

Resilience and regulation—antithesis or a smart combination for future healthcare service improvement?

Researchers and policymakers wonder if regulation and resilience can go together and be a smart combination for healthcare improvement. Briefly, regulation is often thought of as directives from above and resilience as the ability to withstand adversity through adaptation. Combining the two, we argue that “regulatory resilience” should play a key part in future solutions to handle the increasing system pressures. Based on insights from research on how resilience and different regulatory strategies intertwine, we suggest future directions [1–3]. We ask how regulators and external inspectors may design and enforce a regulatory regime and thereby contribute to resilience capacities of adaptation, anticipation, and learning in complex systems. Such a focus contradicts the classic assumption which sees regulation and resilience as distinctive concepts—or even in direct conflict. As resilience requires flexibility and adaptive capacity, it presupposes sufficient autonomy to make decisions [4]. Although different regulatory approaches are taken across the globe and co-exist within national systems, regulation is often perceived—and portrayed—as an instrument of prescription, seeking compliance. Yet, few studies have investigated, and fewer still contradicted, these assumptions.

What does regulation and resilience in healthcare entail?

Regulation is used by governments for behavioral modification and as a risk-controlling mechanism [1]. Varying strategies have emerged, depending on country and sector, ranging from deterrence to compliance-based strategies and from prescriptive to performance-based regulation. Here, we deal with that classic version of regulation referred to as performance-based regulation, including external inspection. We conceptualize resilience in healthcare as a capacity to adapt to challenges and changes at different system levels, to maintain high-quality care [5]. This means understanding how systems adjust their functioning prior to, during, or following events (changes, disturbances, and opportunities) and thereby sustain required operations under both expected and unexpected conditions [5, 6]. Key resilience mechanisms are the potentials of responding, monitoring, learning, and anticipating disruptions [6]. Even though recent findings [7] demonstrate contrasts in different countries’ compliance-based focus, for instance by the maximum variety in the regulatory systems of Norway and the USA (a more compliance-based against a less compliance-based system), there is a generic challenge in

the fact that regulation in practice often promotes top-down compliance to safety standards and procedures. Regulation as such echoes what the government expects from the regulatees, and it constitutes work-as-imagined—what regulators think regulatees should be doing.

Tradeoffs and workarounds meet regulatory demands

However, in complex systems, work as done will always differ from top-down expectations due to front-line performance variability, tradeoffs, and workarounds. This gap between expectations and reality often causes concern, illustrated by idealistic government policies and regulations which cannot be implemented in practice [2]. The coronavirus disease (COVID-19) pandemic did however demonstrate top-level government recognition of the value of decentralized decision-making. Studies elaborate how governments across the globe were “forced” to introduce and/or strengthen locally based adaptive activities and decision-making processes in their policies [8, 9]. The resilience potential of responding was illustrated in the ways the governments of New South Wales, Australia, and Ontario, Canada, “relaxed numerous pre-pandemic regulations,” for instance by waiving the waiting period for health insurance access [8]. The policy actions of the Norwegian government were shown to support system-wide resilience, by means of a top-down restructuring process of the entire health service in close cooperation with lower-level operationalization of the policies, in order to prevent, control, and treat infection [9]. We argue that the future in regulation and inspection should acknowledge that adaptations and deviations are very often sources of safety and the delivery of high-quality care [4, 10].

Regulatory pyramids and various approaches to regulation and resilience—fostering public trust

The pyramid construction in Fig. 1 is inspired by responsive regulation [11]. The idea is that regulators and inspectors can move up and down the pyramid’s strategies to meet their regulatory goals while being sensitive to front-line contextual characteristics. Laws, internal control or performance-based regulation, and self-regulation mechanisms are strategies with various degrees of details and compliance and enforcement options.

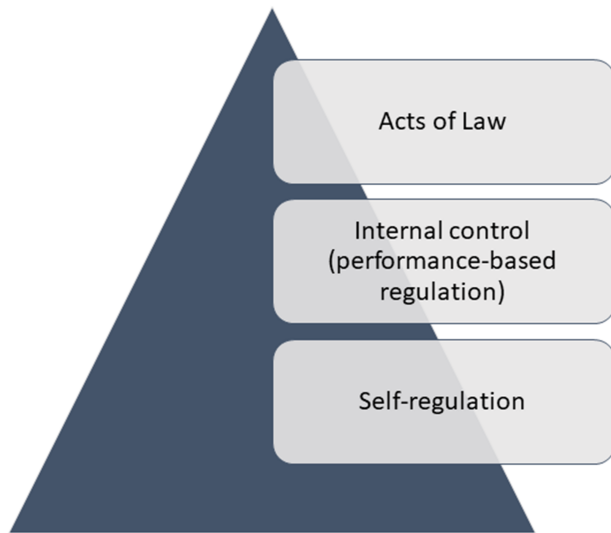


Figure 1 A simplified version of the pyramid of different regulatory strategies [1].

A literature review found that, contrary to commonly held views, regulation as part of a bureaucratization process does not necessarily hinder efficient safety management [12]. Elements of adaptation, anticipation, and learning may be cultivated in responsive regulation [12]. Self-regulatory approaches as promoted in responsive regulation may facilitate local interpretation, increase the levels of system responsibility, and reinforce incentives for more active front-line and local managerial involvement. Adapting regulation to local context leaves more room for attention to uncertainties and variations and improvisations if required [1, 3]. Healthcare organizations that demonstrate their safety system and involve stakeholders in decisions that affect them are important determinants of a proactive risk management approach in line with resilience thinking [2].

Important ingredients to make things work for both regulators and regulatees are trust and legitimacy. These cannot be underestimated. To illustrate the point: one of the explanations to how the Norwegian policy-level processes succeeded in providing lower levels with relevant adaptive capacity to cope with the pandemic were “distinctive features” of Norwegian society. A high level of trust by authorities in the Nordic model was seen as essential to foster system-wide adaptive capacity [9]. In an international context, where much of the healthcare system relies on collaborative funding, private, and insurance-based funding, the question of trust and legitimacy may look very differently. Yet, the large amount of funds invested in current regulation with little evidence of “returns” in improving healthcare could perhaps make governments reluctant to “give away” more autonomy to the regulatees.

On the other hand, in the Norwegian case, the ability to “regulate performance” during the pandemic may have been positively associated with the flexibility shown in the pyramid of different regulatory strategies. This can be taken further by developing a framework of “value driven regulation,” combining responsive regulation, risk-based regulation, smart regulation, and system-based regulation [13]. Such a sensible construction of a regulatory framework can be crucial to achieving a regulatory system that is invaluable

from a resilience perspective [1, 2]. Indeed, the ways regulatees, such as hospitals, nursing homes, or homecare, are expected to work and how they apply regulations are moving toward more system-oriented approaches [14]. We see this in the Norwegian system, where external inspectors are explicitly expected to apply regulation, inspection, and sanction directed at the managerial level of healthcare providers. Others have pointed to sufficient knowledge and competence as crucial factors to legitimacy and public trust in external inspectors’ conduct and decision-making [13, 15]. Moving ahead, policymakers in the patient safety and quality domain thus need to focus on the argument that regulatory work may increase its relevance if adaptive capacity is ensured across system levels.

Regulatory resilience—a key concept in future healthcare service improvement

Time- and resource-consuming regulatory compliance can compromise the ability of staff to be flexible. Compliance measures can thus be anti-resilient. Regulatory inspectors can struggle to balance enforcement with learning because written information from inspectors to regulatees hampers real knowledge exchange and obscures weak signals which might be telling them something important [16]. Part of ensuring public trust and legitimacy in regulatory interventions is to encourage involvement of regulatees, managers, healthcare professionals, patients, and next of kin. Norway involves stakeholders as co-regulators [17]. Although other regulatory systems have been sympathetic to different stakeholder views [17], meaningful stakeholder inclusion is often still lacking [2, 7]. And, ensuring a more meaningful and relevant evaluation process genuinely incorporating stakeholders may motivate health professionals to more fully engage in regulatory interventions to improve services [7, 18]. On that note, multilevel stakeholder involvement may be key in facilitating system resilience [2, 5, 17].

The overall message here is that regulators, inspectors, healthcare organizations, managers, healthcare professionals, patients, and families are sources of resilience, implying that the regulators need to offer incentives for collaborative involvement in regulatory design and implementation [1, 5, 19]. Bringing people together in reflexive spaces has great potential to foster reflections about current challenges and adaptations in daily work practices [19]. Based on the idea of regulatory resilience, we believe that regulators may contribute to creating better conditions for resilient performance in healthcare if they adapt that model rather than the high-level prescriptive model.

All in all, regulatory resilience can provide regulators and inspectors with new ideas for design and development of their regulatory regime in ways that may contribute to increasing the capacities of adaptation, anticipation, and learning. This new look at resilience and regulation can help overcome the rigidity of compliance regimes, which we know is impossible to achieve in complex adaptive healthcare systems. It may also add to the missing link between much of the current knowledge about regulation and “return” in quality improvement.

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Author contributions

S.W. received the invitation and discussed the idea of topic with D.G. S.W. contacted S.F. Ø., who made the first draft of the manuscript, in close collaboration with S.W. J.B. and D.G. made substantial contributions to the final manuscript.

Conflict of interest

Professor Braithwaite is ISQua President and an Academy member, Professor Siri Wiig is an Academy member, and Professor David Greenfield is an Academy member and in lead of the editorial project.

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Data availability

Not applicable.

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