, constructively challenge and systemically improve the quality and safety of care. To achieve this—and to minimise the risks of future regulatory crises and failures—much more attention needs to be paid to how regulators themselves are organized, how regulatory activities are structured, and how regulatory cultures and practices are shaped and supported. The principles of regulatory high-reliability described here offer some well-established organizational foundations on which regulators might build.

References

1. Oikonomou E, Carthey J, Macrae C, Vincent C. Patient safety regulation in the NHS: Mapping the regulatory landscape in healthcare. *BMJ Open* 2019;9: e028663.
2. Vincent C, Carthey J, Oikonomou E, Macrae C. Redesigning safety regulation in the NHS. *BMJ* 2020;368: m760.
3. Kirkup B. Reading the Signals: Maternity and Neonatal Services in East Kent – The Report of the Independent Investigation. London: Controller of Her Majesty's Stationery Office, 2022.
4. Ockenden D. Findings, Conclusions and Essential Actions from the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust. London: Controller of Her Majesty's Stationery Office, 2022.
5. Macrae C. Early Warnings, Weak Signals and Learning from Healthcare Disasters. *BMJ Qual Saf* 2014;23(6):440–445.
6. Dash P. Review into the Operational Effectiveness of the Care Quality Commission: Full Report. London: Department of Health and Social Care, 2024.
7. Nursing and Midwifery Council. The Nursing and Midwifery Council: Independent Culture Review. London: NMC, 2024.
8. Hutter BM, Lloyd-Bostock S. Regulatory Crisis: Negotiating the Consequences of Risk, Disasters and Crises. Cambridge: Cambridge University Press, 2017.
9. Macrae C. Book review: "Regulatory Crisis: Negotiating the Consequences of Risk, Disasters and Crises". *Br J Sociol* 2019;70(4):1626–1628.
10. Macrae C. Close Calls: Managing Risk and Resilience in Airline Flight Safety. London: Palgrave Macmillan, 2014.
11. Roberts KH. Some characteristics of one type of high reliability organization. *Organ Sci* 1990;1(2):160–176.

12. Rochlin GI, La Porte TR, Roberts KH. The self designing high reliability organization: aircraft carrier flight operations at sea. *Nav War Coll Rev* 1987 Autumn;76–90.
13. Weick KE. Organizational culture and high reliability. *Calif Manage Rev* 1987;29:112–127.
14. Schulman P. The negotiated order of organizational reliability. *Adm Soc* 1993;25(3):353–372.
15. Pronovost PJ, Berenholtz, SM, Goeschel, CA et al. Creating high reliability in healthcare organizations. *Health Serv Res* 2006;41(4):1599–1617.
16. Vogus TJ, Iacobucci D. Creating highly reliable health care: how reliability-enhancing work practices affect patient safety in hospitals. *ILR Rev* 2016;69(4):911–938.
17. Chassin MR, Loeb JM. High-reliability health care: getting there from here. *Milbank Q* 2013;91(3):459–490.
18. Weick KE, Sutcliffe KM, Obstfeld D. Organizing for high reliability: process of collective mindfulness. In: Sutton RS, Staw BM (eds), Research in Organizational Behaviour. Vol 1. Stanford: Jai Press, 1999, pp. 81–123.
19. Weick KE, Sutcliffe KM. Managing the Unexpected: Assuring High Performance in an Age of Complexity. 1st ed. San Francisco: Jossey Bass, 2001.
20. Macrae C. Regulating Resilience? Regulatory Work in High-Risk Arenas. In: Hutter B (ed), Anticipating Risks and Organising Risk Regulation. Cambridge: Cambridge University Press, 2010, pp. 139-160.
21. Schulman PR. General attributes of safe organisations. *Qual Saf Health Care* 2004;13(Suppl II): ii39-ii44.
22. Weick KE, Roberts KH. Collective mind in organizations: heedful interrelating on flight decks. *Adm Sci Q* 1993;38:357–381.
23. Rochlin GI. Informal organizational networking as a crisis-avoidance strategy: US naval flight operations as a case study. *Ind Crisis Q* 1989;3(2):159–176.

24. Macrae C, Draycott T. Delivering high reliability in maternity care: in situ simulation as a source of organisational resilience. *Saf Sci* 2019;117:490–500.