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Investigating Hospital Supervision: A Case Study of Regulatory Inspectors' Roles as Potential Co-creators of Resilience

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Objectives: The aim of this study was to explore if, and in what ways, there has been changes in the supervisory approach toward Norwegian hospitals due to the implementation of a new management and quality improvement regulation (Regulation on Management and Quality Improvement in the Healthcare Services, hereinafter referred to as “Quality Improvement Regulation”). Moreover, we aimed to understand how inspectors’ work promotes or hampers resilience potentials of adaptive capacity and learning in hospitals.

Methods: The study design is a case study of implementation and impact of the Quality Improvement Regulation. We performed a document analysis, and conducted and analyzed 3 focus groups and 2 individual interviews with regulatory inspectors, recruited from 3 county governor offices who are responsible for implementation and supervision of the Quality Improvement Regulation in Norwegian regions.

Results: Data analysis resulted in 5 themes. Informants described no substantial change in their approach owing to the Quality Improvement Regulation. Regardless, data pointed to a development in their practices and expectations. Although the Norwegian Board of Health Supervision, at the national level, occasionally provides guidance, supervision is adapted to specific contexts and inspectors balance trade-offs. Informants expressed concern about the impact of supervision on hospital performance. Benefits and disadvantage with positive feedback from inspectors were debated. Inspectors could nurture learning by improving their follow-up and add more hospital self-assessment.

Conclusions: A nondetailed regulatory framework such as the Quality Improvement Regulation provides hospitals with room to maneuver, and self-assessment might reduce resource demands. The impact of supervision is scarce with an unfulfilled potential to learn from supervision. The Government could contribute to a shift in focus by instructing the county governors to actively reflect on and communicate positive experiences from, and smart adaptations in, hospital practice.

Key Words: adaptive capacities, learning potentials, regulation, supervision, hospitals, management

Abbreviations: NBHS = Norwegian Board of Health Supervision, CG = county governor, The Quality Improvement Regulation = regulation on management and quality improvement in the health care services.

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In this article, we address an empirical gap in the resilience literature¹ by exploring the link between resilience and supervision as a regulatory instrument in health care. We investigate the inspectors’ roles as potential co-creators of resilience in hospital context (Box 1).

Box 1 Resilience in Healthcare and its potentials^{2–4}

- Resilience is regarded as the ability of a system to be able to perform as needed under a variety of conditions.
- As health services often are carried out with a significant degree of uncertainty, flexibility is crucial.
- If an adverse event or disruption occurs, services are adapted and usually carried out with success.
- Resilience focuses on the reasons and preconditions for why things actual do work successfully and the mechanisms involved, hereby the potential to learn from experience and adapt to circumstances.
- The ability to adapt is considered as the capacity to modify behavior, response and activity. These processes are often based on previous experiences, which connects adaptation to the basic potential of learning. The potential to learn entails how the organization’s responses lead to success or non-effective outcomes. A “lesson learned” could for example be revision of a procedure or uptake and use of new innovative technology.

Resilience and Regulation

Despite several interventions and focus on patient safety culture and learning, health care still struggles to learn from adverse events and there is a lack of openness and sharing of positive outcomes and success, as well as the bad outcomes.^{2–3} Supervision as a regulatory instrument is an internationally known quality intervention.^{4,5} In Norway, these actions are administered and carried out by the Norwegian Board of Health Supervision (NBHS) at the national level and the county governors (CGs) at the regional level (Table 1). With regard to health care supervision, the reasonably new *Regulation on Management and Quality Improvement in the Healthcare Services*¹⁰ from 2017 (hereinafter referred to as the *Quality Improvement Regulation*) is considered one of the most important governmental tools implemented to support local quality and safety efforts in hospitals (Box 2). Its impact on the services performance is still unknown from all perspectives (inspectors, hospital managers, health care professionals).

TABLE 1. The Norwegian Supervisory Regime—Context, Purposes, Policy, and Practice^{2,6-9}

Context	<ul style="list-style-type: none"> • The NBHS and the county governors constitute the governmental bodies responsible for supervisory activities across Norway. • The NBHS is the superior, national public institution organized under the Ministry of Health and Care Services. • The county governors are responsible for carrying out policies provided by the national government, including implementation and supervision at the regional level of health care. • There are 11 county governor regions per January 1, 2019. • Each county governor’s office consists of 1 chief county medical officer, 1 or several assistant chief county medical officers, and several inspectors.
Purposes	<ul style="list-style-type: none"> • Ensure that the health care services comply with the applicable legal requirements. • Reinforce safety and quality in the health care services, and increase trust between health care personnel, the services, and the public.
Policy and practice	<ul style="list-style-type: none"> • Two main categories of supervision conducted by the county governors: <ol style="list-style-type: none"> 1. Planned/system audits. Modus operandi: proactive/preventative supervision; identify risk areas 2. Individual cases of deficiencies/adverse events–related supervision. Modus operandi: reactive supervision; identify causality and breach of prudence • In planned/system audits, the NBHS provide the county governors with associated guidelines, including a template for how to write a report after supervision. • The county governors are instructed to start any supervision with a description of good performance, to be able to assess a possible deviation. Part of the assessment is to establish if the deviation is in breach with professional responsibility and diligent care. If the county governor concludes with a deviation from successful practice, this does not necessarily voice professional irresponsibility. • Inspectors produce concluding reports after conducting supervision, identifying breach of legal requirements. 200–400 planned/system audits are conducted each year and 3000–4000 adverse event–related cases assessed each year.

Box 2 Regulatory changes in quality improvement and patient safety in Norway

- Regulators adjusted and replaced the former *Internal Control Regulation in the Healthcare Services*¹¹ into the *Regulation on Management and Quality Improvement in the Healthcare Services*¹⁰ (hereinafter referred to as the Quality Improvement Regulation), effective from January 1, 2017.
- The overall aim is to contribute to professionally sound practice, quality improvement and patient and user safety, and compliance with other requirements.
- The managerial level and the role of hospital leaders in risk management and quality improvement gained explicit focus with the new Quality Improvement Regulation.
- The new Quality Improvement Regulation requires the hospitals to ensure the establishment of systematic management of hospital activities by introducing the PDSA cycle (plan, do, study, act): plan how to reduce risk; ensure active and practical implementation of measures and barriers; evaluate the impact of these activities, including evaluation of deficiencies and adverse events to prevent similar future cases; and improve procedures and routines.
- The PDSA thinking represents a shift in the regulatory design: from risk overview to specified steps.
- Both the former and the present Quality Improvement Regulation are performance based with functional requirements, meaning that the government does not regulate in detail to make it fit any organizational context in health care. This implies that the inspectors base their evaluation of the inspected organization’s system for management and quality improvement on nondetailed rules.

Previous research indicates that the Norwegian CGs lack systematic practice and methods for measuring their regulatory work’s effectiveness.¹² In an international health care perspective, the

connection between supervision and effect remains disputed.^{4,12-14} In addition, there are different strategies and policies within different regulatory regimes, and observations from the Netherlands show implementation challenges in organizing risk-based supervision.¹⁵ The literature lacks studies looking at regulation and resilience, concepts often considered as counterparts.^{3,16-19} Most studies about regulation focus on deviation and noncompliance, not on how regulatory bodies adapt to challenges in the regulated context and contribute to adaptive capacity (or not) in the regulated organizations. Thus, there is a need for research that can contribute to increased understanding and knowledge about supervision as a regulatory activity, including inspectors’ experiences and how they think of and approach the implementation of new regulations. Furthermore, we lack *multilevel* resilience studies in health care research, involving the perspectives from all organizational levels.^{1,20} These indications underline the rationale for our study.

Aim and Research Questions

The aim of this study was to explore if, and in what ways, there have been changes in the supervisory approach toward Norwegian hospitals due to the implementation of the new Quality Improvement Regulation. Moreover, we aimed to understand how county-level inspectors work to promote or hamper resilience potentials of adaptive capacity and learning in hospitals. This study addressed 2 research questions:

- 1) How do Norwegian CGs adapt to changes in the Quality Improvement Regulation, to improve their practice as inspectors and regulators?
- 2) How do Norwegian CGs work to promote (or hamper) adaptation and learning in hospitals?

Theoretical Framework

This study drew on the theory of responsive regulation to explore the supervisory approach and possible work changes due to the implementation of the new Quality Improvement Regulation. According to Braithwaite,²¹ regulating actors including the government chooses from a pyramid of regulatory strategies. At the top of the pyramid, we find the most interventionistic strategies (e.g., detailed legislation), whereas the less coercive strategies

are at the bottom (e.g., self-regulation).²¹ The choice of regulatory design leads to different implications for practice.²² The new Quality Improvement Regulation adopts a strategy of enforced self-regulation, representing a nondetailed regulatory framework for how organizational systems approach and comply with a minimum level of governmental requirements. This encouraging of localized internal control may be subject to governmental enforcement and sanctions, for example, by supervision.

We address the second research question by deploying the theoretical framework of resilience and the concepts of adaptive capacities and learning potentials (Box 1).^{23–25} We considered this framework useful in the analysis because enforced self-regulation may have similarities with localized adaptation and learning. In this study, adaptive capacity was interpreted in relation to how inspectors described their work to adapt and apply the Quality Improvement Regulation, including how regulatory boundaries in their work (scope of action, room for maneuver) might promote or hamper hospitals’ ability to adapt. The results and discussion therefore address adaptation as both a capacity at the inspector level and at the hospital level. Learning potentials were operationalized as to how the informants experienced and expected hospitals to implement supervisory feedback into practice.

METHODS

The study design is a single embedded case study.²⁶ We defined the case as the design and implementation of the Regulation and its impact on management, quality and safety improvement across 3 system levels: (1) governmental bodies of regulation, (2) CG-regional supervision, and (3) hospitals, including hospital managers. This article focuses on the CGs’ perspectives.

Data Collection and Analysis

Data collection includes interviews (focus group and individual) and document analysis. Before conducting the interviews, S.F.O. read key white papers (governmental documents stating the contemporary policy in a specific area)^{2,6,11,27–31} along with the former and the new Quality Improvement Regulation, to gain insight into the defining governmental guidelines and recommendations, framing the study context (Box 3). Documents were retrieved by searching public, government-based Internet sources such as Lovdata, the Norwegian Directorate of Health, the NBHS, the Ministry of Health and Care Services.

Box 3 Key documents identified, selected, and analyzed

- *Internal Control Regulation in the Healthcare Services*. Oslo: Ministry of Health Services; 2002 (2 pages).
- *Policies for the Follow-up and Concluding of Supervision in Cases of Breach of Legal Requirements*. Oslo: Norwegian Board of Health Supervision; 2011 (8 pages).
- *White Paper Meld. St. 10 (2012–2013) High Quality–Safe Services*. Oslo: Ministry of Health and Care Services; 2012 (135 pages, with exceptions).
- *Regulation on Management and Quality Improvement in the Healthcare Services*. Oslo: Ministry of Health and Care Services; 2017 (3 pages).
- *Guidelines Document Relating to Regulation on Management and Quality Improvement in the Healthcare Services*. Oslo: Norwegian Directorate of Health; 2017 (57 pages).
- *Guidelines Document for Planned/System Audits*. Oslo: Norwegian Board of Health Supervision; 2018 (22 pages).
- *White Paper Meld. St. 9 (2019–2020) Quality and Patient Safety 2018*. Oslo: Ministry of Health and Care Services; 2019 (43 pages).
- *Annual Report 2018 From the Norwegian Board of Health Supervision*. Oslo: Norwegian Board of Health Supervision; 2019 (117 pages).

Document analysis is considered a systematic procedure for examining documents, requiring the data to be interpreted to retrieve meaning.³² Document analysis was used in merge with qualitative interviews, to enrich the phenomenon, hence drawing upon 2 different sources of evidence in this study. Because governmental documents formed the foundation of the Quality Improvement Regulation, it was key to investigate these initially. Moreover, conducting the document analysis before the interviews helped to generate new questions and helped when informants did not remember specifics about the implementation process.³²

County governors’ inspectors were recruited by request to the chief county medical officer at 3 different CG’s offices in 2 regions. A total of 3 focus group interviews with respectively 4, 3, and 3 informants (1 chief county medical officer, 2 assistant chief

TABLE 2. Examples of the First Theme

Quote	Subcategory	Theme
“To be perfectly honest, I do not think that our practice has changed. Because we already did that (red.: assessed management responsibility)” (Focus group 1)	Perceptions—the new Quality Improvement Regulation	Changes in inspectors’ work due to the new Quality Improvement Regulation
“I have not noticed any change because of the new Quality Improvement Regulation, at the level that I work. But I work a lot on reading the written feedback and assessing the totality of these issues and there is not much trace of the new Quality Improvement Regulation. I am happy if there is any trace of regulation at all.” (Focus group 1)		
“...one could have had a discussion about how to use this (red. the regulation) as a helpful tool in our job to...(…) prevent errors in the services... (…), it may sound a bit depressing, but I think that all good suggestions from us got a kind of polite ‘Sunday dinner reception,’ but then on Monday it was like ‘back to business.’” (Individual 2)		

TABLE 3. Examples of the Second Theme

Quote	Subcategory	Theme
<p>“We make changes all the time, we adjust. We have dealt with this in terms of assigning responsibility.” (Focus group 1)</p> <p>“And the Quality Improvement Regulation accommodates everything, and it accommodates our opportunity to look at their entire system and actually conclude that they do not secure their services well enough. And if things were very precise, then you can deviate from things that are not important, that do not really consider the complexity. Thus, very precise legislation is a little scary.” (Individual 1)</p>	Supervisory methods	Inspectors’ work to apply regulation and facilitate adaptive capacities

county medical officers, 7 inspectors) and 2 individual interviews (1 chief county medical officer and 1 former assistant chief county medical officer) were conducted. S.F.O. and S.W. participated together in conducting 2 focus group interviews, whereas S.F.O. alone conducted 1 focus group and 2 individual interviews (1 by telephone). Semistructured focus group interviews were applied to reach deliberation and discussions about the supervisory activities among the informants. This interaction led to expressions of different viewpoints, yet a lot of the discussion led to collective agreement among the informants.³³ Focus group interviews lasted 1 hour and 5 minutes, 1 hour and 10 minutes, and 1 hour and 35 minutes, whereas the 2 individual interviews lasted 50 and 55 minutes.

Topics in the interview guide covered the following: compare former and new Quality Improvement Regulation and adaptations of work practices, expertise within the CGs, and future expectations of development in supervisory activity. All interviews were tape recorded and transcribed.

The transcribed data material was analyzed through a qualitative content analysis.³⁴ All interviews were initially read and analyzed by S.F.O., identifying and condensing all meaning units, and identified codes, subcategories, and themes. Thereafter, S.W. and G.S.B. read the interview material and discussed subcategories and themes with S.F.O., to agree on and refine the analysis. The analysis was in part done by inductively identifying codes with the potential of being operationalized within the concept of resilience in health care, and deductively by targeting the resilience capacities of adaptation and learning in our predetermined

questions. The following subcategories were identified: perceptions (of the new Quality Improvement Regulation), supervisory methods, management, competence, variation, collaboration between the CGs and the NBHS, culture, trust, hospital strategy, resilience in health care, and positive feedback. These subcategories were sorted into 5 themes.

RESULTS

The results are presented theme-wise, with one table for each theme to illustrate initial quotations, subcategories, and themes.

Changes in Supervisory Work Due to the New Quality Improvement Regulation

Our informants described no substantial change in the supervisory approach due to the new Quality Improvement Regulation. All informants perceived the Quality Improvement Regulation as easier to understand and more pedagogical. Some argued that it was perhaps easier to identify deficiencies compared with former Internal Control Regulations. However, in one aspect, the informants described their work differently, and that was the ascribing of management responsibility. The Quality Improvement Regulation’s strong management focus was portrayed crucial in this process, and all agreed this was key in hospitals’ quality improvement work and implementation of measures after supervision.

Regardless of the Quality Improvement Regulation, informants expressed concern about lack of manpower-resources and

TABLE 4. Examples of the Third Theme

Quote	Subcategory	Theme
<p>“...if we are diffuse, we become more difficult to use, if we are specific and the more specific we can be, the more I think we can be of help for improvement out there.” (Focus group 1)</p> <p>“one should ... I would call it advice in closing of deviations and long-term corrections of already existing cases. It must be a separate process. But I think the county governors should be much tougher and make follow ups. There are some departments [in a hospital] in the (county governors) office that I worked in ... we could name three bad (hospital) departments that had bad things happening all the time, (out) of maybe 200 departments: three departments. To get what’s up with those. To get it resilient, right. They don’t learn from their mistakes; they are unwilling or have something against it.” (Individual 2)</p> <p>“We won’t give up until we have evaluated whether the measure had an effect. Always. (...) But we do not, we do not check if they have actually done what they tell us, (...), we can just ask them about what they have done and then they give us an answer.” (Focus group 1)</p>	Supervisory methods	Learning from supervision

TABLE 5. Examples of the Fourth Theme

Quote	Subcategory	Theme
“(Supervision) works when you do follow-ups, but you might come back three years later and then not much has happened. It’s hard to know what time to drop it.” (Focus group 2)	Supervisory methods Management	Supervisory impact on hospital performance
“(I) do not think that the Quality Improvement Regulation can contribute that much. It is also about getting managers to keep up with this, to make it an active and learning system. Because you can do as much supervision as you want, if no one does that (part) (red.: it does not matter).” (Focus group 2)		
“The biggest challenge is related to what kind of effect our activity really has (further) down the services, whether it even gets there.” (Focus group 3)		

increased case volume (e.g., follow-up of reported adverse events and patient complaints). One of the changes in supervisory method was the introduction of a new report template, with requirements for more thorough information, as requested by the health care service. Informants discussed the use of positive feedback, where some believed they had improved their practice of giving praise to hospital managers during the concluding supervision meeting. One county acknowledged that they had yet to practice giving positive feedback (Table 2).

Inspectors’ Work to Apply Regulation and Facilitate Adaptive Capacities

Our findings indicated that inspectors must do quite a lot of work to adapt, interpret, apply, and interact with both the Quality Improvement Regulation and the hospitals. This takes a lot of forms and has a range of predecessors: variation in guidance, flexibility in the Quality Improvement Regulation, and diversity of the regulated hospitals. Inspectors respond to this by balancing trade-offs, risk prioritization, and maneuvering within scope of action.

Our data indicated that adaptive work is laborious, as inspectors must mature in their work to comprehend a new regulation. According to our informants, the NBHS provides guidance in some cases, depending on the type of regulatory design. The inspector’s evaluation of deviance from The Patients’ Rights Act³⁵ is, for example, more actively guided by superior government compared with cases with an additional evaluation of the hospital’s self-assessment of risk, that is, the Quality Improvement Regulation. Regardless, the inspectors described constant, dynamic-adaptive work to specific circumstances (e.g., hospital size, type of personnel, and type of patients). This was backed up by documentary evidence about the inspectors’ interpretive work to “benchmark” certain legal requirements. They also balance trade-offs between

system and individual responsibility and causality in their assessments of adverse event–based supervision of patient harm and patient complaints (described as time-consuming). Some informants insisted that supervision should be risk based, calling for a chance to prioritize according to severity and do follow-ups of hospital departments with repeatedly severe cases, rather than having to evaluate every case. In addition, inspectors initiate every adverse event–related supervision case or planned/system audit with an evaluation of whether the hospital conduct is reasonable, safe, and prudent.

The inspectors inform the hospitals about existing regulatory boundaries. Too many details and procedures could strain the hospitals and be distracting because it narrows the scope, inspectors claimed. They stressed that the new Quality Improvement Regulation is not too narrow, providing inspectors with the opportunity to look at the entire system. However, a disadvantage with nondetailed regulation is that several hospitals implement a minimum version. Thus, guidance on what a minimum standard of compliance encompasses might help but could limit the big hospitals, informants argued. Inspectors described differences in how hospitals monitor and analyze risks and adverse events. Some expressed concern about the hospitals’ capability in identifying and managing risks; thus, hospitals should get more involved in the evaluation of their activities (Table 3).

Learning From Supervision

Inspectors expressed concerns about the extent to which supervision nurtures learning processes in hospitals but pointed to several elements that could better facilitate learning. Some stressed that a time gap between the adverse event and supervision, and unclear or diffuse CG feedback, hampers learning. Thus, the more

TABLE 6. Examples of the Fifth Theme

Quote	Subcategory	Theme
“One thing we certainly could be better at doing is to monitor to what extent the hospitals we supervise manage to implement the changes they report that they will implement, in the wake of supervision.” (Focus group 3)	Resilience in health care management	Improvement potentials in supervisory practice
“We may need to ask in a different way because we do not get much information about what is going well. It’s when things do not go well that it’s reported to us.” (Focus group 3)		
“I believe that the big challenges regarding quality in healthcare are almost always management related. (...) we evaluated big hospitals, and we saw all the time that some clinics had horrible cases, and some clinics had strikingly horrible cases, within the same hospital system, right, and why? There are differences in leadership. (...) people die in healthcare because of management failure, I believe.” (Individual 2)		

specific and predictably performed supervision and feedback, the more helpful for hospital improvement processes.

Supervision was experienced as a welcomed effort, especially in cases of planned/system audits. On many occasions, hospital managers view it as a free consultancy service, whereas others perceive supervision as a formal torment, informants argued. Some experienced that the hospitals rarely ask for advice, whereas others described a lot of inquiries about implementation assistance. In some cases, hospitals even misunderstand supervision reports. Informants described huge differences among hospitals in how they draw on their adverse events and complaints and make use of CG warnings. Our informants suggested differences in the hospitals' quality improvement maturity and that hospital-work postsupervision possibly depends on the individuals involved.

Informants stressed how supervision might nurture learning if the inspectors do not intimidate the hospital personnel, because intimidation could lead them to not report deficiencies. Nonetheless, it was considered important that the CGs "toughen up" in following cases through, to make sure that the hospitals learn from adverse events and other deficiencies from the Quality Improvement Regulation (Table 4).

Supervisory Impact on Hospital Performance

Informants agreed on the purpose of supervision as promoting patient safety. However, the biggest concern among informants related to whether supervision has an efficient and relevant impact on hospital performance: they questioned if supervision has *any* improvement effect at all.

Experiences showed that supervision could be helpful for hospital performance if inspectors followed the progress of the complaints about adverse events and hospitals' attempt to learn from these, although inspectors sometimes investigated cases with no expectation of any quality improvement. However, a cross-county sepsis supervision was mentioned as having a systematic follow-up, resulting in evidence of successful impact on patient outcome (e.g., data showed a reduction in time interval between patient arrival in emergency unit and antibiotic administration). This specific sepsis supervision approach was successful because it was thematically narrow and exact, and improvement activities were systematically monitored and evaluated after supervision, to understand the impact. Inspectors described the hospitals as eager to compare their own achievement with others.

Informants questioned whether hospitals always understand what concern the inspectors, stressing that tradition and communication play into supervision. Some even claimed that medical doctors look at the chief county medical officer as a bureaucrat and too reactive, which is why there is a perception of lack of respect. One informant described the CGs as conservative: not in sync with the knowledge base and pedagogy needed to nurture learning and improvement.

Supervision is not efficient if hospitals lack leadership, informants argued. They were hesitant to whether hospitals are aware of and comprehend the new Quality Improvement Regulation because it seems to disappear in the daily hospital workflow. The idea of internal control does not resonate with all health care professionals: thus, inspectors must target the processes and deficiencies to have consequences for patients. In this work, expertise-oriented inspectors are crucial. Our documentary evidence stressed the importance of evaluating the supervision team's competence initially to all inspections. Although self-assessment could increase the hospitals' sense of responsibility and be timesaving for the CGs, some informants stressed that it probably best suit and have positive impact on large, top-rated teaching hospitals (Table 5).

Improvement Potentials in Supervisory Practice

The informants suggested several improvement potentials in their work. They argued that the CGs could improve their follow-ups of hospital implementation efforts after supervision and have more of an open dialogue-based practice. Document findings, for instance, showed that in the concluding meeting, inspectors should strive to involve all relevant hospital participants and come to an agreement about the facts. Agreement was stressed to be the best basis for further improvement.

Informants saw a potential in highlighting some of the more positive findings from regulatory activity in their reports and that this could have beneficial impact on hospital performance. The inspectors acknowledged a need of methods for identifying and communicating successful hospital practice, as supervision might run a risk by not indicating positive elements. However, several informants stressed that supervision does not shine a light on every aspect, and thus, too much positive feedback could misleadingly impact the hospital to think that everything about their system is fine. In the analyzed documents, we did not discover any references to or discussion about including positive elements into hospital supervision reports.

There were concern and frustration about the lack of a case record (data about former supervision and evaluations), which leads to a time loss in the inspector's evaluation work. Surprising to the informants, the hospitals do not criticize the CG's lack of risk overview, derived from a lacking case record. Getting national consistency in how deficiencies are assessed is required, partly because inspectors struggle with evaluating and appointing the hospital manager's responsibility. Furthermore, our data indicated a lack of collaboration between different CG offices. Expertise-oriented inspectors (to build trust) and more extensive involvement of the hospitals by using self-assessment were suggested necessary future developments. One informant even called for a revolution in supervisory work, that is, having more proactive methods (Table 6).

DISCUSSION

Overall, our findings showed that the Quality Improvement Regulation caused limited changes in regulatory practice, whereas at the same time, it constitutes a flexible framework for inspectors. This raises a set of important implications for how a new regulation in general can influence the way regulators, including inspectors, support improvement and learning in health care organizations. In the following section, we discuss the findings and relate them to the theoretical framework of resilient health care and responsive regulation.

Room for Maneuver and the Need to Multithink Resilience

Past research points to variability and adaptation to circumstances as crucial in a clinical environment, given its embedded complexity.³⁶ Referred to as the regulator paradox, regulators seek to eliminate variation, but within the variation lies valuable information about quality.²⁴ Acceptable variation is even a part of the professional "craft" in health care.³⁷ Some inspectors wanted more freedom to pick cases based on risk, which in our view implies adaptive capacity. If the amount of cases increases with additional manpower-resources not being granted, it will undermine the CGs' ability to do their job. Consequently, this could lead to severe cases being swamped by less severe cases. In our view, the Quality Improvement Regulation promotes hospital self-assessment and could possibly relieve the inspectors in picking cases for evaluation.

Our data indicated consistency as important when inspectors administer cases and complaints. On one hand, consistency could devalue the inspector's flexibility. On the other hand, given the

function as a monitoring tool, data from previous cases could benefit inspectors time-wise and help with prudence interpretation and thus (although there are context specifics) hinder very different interpretations in cases that are similar. We therefore believe that a case record could benefit hospitals and patients in terms of equal treatment and fair proceedings. Furthermore, lack of collaboration between different CG's offices could hamper learning among the inspectors. Likewise, lack of consistent practice and sharing of case evaluations could lead to less nurturing of learning across hospitals. Previous research on learning from complaints in health care lacks focus on the process and handling of single cases into system-level improvement.³⁸ Based on this analysis, there may be an unfulfilled potential looking into former supervision, including to monitor and thus gain insights from inspectors' positive hospital feedback. Therefore, it would seem important for health care regulators to actively develop national records that can collect data from previous and ongoing cases and facilitate internal collaborations.

Inspectors described situations where they could promote adaptation by not interfering with the hospital's choices of activity. On the other hand, they described situations where inspectors must be strict in their evaluation and feedback, leaving the hospitals with less room for maneuver. This coincides with previous research about responsive regulation.²¹ Both the former and the new Quality Improvement Regulation were designed to promote enforced self-regulation. In contrast, specific obligations could stimulate the implementation of quality improvement activities more than a general-framework legislation.³⁹ This implies that having a nondetailed regulatory framework on one hand promotes room to maneuver, for both inspectors and hospitals, but on the other hand, it could hamper quality improvement implementation that sometimes requires a stringent approach. Informed by resilient health care as our driving perspective, our study thus shows that adaptive capacities are in a squeeze. This duality should be more broadly acknowledged by the resilience in health care research field.

Learning From Successful Practice: Misleading or Helpful?

Although deficiencies conveyed by supervision form an important basis for development in the health care services, learning is not addressed as a formal supervision purpose.^{27,28} Hence, learning from success is not in the inspector's scope. In cases of patient harm or complaints, the NBHS encourages the CGs to retrieve information to confirm or invalidate whether the inspected hospital used the adverse event for the purpose of learning, as a prevention strategy.²⁷ As indicated in our study, good reasons for avoiding positive feedback to the hospitals exist, as this could be misleading.⁶ However, we also found evidence of the contrary, as positive feedback was added to the new report template after the implementation of the Quality Improvement Regulation. We think this supports the idea of sharing smart adaptations in hospital performance, in the inspectors' communication with hospitals. In the 2012 European Partnership of Supervisory Organisations report,⁴⁰ Norwegian supervisory authorities were recommended to focus less on identifying noncompliance, as this led to missed opportunities of identification and sharing of successful practices. In line with this, our inspectors described lack of positive feedback a possible risk. A key takeaway message is that supervision embeds several considerations, including trade-offs,⁴¹ which the CGs have a complex task in balancing. In our view, some of these considerations could counteract the ability to promote flexibility. We believe this implies a critique of resilient thinking. Du Plessis and Vandeskog⁴² illustrate some of the critique, claiming "resilience" to be a manifestation of "bullshit" believed to promote successful

operations and thus legitimize management strategies. Hence, we realize that we need to pay attention to this ambiguity and ambivalence, upon exploring adaptive capacity and learning potential in practical supervisory context.

A Failed Governmental Strategy? Indications of a New Dawn in Supervisory Activity

Previous studies emphasize that the impact of supervision remains unsettled.^{4,12,13} Like our data indicated, there is lack of faith in the supervisory system's ability to facilitate quality improvement in hospitals, in general and after the Quality Improvement Regulation implementation. In our view, this may influence how hospitals value supervision. It could also weaken inspectors' sense of purpose and motivation. In the long run, a weak and incomplete plan for evaluation and follow-up could lead to less trust in public government. This perspective coincides with Organisation for Economic Co-operation and Development's impact evaluation of regulatory policies,⁴³ encouraging a culture of regulatory experimentation and evaluation.

The inspectors in this study insisted that they did not change their practice because of the new Quality Improvement Regulation. However, a new report template was introduced, and they experienced a development toward expertise-oriented inspectors and more frequent use of hospital self-assessment and involvement. These aspects are recognized in recent research about regulator-regulatee interactions and in reflections of how to promote resilience in regulation.^{3,43,44} Given right preconditions (e.g., risk-based information collected by experts and trained inspectors), internal audit results shared with external inspectors could reduce the supervisory burden and provide inspectors with insight into hospital improvement of quality and safety.⁴⁵ This information exchange could enrich the learning potential.¹⁹ If regulators went beyond basic guidance, it helped the regulatees to operationalize rules into practical work, which in turn helped regulators improve, adapt, and modify a regulation.⁴⁴ Our findings, however, relate to inspectors' experiences and do not provide empirical evidence from the regulatee's perspectives. Nevertheless, we want to stress the importance of developing inspectors' practices into helping hospital managers "translate" supervision reports and frame problems into relevant improvement measures. The Quality Improvement Regulation per se allows for flexible interaction with the hospitals, but whether this is exercised is yet to be further explored. Because supervision de facto is an evaluation of what hospitals *actually* do based on regulatory requirements and expectations, it is important to underline the importance of enabling co-creation of flexibility and learning in the regulatory system. It is equally important to highlight that inspectors, perhaps unfairly, are expected to master the tough skill of moving fluidly between different strategies of the regulatory pyramid. Based on our analysis, there are indications that the supervisory system examined here is not sufficiently built for handling the trade-offs it suffers from and the complexity it is supposed to evaluate.

STRENGTHS AND LIMITATIONS

This study has some limitations: (a) The sample size could be considered a limitation. Nevertheless, the narrow study aim required fewer informants, whereas the information power adequately supported our effort to ensure trustworthiness.^{34,46} Moreover, the CG offices were chosen because these counties are represented in the embedded case study, which included 3 hospitals and 3 CG bodies. This implies a reason for the small sample. (2) The Chief County Medical Officer was present in our first focus group interview, which possibly restrained the other informants. In the following 2 focus groups, we did not include the chief county medical

officers, and they were interviewed separately. (3) We did not include the perspectives of hospital managers. This perspective is covered in a forthcoming article. The perspectives of macrolevel governmental bodies of regulation are reported in an already published article.⁴⁷

CONCLUSIONS

Our findings revealed that adaptations and changes in supervisory activities stem from measures and requirements other than the new Quality Improvement Regulation. We have pointed toward trade-offs in supervisory work, indicating that the adaptive capacity fostered in the concept of resilience in health care is far more complex than at first blush. Our study indicates that having a nondetailed regulatory framework provides hospitals with room to maneuver. However, this could hamper implementation efforts and might suit big, professional hospital systems. Informants expected a future increase of hospitals' self-assessment, which we believe requires extensive information exchange between authorities and hospitals, with expertise-oriented inspectors as crucial. In turn, it could promote cross-sectional learning and help in building trust between these stakeholders. This is key, as our findings revealed doubt to what impact supervision really has on hospital performance. A development toward acknowledging successful practices in hospital activities was partly described as positive, partly as misleading. Perhaps this shines a light on the bridging of Safety-I and Safety-II in resilience thinking, where we should focus both on the *prevention* of adverse events and on the *reasons behind* the freedom from adverse events.²⁵ The government could contribute to this shift in focus by instructing the CGs to actively reflect on and communicate positive experiences from and smart adaptations in hospital practice. We therefore recommend further research to investigate how resources, success factors, and challenges⁴⁸ could be included in supervision reports to better inform hospital improvement work in a resilience perspective.

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REFERENCES

- Berg SH, Akerjordet K, Ekstedt M, et al. Methodological strategies in resilient health care studies: an integrative review. *Saf Sci*. 2018;110:300–312.
- Ministry of Health and Care Services. *Meld. St. 9 (2019–2020) Kvalitet og pasientsikkerhet 2018*. Oslo: Ministry of Health and Care Services; 2019. Available at: <https://www.regjeringen.no/no/dokumenter/meld.-st.-9-20192020/id2681185?q=tillit&ch=#kap8>. Accessed January 8, 2021.
- Wiig S, Aase K, Bal R. Reflexive spaces: leveraging resilience into healthcare regulation and management [published online January 31, 2020]. *J Patient Saf*. doi:10.1097/PTS.0000000000000658.
- Flodgren G, Pomey MP, Taber SA, et al. Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes. *Cochrane Database Syst Rev*. 2011;CD008992. doi:10.1002/14651858.CD008992.pub2.
- WHO: Handbook for National Quality Policy and Strategy. A practical approach for developing policy and strategy to improve quality of care. Co-developed by the World Health Organization and countries pursuing national quality initiatives. 2018. Available at: <https://apps.who.int/iris/bitstream/handle/10665/272357/9789241565561-eng.pdf?ua=1>. Accessed January 8, 2021.
- Norwegian Board of Health Supervision. *Veileder for tilsyn utført som systemrevisjon*. Oslo: Norwegian Board of Health Supervision; 2018. Available at: https://www.helsetilsynet.no/globalassets/opplastering/publikasjoner/internserien/veileder_systemrevisjon_internserien4_2018.pdf. Accessed January 8, 2021.
- Act of 2 July 1999 No. 64 relating to Health Personnel etc. (The Health Personnel Act). The Ministry of Health and Care Services; 1999. Available at: <https://lovdata.no/dokument/NL/lov/1999-07-02-64> and <https://www.regjeringen.no/no/dokumenter/act-of-2-july-1999-no-64-relating-to-hea/id107079/> (in English, translated version). Accessed January 8, 2021.
- Ministry of Local Government and Modernization. *Royal Assent*. Oslo: Ministry of Local Government and Modernization; 2017. Available at: <https://www.regjeringen.no/contentassets/4a373ab19ace42ac99fbb41f1331c3e/fylkesmannsstrukturkgres.pdf>. Accessed January 8, 2021.
- Norwegian Board of Health Supervision. *Introduction to the Supervisory Authorities and the Supervision of Child Welfare Services, Social Services and Health And Care Services in Norway*. Oslo: Norwegian Board of Health Supervision; 2019. Available at: <https://www.regjeringen.no/contentassets/4a373ab19ace42ac99fbb41f1331c3e/fylkesmannsstrukturkgres.pdf>. Accessed January 8, 2021.
- Regulation on management and quality improvement in the healthcare services. In: *Norwegian: Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten. FOR-2016-10-28-1250*. Oslo: Ministry of Health and Care Services; 2017. Available at: <https://lovdata.no/dokument/SF/forskrift/2016-10-28-1250>. Accessed January 8, 2021.
- Internal Control Regulation in the Healthcare Services. In *Norwegian: Forskrift om interkontroll i sosial- og helsetjenesten. FOR-2002-12-20-1731*. Oslo: Ministry of Health Services; 2002. Available at: <https://lovdata.no/dokument/LTI/forskrift/2002-12-20-1731>. Accessed January 8, 2021.
- Schaefer C, Wiig S. Strategy and practise of external inspection in healthcare services—a Norwegian comparative case study. *Saf Health*. 2017;3:3.
- Hovlid E, Frich JC, Walshe K, et al. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. *BMJ Open*. 2017;7:e016213.
- Macrae C, Wiig S. Resilience: From Practice to Theory and Back Again. In: Wiig S, Falbruch B, eds. *Exploring Resilience. A Scientific Journey From Practice to Theory*. Cham, Switzerland: Springer Open; 2019:121.
- Helsloot I, Scholtens A, Haen J. Some observations on the troublesome implementation of risk-based inspections in the Netherlands. *Saf Sci*. 2002;122:1045072.
- Macrae C. Reconciling regulation and resilience in healthcare. In: Hollangel E, Braithwaite J, Wears R, eds. *Resilient Health Care*. Boca Raton, FL: Ashgate; 2013:111–123.
- Øyri S, Wiig S. Regulation and resilience at the macro-level healthcare system—a literature review. Proceedings of the 29th European Safety and Reliability Conference. September 22–26, 2019 Hannover, Germany. doi:10.3850/978-981-11-2724-3_0075-cd.
- Wiig S, Haraldseid-Driftland C, Tvette Zachrisen R, et al. Next of kin involvement in regulatory investigations of adverse events that caused patient death: a process evaluation (part I—the next of kin's perspective) [published online October 22, 2019]. *J Patient Saf*. doi:10.1097/PTS.0000000000000630.
- Wiig S, Schibevaag L, Tvette Zachrisen R, et al. Next-of-kin involvement in regulatory investigations of adverse events that caused patient death: a process evaluation (part II: the inspectors' perspective) [published online October 22, 2019]. *J Patient Saf*. doi:10.1097/PTS.0000000000000634.
- Berg SH, Aase K. Resilient characteristics as described in empirical studies on health care. In: Wiig S, Falbruch B, eds. *Exploring Resilience. A Scientific Journey From Practice to Theory*. Cham, Switzerland: Springer Open; 2019:79–87.

21. Braithwaite J. The essence of responsive regulation. *UBC Law Rev*. 2011; 44:475–520. Available at: http://johnbraithwaite.com/wp-content/uploads/2016/03/essence_responsive_regulation.pdf. Accessed January 8, 2021.
22. Hood C, Rothstein H, Baldwin R. *The Government of Risk: Understanding Risk Regulation Regimes*. Oxford, UK: Oxford University Press; 2001.
23. Hollnagel E, Braithwaite J, Wears RL. *Resilient Health Care*. Surrey, UK: Ashgate Publishing Limited; 2013.
24. Hollnagel E. *Safety-I and Safety-II: The Past and Future of Safety Management*. Boca Raton, FL: CRC Press; 2014.
25. Hollnagel E. (2018a). *Safety-II in Practice. Developing the Resilience Potentials*. New York, NY: Routledge; 2018.
26. Yin RK. *Case Study Research. Design and Methods*. Thousand Oaks, CA: Sage Publications; 2014.
27. Norwegian Board of Health Supervision. *Retningslinjer for oppfølging og avslutning av tilsyn ved lovbrudd i virksomheter*. Oslo: Norwegian Board of Health Supervision; 2011. Available at: https://www.helsetilsynet.no/globalassets/opplaster/publikasjoner/interntserien/retningslinjer_avslutning_tilsyn8_2011.pdf. Accessed January 8, 2021.
28. Ministry of Health and Care Services: Meld. St. 10 (2012-2013). *God kvalitet—trygge tjenester. Kvalitet og pasientsikkerhet i helse- og omsorgstjenesten*. Oslo: Ministry of Health and Care Services; 2012. Available at: <https://www.regjeringen.no/contentassets/b9f8d14c14634c67a579a1c48a07c103/no/pdfs/stm201220130010000dddpdfs.pdf>. Accessed January 8, 2021.
29. NOU 2015:11 In Norwegian: *Med åpne kort. Forebygging og oppfølging av alvorlige hendelser i helse- og omsorgstjenestene*. In English: *White Paper 2015:11. Departementenes sikkerhets- og serviceorganisasjon*. Oslo: Informasjonsforvaltning; 2015. Available at: <https://www.regjeringen.no/no/dokumenter/nou-2015-11/id2459861/>. Accessed January 8, 2021.
30. Norwegian Directorate of Health: In Norwegian: *Veileder til forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten*. In English: *Guidelines to Regulation on Management and Quality Improvement in the Healthcare Services*. Oslo: Norwegian Directorate of Health; 2017. Available at: <https://lovdata.no/static/ROO/is-2017-2620.pdf>. Accessed January 8, 2021.
31. Norwegian Board of Health Supervision. *Årsrapport 2018 fra Statens Helsetilsyn*. Oslo: Norwegian Board of Health Supervision; 2019. Available at: <https://www.helsetilsynet.no/globalassets/opplaster/publikasjoner/aarsrapporter/aarsrapport2018.pdf>. Accessed January 8, 2021.
32. Bowen GA. Document analysis as a qualitative research method. *Qual Res J*. 2009;9:27–40.
33. Kvale S, Brinkmann S. *Interviews: Learning the Craft of Qualitative Research Interviewing*. Thousand Oaks, CA: Sage Publications; 2009.
34. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today*. 2004;24:105–112.
35. Act of 2 July 1999 No. 63 relating to Patients' Rights (The Patients' Rights Act). The Ministry of Health and Care Services; 1999. Available at: <https://lovdata.no/dokument/NL/lov/1999-07-02-63> and <https://app.uio.no/ub/ujur/oversatte-lover/data/lov-19990702-063-eng.pdf> (in English, translated version). Accessed January 8, 2021.
36. Anderson JE, Ross AJ, Back J, et al. Implementing resilience engineering for healthcare quality improvement using the CARE model: a feasibility study protocol. *Pilot Feasibility Stud*. 2016;2:61.
37. Braut GS. Ei ny helseteneste?—Er det rom for variasjon, avvik og feil? *Omsorg*. 2001, nr. 1.
38. Van Dael J, Reader TW, Gillespie A, et al. Learning from complaints in healthcare: a realist review of academic literature, policy evidence and front-line insights. *BMJ Qual Saf*. 2020;29:684–695.
39. Wagner C, Gulácsi L, Takacs E, et al. The implementation of quality management systems in hospitals: a comparison between three countries. *BMC Health Serv Res*. 2006;6:50.
40. EPSO. Report of a peer evaluation of the Norwegian Board of Health Supervision (Statens Helsetilsyn). Performed by a delegation of the European Partnership of Supervisory Organisations in Health Services and Social Care 2020. Available at: https://www.helsetilsynet.no/globalassets/opplaster/om_helsetilsynet/EPSO_peer_evaluation_engl2012.pdf/. Accessed January 8, 2021.
41. Hollnagel E. *The ETOO Principle: Efficiency-Thoroughness Trade-Off*. New York, NY: Routledge; 2018b, 2018.
42. Du Plessis EM, Vandeskog B. Other stories of resilient safety management in the Norwegian offshore sector: resilience engineering, bullshit and the de-politicization of danger. *Scand J Manag*. 2020; 36:101096.
43. Coglianese C. Measuring regulatory performance—evaluating the impact of regulation and regulatory policy. Expert paper no 1; OECD, 2012. Available at: https://www.oecd.org/gov/regulatory-policy/1_coglianese%20web.pdf. Accessed January 8, 2021.
44. Kudesia RS, Lang T, Reb J. How institutions enhance mindfulness: Interactions between external regulators and front-line operators around safety rules. *Saf Sci*. 2020;122:104511.
45. Hanskamp-Sebregts M, Robben PB, Wollersheim H, et al. Transparency about internal audit results to reduce the supervisory burden: a qualitative study on the preconditions of sharing audit results. *Health Policy*. 2002; 124:216–223.
46. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qual Health Res*. 2016;26: 1753–1760.
47. Øyri SF, Braut GS, Macrae C, et al. Exploring links between resilience and the macro-level development of healthcare regulation—a Norwegian case study. *BMC Health Serv Res*. 2020;20:762. doi:<https://doi.org/10.1186/s12913-020-05513-x>.
48. Hegde S, Hettinger AZ, Fairbanks RJ, et al. Qualitative findings from a pilot stage implementation of a novel organizational learning tool toward operationalizing the Safety-II paradigm in health care. *Appl Ergon*. 2002; 82:102913.