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Reimagining healthcare regulation to enable improvement, learning, and safety

Amid growing pressures on health systems, Josje Kok and colleagues argue that healthcare regulation must evolve beyond compliance driven approaches

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Healthcare regulation refers to the formal oversight of healthcare practices and organisations through standards, monitoring, and accountability mechanisms.[1 2] Although often operating in the background, regulation shapes how care is organised, delivered, and accounted for.

Healthcare staff often experience regulation as intrusive and ineffective, interfering with important clinical care.[3 4] Indeed, when poorly aligned with clinical realities, regulatory influence can undermine learning and improvement, contributing to frustration and disengagement.[4] However, when better aligned, regulation can actively support improvement.[3 5]

The consequences of regulatory misalignment are especially urgent amid growing pressure on health systems, driven by workforce shortages, ageing populations, and rising demand for complex care. Clinicians and healthcare leaders are expected to ensure safe, compassionate, high quality care while navigating fragmented systems, uncertainty, and ongoing resource constraints.[8 9] In this context, regulatory approaches that are poorly attuned to everyday clinical realities risk compounding pressures rather than supporting safe and resilient care.

Historically, healthcare regulation has focused on safeguarding minimum standards of quality and safety. This compliance driven approach, centred on adherence to rules and standards, remains essential, particularly in dealing with serious failings or misconduct. However, public and political expectations have expanded. Governments increasingly expect regulators to not only enforce standards but also drive improvements, steward health systems, and maintain public trust.[10]

Yet regulation does not always achieve its aims. In some settings, compliance driven approaches result in formal adherence without meaningful gains in safety or quality, particularly as care becomes more complex and distributed.[11 12] This raises a central question: how can regulation safeguard standards while also enabling learning, improvement, and resilience?

Previous work has called for greater coordination and streamlined regulatory systems in healthcare.[4 13 14] Beyond such structural reform, we argue that regulation should become more learning oriented and responsive, explicitly recognising that regulatory impact depends not only on formal rules and structures but on how regulatory expectations are enacted in practice. This requires dialogue, shared learning, and attention to how work is actually done rather than how it is prescribed or assumed.

When regulation helps—and when it hinders

Healthcare regulators commonly aim to improve performance, ensure accountability, and foster public trust,[10] despite wide variation in authority, scope, and methods (box 1). Regulatory scrutiny can be time consuming and resource intensive, and it is often experienced as particularly burdensome when requirements seem disconnected from clinical realities. Providers often report increased administrative burden and reduced capacity for delivering care.[4 15] When frameworks are rigid or misaligned, regulation can have unintended effects, diverting attention towards measurable compliance tasks rather than meaningful improvement and encouraging the decoupling of policy and practice—when rules are followed in form but not in spirit.[12 16]

Box 1: How healthcare regulators vary in statutory authority, scope, and methods

Statutory authority

Some regulators have enforcement powers; others focus on guidance and improvement, depending on jurisdiction. Examples of those with enforcement powers include

- Professional registration bodies such as the UK General Medical Council
- Quality and safety regulators such as the Care Quality Commission (CQC) in England or Health and Youth Care Inspectorate in the Netherlands
- Healthcare delivery regulation through Centers for Medicare and Medicaid in the United States

Scope

Regulation can be specifically for hospitals, clinics, social care, mental health, occupational health, youth care, specific professional groups, technologies, medicines, etc or cover all health services and professionals

Methods

Regulators' actions range from supportive feedback to formal investigations and enforcement. For example:

- Licensing and accreditation (eg, medical councils, accreditation bodies)
- Setting standards and policies (eg, national or regional quality regulators)
- Conducting inspections and site visits
- Rating performance or issuing judgments
- Investigating complaints and safety incidents

- Enforcement actions, including fines, service restrictions or closures, disciplinary proceedings, or referral to prosecutorial authorities (jurisdiction dependent)
- Providing feedback, guidance, or reports

Unintended effects arise not simply from regulation itself, but from how regulatory activities and authority are enacted. Regulation shapes priorities, behaviour, and sense-making through the signals it sends, the interactions it structures, and the extent to which it enables feedback and adaptation. In this sense, regulation is inherently relational and dynamic[7 17]: its impact depends not only on what is regulated but on how regulatory expectations are communicated, interpreted, and adjusted.

For example, in the US the Joint Commission, the independent organisation that accredits healthcare facilities, introduced pain management standards—including framing pain as the "fifth vital sign"—to improve recognition and treatment. In practice, however, these standards operated as a strong performance driver, contributing to an overprescribing culture and unintended patient harm.[18] Limited feedback loops and insufficient mechanisms to detect emerging risks meant that unintended consequences were slow to be recognised and addressed, illustrating how regulatory signals enacted without adaptive monitoring can misfire (table 1).

Table 1 | Examples of positive and negative regulatory impact from similar regulatory tools depending on implementation design, incentive structures, and the presence of feedback, dialogue, and opportunities for learning

Example	Regulatory action	Impact observed	Mechanism/explanation
Dutch Health and Youth Care Inspectorate: patient or family involvement in adverse event investigations[19]	Mandated involvement of patients and next of kin in investigations	Increased involvement of patients and families across hospitals; shift from narrowly technical reviews towards more inclusive and transparent learning processes	The mandate legitimised experiential knowledge without introducing performance ranking or punitive incentives, enabling cultural change through relational engagement rather than compliance alone
England's Care Quality Commission: oral health in care homes[6]	Targeted inspections coupled with national reporting and collaboration with sector partners following widespread neglect	Marked improvements in oral health across inspected and non-inspected sites	Sustained national attention, public signalling of priority, and opportunities for local adaptation supported alignment between regulatory expectations and everyday care practices, rather than one-off performance pressure
US Joint Commission: pain standards[18]	Introduction of pain management standards emphasising systematic assessment and treatment	Contributed to overprescribing culture and unintended patient harm	Accreditation pressures that prioritised compliance over clinical outcome, simplified performance signals, and limited feedback mechanisms to detect emerging harms shaped clinician behaviour in counterproductive ways
Dutch Health and Youth Care Inspectorate: quality indicator for anastomotic leakage after colorectal surgery[5]	Public reporting of anastomotic leakage rates after surgery	Increase in stoma formation in one hospital; reduction in leakage achieved through unintended goal displacement	Indicator driven optimisation under reputational pressure, followed by recognition of unintended effects through biannual meetings between regulator and professional society, enabling indicator revision and showing the corrective role of feedback loops and structured dialogue

By contrast, regulation can support learning and improvement when authority is used to reframe expectations and enable reflection. For example, the Dutch Health and Youth Care Inspectorate mandated patient and family involvement in adverse event investigations around the mid-2010s (table 1). At the time, hospitals were reluctant to involve families, fearing blame, reputational damage, and legal repercussions. By explicitly legitimising participation, the inspectorate used its formal power to lower barriers, resulting in increased involvement and a shift from narrow technical reviews towards more transparent learning processes.[19] This reshaped relationships and expectations, creating conditions for learning while reframing what counted as a "good" investigation and whose knowledge mattered, without prescribing exact patient involvement.

The examples here highlight a central insight: regulatory impact depends less on the formal content of rules than on how regulatory expectations are translated into everyday practice. Similar regulatory tools generate different effects depending on implementation, design, incentive structures, and whether mechanisms for feedback and adaptation were in place. Studies of external assessment show that regulatory influence is mediated through factors such as what organisations focus on, how they interpret signals, and whether feedback and engagement are enabled, rather than enforcement alone.[7 20] Similarly, research on regulatory approaches to "just culture" shows that inspectors' communication, tone, and relational stance influence whether regulation is experienced as fair and constructive, or as punitive and disengaging.[21]

When regulatory standards focus primarily on "work as imagined," they risk misfiring in complex settings, constraining adaptive practice or encouraging superficial compliance. This is particularly problematic in healthcare because many dimensions of quality, such as person centredness, and safety culture cannot be captured through static benchmarks or indicators.[12 22] Conversely, when providers lack understanding of regulatory intent, requirements may be experienced as arbitrary or punitive, reinforcing disengagement and gaming behaviours.[16] Opportunities for dialogue and learning are then diminished.

Together, these dynamics point to the need for regulatory approaches that move beyond enforcement to include strengthening dialogue, shared learning and understanding of practice, and structured engagement among regulators, healthcare providers, patients, and carers.

Creating a more constructive regulatory environment

Amid growing systemic strain and uncertainty, regulation should evolve to foster learning and enable appropriate responses in

complex systems. Although regulators do not directly deliver improvement, regulatory actions inevitably shape improvement dynamics through the conditions they create, signals they send, and relationships they foster. Three interconnected, practice informed strategies can support a more constructive and collaborative regulatory environment: research and feedback loops, education for regulators and providers, and structured forums for engagement.

Regulation as a science: research and feedback loops

Regulatory practice should be evidence informed and open to scrutiny, much like clinical care. Because evidence is necessarily incomplete in complex systems, regulatory work involves ongoing sense-making and adaptation rather than the application of fixed rules.[22] A scientific approach therefore requires routine feedback loops that examine how regulatory activities—such as inspection frameworks and performance indicators—shape behaviour in practice, including unintended consequences.[23]

As the examples in table 1 show, structured monitoring and feedback can enable regulators to identify unintended responses to national indicators and adapt expectations through dialogue with professional groups.[5] Such feedback need not rely on new data infrastructures: inspection findings, provider responses and co-development activities, patient and carer input, and enforcement outcomes already constitute rich sources for evaluative learning. When used systematically, these feedback loops can support learning oriented regulation while maintaining accountability.

Some regulators already collaborate with researchers to examine and refine their methods, including ethnographic studies that have informed changes in inspection practice[24 25] and how next of kin are involved in post-incident practices.[26] However, such efforts are often project based and vulnerable to funding cuts. Embedding a scientific orientation requires both independent research and in-house evaluation. Arm's length research contributes to external credibility and to surfacing uncomfortable findings, while embedded learning structures increase the likelihood that insights are acted on promptly. The challenge is not to generate more evidence but to make inquiry, evaluation, and adaptation routine features of regulatory infrastructure.

Education for regulators and providers

Regulatory work is a distinct professional domain that requires specific competencies, particularly when regulatory roles involve relational and facilitative work.[7] Regulatory positions are often filled by people with clinical backgrounds, on the assumption that experience of care delivery equips them to regulate effectively. Clinical expertise is important but insufficient. Impactful regulation also requires familiarity with safety and improvement science,[27] regulatory principles, and the ability to analyse the relationship between what is 'work as imagined' and what happens in practice.[21]

Targeted education can strengthen regulatory consistency, fairness, and legitimacy, particularly in inspection, investigation, and engagement activities where judgment and discretion are central. Inspectors should be supported to develop skills in systems thinking,[27] learning oriented communication, and interpreting variation without defaulting to blame. Providers, in turn, should be supported to understand regulatory intent, including how standards are interpreted and how learning is expected to occur. For example, the Dutch Food and Consumer Product Safety Authority (NVWA) collaborates with the Faculty of Veterinary Medicine to offer an elective course in supervision for veterinary students, combining theory with practical insights into regulatory work.[28] Such initiatives help future professionals understand the logic of regulatory work.

Including patients and carers in educational initiatives can also promote shared language and appreciation of the dilemmas and lived realities of care delivery.

Structured forums for engagement

Because regulation is highly visible, politically sensitive, and consequential, regulators, providers, and patients need structured spaces for dialogue, reflection, and joint sense-making. Sustained system pressures make such forums increasingly important, particularly for tackling cross-cutting challenges such as workforce shortages, digitalisation, and the regulation of artificial intelligence.[29] Many of these pressures are shared across countries, creating opportunities for mutual learning and anticipatory sense-making. Well designed forums can support regulatory learning without weakening independence, by clarifying expectations, surfacing tensions, and informing how standards and priorities are interpreted in practice.

Some forums already operate in this way. For example, the Medical Council of New Zealand's consumer advisory group provides structured patient input that informs regulatory priorities and deliberations, helping to mediate professional, public, and political expectations and strengthen legitimacy.[30] International platforms such as the International Society for Quality in Health Care (ISQua) and the International Forum on Quality and Safety in Healthcare convene regulators, users, providers, and researchers around quality improvement and peer learning. Forums such as the International Regulator Conference and the Nordic Supervisory Conference provide spaces where regulators can share experiences among peers. Although such platforms do not determine regulatory decisions, they enable comparison, reflection, and diffusion of practice based insights across settings, supporting adaptive responses to common challenges.

Without such forums, regulatory learning remains fragmented and reactive. With them, regulation is better positioned to evolve in ways that are credible to the public, defensible to policymakers, and meaningful to those delivering care.

These proposals are not without constraints. Regulatory reform is shaped by political priorities, media scrutiny, public accountability, and resource pressures, all of which limit the scope for experimentation and deliberation. Regulators must balance openness with independence, learning with enforcement, and engagement with the need for timely and visible action. Importantly, our examples show that more learning oriented and relational practices are already being enacted within existing regulatory mandates and constraints. The challenge is therefore less about radical redesign than about consolidating, legitimising, and scaling practices that support learning and improvement while maintaining public trust. Sustained dialogue and collaboration between regulators, providers, and the public are essential to ensure regulation supports resilient, high quality care.

Key messages

- Healthcare regulation must evolve to support safe, resilient, and high quality care amid growing systemic pressures and complexity
- How regulators engage with clinicians, organisations, and the public directly shapes trust, professional morale, and quality of care
- Regulatory approaches should move beyond compliance driven models toward learning, reflection, and relationship centred improvement

- Effective regulation maintains accountability for serious failings while supporting learning and adaptive practice in everyday care
- Regulatory impact depends on context, collaboration, and responsive practices across health systems, and rigid approaches can produce unintended harms

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