Healthcare Regulation and Resilience

- a Norwegian Multilevel Case Study

by

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Suit the action to the word,

the word to the action.

William Shakespeare, *Hamlet*

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Stavanger, March 18, 2021.

Sina Furnes Øyri

Summary

Introduction: A new regulatory framework (the Quality Improvement Regulation) to support local, management-based quality and safety efforts in hospitals was introduced to the Norwegian healthcare system in 2017. This thesis explores healthcare regulation and resilience through the Quality Improvement Regulation, by investigating its possible links to adaptive capacity in hospital management of quality and safety enhancing activities. The literature lacks studies exploring how regulation and resilience intertwine, two concepts often considered as counterparts. Hence, there is a gap in knowledge about regulatory and supervisory impact on quality and safety, and attention to hospital managers' competences and responsibilities as key elements to resilience in healthcare. This thesis therefore casts a new light on how regulators and inspectors may design, inspect, and enforce a regulation regime, and thereby contribute to adaptive capacity, anticipatory capacity, and learning as key elements in different hospital contexts. Overall outputs from this thesis are important to the development and implementation of future regulatory amendments.

Aim: The overall aim of this thesis was to explore the rationale, expectations, implementation, and management of the Quality Improvement Regulation. The overall and leading research question was: How does a new healthcare regulation implemented across three system levels contribute to adaptive capacity in hospital management of quality and safety?

Methods: The study was designed as a multilevel, single embedded case study. Data was collected by approximately 500 pages of documentary evidence, 29 individual interviews and 3 focus group interviews (10 participants): in total 39 participants. Data was analyzed by legal dogmatic and qualitative content analysis. Three levels of stakeholders were included from the Norwegian healthcare system: macro-level (three governmental regulatory bodies), meso-level (three County Governors), micro-level (three hospitals retrieved from two regional health authorities). Macro-level participants were seven strategic participants positioned at the Norwegian Ministry of Health and Care Services, the Norwegian Directorate of Health, and the Norwegian Board of Health Supervision. Meso-level participants were two chief county medical officers, three assistant chief county medical officers, and seven inspectors, recruited

from three County Governors. Micro-level participants were 20 hospital managers or quality advisors selected from different levels at three hospitals.

Findings: Paper I (macro-level) explored the governmental rationale for developing the Quality Improvement Regulation, expectations towards hospital management and its expected influence on resilience. Data retrieved from documentary evidence and individual interviews indicated that the rationale for the Quality Improvement Regulation's design was to make it flexible to various hospital contexts. In turn, the macro-level expected hospital managers to anticipate local risks. However, the study found that the Government expected the generic regulatory design to come across as challenging for hospital managers and clinicians. Paper II (meso-level) investigated into changes in the supervisory approach and inspectors' work to promote or hamper adaptive capacity and learning in hospitals. Evidence emerged from documents and focus group interviews and indicated that despite supervision being adapted to specific hospital contexts and the inspectors' trade-offs, there was a general concern about the lack of impact of supervision on hospital performance. Paper III (micro-level) explored hospital managers' perspectives on implementation efforts and the following work practices, to understand if, and how, the new Quality Improvement Regulation influenced quality and safety improvement activities. Across interview data, participants experienced the Quality Improvement Regulation as more suitable to variation and different contexts compared to the previous regulatory framework. However, findings revealed no change in practice related to quality and safety activities, solely due to the new regulatory framework, despite recent structural and cultural changes to quality improvement systems in hospitals. Data reported that lack of time, competence and/or motivation affected hospital implementation.

Conclusions: This thesis represents a rare glimpse into regulatory implementation efforts across three system levels, set out in a resilience in healthcare perspective. This thesis revealed that regulators considered the perspective of variation, complexity, and uncertainty in hospital settings to be important when designing the Quality Improvement Regulation. The latter resonates with resilience in healthcare concepts and contradicts previous research. The Quality Improvement Regulation contributed to context adaptation, by supporting nondetailed risk based organizing and management of quality and safety. However, hospital managers' autonomy and adaptive

capacity to tailor quality improvement efforts were imperative for the regulatory requirements to have any relevant impact on hospital practice. Limited involvement of clinicians in the regulatory development process could hamper quality improvement efforts. Inspectors could nurture learning by improving their follow up, use expert inspectors, and add more hospital self-assessment activities. This thesis highlights the importance of ensuring that any macro-level quality improvement initiatives and regulatory requirements are accompanied by appropriate resourcing, support, and advanced preparation to ensure the best possible chance of getting implemented effectively.

Thesis at a glance

	Paper I	Paper II	Paper III
Research question (s)	• What was the regulatory rationale for developing a management focused regulatory framework (the Quality Improvement Regulation) for quality and safety improvement in healthcare? • How do the regulatory bodies expect the new Quality Improvement Regulation to influence resilience in hospitals?	• How do Norwegian County Governors adapt to changes in the new Quality Improvement Regulation, to improve their practice as inspectors and regulators? • How do Norwegian County Governors work to promote (or hamper) adaptation and learning in hospitals?	• How do hospitl managers work to improve quality and what are their experiences with implementing the Quality Improvement Regulation?
Method (s)	Documentary evidence, and semi structured individual interviews with key regulators and policy makers at the Ministry. Directorate, and Inspectorate.	Documentary evidence, focus group interviews, and semi structured individual interviews with inspectors at County Governor offices.	Semi structured individual interviews with hospital managers and advisors.
Findings	The new Quality Improvement Regulation's design was based on the rationale of making it flexible to different hospital contexts. Hospital managers were expected to anticipate local risks. Its nondetailed regulatory design was however expected to be challenging for managers and clinicians.	Supervision was adapted to specific hospital contexts and inspectors balanced trade-offs. There was however concern about the lacking impact of supervision on hospital performance. Inspectors could nurture learning by improving their follow up, use expert inspectors and add more hospital self-assessment into their practice.	Participants experienced the Quality Improvement Regulation as more suitable to variation and different contexts compared to the previous regulatory framework. No change in practice, solely due to the new regulatory framework was reported. Structural and cultural changes to quality improvement were revealed. Lack of time, competence and/or motivation affected implementation.

Abbreviations

ICR/Internal Control Regulations: Internal Control Regulations in the Healthcare Services

LHT: Local Health Trust

RHA: Regional Health Authority

PDSA: Plan, Do, Study, Act

The Directorate/NDH: The Norwegian Directorate of Health

The Inspectorate/NBHS: The Norwegian Board of Health Supervision

The Ministry/MHCS: The Ministry of Health and Care Services

QIR/the Quality Improvement Regulation: Regulation on management and quality improvement in the healthcare services

Cf.: confer

N.d.: no date

Definitions

Adverse event. The definition used by regulatory bodies in the Norwegian healthcare system is linked to the Norwegian principle of sound professional practice and prudent conduct, and sees an adverse event as related to *consequences* for the condition of the patient (MHCS, 2015 a). However, because of this thesis' focus on hospital management, it adopts the WHO's (2005) definition of an *adverse event*: "An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable".

Hospital manager. This thesis defines a hospital manager to be a hospital employee "who has subordinates, oversees staff, is responsible for staff recruitment and training, and holds budgetary accountabilities" (Parand et la., 2014). All levels of hospital managers were targeted, including clinical "front line" managers and those with special roles as quality advisors (Spehar et al., 2012).

Implementation. In this thesis, implementation appears as a mechanism for governmental regulatory initiatives as well as the active, practical operationalization of quality improvement efforts and activities in supervisory and hospital context.

Patient safety. Patient safety as one dimension to quality is defined as "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (Vincent, 2006; 2010). Both performance and lack of performance apply (NDH, 2017).

Professionally sound practice; prudent conduct. Healthcare services must be offered and provided in line with the principle of sound professional practice and prudent conduct (MHCS, 1999 a; the Health Personnel Act § 4). The implication is that the quality of the service should correspond to a certain level. This required level of quality applies to municipal healthcare providers and organizations, and the specialized healthcare system, both in private and public sectors (NDH, 2017).

Rationale. The governmental rationale investigated in this thesis follows aspects related to motives, purposes, and intentions with the regulatory revision.

Regulatee. The subject under control or regulation. In this thesis the term applies to the micro-level hospital organizations.

Safety. In this thesis, *safety* is understood as one dimension to quality (Sheps & Cardiff, 2013). Also, it is applied as the preventive measures put in place to reduce potential adverse events and the proactive measures that seek to reduce the negative consequences and maintain regular performance (Aven et al., 2004). To illustrate: a specific patient injury can potentially occur during or

after surgery, but with uncertainty to whether it will happen, when it will occur, and what consequences it will lead to (Sollid, 2015).

Stakeholder. This thesis adopts the following definition: “A stakeholder in an organization is (by definition) any group or individual who can affect or is affected by the achievement of the organization’s objectives” (Freeman et al., 2010).

Trade-off. A trade-off is a balancing act between different qualities and situations or “multiple goal conflicts” (Bergström & Dekker, 2019:398).

Quality. This thesis leans on the Institute of Medicine, and the Norwegian adoption of the conceptualization of quality. *Quality* consists of six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness, and equity (IOM, 2000; Darzi & Johnson 2008; Doyle et al., 2013; Aase, 2018).

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PART 1

1 Introduction

The publication of the iconic report about medical errors, “To Err is Human” put international attention on quality and patient safety at the beginning of the new millennium (IOM, 2000; Wears & Sutcliffe, 2020). As a response, a wide span of efforts to analyze and reduce malpractice and patient injuries were introduced, at all organizational levels. Yet, international studies show that despite significant efforts, also in terms of regulating, controlling, and supervising the healthcare sector, improving quality and safety remains a major healthcare issue, and adverse events rates are still high (WHO, 2018; NDH, 2019 a; Busse et al., 2019). Wears and Sutcliffe (2020) argue that several things have gone wrong in “the patient safety movement”, causing failed results. Challenges relate to a lack of conceptual clarifications and an eager to generalize context as well as a limited perspective on risk reduction (Wears & Sutcliffe, 2020). The persistent issues of improving quality have led to a 20-year process of rebranding, from *quality improvement* to *patient safety*, and back again (Brook, 2010). In recent years, many researchers have called for an approach to safety where high quality links to efficient adaptation and learning from everyday success and not just from adverse events (Nemeth et al., 2008; Hollnagel et al., 2013, Mannion & Braithwaite, 2017; Hollnagel, 2018 a; Sujan, 2018; Sujan et al., 2019; Wiig & Fahlbruch, 2019; Hegde et al., 2020; Wiig et al., 2020 a). Others have voiced a general concern for slow progress, lack of advancement in safety science and research activities, with a suggestion of studying aspects of complexity and adaptation in the context of organizational safety (Woodward, 2019; Rae et al., 2020). Some even claim that there are misconceptions within the research community (Leveson, 2020). Common to these critical perspectives is that safety research and safety management need to move forward. New strategies for management of healthcare organizations and risk reducing activities are called for in a national and international perspective.

A series of previously conducted external hospital inspections across health-regions in Norway identified several challenges to systematic quality and safety improvement (NBHS, 2008, 2011, 2013; MHCS, 2012, 2015, 2016):

- Lack of management responsibilities,

- Lack of structure to ensure prudent professional qualifications,
- Lack of systematic collecting of and evaluation of risks, and adverse events,
- Lack of implementation of planned work tasks,
- Lack of evaluation of efforts, post implementation.

The Quality Improvement Regulation (QIR) was introduced into the Norwegian healthcare regulation regime in 2017, responding to these challenges (MHCS, 2016). The regulatory change was reckoned important to highlight management of and managers' role in quality and safety work, whilst providing space to deal with local risks. Consequently, the topic of this thesis is to explore healthcare regulation's support for adaptive capacity in hospital management of quality and safety. This thesis recognizes resilience as a system capability of *adaptive capacity*, not as purely an individual capacity (Haavik, 2020; Wiig et al., 2020 b). This thesis sees adaptive capacity as a potential found in the adaptation and workarounds of *hospital management*, in regional *inspectors' work practices*, as well as embodied in regulation and *regulatory regimes' design and enactment* (see elaboration in chapter 3.3). All these aspects are recognized as system components that have potential to influence the overall system performance, resonating with the resilience in healthcare perspective (Hollnagel, 2018 a; Hybinette et al., 2021). Because uncertainty and variation are natural parts of daily hospital work in a complex adaptive system, adaptation to variation is considered key. New and often unpredictable situations occur daily, making local level improvisation necessary (Hollnagel, 2014). Despite awareness about the elements of variation and uncertainty in healthcare, perhaps the role of individual health personnel has gotten too much attention and responsibility, rather than putting emphasis on the healthcare *system* (Leveson, 2020). This thesis' main contribution is therefore the merge of healthcare regulation, supervision, and hospital management in a macro, meso, micro-level perspective on resilience. It provides significant contribution to knowledge about resilience in healthcare theory's application of adaptive capacity in regulatory regimes, by involving stakeholders across micro, meso, and macro-levels in context sensitive regulation design. It moreover takes a deep look into the rationale, the expectations and the implementation and management of the Quality Improvement Regulation, in a multilevel perspective across macro, meso, and micro-levels of the healthcare system.

2 Background

Lots of effort has been put into increasing overall healthcare quality over the last three decades, and awareness about indicators for patient safety has been a broad-scale effort throughout the globe (Busse et al., 2019; Quentin et al., 2019). The link to the "quality movement" in healthcare goes back to Edwards Deming and his method for problem solving, which again built on Walter Shewhart's three step process of specification, production and inspection from the late 1930's (Moen & Norman, 2010). Based on this idea, Deming developed the Plan, Do, Study Act Cycle (PDSA) during the 1950's. This cycle, or method, aims at enabling change to result in improvement (Deming, 1986; Moen & Norman, 2010). Although it was originally set to apply on small scale change and testing, and its feasibility is debated, the PDSA cycle has gained popularity in healthcare as a model for improvement (Ogrinc et al., 2012; Ogrinc & Shojania 2014; McNicholas et al., 2019). On their respective web sites, both the National Health Service (NHS) and the Institute for Healthcare Improvement (IHI) emphasize and offer PDSA cycle work sheets as key tools for improvement (NHS, 2018; IHI, 2021).

Whereas regulation and standardization are expected to be important structural elements to improve quality and safety in healthcare, regardless of how countries set up their healthcare regime, resilience in healthcare has attained attention during the past ten years (Macrae, 2013, Chuang, 2013; Nyssen & Blavier, 2013). Since the late 1990's, the role of regulation in quality improvement has been scrutinized (Walshe, 2003; Adil, 2008; Stoopendahl & van de Bovenkamp, 2015; van de Bovenkamp et al., 2017; Shaw et al., 2019; Leistikow & Bal, 2020). Some of this work includes how policy implementation and external regulators influence regulated organizations (de Bree & Stoopendahl, 2020). Yet, overall, it remains muddled how and if certain regulatory strategies work as intended and really grasp the variation and uncertainty in providing healthcare services (Brennan, 1998; Walshe, 2003; Chuang, 2013). There are significant knowledge gaps in this research field.

2.1 The gaps in knowledge

The Management Challenge

Management of and leadership in healthcare is reckoned as one of the fundamental elements to quality and safety, particularly related to implementation of improvement activities (Botwinick et al., 2006; Lyons et al., 2020). To develop efficient management in the interface of minimizing "production" of risk and promoting the capacity to "withstand" risk, in addition to designing institutions set to manage risks, are enduring key challenges (Baldwin & Cave, 1999). The Mid Staffordshire inquiry in 2013 and the Morecambe Bay inquiry in 2015 found issues with poor management and lack of organizational oversight of safety (Francis, 2013; Kirkup, 2015). A progress report from 2018 called for stronger leadership commitment and acknowledgment of quality and safety as integral to the operational culture of healthcare organizations (Gandhi et al. 2018). Some have pinpointed how improvement projects in other industries can contribute to learning even in healthcare, especially related to why resources, culture and engagement are important elements to system wide quality improvement (Macrae & Stewart, 2019). Some scholars argue that one of the reasons to lacking engagement amongst clinicians associates with the past merge of safety and managerialism in healthcare (Wears & Sutcliffe, 2020). A recent published study of patient safety strategies and the role of first line hospital managers highlighted how results from a widely spread measurement tool for safety culture (the HSOPSC survey) was not used by the managers in promotion or improvement of patient safety culture (Hedsköld et al., 2021). The lacking use of it was explained as stemming from difficulties with interpretation of the results, with a lack of interpretation and operationalization support from higher level hospital management (Hedsköld et al., 2021). One important issue is therefore how regulators should address and support issues of organizational leadership, engagement, and management of quality and patient safety (Grote, 2019; Oikonomou et al, 2019; Burgess et al., 2019). However, concern has been raised that quality improvement measures at local levels do not necessarily evolve into initiatives that look at the bigger picture of system complexity (Macrae & Stewart, 2019). Thus, it is a paradox that regulators ask for locally based and led quality improvement measures but expect a system change.

Regulatory Approaches

A central purpose of regulation is to control the risks to society and thereby tailor regulatory practice with benefit to society (Sparrow, 2000). More specifically in relation to healthcare, the overall aim of regulation of quality and safety is to reduce the patients' risk of harm by healthcare itself (Healy, 2011). Past research on regulatory activities, and interventions' effectiveness in healthcare has however demonstrated various outcomes (Walshe, 2003; Flodgren et al., 2011; Healy, 2011, 2016; Schaefer & Wiig, 2017, Hovlid et al., 2017). Also, regulation of safety is under scrutinized and under investigated in healthcare, with evaluations lacking (Healy, 2011; Quick, 2017). External approaches to quality improvement, such as supervision and regulation, often treat healthcare organizations similarly regardless of size, context, competence, skills, resources, and objectives, which implies a naive outlook on organizations (Walshe, 2003). Moreover, the effects of external inspections in healthcare are unclear, with not much existing knowledge about inspectors' approaches and methods (Schaefer & Wiig, 2017; Hovlid et al., 2020 a, b; Johannesen et al., 2020). A recent study did however link the promotion of leadership with external inspection, stressing how external inspection may "boost" the way hospitals manage their internal work of improving quality and patient safety (Husabø et al., 2020). Moreover, for healthcare organizations to trust the outcome of inspections, inspectors need to possess the appropriate knowledge and skills (Hovlid et al., 2020 a). The quality of how regulatory practice is formed should therefore be considered imperative, also to gain legitimacy in the public in general (Sparrow, 2000). More knowledge about this is needed.

A new regulator, the Care Quality Commission, was established in the UK back in 2000 (Adil, 2000). It was suggested to regulate parts of the healthcare system on a risk-based approach driven by outcomes, meaning that risks were supposed to be measured against the objectives set out in the policies (Adil, 2000). One of the objectives was to leave less of a regulatory burden with the services (Adil, 2000). However, more recent research from the British National Health Service has revealed practical challenges and difficulties with identifying the most relevant or essential rules among a vast number of guidelines and standards that clinicians were expected to comply with (Carthey et al, 2011). Previous research on institutional factors shaping safety professionals' roles, has pointed to the large growth in demand for safety professionals' expertise to translate

and interpret legislation (Hale et al., 2015; Provan et al., 2017). Equivalently, concerns relate to if the complexity and demands of external regulation distract organizations rather than support them in their efforts to improve quality and safety (Oikonomou et al, 2019). In the literature, this is also referred to as "regulatory pressure" (van de Bovenkamp et al., 2020). It is hence vital to investigate how regulators shape and co-opt organizational activities, beneficial to effective management of improving quality and safety. Moreover, the complexity and variation in healthcare suggests that detailed rules and regulations that adequately fit every context can be challenging, and at times impossible to provide. "Fuzzy" boundaries in a complex adaptive system complicate action and behaviour (Plsek & Greenhalgh, 2001). Regulatory approaches that are responsive towards flexibility and local adaptation are thus useful, if not paramount (Coglianese & Lazer, 2003; Gilad, 2011; Leistikow & Bal, 2020; Wiig et al., 2020 a).

A growing corpus of research has recently conceptualized the processes that underpin quality and safety in complex system settings (Hollnagel, 2013; Gandhi et al. 2018; Macrae & Wiig, 2019; Hegde et al., 2020; Anderson et al., 2020). Moving from prescriptive regulation (strict, detailed rules) to supervision of system management has in the previous shown to influence the process of reducing gaps between formal introduction and actual world implementation, referred to as decoupling and recoupling of healthcare regulation (Meyer & Rowan, 1977; de Bree & Stoopendahl, 2020).

Regulation and Resilience crossing Macro-Meso-Micro

The healthcare system is characterized by being a complex, adaptive system and previous research urges detection of how multiple levels influence implementation of changes (Robert et al., 2011; Reiman et al., 2015). Resilience as "the capacity to adapt to challenges and changes at different system levels, to maintain high quality care" (Wiig et al., 2020 b), is therefore a theoretical concept that supports the idea of multiple levels' influence on quality and safety. Critiques argue that regulation and resilience are hopeless opposites, but few studies have scrutinized the assumption (Macrae, 2013; Berg et al., 2018; Ellis et al., 2019; Iflaifel et al., 2020). A remaining issue in resilience in healthcare research is to investigate multilevel perspectives, including how management responsibilities and managers' contributions to quality and safety enhancement are understood (Parand et al., 2014).

Despite that several healthcare studies have investigated into organizational adaptive capacity, few *multilevel* studies have linked this to regulatory activities (Macrae, 2013; Bal et al., 2015; Stoopendaal et al., 2016; Berg et al., 2018; Øyri & Wiig, 2019; Wiig et al., 2019 a, b; Wiig et al., 2020 b; Leistikow & Bal, 2020). Research linking resilience across system levels with examination of how regulation affects meso and micro-levels is encouraged (Anderson et al., 2020). Existing knowledge about the association between quality improvement and adaptive capacity emphasizes how managers play an essential part in recognizing conditions that require flexibility (Grote, 2019). It highlights the value of engaging participants from all levels in healthcare (Batalden & Davidoff, 2007; Grote, 2019). Scholars have suggested that resilience studies with focus on theoretical "blunt" end (which normally refers to administrative and bureaucrat levels of stakeholders) and "sharp" end (which normally refers to personnel close to clinical work operations) levels in the healthcare system, may hamper collaboration (Johnson & Lane, 2017; Hollnagel, 2018 a). Those with supporting roles for quality and safety "delivery" at both the individual patient level and at a managerial, policy level, have a challenging work task of "juggling" (Johnson & Lane, 2017). Illustrated by hospital managers' position between governmental requirements and expectations on one hand, and administrative demands and clinical practice and patients to care for on the other, this thesis recognized that their viewpoints were important to explore. This ties well with a recent report showing adequate and continuous development of healthcare professionals' competences as particularly important for resilience (Hedsköld et al., 2021). Recent work has also highlighted how managers' situational response to shifting circumstances is a crucial part of the adaptive strategies applied to enhance system resilience (Hybinette et al., 2021).

Summary of knowledge gaps

Most studies about regulation address deviation and noncompliance, not how regulatory bodies adapt to challenges in the regulated context and contribute to adaptive capacity (or not) in the regulated organizations (Barber, 2002; Carthey et al., 2011; Macrae, 2013; Johannesen, 2020; Johannesen et al., 2020). Bearing in mind that the literature lacks studies looking at regulation and resilience, concepts often considered as counterparts, this thesis adds value to the absence in previous research (Macrae, 2010, 2013; Øyri & Wiig, 2019; Wiig et al 2019 a, b; Wiig et al., 2020 b). Thus, the present study contributes to increased

knowledge about regulators' activity and inspectors' experiences, by grasping how they think of and approach implementation of the Quality Improvement Regulation. Also, it fills in some of the gaps in knowledge about how the field of hospital management deals with and experiences regulatory initiatives, activities, and requirements. Lastly, considering that the Ministry has requested knowledge about how the hospitals have complied with and implemented the Quality Improvement Regulation, this thesis accommodates this governmental knowledge request (MHCS, 2019).

2.2 Aim and research questions

This thesis focuses on healthcare regulation and resilience. The overall aim was to explore the rationale, expectations, implementation, and management of the Quality Improvement Regulation. More specifically, it aimed to investigate a multilevel perspective of how governmental healthcare regulation and adaptive capacity is linked, including what makes regulation important to and effective in hospital management practice. The overall and leading research problem for this thesis, is:

How does a new healthcare regulation implemented across three system levels contribute to adaptive capacity in hospital management of quality and safety?

The objectives were to develop knowledge in a resilience perspective, about:

1 governmental rationale and expectations in relation to the Quality Improvement Regulation (Paper I),
2 if, and in what ways, there have been changes in the supervisory approach towards Norwegian hospitals, due to the implementation of the new Quality Improvement Regulation (Paper II),
3 hospital managers' perspectives on implementation efforts and the following work practices, to understand if, and how, the new Quality Improvement Regulation influences quality and safety improvement activities (Paper III).

The following research questions guided the three sub-studies:

i) What was the regulatory rationale for developing a management focused regulatory framework (the Quality Improvement Regulation) for quality and safety improvement in healthcare? (Paper I),
ii) How do the regulatory bodies expect the new Quality Improvement Regulation to influence resilience in hospitals? (Paper I),
iii) How do Norwegian County Governors adapt to changes in the new Quality Improvement Regulation, to improve their practice as inspectors and regulators? (Paper II),
iv) How do Norwegian County Governors work to promote (or hamper) adaptation and learning in hospitals? (Paper II),
v) How do hospital managers work to improve quality and what are their experiences with implementing the Quality Improvement Regulation? (Paper III).

What this thesis adds – key take home points across sub studies

The work presented in this thesis, across all three papers, adds to the literature and current knowledge on regulation and resilience in healthcare. The intertwined findings of this work bring new knowledge about adaptive capacity at three system levels.

- It puts the regulator-regulatee dimension in front and center, to understand the relationship between regulatory development, enactment and supervision, and implementation at the hospital level.
- In a regulator perspective, healthcare regulation is central to quality and safety, and this thesis displays issues with the development and practical incorporation of the current regulatory framework.
- Challenges to improvement work get highlighted across system levels, speaking for new perspectives of governmental, regulatory development processes, and collaboration between macro, meso, and micro-levels. Thus, this thesis adds to the gap in knowledge about how resilience with emphasis on adaptation can be operationalized and supported at all levels.
- It opposes the idea that regulation per se is a negative catalysator for achieving adaptive capacity across the healthcare system.

2.3 Quality and Safety Challenges in the Norwegian Healthcare Services

Over the past 10 to 15 years, patient safety and efforts to increase hospital quality has developed into a key policy area in the Norwegian healthcare system (MHCS, 2006). Several measures and activities have been introduced, at different levels. Stated in the Act of Governmental Supervision with the Healthcare Services (the Health Supervision Act) § 5 (MHCS, 2017), every healthcare provider is required to establish an internal control system and the County Governors are required to inspect these internal control systems.

The roots of the explicit application of "internal control" in the Norwegian healthcare system goes back to the enactment of the Internal Control Regulations in 2002 (ICR, 2002), leading up to the current Quality Improvement Regulation (see Figure 1 on the next page for timeline of the development of the regulatory regime). The Norwegian regime for internal control in healthcare is founded on performance-based principles for regulation, inspired by safety and risk management principles in the Norwegian petroleum industry (PSA, 2019). The offshore experience with internal control was transformed onshore to Internal Control Regulations of 1991, enacted in 1992 (Ministry of Local Government, 1991). This process merged with the follow up of the Work Environment Act of 1977 (Ministry of Labor and Social Affairs, 1977), influenced, and inspired by "The Robens Report" in the UK, reframing the Health and Safety at Work Act in 1974 with a move towards *self-regulation* (Reason, 1997; Lindøe & Baram, 2019; HSE, 2020). The offshore Internal Control Regulations (1991) met the same fate of being redesigned as the Internal Control Regulations (2002) in healthcare did, 11 years later. However, core stakeholders such as the Confederation of Norwegian Enterprise (NHO) and the Norwegian Confederation of Trade Unions (LO) mobilized and challenged the Ministry and policy makers to redesign the regulatory framework as part of the "tripartite governance" (Lindøe & Baram, 2019). The outcome was the Internal Control (HSE) Regulations (Ministry of Labor and Social Affairs, 1996) where the legal part (four pages) was repacked and integrated in a pamphlet of 27 pages, with user friendly comments and guidelines. The 2002 Internal Control Regulations in healthcare was indeed a blueprint of the 1996 Internal Control Regulations in the petroleum industry. In

the comparison of the internal control regime in the petroleum industry with the internal control regime in healthcare, the time span of reflection leading to the revised regulations differs greatly. The transformation of the regulatory framework in the Norwegian petroleum industry took five years, against 14 years in the Norwegian healthcare context. This thesis limits its looks at the internal control regime and development of quality improvement in healthcare to the last 20 years.

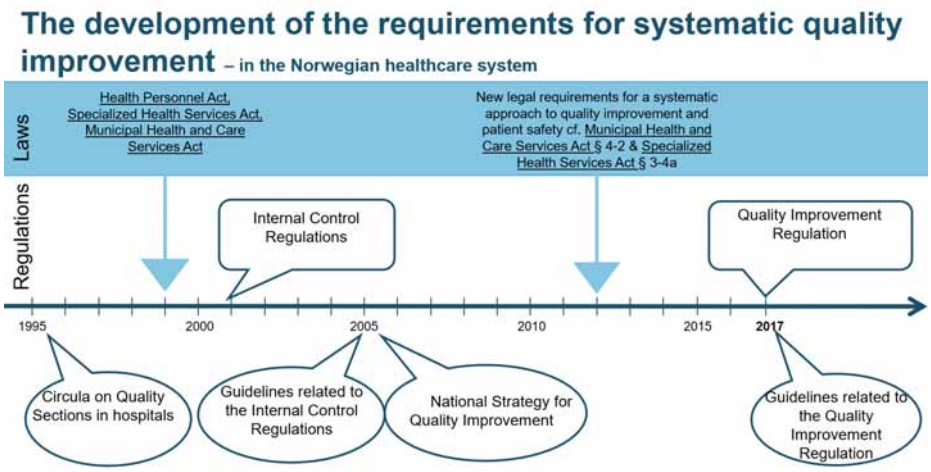

Figure 1: Timeline of the Norwegian regulatory internal control regime in the context of healthcare (NDH, n.d.) [1]

Previously conducted external hospital supervision across health regions in Norway, identified several challenges to systematic quality and safety improvement (see page 1 and 2) (NBHS, 2008, 2011, 2013; MHCS, 2012, 2015, 2016). Hospital managers' attitudes, values and organizational culture for learning were associated with noncompliance with governmental requirements (NBHS, 2008, 2011, 2013; MHCS, 2012, 2015; Wiig et al., 2018). Besides, lack of familiarity with and implementation of the previous regulatory framework for quality and safety improvement was revealed in these external inspections too (ICR, 2002).

[1] Translated and adjusted version of an original figure retrieved from the Inspectorate (NDH, n.d.).

In addition to external inspections, several macro-level initiatives have been launched in recent years: annual quality and patient safety reports to the Norwegian Parliament "Storting" (White Papers), national quality indicators, the National Strategy for Quality Improvement in Health and Social Services (2005 - 2015) (NDH, 2005) and "action plans", including the national "Program for Patient Safety" (MHCS, 2014 a) and the National Action Plan for patient safety and quality improvement (2019-2023) (NDH, 2019 b). The latter was originally launched in 2011 as a three- year "Patient Safety Campaign" and was continued as a five-year patient safety program from 2014 onwards (MHCS, 2014 b). The objective with the Program was to initiate a broad scale effort to reduce patient injuries (MHCS, 2012; Deloitte, 2019). It aimed at several areas where it was assumed crucial to increase the quality, including "Safe Surgery" and "Management of Patient Safety". It quantified several objectives, for instance: to reduce infections, to improve survival rate, and to improve patient safety culture (MHCS, 2014 a, b). Specific improvement projects were developed to meet the relevant challenges. These specific improvement projects were accompanied by regulatory activities such as laws and regulations because the latter held governmental enforcement options (NBHS, 2014). Along with the described macro-level initiatives, the Government's regulatory response to the observed challenges in hospital management of quality and safety was therefore to revise the Internal Control Regulations (2002), resulting in the design and enactment of the Quality Improvement Regulation (2016).

2.3.1 Governmental Regulatory Response

Through the Quality Improvement Regulation, the regulators require all healthcare service providers and organizations to establish a system for risk management and responsibility for the internal control system (Table 1 compares the design of the previous Internal Control Regulations and the current Quality Improvement Regulation). It applies to both the municipal healthcare providers and organizations, and the specialized healthcare system. However, this thesis is limited to the public hospital setting. The Quality Improvement Regulation was designed to embed a "Plan, Do, Study, Act (PDSA)" methodology in quality improvement activities, referring to the four-step management logic developed by Deming (1986). For an illustration of a plain PDSA cycle, see Figure 2 below. The Quality Improvement Regulation

requires hospitals to plan and establish barriers to discover risk, adverse events, and near misses before they result in consequences for the patients, and to handle, correct and evaluate adverse events and near misses. The focus on the managerial level and the role of managers in risk management and quality improvement increased significantly with the new regulatory framework, as it *explicates* the managerial responsibility to improve quality. The obligation to delegate tasks from one management level to another in daily work operations was specified, and one new substantial provision was added cf. § 8 litra f): The obligation to systematically evaluate risk management and quality improvement measures (yearly).

Figure 2: PDSA (Moen & Norman, 2010)

More specifically, the unusual PDSA design provided in the Quality Improvement Regulation consists of the following four steps, displayed in Table 2 (two specific examples of activities are given for each of the steps, all retrieved from the Guidelines document (NDH, 2017) relating to the Quality Improvement Regulation).

Table 1: Two different regulatory designs

ICR (2002)		QIR (2016)	
Section	**Heading and content**	**Section**	**Heading and content**
§1	Purpose	§1	Purpose
§2	Scope (organizational)	§2	Scope (organizational)
§3	Internal control	§3	Responsibility for the management system
§4	The content of internal control	§4	Definition
§5	Documentation	§5	Scope and documentation
		§6	Duty to plan
		§7	Duty to implement
		§8	Duty to evaluate
		§9	Duty to correct
		§10	Commencement

Table 2: The Quality Improvement Regulation's PDSA design (QIR, 2016)

PDSA step	Key areas and improvement tasks	Examples of specific activities
The duty to plan **(§6)**	• Plan tasks and activities • Gain overview of responsibility, laws, regulations, guidelines and of deviations. • Gain overview of adverse events, risks, and areas of significant need for quality improvement • Plan how to minimize these risks.	Example 1: identify and discuss deviances reported to the hospital's system for adverse event reporting. Example 2: structured identification and analysis of the last 50 mortalities at the relevant hospital, through medical records.
The duty to implement (do) **(§7)**	• Ensure that activities relevant regulations and guidelines are known • Develop and implement procedures and routines to reveal, correct and prevent breach and violation of sound professional practice and systematic quality improvement	Example 1: conduct a weekly, 15-minute interdisciplinary meeting to visually display ideas for improving the quality in areas where patient complaints exist. Example 2: relevant department or unit manager conducts a patient safety "visit" with the objective of identifying risks and possible areas for improvement and to encourage collaboration between the management level and "front line" clinicians.
The duty to evaluate (study) **(§8)**	• Assess implementation of activities, plans, including systematic quality improvement efforts • Evaluate if regulations are met • Review deviations, adverse events to prevent similar events • Minimum one annual systematic review of the management system	Example 1: corroborate the implemented efforts by using dashboard indicators. Example 2: aggregate data from patient complaints about waiting time, to reduce waiting time.
The duty to correct (act) **(§9)**	• Correct unsound practice and regulatory violations • Ensure implementation of systematic quality improvement efforts • Improve necessary procedures, instructions, routines to reveal, correct violations	Example 1: apply small scale testing to ensure that recent technology and new treatment is efficient. Example 2: conduct a Pareto diagram/chart to uncover what causes certain registered issues at the relevant hospital unit.

2.4 The Norwegian regulatory and supervisory regime

The Norwegian regulatory and supervisory regime is complex, with several policymaking and governing bodies and a range of different regulatory strategies and different legal sources. The following categories are relevant legal sources in the Norwegian regulatory regime (Eckhoff, 2001) (laws, regulations and prerogatives apply specifically to this thesis):

- Laws and regulations (in Norwegian: “lov og forskrift”)
- Prerogatives (in Norwegian: “forarbeider”)
- Case law (Supreme Court rulings in particular) (In Norwegian: “rettspraksis”)
- Legal arguments, indirectly retrieved from knowledge about the values and considerations that laws and regulations rest on (in Norwegian: “reelle hensyn”)
- Practices retrieved from additional governmental bodies
- International law
- Legal theory
- Customs; traditions; practices (in Norwegian: “sedvane”).

Laws determine rights and duties, and are adopted, amended, and terminated by Parliament. Regulations are decisions concerning the rights or obligations of an indefinite number or an indefinite circle of persons (the Public Administration Act, § 2 (1) litra c) (Ministry of Justice, 1967). Regulations are usually adopted by a ministry or directorate and have countrywide application. Regulations supply the provisions of laws (Lovdata, 2020). A prerogative relates to the regulatory development process (any law or regulation builds on its prerogative) and is a document that states narrative of facts and circumstances of policies in the relevant law or regulation. It indicates the regulator’s intention, and elaborate words, expressions and phrases in the specific law or regulation (Blandhol et al., 2015). The development process differs between a law and a regulation, whereupon laws are determined by Parliament and not by a ministry or directorate. Prerogatives related to laws are thus more comprehensive and the elaborative process more extensive compared to prerogatives associated with regulations. Prerogatives related to regulations

are also considered less accessible compared to prerogatives associated with laws and are rarely used by the Court in interpretive matters concerning regulations (Lilleholt, 2003).

Examples of non-statutory and non-legally binding instruments are guidelines and standards (Boe, 1996). These instruments are nevertheless normative and provide guidance by indicating desirable and recommended actions, activities, or measures (NDH, 2017).

One important distinction is the pair of legal concepts: *de lege lata* and *de lege ferenda*. De lege lata refers to *current* law, whilst de lege ferenda refers to what regulation of a certain area *should* be like (Eckhoff, 2001). This thesis elaborates both angles in its discussion about the regulatory regime of internal control. *De lege lata* explicates the development and enactment of the current regime (cf. the present Quality Improvement Regulation). A de lege ferenda judgement on the other hand is the obligation for the governing system (the political, democratically based system, represented by the Ministry) in their job of for instance considering societal changes that request further development of the present regulatory regime. To this thesis, a *de lege ferenda* applies to the discussion of how the regime could benefit from adaptive capacity, if developed and adjusted even further.

2.4.1 The Ministry of Health and Care Services

Purposes, Policy, and Practice

The *Ministry of Health and Care Services* directs the Norwegian healthcare services through comprehensive legislation, annual budgetary allocations and by means of various governmental institutions such as the Norwegian Board of Health Supervision and the Norwegian Directorate of Health. The Ministry governs the Regional Health Authorities (four in total) by issuing annual provisions that govern the proceedings of these trusts (in Norwegian: “Oppdragsdokument”). Thus, there is a direct line of governance going from the Ministry and through the RHT’s, see Figure 3 below.

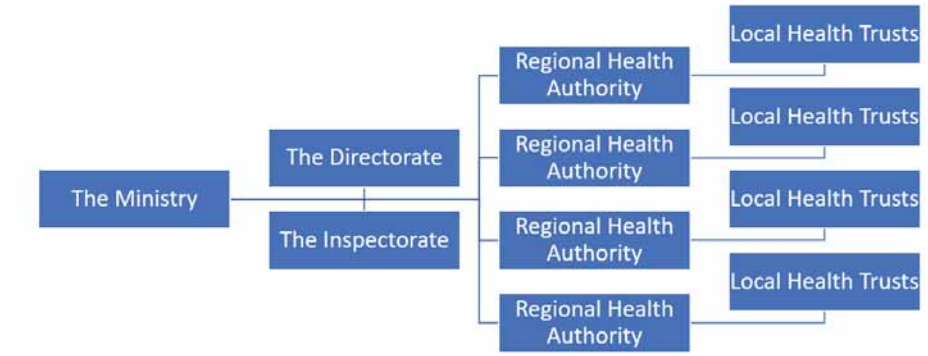

Figure 3: Governance line and affiliations between the Ministry, the Directorate, the Inspectorate, the RHAs and the LHTs.

2.4.2 The Norwegian Directorate of Health

Purposes, Policy, and Practice

The *Norwegian Directorate of Health* is a regulatory, governmental body with authority to implement and carry out the Ministry's health policies (NDH, 2019 a). Its public mandate is to monitor the development of Norwegian healthcare services (NDH, 2019 a). The Directorate is set to administer and interpret legislation and regulations, and to provide strategic guidance on measures and competences for healthcare professional related issues (NDH, 2019 a). It was for instance responsible for the development and issuing of the Guidelines document accompanying the Quality Improvement Regulation (NDH, 2017).

2.4.3 The Norwegian Board of Health Supervision and the County Governors

Purposes, Policy, and Practice

The *Norwegian Board of Health Supervision* and the *County Governors* constitute the governmental bodies responsible for supervisory activities across the Norwegian healthcare system. The Inspectorate is the superior supervisory institution; a national public institution organized under the Ministry. The County Governors are responsible for carrying out policies provided by the national government, including external inspection of regulatory implementation at the regional level of healthcare (NBHS, 2019 a). As of 01.01.2019, regions were re organized into 11 County Governor regions

(Ministry of Local Government and Modernization, 2017). Each County Governor office consists of one chief county medical officer, one or several assistant chief county medical officers and several inspectors with different professional backgrounds.

The main purpose with the supervisory regime is to ensure that the healthcare services comply with the applicable legal requirements. It is set out to reinforce quality and safety in the healthcare services and to increase trust between healthcare personnel, the services, and the public (NBHS, 2019 a). Two main categories of supervision exist:

1. Planned, system audits. Modus operandi: proactive/preventative supervision, to identify risk areas. 200-400 planned/system audits are conducted each year (NBHS, 2019 a).
2. Individual cases of deficiencies/adverse events related supervision. Modus operandi: reactive supervision, to identify causality and breach of prudency. 3000-4000 adverse event-related cases are assessed each year (NBHS, 2019 a). Table 3 offers an illustration of the alternative sanctions issued by the supervisory authorities (and the number of each sanction during 2019).

The process of supervision

Inspections as part of planned, countrywide supervision (system audits) targeting the specialized healthcare system, are initiated by the Inspectorate. The topic in planned, countrywide supervision is typically picked based on an increased risk of adverse events in a specific area or context (MHCS, 2018). Adverse event-related supervision on the other hand, starts with a specific adverse event, patient injury, or complaint, and is performed by the regional supervisory authority, the County Governors. Different aspects of regulatory requirements form the inspectors' evaluations, for instance (NBHS, 2020 a, b):

- The obligation of sound professional practice and prudent conduct.
- The duty to work systematically with management and improve quality. To illustrate: The Quality Improvement Regulation is specifically relevant for inspection with spotlight on how hospital organizations govern and enforce their systematic, internal management of quality and safety.

In planned, system audits, the Inspectorate provides the County Governors with associated guidelines, including a template for how to write a report post-supervision (NBHS, 2018). The County Governors are instructed to start any planned, system audit or adverse events related supervision with a description of sound professional practice and prudent conduct, to be able to assess a possible deviation from the applicable legal requirements. Part of the assessment is to establish if the deviation is in breach with sound professional practice. The County Governors produce concluding reports after conducting supervision, identifying either breach of legal requirements, including breach with sound professional practice and prudent conduct, or no regulatory breach, cf. the Health Supervision Act (2017). Breaches can for example be related to violation of the Specialized Health Services Act (1999), cf. the Quality Improvement Regulation. If the County Governor concludes with a deviation from good practice, this does not necessarily voice professional irresponsibility (Molven et al, 2006).

Table 3: Types and numbers of the sanctions issued by the Inspectorate during 2019 (NBHS, 2020 c)

Sanction	**Numbers**
Notifications to health personnel (a decrease compared to 2018)	269
Revocations of authorizations	145
Institutions in the specialized healthcare services receiving notifications about breach of sound professional practice: prudent conduct	51
Police reports filed against health personnel	12
Police report filed against healthcare organizations	6
Warnings of enforcement fines	5
Impositions (legally binding individual decisions) (in Norwegian: “pålegg”)	3

2.4.4 Development process of governmental regulations

A specific regulation has its legal basis in one or several Acts of law. In the case of the Quality Improvement Regulation, four Acts form its legal basis, see Table 4.

Table 4: The QIR's legal basis

English title	Original title in Norwegian
The Health Supervision Act	Lov 15. desember 2017 nr. 107 om statlig tilsyn med helse- og omsorgstjenesten m.m. (helsetilsynsloven) § 7. (MHCS, 2017)
The Specialized Health Services Act	Lov 2. juli 1999 nr. 61 om spesialisthelsetjenesten m.m. (spesialisthelsetjenesteloven) § 2-1a tredje ledd og § 3-4a andre ledd. (MHCS, 1999 b)
The Municipal Health and Care Services Act	Lov 24. juni 2011 nr. 30 om kommunale helse- og omsorgstjenester m.m. (helse- og omsorgstjenesteloven) § 3-1 tredje ledd og § 4-2 andre ledd. (MHCS, 2011)
The Dental Health Services Act	Lov 3. juni 1983 nr. 54 om tannhelsetjenesten (tannhelsetjenesteloven) § 1-3a. (MHCS, 1983)

Any regulatory change must go through a certain democratic and bureaucratic process before it can entry into force (illustrated in Figure 4). The requirements to adapt or change a specific *regulation* are less comprehensive than the development process of an *Act of Law*. The requirements concerning regulations are specified in the Public Administration Act (Ministry of Justice, 1967). According to this Act, all stakeholders have the right to give their opinion during the process: cf. Section 37 (2):

> Public and private institutions and organizations for enterprises, professions and skilled trades or interest groups which the regulations concern or will concern, or whose interests are particularly affected, shall be given an opportunity to express their opinions before the regulations are issued, amended, or repealed.

Figure 4: Traditional process of developing governmental regulations

In a letter sent from The Ministry to the Directorate in 2013, the background for revising the Internal Control Regulations was described as the need for uniting the internal control regime and systematic quality improvement and patient and user safety. As argued earlier, requirements of management and leadership, risk management, coordination of services and causal analysis of adverse events were listed as areas important to *clarify* in the proposal for a new regulatory framework. The Ministry delegated the task of drafting the new regulatory framework to the Directorate. However, disagreement between the governmental bodies about the design, resulted in the Ministry taking over the drafting process. More specifically, the process of developing the Quality Improvement Regulation then continued with a memorandum/draft of the new regulation, sent from The Ministry to relevant stakeholders. The intention of this hearing was to give the stakeholders an opportunity to review the draft and give feedback on title and content. The draft was sent October the 30th 2015, followed by a deadline on the hearing draft set to February the 1st 2016. By this deadline, The Ministry received 72 written statements, whereas 15 of these had no comments. After hearing comments were received, they were assessed by the Ministry and concluded in the Prerogative document (MHCS, 2016 b). In turn, this process led to the enactment of the Quality Improvement Regulation (see illustration in Figure 5).

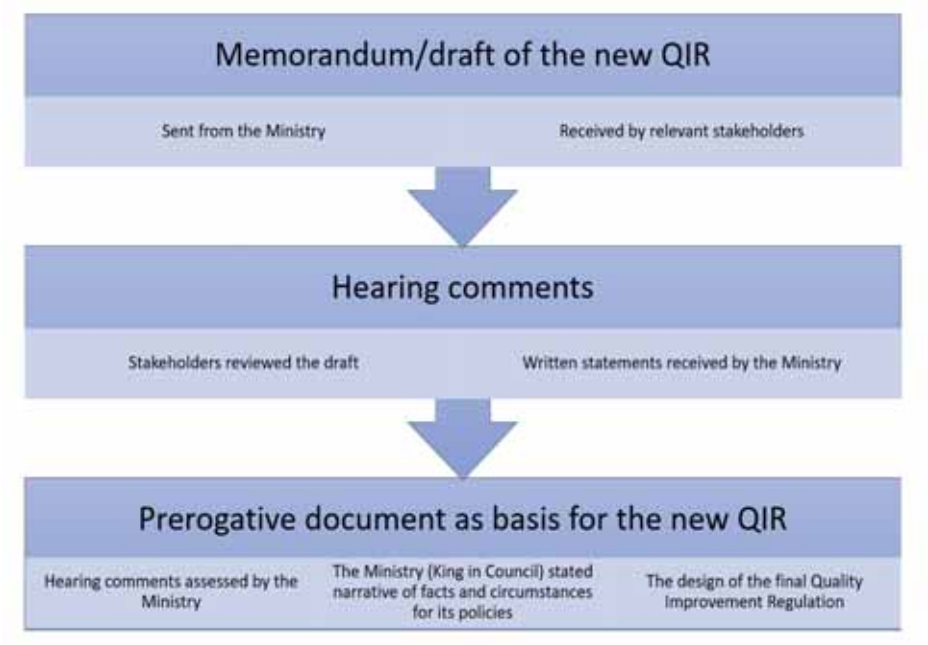

Figure 5: The specific QIR development process

2.5 The Norwegian specialized healthcare system

Four regional health authorities are set to implement the national health policies, and to plan, organize, govern, and coordinate all subordinated local health trusts (hospitals) in their region (MHCS (the Health Trusts' Act) 2001). Every hospital should be organized with a responsible manager at all levels (MHCS, 1999 b). For each organizational unit in the hospital (e.g., clinic (division or similar), department or equivalent, and sections), one manager with overall responsibility for the unit, both administratively and professionally must be appointed (MHCS, 2013 a). Some key facts about the Norwegian specialized healthcare system are presented below:

- 1,987,263 million patients treated and/or hospitalized in 2019 (SSB, 2020 a).
- 114,028 thousand people employed in the specialized healthcare services in 2018 (Morgan et al., 2017). The overall level of staffing by higher level health personnel is relatively high, with more than 50% of hospital

employees being either physicians or nurse/midwives (Morgan et al., 2017).

- 2667 EUR (28500 NOK) in operating expenses per inhabitant in 2020 (SBB, 2020 b).
- Indications of an 11,9 % adverse event rate in 2018, against 13,7 % in 2017 in the hospital context (MHCS, 2019). In 2019 a slightly raise was registered with a rate of 12,4 %. However, statistics for the period of 2012-2019, indicate a reduction of 35% in serious patient injuries and a 65% reduction in injuries causing death (NDH, 2020 a).
- The most frequent types of patient injuries registered in 2019 were medication related injuries, surgical complications, urinary tract infection, and lower respiratory tract infection (NDH, 2020 a).

2.6 Structure of the thesis and list of papers

This thesis consists of two parts. Part 1 is divided into 7 chapters. Part 2 contains three original, peer reviewed and published research articles, and appendices.

Paper I
Øyri, S.F., Braut, G.S., Macrae, C. & Wiig, S. Exploring links between resilience and the macro-level development of healthcare regulation- a Norwegian case study. *BMC Health Services Research* 20, 762 (2020).
https://doi.org/10.1186/s12913-020-05513-x

Paper II
Øyri, S.F., Braut, G.S., Macrae, C. & Wiig, S. Investigating hospital supervision: a case study of regulatory inspectors' roles as potential co-creators of resilience. *Journal of Patient Safety*: March 2021 - Volume 17 - Issue 2 - 122-130.
doi: 10.1097/PTS.0000000000000814

Paper III
Øyri, S.F., Braut, G.S., Macrae, C. & Wiig, S. Hospital managers' perspectives with implementing quality improvement measures and a new regulatory framework - a qualitative case study. *BMJ Open* 2020;10**:**e042847.
doi: 10.1136/bmjopen-2020-042847

3 Theory

This thesis applies theories of risk regulation to explore the design, development, and implementation of the Quality Improvement Regulation. The concept of resilience in healthcare, with emphasis on adaptive capacities was adopted in this study to understand how regulators expected the Quality Improvement Regulation to influence hospital managers' quality and safety work practices. Moreover, it was applied to understand how external inspectors promoted or hampered adaptive capacity and learning in hospitals. According to Rasmussen (1997), different theories are needed to explain processes at different system levels because the environmental stressors affecting the risk management process are accordingly different. For instance, the research disciplines of law and political science at the governmental level, affiliate with stressors like changes in public awareness, whilst management and organizational disciplines have stressors like changes in competence and training (Rasmussen, 1997). Therefore, and as the appropriate competence of regulators, inspectors, and managers is a crucial factor, two sets of theories were applied in this thesis.

3.1 Risk Regulation

This thesis defines the phenomenon of *regulation* generally and specifically:

1. as a general governmental mechanism (representing society's requirements imposed on the healthcare services, on behalf of patients and users) (Baldwin & Cave, 1999; Hopkins & Hale, 2002; Walshe, 2003; NBHS, 2014). This includes external inspection and supervision.
2. as one specific Norwegian regulatory framework, referred to as *the Quality Improvement Regulation* with a capital "R" in "regulation" (MCHS, 2016).

External inspection/supervision is a regulatory activity initiated and led by governmental inspectors, set out to assess healthcare organizations performance and/or individual performance (Baldwin & Cave, 1999; Hopkins & Hale, 2002; Walshe, 2003). This thesis focuses on organizational performance. Supervision assessments are based on a regulatory framework of

ideas and legal standards for sound professional practice and prudent conduct, and the minimum standards required (Shaw et al., 2019; Hovlid et al., 2020 a).

A regulatory system of *Internal Control* is defined as *enforced self-regulation,* involving stakeholders directly in the operationalization of Government issued requirements. It is characterized by the healthcare organizations' individual responsibility to apply systematic measures to ensure that all activities are planned, organized, carried out and maintained in accordance with governmental requirements and health legislation in general (ICR, 2002; QIR, 2016). It is linked to *performance-based* regulation, understood as a regulatory instrument that requires certain outcomes (achieved or avoided) without specifying any solutions (Coglianese & Lazer, 2003). The terms "performance-based" and "internal control" are used interchangeably in this thesis.

This thesis' understanding of risk is defined as the consequence of any activity, with associated uncertainty (Aven, 2016). This interdisciplinary perspective, where risk is not unilaterally viewed as a socially constructed phenomenon or as statistically calculated, is considered the most relevant approach within modern risk research (Renn, 2008 a, b, c). *Risk regulation* is understood as various forms of risk management, including how laws and regulations are used to deal with risks in the healthcare services (Engen et al., 2016). The choice of regulatory technique and modes of enforcement related to regulating risks, is for instance associated with whether regulators choose a blame orientation or a collective design, and the degree of participation (Baldwin & Cave, 1999). It also raises questions about whether risk regulation should be based on rational decisions made by experts or rather on "lay" approaches (Baldwin & Cave, 1999). The conduct of regulation is additionally complicated by imbalance of power between different actors, for instance discussed by Mintzberg's (1984) power and organizational life cycles. This implies an issue for regulation aiming at reducing risk, as it is rooted in an asymmetric relation of power between regulators empowered with legal control on one hand, and the regulatees on the other. The concept of a risk regulation *regime* seeks to explain and analyze the many components of risk regulation that interact, such as different ideas, rules and practice associated with the regulation of risks (Hood et. al, 2001). According to Hood and colleagues (2001), risk regulation regimes are systems with interacting parts, such as the relationship between policy makers and people at the "front line". To understand risk regulation as

phenomenon, it can be conceptualized as governmental control and a control system constructed to interfere with "market or social processes to control potential adverse consequences to health" (Hood et al., 2001). Any control system needs at least three components including *standard setting* (ways of setting standards to distinguish preferred or less preferred systems*), information gathering* (produce knowledge) and *behavior modification* (be able to change the system) (Hood et al., 2001). Broadly, regulation to control risk is operationalized by the means of enforcement of product or behavioral (modification) standards (Hood et al., 2001). Contextual elements of importance in the operationalization, is how risk is defined, the type of risk, how it is distributed between the stakeholders, the amount of regulation attached to the certain type of risk, how regulation is organized and the conventions and attitudes of the regulators (Hood et al., 2001). What Sparrow (2000) refers to as the *regulatory craft* is part of how risk may be controlled by governmental influence.

Whereas risk acceptance criteria express the acceptable level of risk related to an activity, a risk analysis is a systematic process for describing and systematizing the kind of activities and risks being dealt with. Risk management through regulatory strategies is primarily based on a multidimensionality of risk (Aven & Renn, 2010). This implies an approach where risk is neither viewed as a socially constructed phenomenon nor plainly statistically calculable, which aligns with the risk perspective in this thesis (denoted on the previous page). It is therefore unimaginable to eliminate all risk associated with an activity, despite our best efforts (Aven, 2016).

The regulatory principle of "command and control" is fundamental in many regulatory regimes, with risk regulation as part of the governmental agenda (Hood et al., 2001). Deterrence and compliance-based regulatory regimes have traditionally linked with different regulation regimes in different parts of the world (Hood et al., 2001). Deterrence approaches relate to punishment and penalties expected to deter the regulatees from breaking the rules, versus compliance-based approaches associated with strategies such as education, persuasion, and dialogue (Hood et al., 2001). Responsive regulation on the other hand represents a hybrid alternative, with emphasis on contextual flexibility. A complex healthcare system contained by uncertainty and variation as natural parts of daily work therefore fuels the importance of adaptive

capacity. Specifically related to aspects in this thesis, a regulatory system which supports a responsive approach towards risk may therefore be essential when developing new healthcare regulation.

3.1.1 Responsive regulation

Responsive regulation provided a way of thinking in this thesis' examination and analysis of regulatory activity across different system levels (Ayres & Braithwaite, 1992; Braithwaite, 2011). According to the essence of responsive regulation, different strategies constitute a pyramid of regulatory choices, with the less coercive strategies at the bottom and the interventionistic strategies at the top. Compliance in a responsive regime links with regulatory response to regulatees who lack information, skills, or competence to comply. In contrast, regulators are likely to escalate up the pyramid and apply deterrence strategies, if regulatees act unwilling to comply or act opportunistic (Hood et al., 2001; Braithwaite, 2011). Different regulatory strategies are displayed in the pyramid below, see Figure 6 (the sanctioning pyramid is displayed on a later page) (Ayres & Braithwaite, 1992; Braithwaite, 2011). Self-regulation of risk (founded in social control: risk assessments are self-initiated and independent of governmental interference) ranges at the bottom. The "purer" legal instrument (legislation with acts of law as the most restrictive instrument for governmental control) is at the top of the pyramid. The phenomenon called internal control (equivalent with performance-based regulation), is a "hybrid": denoted as enforced self-regulation (Ayres & Braithwaite, 1992). It aims to influence and co-opt the regulatees' ability and will to establish "internal governance" (Lindøe & Baram, 2019). Self-regulation as an alternative to pure enforcement is however accompanied by a "risk of verification" (Sparrow, 2000). Regulators become more reliant on the data provided by those being regulated, and bias will naturally be embedded when regulatees conduct internal audits and self-report compliance (Sparrow, 2000).

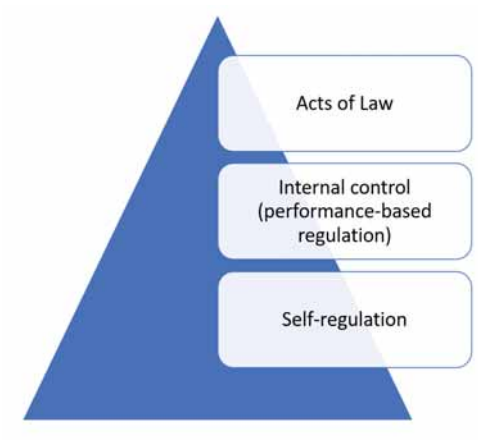

Figure 6: A simplified version of the pyramid of different regulatory strategies

Through legislation such as the Quality Improvement Regulation, the specific measures and activities will have to be self-chosen by the hospital managers. Hence, performance-based regulation represents regulatory governmental control *through* enforced self-regulation of risk. It was thus relevant to elaborate the relationship between risk, regulation, and supervision in this multilevel study, due to the different stakeholders' various views, expectations and experiences connected to regulatory activity. In this thesis, competence, capacity, risk, and context were considered influential elements to how regulatory activity was efficiently valued. These flexibility values are mirrored in the responsive pyramid. Regulators' responsiveness towards strategies and sanctions are therefore argued to facilitate legitimacy in the regulatory system (Braithwaite, 2011). In turn, regulatees are more likely to comply because that is the rational thing to do. This type of regime encourages the democratic value of cooperation between public and private stakeholders and in-between public governance. Regulation is thus seen as a constructive collaboration between state, professional, and public stakeholders (Quick, 2017). As responsive regulation theory maps the perspectives of multiple stakeholders and strategies, it was a sensible perspective to apply to the present multilevel study (Healy, 2011). See Figure 7 for an illustration of the collaborators implied by this thesis' context.

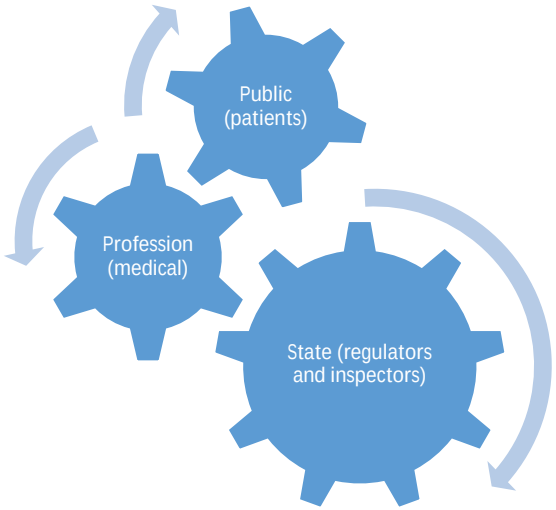

Figure 7: Collaboration between state-profession-public.

Responsive regulation urges a non-dogmatic approach to regulation, stressing contextual insight, including time and history, as fundamental parts of context (Braithwaite, 2011). The pyramids are theoretical constructions, predominantly offering the "presumption" that lower levels are the best place to start before turning to more interventionistic strategies and sanctions (Braithwaite, 2011). "Pyramidal responsiveness" therefore represents a dynamic theoretical model even in the most serious cases, where dialogue and persuasion are tried before more punitive attempts (Braithwaite, 2017). The key idea in responsive regulation is this dynamic movement up and down the pyramid (see Figure 6 and Figure 8), based on sensitive and ongoing analysis of what the most appropriate approaches to different circumstances for different risks are. In consequence, it increases demands on the regulatees' interpretation and adaptation.

Nevertheless, the "soft" approach in self-regulation is followed by the control mechanism of external inspection (more of a "hard" law approach) (Lindøe & Baram, 2019). The middle level strategy (see Figure 8) in the pyramid is thus part of the "negotiation" between regulators and regulatees (Lindøe & Baram, 2019). Moreover, the escalation up the pyramid connects to *who* the punisher is: if regulatees do not sanction their own "bad behavior" according to lower

levels of the pyramid, for instance through internal education and learning, regulators have the option of enforcing stronger sanctions (Braithwaite, 2011). Oppositely, there is an incentive for regulatees to independently modify behavior, to avoid higher level sanctions (see Figure 8 displaying an example of Braithwaite's pyramid (2011:482) of sanctions as constructed on the regulation of pharmaceuticals). This is reckoned one of the positive forces with flexibility offered in a responsive regulatory regime. Failure of compliance with lower-level responsiveness is however linked to lack of management competence, according to Braithwaite (2017).

Figure 8: Example of Braithwaite's pyramid of sanctions (2011)

Relating the different options of sanctions to the Norwegian supervisory setting, the remedies are set in two main categories (see details in Figure 9) (NBHS, 2017):

1) notification about breach of conduct, or

2) administrative sanctions.

Police reports and potential criminal prosecution are limited to cases where the Penal Code (2005) is applicable, for instance violence against a patient or theft of medication but is only sporadically relevant in cases where the County

Governor suspects a major deviance from sound professional practice and prudent conduct (i.e., the Norwegian Health Personnel Act, 1999).

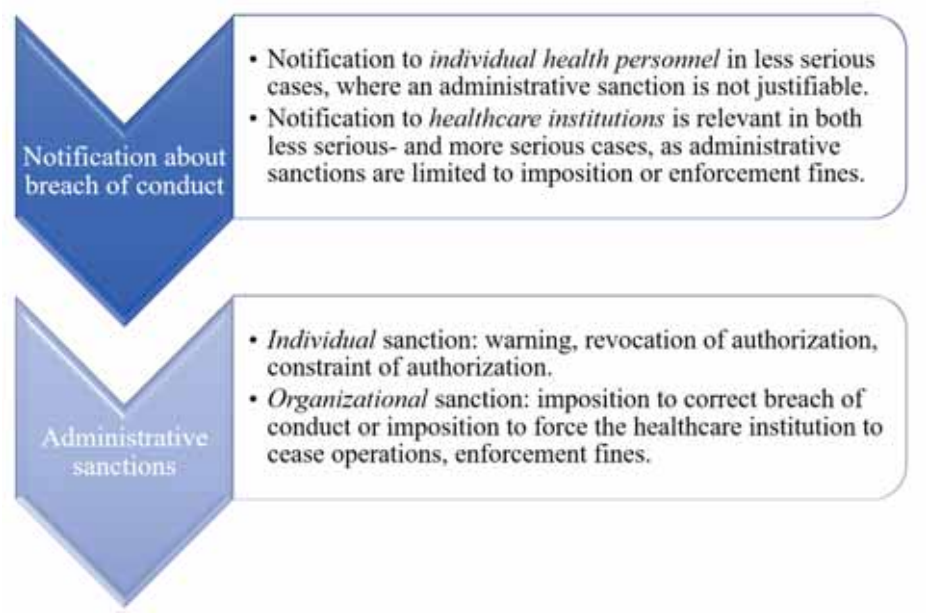

Figure 9: Options to sanction in the Norwegian supervisory regime.

3.2 Resilience in healthcare

Resilience in healthcare constitutes a valuable framework that helps to understand how systems can function and improve despite disruptions and adverse events (Furniss et al., 2014). A core idea is that resilience is "the ability of the healthcare system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required performance under both expected and unexpected conditions" (Hollnagel et al., 2006, 2013:xxv). This thesis applies a definition in line with the Resilience in Healthcare Research Program (2018-2023), defining resilience as "the capacity to adapt to challenges and changes at different system levels, to maintain high quality care" (Wiig et al., 2020:6 b).

Two approaches to safety have recently been delineated in safety science: "Safety I" and "Safety II" (Hollnagel et la., 2015). The traditional safety

perspective Safety I, views safety as the absence of adverse events and near misses, with emphasis on linear processes and reactive measures (Hollnagel, 2014). In contrast, Safety II in line with "resilience", is about creating and obtaining high quality services, and looks broader at risk and safety than Safety I (Hollnagel et al., 2013). It emphasizes the importance of focusing on what makes things go right, and that it can be hard to precisely predict and anticipate future events (Hollnagel et al., 2015; Ball & Frerk, 2015; Woodward, 2019). Hence, the assumption is that people must continually adjust and adapt to variability. Resilience is therefore regarded a key priority in healthcare (Hollnagel et al., 2006, 2013; Wiig & Fahlbruch, 2019).

Four potentials of monitoring, responding, anticipating, and learning are traditionally applied to analysis in resilience in healthcare research approaches (Hollnagel et al., 2015). However, this thesis did not aim for a complete analysis of the four Hollnagel developed resilience potentials. Recent critique points to overreliance on the founding authors of resilience theories (Iflaifel et al., 2020). According to Iflaifel et al. (2020), no gold standard for conceptualization of resilience in healthcare exists despite similarities in the tools that resilience in healthcare studies apply. It is suggested to increase the international focus to overcome overreliance on the Hollnagel potentials, as well as including "flexibility, trade-offs, and robustness" to reach consistency in the conceptualization of resilience in healthcare (Ellis et al., 2019; Iflaifel et al., 2020). The potentials of *anticipation* (know what to expect; anticipate future developments), *adaptation* and *flexibility*, are nevertheless key to understand how healthcare organizations can deliver services despite challenges or disruptions (Hollnagel et al., 2006; Macrae & Stewart, 2019; Macrae & Wiig, 2019; Kyriakidis & Dang, 2019). The learning potential (how sources of adverse events, near misses and success are dealt with to improve the system), relates to competence, equipment, time, resources, and leadership (Hollnagel, 2018 a).

This thesis therefore partly expanded on perspectives from Hollnagel's resilience potentials, but mainly focused on adaptation, including anticipation, and learning potentials. It was a deliberate choice, as the four main potentials as basic for collecting and interpreting the data, were found to not fully grasp the complexity in the multilevel perspective of how regulation and resilience relate. Support for this argument is found in Le Coze (2008) about modelling

in safety science. One of the issues discussed, is how micro, meso, and macro linking has been a "forever" challenge in social sciences, partly due to different definitions, concepts and methodology applied in human factors (individual) and organizational studies of accident investigations (Le Coze, 2008). This thesis argues that by applying principles from resilience in healthcare, the traditional micro-level perspective as in human factors, and meso, macro, level perspectives as in organizational factors, are linked. Accordingly, resilience in healthcare was chosen over "competing" theories in risk management and safety sciences, mainly due to its nature of continuous attention to flexible improvement processes (Le Coze, 2008). Moreover, resilience in healthcare takes a system approach to safety, which made the choice of applying resilience in healthcare as the "driving" multilevel perspective on quality and safety in this thesis, a sensible one. Worth adding is that resilience in healthcare as a theoretical framework has developed during the timespan of the work on this thesis. New literature has added to the field, including efforts to conceptualize and reach a common definition. The internationally spanned resilience in healthcare research program represents one of these efforts (Wiig et al., 2020 b).

Work as Imagined versus Work as Done

According to Hollnagel (2018) it is key to question why people act the way they do. How and where people work is connected to different phases or modus operandi: the planning phase of work operations, the managing phase of actual work and the phase of analysis after work has taken place (regardless of the outcome) (Hollnagel, 2018 a). The planning phase of work operations is often referred to as *work as imagined* (Hollnagel, 2018 a). This includes processes such as designing laws and regulations, management of quality and safety measures and external inspection and supervision (Anderson et al., 2020). Hence it describes what regulators, governmental authorities and administrative managers *believe* and/or *wish* would occur in patient care. Actual unfolding of practical and clinical work; what healthcare professionals *do*, is often characterized by the concept *work as done* (Hollnagel, 2018 a; Anderson et al., 2020).

There is often an alignment challenge between *work as imagine* and *work as done*, and as a way of understanding resilience in healthcare, researchers need to explore and address this challenge (Hollnagel, 2018 a; Anderson et al., 2016).

Repeatedly, rules, regulations and procedures are perceived to hamper efficient management of clinical practice. This notion and thereby how regulatory practices best are formed, needs more scrutiny and attention in research.

3.2.1 Adaptive capacity and the link to Anticipation and Organizational Learning

This thesis sees adaptation to variation as a necessary quality and safety component. Hence, efforts to manage and improve quality and safety depend on adaptation and tailoring to local conditions and context. The degree and type of adaptation, however, depends on the specific quality and safety challenge in the specific hospital setting (Vincent & Amalberti, 2016). Berg and Aase (2019) have identified empirical studies looking at adaptive capacities at different system levels. At the level of individual clinicians, adaptive capacities included dealing with unexpected situations, developing rules and procedures, and improvising (Berg & Aase, 2019). Others have emphasized the importance of management guidance to enable understanding of what is operationally needed to manage conditions of unexpected events (Olmos-Ochoa et al., 2019; Amalberti & Vincent, 2020; Pimentel et al., 2020). Moreover, Berg and Aase's study (2019) found that the ability to anticipate was closely linked with the ability to adapt. "Anticipatory regulation" at the management level was described as the ability to anticipate resources needed, such as staffing levels, in line with patient demand (Berg & Aase, 2019). Furthermore, managers must have the capability of sensing and preparing (themselves and the team) for switching between appropriate modes of operation (Grote, 2019). Adaptations at an organizational level could therefore relate to accommodating systemic risk factors such as resources and time, by for example facilitating daily learning during short breaks (Reason, 2001, 2002; Hollnagel, 2004; Cagliano et al., 2011; Basheer et al., 2018).

Past research has also pinpointed how people in complex adaptive systems, such as the healthcare system, continuously adapt to new challenges, regardless of well-intentioned attempts to reduce "human variability" (Reiman et al., 2015; Woodward, 2019). Even when safety is targeted an official, formal organizational priority, interventions are often designed inappropriately with regards to the complex reality (Reiman et al., 2015; Woodward, 2019). Several

descriptions address tensions between different trade-offs and between adaptive capacity and anticipation in safety systems (Reiman et al., 2015; Grote, 2019). One of the tensions described by Reiman and colleagues (2015) relates to response to contingencies. It includes a trade-off between building anticipatory capacity and "systematically and repeatedly respond to expected contingencies versus building capacity to adapt and flexibly respond to any contingency" (Reiman et al., 2015:88). This tension can illustrate some of the complexity surrounding interactions across system levels. It points to how there is a constant, embedded conflict in regulating and managing healthcare. To this thesis' understanding, a necessary level of flexibility and adaptive capacity can be safeguarded in the regulatory regime, without compromising on implementation and resource support for managers. The latter is needed to ensure that processes and activities are in line with governmental expectations of high-quality care, regardless of occurring and unexpected situations. The learning aspect adds to hospitals' anticipatory potential as it can either be facilitated or hampered through prioritizing of learning episodes or breaks. Both meso-level inspectors and micro-level hospital managers have potential to act as learning facilitators.

Theories of organizational learning emphasize the importance of detecting and correcting knowledge that potentially could hamper learning, and how this impacts information about organizational problems from lower-level managers, through middle managers on its way to the top management level (Argyris, 1977). The detection and correction process where organizations take corrective action to deal with errors without questioning underlying objectives and policies, is called single loop learning, whilst double loop learning takes underlying causes of the error into consideration (Argyris, 1977). The double loop learning process implicates a thorough analysis of root causes, interconnections, and potential pitfalls with current policies. This requires organizations to encourage opposition and confrontation to objectives, norms, and ideas so that "policies and practices" are challenged, and information about organizational issues are getting across lower level to middle level managers, and thus reaches the top managers (Argyris, 1977). In turn, double loop learning can be linked to the resilience idea of uniting work as imagined and work as done, in the sense that problem solving is followed by reevaluation and reframing of policies and practices (Argyris, 1977). Collaborative learning has

recently been linked with resilience, for instance in the resilience research facilitated by Wiig and colleagues (2020 b). This research indicates how there is a call for studies addressing double loop learning as part of detection and correction across system levels.

3.3 The relationship of Regulation, Quality, Safety and Resilience

There is not always a clear distinction between the concepts of quality and safety in healthcare. Some definitions view safety as an "attribute of quality", and successful healthcare outcomes as results from quality efforts (Sheps & Cardiff, 2013). According to Sheps and Cardiff (2013) this view misses that trade-offs, complexity, and variability are important elements in healthcare. The Ministry demonstrates a corresponding view, extracting end-result from their definition of quality due to uncertainty over outcomes at the individual level (MHCS, 2015 a). As explicated in this thesis' Definition section, safety is here viewed as one dimension to quality. In a Safety II perspective, resilience relates to the capacity to adapt to challenges and disruptions. It was recently argued that safety research should take context into consideration too, which links with safety viewed as an *activity* (Bergström & Dekker, 2019; Rae et al., 2020). In turn, regulation as a governmental mechanism for behavioral modification is linked to the capacity to adapt, in terms of how regulation is designed to accommodate flexible solutions in the targeted area of performance. This relates to resilience. However, some regulatory strategies differ to resilience, especially if these are highly detailed and specified, with governmental requirements being carried out and inspected based on "strict" compliance. Quality and safety are on one hand normative concepts since the healthcare system at different levels strives to increase and improve quality and safety based on certain indicators, including regulatory expectations. On the other hand, the concepts are relative to the world they are operationalized into. Hence, they are context dependent, which links to adaptive capacity.

Also, attention to safety in healthcare has expanded both in terms of increased emphasis and understanding of underlying causes and system processes but mainly due to an increase in adverse events that are possible to prevent (Vincent & Amalberti, 2015). Quality and safety can be considered a moving target

(Vincent & Amalberti, 2015). This demonstrates that there is a relativism in using strict definitions and very detailed regulation of quality and safety, because targeted areas of performance shift with time, making it similarly difficult to judge improvement over time (Vincent & Amalberti, 2015).

This thesis' underlying model of adaptive capacity, as illustrated in Figure 10 below, has interdependencies to three parts of the theories applied:

(I) performance-based regulation (cf. internal control)
(II) risk regulation and management
(III) resilience in healthcare

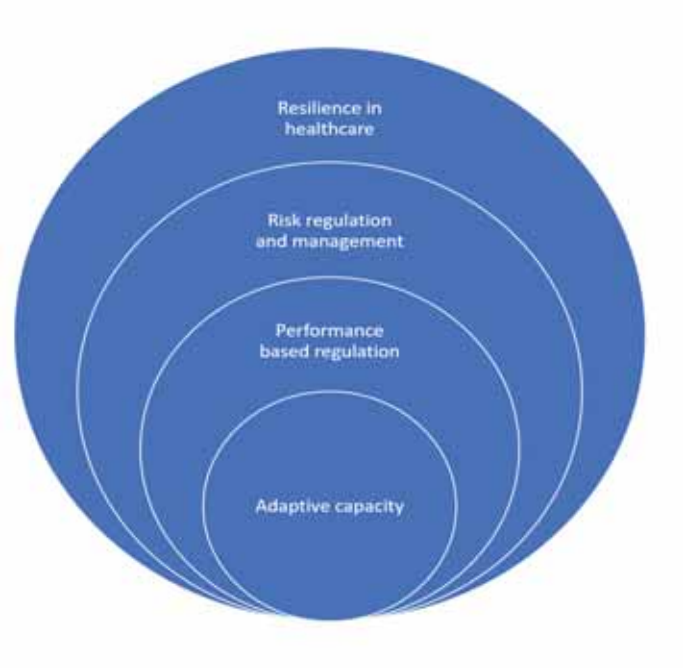

Figure 10: Interdependencies between this thesis' theoretical perspectives (model of adaptive capacity).

Adaptive capacity as a system capability in different system layers was in this thesis considered the underlying and unifying aspect because it embodies:

1) clinical improvisation at lower levels and in daily workarounds,

2) inspectors' trade-offs in their evaluations and methods,
3) performance-based regulatory regimes' design and enactment.

Resilience in healthcare theory and responsive regulation theory therefore interdependently played a pivotal role in this thesis' planning phase, during the development of interview guides and in the application to empirical data. Applying these two theoretical frameworks to whether and how the performance-based regulatory regime in risk regulation and management in the Norwegian healthcare setting links with adaptive capacity, was essential to understand, interpret and integrate the findings.

4 Methodology

4.1 Philosophical positioning

This thesis' philosophy of science perspective is set out in a frame of reference which possibly strained and influenced the findings. What models the researcher draws on and applies, and what elements of the social world under scrutiny, will all be defined by the epistemology and underpinning philosophical assumptions of the research. Part of this is the choice of theoretical perspectives. Therefore, it is important to clarify these conditions. Figure 11 illustrates this thesis' epistemological commitments, inspired by Crotty (1998). The left column indicates the four basic elements in any conducted research, whereas the column to the right displays how these elements relate specifically to this thesis.

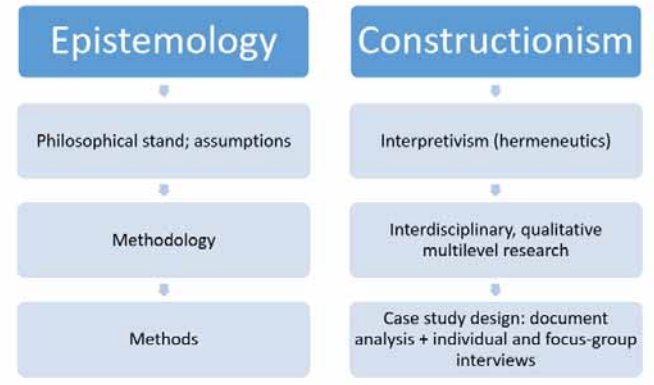

Figure 11: Epistemological commitments

Subjectivity is fundamental in all interpretation in human science, including in legal dogmatic and the interpretation of law. This thesis puts forward how self-understanding, conception of practice and hermeneutics, plays an important role in interpretation. However, the work in this thesis was not initially tied very closely with one particularly perspective. Thus, it did not pick the paradigm of hermeneutics to follow precisely, but to illustrate the choices of methodology (Crotty, 1998). Hence, the epistemological and theoretical assumptions that frame this thesis' methodology relate to what Crotty (1998) refers to as

"thinking through…but to not hesitate to think beyond…". The following section illustrates the thesis' broader perspective of interpretivism, that includes hermeneutics, as well as the broader epistemological commitments implied by constructionism.

Constructionism is about construction of meaning and meaningful reality (Crotty, 1998). It sees neither meaning as entirely subjective, constructed separately from the external world, nor can any object be described isolated from the person experiencing it. Constructionism in turn, underpins interpretivism. In this thesis, constructionism was concerned with how regulators, inspectors, and managers constructed the systems of regulation, supervision, and improvement activities.

Interpretivism emerged as an opposition to the natural sciences and positivistic approach towards universalism, causality, predictability and generalizing method (Crotty, 1998). Interpretivism on the other hand seeks to understand and explain human and social reality by meaning complexes (Weber, 1962; Crotty, 1998). From the interpretivist viewpoint, meaning derives from layers of interpretation, with potential to reveal implicit meanings and intentions (Crotty, 1998). In legal hermeneutics, arriving at textual meaning emphasizes both identification of intent as well as how the text should be applied. The implication to this thesis involved how the researcher interpreted and understood documentary evidence, theoretical concepts, and the empirical data. Likewise, it applied to for instance hospital managers' interpretation and understanding of regulatory expectations, inspectors' assessments of legal standards, and hospital operationalization of quality and safety activities.

Hermeneutics makes up the doctrine of interpretation of meaningful phenomena (Mantzavinos, 2016). The term comes from the Greek hermeneuein, which means translating/explaining/interpreting (Oxford University Press, 2019). Early hermeneutics was defined by the German philosopher Wilhelm Dilthey as a method of interpretive logic (Ritzer, 2005). Today, hermeneutics is viewed as a fundamental theory and reflective problematic discourse. The German philosopher Hans-Georg Gadamer's philosophical hermeneutics put focus on human understanding as dependent on preconception and recognized that it is impossible to overlook the interpreter's historical standpoint (Gadamer, 2004). A meaningful phenomenon has a

meaning, which to be understood, must be interpreted (Gadamer, 2004). This process of clarification and reinventing conditions for understanding is called the hermeneutic circle (Ritzer, 2005). Self-reflexivity and preunderstanding as basic points in this process of interpretation, is reflected upon in chapter 4.6 "The researcher's role". In this thesis, hermeneutics thus served as backdrop for the analysis. It was implicitly present in the researcher – participant interaction, and in the researcher - legal text interaction. It was therefore not particularly represented in the methodologies of the published papers.

Resilience in healthcare – this thesis' perspective

The term resilience is linguistically retrieved from Latin and means "to recoil" (Merriam-Webster, 2020). However, different scientific paradigms exist. In this thesis, resilience was applied as a system ability (Berg et al., 2018), which in turn implies that the healthcare system is an ontological category. Ontology refers to theories about the relationships between the nature of reality and human interactions and practices. In qualitative research, this relationship is reflected on along a continuum. Ontological assumptions range from whether the researcher believes reality exists *separate from* or *along with* human interactions and practices (Braun & Clarke, 2013). Moreover, within the healthcare system the stakeholders may have individual goals, and practices or abilities that they do not inevitably share. With reference to methodological holism (Ylikoski, 2012), resilience in healthcare is thus more than the sum of its actors' individual actions. In its effort to overcome the viewpoint on resilience as an individual potential, this multilevel study addressed and operationalized three levels of the Norwegian healthcare system (macro, meso, micro) (Berg et al., 2018).

Regulation – this thesis' perspective

Legal and regulatory matters are primarily developed, applied, and disputed within national borders, making legal terminology and regulatory activities multifaceted and not easy to interconnect on an international scale. The social and organizational processes that this thesis considers regulation to act on are based on what is portrayed as an interaction between the law and society (Lilleholt, 2003; Mathiesen, 2005). This implies two elements:

1. The content of the law is shaped by societal conditions,
2. Legislation may have strong influence on the societal development.

This interaction indicates therefore that the law is both a product of the societal, cultural environment *and* an active cultural element (Lilleholt, 2003). In turn, this thesis implies that regulation has the *potential* to influence and shape practices in hospital organizations, yet the conditions in the hospital organizations may influence and shape the governmental levels (regulators and inspectors) as well.

4.2 Study design

This thesis has a single embedded case study design (Yin, 2014). The case was defined as the design, implementation and enactment of the Quality Improvement Regulation and its impact on management and quality improvement, across three system levels in two health regions. More specifically, three levels were examined in three sub studies: governmental bodies of regulation (macro-level), regional supervision (County Governors; meso-level), and hospital managers (micro-level). See Table 5 below for an overview.

Table 5: Overview of the thesis

Level	Stakeholder	Methods	Sub study
Macro	Government officials	Documents approx. 500 pages Interviews: 7 participants	Sub study I Paper I
Meso	Inspectors	Documents approx. 300 pages Interviews: 12 participants	Sub study II Paper II
Micro	Managers	Interviews: 20 participants	Sub study III Paper III

Rationale for choice of study design

There are no definite criteria for when a case study is appropriate to conduct, even though there are good *reasons* for doing a case study (Yin, 2014). A case study design "arises out of the desire to understand complex social phenomenon and allows for a holistic and real-world perspective" (Yin, 2014:4). Yin (2014) lists three elements of situations where a case study would be preferable, 1) the research question(s) seeks to explore the phenomenon in terms of "how?" and "why?", 2) the research does not require control over behavioral events, 3) the

study focuses on contemporary events. Additional reasons for choosing a case study design can be that the research is exploratory, descriptive, and explanatory, that it aims to generate theory and/or that findings can contribute to initiate change, or difficulty of isolating variables due to interactions in complex and dynamic healthcare contexts (Robert et al., 2011; Alvesson & Kärreman, 2011; Yin, 2014). The idea is that case studies may contribute to understand "multilevel phenomenon such as organizational change and reactions to crisis" (Hitt et al., 2007:1393). Accordingly, this thesis presents a PhD project that studied ongoing implementation of a regulatory change: the operationalization of the Quality Improvement Regulation into healthcare across system levels.

The case study approach allows the researcher to choose between a holistic or an embedded design (Yin, 2014). It is considered holistic if the researcher examines one unit of analysis and embedded if several study units are examined (Blaikie, 2010; Yin, 2014). If the study's case is about a single organization such as a hospital, the analysis can still include employees and clinical staff, making these units embedded (Yin, 2014). Accordingly, this thesis' embedded case study design was chosen to gain a deeper understanding of the single regulatory framework (the Quality Improvement Regulation) across the macro, meso, micro- levels of analysis (Miles et al., 2014). See Figure 12 below, inspired by Yin's (2014) basic type of a single embedded case study design.

Figure 12: Basic type of a single embedded case study design (Yin, 2014)

4.2.1 A multilevel approach - crossing system boundaries

In the next, some key advantages associated with multilevel case study research are elaborated (challenges are explained in chapter 6.2.2).

The embedded case study presented in this thesis required research at various system levels (Blaikie, 2010). The aim with choosing a multilevel embedded design was to explore how expectations and experiences at higher level or macro and meso units, and lower level or micro units related (Diez-Roux, 2002; Costa et al., 2013). Scholars have suggested that if the extended aim of the research is to improve healthcare, researchers need to increase multilevel interventions (Hitt et al., 2007). Previous research has for instance argued that traditional organizational theory and its models have not been successful in grasping the complexity in the healthcare system, arguing that it likely relates to the fact that a system can be understood only as an integrated whole (Anderson et al., 2005). Because the complexity stems from the "intricate relationships" between components", deconstructing a system into bits and parts without considering interactions would destroy what the analytical method seeks to understand (Cilliers, 1998:2).

According to Rasmussen (1997), different levels of stakeholders have different impact on the risk management process. These levels are intertwined through processes of information and decision making of which researchers need to understand "the patterns of relationships among its agents" (Anderson et al., 2005:672). One of the main advantages with a multilevel approach is therefore the opportunity to explore different realities within the same study. Accordingly, the focus of this thesis was the different realities at three system levels. In addition, it draws attention to how quality improvement efforts either were facilitated or hindered as a result from this (see the governance complexity displayed in Figure 13). By exploring the macro-level in healthcare, the thesis searched for understanding of how efforts to manage and improve quality at the meso and micro-level were impacted by broader governmental influences and, in turn how the macro-level was influenced by developments in meso and micro practices (Robert et al., 2011). By exploring the meso-level, the idea was to gain knowledge on regulatory development and design structures' influence on supervision and the processes for managing quality, including potential issues

with implementation (Robert et al., 2011). Lastly, the rationale for exploring the micro-level was to understand how local level factors in the investigated hospitals possibly influenced the management of quality (Robert et al., 2011).

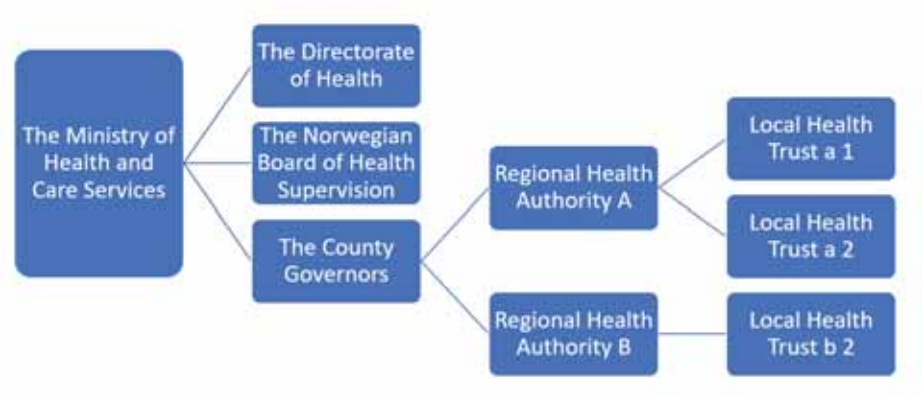

Figure 13: Governance complexity in this thesis' study setting. [2]

4.3 Methods

4.3.1 Case selection

The embedded units were selected in the initial phase of the PhD project. The Ministry, the Directorate and the Inspectorate were evidently macro units as these are regulators and policy makers responsible for healthcare oversight in general. The County Governor meso-units were selected to inform the supervisory context, as regional supervision exists and interacts with hospital context, and maneuvers between detailed regulation and governmental enforced hospital self-regulation. The hospital units were selected to investigate experiences with implementation of the Quality Improvement Regulation. Selection criteria for the three hospitals were:

1. university hospitals with assumed competence on quality improvement,
2. located in different parts of the country,

[2] Figure 1 shows this thesis' study setting and not how the Ministry in general also has a direct link to the RHAs.

3. relatively similar tasks and areas of performance.

The three selected County Governor offices were chosen because the counties they represented were matched with the third unit of analysis in the embedded case study: the three hospitals. For an illustration of key aspects with the methodology of the three sub studies, se Table 6 below.

Table 6: The methodology of the thesis' three sub studies.

SUB-STUDY	Sub-Study I	Sub-Study II	Sub-Study III
AIM	Explore governmental rationale & expectations towards hospital management.	Investigate into changes in supervisory approach & inspectors' work to facilitate adaptive capacity and learning in hospitals.	Investigate hospital managers' perspectives on implementation efforts and the resulting work practices, to understand if, and how, the new Quality Improvement Regulation influenced quality and safety improvement activities.
RESEARCH QUESTION(S)	What was the regulatory rationale for developing a management-focused regulatory framework (the Quality Improvement Regulation) for quality and safety improvement in healthcare? How do the regulatory bodies expect the new Quality Improvement Regulation to influence resilience in hospitals?	How do Norwegian County Governors adapt to changes in the new Quality Improvement Regulation, to improve their practice as inspectors and regulators? How do Norwegian County Governors work to promote (or hamper) adaptation and learning in hospitals?	How do hospital managers work to improve quality and what are their experiences with implementing the Quality Improvement Regulation?
STUDY LEVEL	Macro-level	Meso-level	Micro-level
UNIT	The Ministry of Health and Care Services; the Norwegian Directorate of Health; the Norwegian Board of Health Supervision	Three County Governor offices	Three hospitals
METHOD	Qualitative Legal Dogmatic	Qualitative	Qualitative
DATA COLLECTION	Documents (approx. 500 pages) Seven individual interviews	Documents (approx. 300 pages) Three focus group interviews (12 participants in total) Two individual interviews	20 individual interviews
PARTICIPANTS	Five leaders and two senior advisors	Two chief county medical officers, two assistant chief county medical officers, one former assistant chief county medical officer, seven inspectors	15 hospital managers and five quality advisors to hospital managers
ANALYSIS	Documents: directed content analysis+ legal dogmatic Interviews: qualitative content analysis	Qualitative content analysis	Qualitative content analysis

4.3.2 Participants and recruitment

The participants in this thesis were mainly recruited by purposive sampling (Braun & Clarke, 2013; Miles et al., 2014). This sampling strategy was chosen because the thesis needed participants who possessed the best knowledge concerning the research topic and the case's unique contexts (Elo et al., 2014; Miles et al., 2014). Some participants were however retrieved through recommendations from other participants, referred to as snowball sampling (Miles et al., 2014). All participants were contacted by e-mail, informed about the study's focus on the specialized healthcare services, and proposed participation. Every participant signed informed consent ahead of the interview (see Appendix 2).

Sub study I (macro-level)
Sub study I focused on the governmental rationale and expectations in relation to the Quality Improvement Regulation, and how it could potentially influence the management of resilience in hospitals. The governmental officials were recommended by this thesis' supervisory team contacts. They were positioned at the Ministry, the Directorate, and the Inspectorate. The participants were considered key figures in the design and development process of the Quality Improvement Regulation (see characteristics in Table 7), recruited to inform this thesis' exploration of governmental rationale and expectations (as a supplement to the documentary evidence in this sub study). Gender balance: 1 man and 6 women.

Table 7: Participants' characteristics in sub study I

Participant number	Position	Educational Background
1	Leader	Economy, Quality Improvement in Healthcare
2	Advisor	Health Professional, Administration in Healthcare, Quality Improvement in Healthcare
3	Advisor	Quality and Safety in Healthcare
4	Leader	Legal Professional, Administration in Healthcare
5	Leader	Health Professional
6	Leader	Engineering, Administration in Healthcare
7	Leader	Health Professional

Sub study II (meso-level)
Sub study II focused on if, and in what ways, there have been changes in the supervisory approach towards Norwegian hospitals, due to the implementation of the new Quality Improvement Regulation. The inspectors were recruited by request to the chief county medical officer at three different County Governors' offices in two health regions (see characteristics in Table 8). Gender balance: 4 men and 8 women.

Table 8: Participants' characteristics in sub study II

Participant number	Position	Educational background	Organization and Region
1	Inspector	Lawyer	A-1
2	Chief county medical officer	Medical doctor	A-1
3	Assistant chief county medical officer	Lawyer, medical doctor	A-1
4	Inspector	Lawyer	A-1
5	Inspector	Lawyer	B-1
6	Inspector	Registered nurse	B-1
7	Inspector	Lawyer	B-1
8	Chief county medical officer	Medical doctor	B-1
9	Former assistant chief county medical officer	Medical doctor	C-2
10	Inspector	Lawyer	C-2
11	Inspector	Lawyer, registered nurse	C-2
12	Assistant chief county medical officer	Medical doctor	C-2

Sub study III (micro-level)
Sub study III focused on hospital managers' perspectives on implementation efforts and the following work practices, to understand if, and how, the new Quality Improvement Regulation influenced quality and safety improvement activities. The inclusion criteria were participants who currently worked as hospital managers or advisors to hospital managers, preferably with clinical experience, situated at all levels within the hospital organizations, e.g., head of clinic, head of department, divisional manager (see characteristics in Table 9). Out of 20 participants, 18 had authorization and license as health personnel and clinical experience from hospital practice. Several of them still worked clinically. The balance in the selection of micro-level participants was crucial:

whether managers had clinical experience and/or mainly administrative background would influence the data. This was especially important due to the analysis within the micro-level along with analysis across macro-meso-micro. Four out of five advisors had previous hospital manager experience and were chosen to highlight the administrative quality improvement and patient safety support system for managers in the selected hospitals. Gender balance: 11 men and 9 women. Included participants were selected on recommendations either from this thesis' supervisory team or other participants in the study, or strategically selected based on their key position in the respective hospital organization.

Table 9: Participants' characteristics in sub study III[3]

Participant number	**Position**	**Educational background***	**Organization and Region**
1	Divisional manager	Medical doctor, specialist, PhD	A- 1
2	Advisor, quality, and patient safety	Registered nurse, MSc in Risk Management	A- 1
3	Legal advisor, quality, and patient safety	Lawyer	A- 1
4	Head of Clinic	Medical doctor	A- 1
10	Head of Clinic	Doctor of Dental Surgery, PhD	A- 1
11	Head of Clinic	Medical doctor, specialist, MSc in Health Management	A- 1
5	Advisor, quality; Clinical Coordinator	Registered nurse, MSc in Risk Management	B- 1
6	Head of Quality	Registered nurse, specialist	B- 1
7	Deputy Head of Clinic	Lawyer	B- 1
8	Medical Director	Medical doctor, PhD	B- 1
12	Head of Department	Medical doctor, specialist; surgeon, PhD, Management courses	B- 1
13	Head of Department	Medical doctor, PhD, Management courses	B- 1

[3] Affiliations (e.g., A – 1 etc.) are presented chronologically in this table, resulting in non-chronologically participant numbers (numbers follow the participant quotations presented in the papers).

14	Head of Department	Registered nurse, specialist	B- 1
17	Head Nurse	Registered nurse, specialist	B- 1
9	Head of Research	Medical doctor, PhD	C- 2
15	Head of Clinic	Medical doctor, specialist; surgeon	C- 2
16	Advisor, quality	Physiotherapist, MSc in Management	C- 2
18	Senior Advisor, quality, and patient safety	Medical doctor	C- 2
19	Head of Department	Medical doctor, PhD	C- 2
20	Head of Quality	Registered nurse, MSc in Health Management	C- 2

4.3.3 Data collection

The data collection consisted of documents, semi structured individual interviews, and semi structured focus group interviews. As a means of triangulation, document analysis was used in merge with qualitative individual and focus group interviews, hence drawing upon two different sources of evidence in this study (Yin, 2014).

Documents

Approximately 500 pages of documents were collected (see Table 10). The documentary evidence was considered legitimate sources of law (Eckhoff, 2001). Documents exempted from public disclosure, and publicly available documents, were retrieved through formal letters sent to three key national policymaking and regulatory bodies in charge of developing and stimulating implementation of new healthcare regulation in Norway (the Ministry, the Directorate, and the Inspectorate). Publicly available documents were also accessed by search through open Internet sources. Documents formed the main empirical foundation in sub study I concerning the regulatory bodies' rationale for revising the Internal Control Regulation into the Quality Improvement Regulation. In sub study II, documents played a vital role in gaining insight into the defining governmental guidelines and recommendations that framed the study context. The documents involve all levels of the Norwegian healthcare

services, including Hearing Comments given from the selected hospitals, County Governors, the Directorate, and the Inspectorate.

Table 10: Documentary evidence identified, selected, and analyzed

Publication year	**Pages**	**Title**
2002	2	*Internal Control Regulations in the Healthcare Services.* (MCHS, 2002)
2011	8	*Policies for the follow up and concluding of supervision in cases of breach of legal requirements.* (NBHS, 2011)
2012	135 (certain exceptions)	*White paper Meld. St. 10 (2012-2013) High quality – safe services.* (MHCS, 2012)
2013	5	*Circular on management in hospitals.* (MHCS, 2013 a)
2013	3	*Assignment letter* of drafting a new regulatory framework, sent from the Ministry to the Directorate. (MHCS, 2013 b)
2013	8	*Project plan* (regarding the development of the new regulatory framework; the QIR) sent from (the Directorate to relevant stakeholders). (NDH, 2013)
2014	2	*Invitation to give input* to the Directorate's draft of the new QIR. (NDH, 2014 a)
2014	47	*Draft of the Hearing Memorandum* sent to the Ministry, provided to them by the Directorate in cooperation with the Inspectorate. (NDH, 2014 b)
2015	41	*Final Hearing Memorandum* submitted to relevant stakeholders, by the Ministry. (MHCS, 2015 b)
2015	344 (certain exceptions)	*White Paper NOU 2015:11. Prevention of- and follow up of serious adverse events in the healthcare services.* (MHCS, 2015 a)
2016	38	*Hearing Comments.* (NBHS, 2016; NDH, 2016) (Hearing Comments related to the selected hospitals and County Governors are excluded from the references due to disclosure).
2016	65	*The Prerogative* document for the QIR, which stated the narrative of the facts and circumstances of its policies. Formal approval was given in Royal Assent. (MHCS, 2016 b)
2016	3	*Regulation on management and quality improvement in the healthcare services (the QIR).* (MHCS, 2016 a)

2017	57	*Guidelines relating to the Regulation on management and quality improvement in the healthcare services (the QIR).* (NDH, 2017)
2017	4	*The Health Supervision Act.* (MHCS, 2017)
2018	22	*Guidelines document for planned/system audits.* (NBHS, 2018)
2019	43	*White paper Meld. St. 9 (2019–2020) Quality and Patient Safety 2018*. (MHCS, 2019)
2019	117	*Annual Report 2018.* (NBHS, 2019 b)

Interviews

A total of 32 interviews were conducted with 39 participants: 29 individual interviews and three focus group interviews.

Individual interviews were chosen for two reasons (Kvale & Brinkmann, 2009). Firstly, because participants were expected to have too busy work schedules for it to be realistic to arrange focus group interviews. Secondly and most importantly, the individual setting may bring forth more honest and explicit response, with no concern for unpleasant disagreement and collegial sanctions. Focus group interviews were applied to reach deliberation and discussions about the supervisory activities amongst the participants. This interaction led to expressions of different viewpoints, yet a lot of the discussion led to collective agreement among the participants (Kvale & Brinkmann, 2009). All interviews, except three individual interviews (telephone interviews) were conducted face-to-face at the participant's workplace. This secured comfortable, familiar interview locations for the participants (Braun & Clarke, 2013). In contrast to the individual face-to-face interviews, I experienced the participants in two of the telephone interviews to be "in a rush" and hence it was a bit more difficult to ask for more on relevant responses (Braun & Clarke, 2013). This did probably relate to the lack of physical presence. Semi structured interview guides (see Appendix 3) were developed prior to the individual interviews and the focus group interviews. The semi structured approach enabled the researcher to ask additional questions based on the participants' answers.

Sub study I (macro-level)

Semi structured interviews with seven participants positioned at the Ministry, the Directorate and the Inspectorate were conducted in the fall of 2018. These

interviews were mainly "factual interviews", meaning that the focus was on fact-based information about the topic's content, rationale, and development process (Kvale & Brinkmann, 2009). A semi structured interview guide was developed, based on theoretical perspectives on resilience and risk regulation regimes and based on information retrieved from the documents (see Appendix 3). It was considered imperative to gain knowledge about the process and phenomenon described in the documentary evidence prior to conducting interviews, and thereby be able to ask follow-up questions and discuss findings and evidence into more detail. The topics included: rationale, experiences of stakeholder involvement and information processes, expectations regarding implementation and capacity for regulatory flexibility. Interview duration varied between one hour and one hour and 30 minutes. I conducted, tape-recorded, and transcribed all seven interviews.

Sub study II (meso-level)

A total of three focus group interviews with respectively four-, three-, three-participants (one chief county medical officer, two assistant chief county medical officers, seven inspectors) and two individual semi structured interviews (one chief county medical officer and one former assistant chief county medical officer) were conducted in the fall of 2018 and early 2019. Topics in the semi structured interview guides (one targeting focus groups and one for individual interviews were prepared) covered (see Appendix 3): comparison of the previous Internal Control Regulations and the new Quality Improvement Regulation and adaptations of work practices, expertise within the County Governors, future expectations of development in supervisory activity. I single-handedly conducted one focus group and two individual interviews (one by phone). In two of three focus group interviews, I moderated while a supervisor operated as secretary, to take notes and observe group processes. The secretary took notes of the group dynamics, for instance related to who was most eager to talk, who interrupted and how participants responded to each other's comments in cases where participants had different descriptions or views. The Chief County Medical Officer was present in the first focus group interview but was not present in the next two focus groups in the remaining two County Governor offices. All interviews were tape recorded and transcribed. I transcribed four interviews whilst an external consultant transcribed the rest. Focus group interviews and individual interviews lasted between one hour and one hour and 30 minutes.

Sub study III (micro-level)
Semi structured interviews with 20 Norwegian hospital managers and quality advisors were conducted during winter and spring of 2019. Based on the preplanned semi structured interview guide (see Appendix 3), open end questions focused on areas of responsibility, work practices, training, implementation of quality improvement measures, regulatory flexibility, the role of supervision in improvement work and learning, experiences connected to structural development and attitudes, cooperation among different levels of government, hospital management levels and "front line". All interviews were conducted and recorded, face to face, at the participants' workplace. Each interview had a duration of approximately one hour to one hour and 30 minutes. I conducted all 20 interviews and transcribed 11 of these. Nine interviews were transcribed by an external consultant.

4.4 Analysis

4.4.1 Document analysis

Document analysis is considered a systematic procedure for examining documents, requiring the data to be interpreted to retrieve meaning (Bowen, 2009). Prior to conducting the interviews in sub studies, I and II, written documents were read and analyzed, to gain an overview of the regulatory process (Miles et al., 2014). Due to my interdisciplinary background consisting of Master of Laws (LL.M.) and MSc in Risk Management and Societal Safety, documents were interpreted and analyzed by both directed content analysis (Hsieh and Shannon, 2005) and legal dogmatic (Pattaro, 2005; Graver, 2008).

Directed content analysis
A directed approach is commonly used when there is a need to develop a complete understanding of the context, in order to identify key categories (Hsieh & Shannon, 2005). According to Hsieh and Shannon (2005), seven steps are present in the analysis: 1) formulate research questions, 2) select the sample which will be analyzed, 3) define categories, 4) outline coding process, 5) implement the coding process, 6) determine trustworthiness, 7) analyze the results from the coding process. The directed approach is slightly closer analytically to the text and the objectives; what this thesis perceives as more

linguistically structured compared to Graneheim and Lundman's (2004) qualitative content analysis (see explication below). Thus, the directed approach shares similarities with legal dogmatic and was hence chosen to support the legal textual interpretation. Documents were read and analyzed deductively by identifying potentials within resilience in healthcare: adaptive capacity; flexibility; anticipation, learning.

Legal dogmatic

Legal dogmatic is considered part of legal methodology and as a specific legal genre (Graver, 2008). Although there is debate about whether legal dogmatic and legal text analysis are different categories (Sandgren, 2007; Graver, 2008), this thesis viewed legal dogmatic as a term for the analysis of legal text. The communicative objective with this analytical process is at the center of interpretation, where the researcher maps and weighs the different interests at stake, in the affected area of regulation (Graver, 2008). Important elements during this process are (Graver, 2008):

1. Avoid adopting a certain position,
2. Remain critical of the available material,
3. Be open to argue for alternative solutions than the most evident,
4. Compare alternative solutions (however, that presupposes insights into the foundational values that the text's reasoning builds upon).

"Aims" in legal interpretation

One type of analysis within legal dogmatic is analysis of aim or objectives. The aim of one specific regulation *can* be analyzed empirically although legal science is traditionally not considered empirical (Graver, 2008). However, laws and regulations embed a qualitative character with aspects of interpretation in line with qualitative methodology (Sandgren, 2007). It was therefore considered reasonable to use empirical material during the analysis of the Quality Improvement Regulation due to its performance-based design of "open" content and scope (Sandgren, 2007). Interpretation close to objectives means that aims can be derived from prerogatives or directly from the legal text. Occasionally it derives from applied understanding of jurists, lawyers, judges (Rognstad & Hagland, 2020). In this thesis, *the objective of* the Quality Improvement Regulation was analyzed by empirical data and legal text documents. It was for instance key to reveal if regulatory expectations were

implemented at the meso and micro-levels. The legal dogmatic approach was thus additionally linked to the politics of regulation (Graver, 2008). By compiling the three case levels, the adequacy to meet with regulators' expectations of the regulatory framework for quality improvement was discussed, as well as if it had any influence on the hospital management level investigated.

Legal sources and the interpretive process

The application of legal dogmatic is an innovative approach in the safety sciences, which adds unique value to the analysis in this thesis. Insights into the regulators' rationale was generated from legal dogmatic style analysis that otherwise could not be gained through other methods. The Quality Improvement Regulation document was analyzed through textual and contextual interpretation based on a set of principles for the valuing of legal sources (see Table 11 for a display of the main legal sources forming the backdrop of this thesis). In a Norwegian regulatory setting, different legal sources have different value in the interpretation and application process (see previous chapter 2.4). Laws and regulations are ranked before prerogatives whereas regulations must give way for the Law; the Act in case of conflict, as laws are ranked higher than regulations.

In general, the interpretive process starts with the wording of the relevant law or regulation to determine what the regulator intended by the exact phrasing (see Figure 14 and Table 12 and below). This activity implies that the interpreter does not look at the words isolated from the context. Words and terms can sometimes hold different meanings and be vague (Lilleholt, 2003). As prerogatives are part of the regulatory context and offer prehistory of the given regulation, the Prerogative associated with the Quality Improvement Regulation (MHCS, 2016 b) was a key legal source in determining background and rationale and gave the interpreter; the researcher the possibility to reach thorough explanations.

Table 11: The main legal sources of this thesis

Description	Key requirements	Size of document
Internal Control Regulations (MHCS, 2002)	Organizational responsibility to apply systematic measures to ensure that all organizational activities are planned, organized, carried out and maintained in accordance with governmental requirements and health legislation	2 pages
The Quality Improvement Regulation (MHCS, 2016 a)	Embodies the overall aim of contributing to professionally sound practice, quality improvement and patient and user safety, and compliance with other governmental requirements and health legislation	3 pages
The *Prerogative* document (MHCS, 2016 b)	Narrative of the facts and circumstances related to the regulatory development process for policies related to the Quality Improvement Regulation	4 pages
The Health Supervision Act (MHCS, 2017)	Government organized inspection with safety and quality in the healthcare services, aiming to strengthen trust between population, health personnel, and the services in general	4 pages

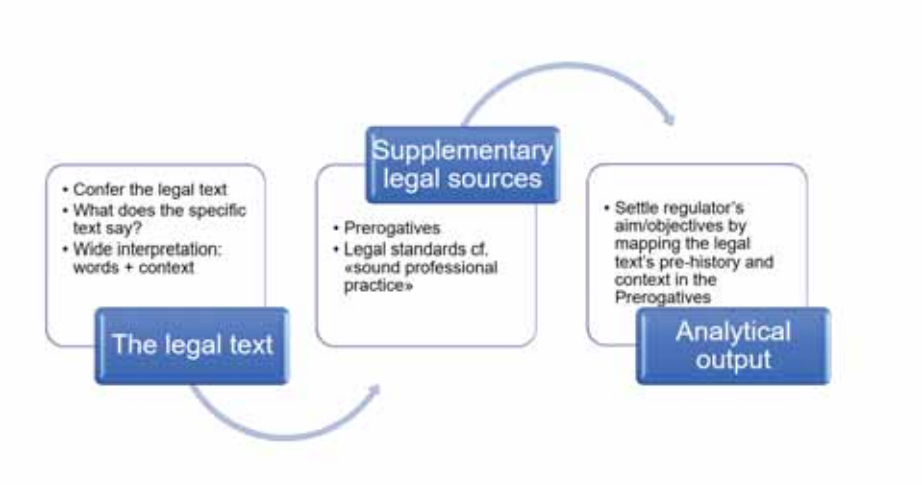

Figure 14: Processing a legal text into an analytical output

Table 12: Two examples of interim product from legal dogmatic document analysis of the QIR

Legal text – section (§)	**What the legal text says**	**The Prerogative**	**Deductive analysis – link to resilience**
§ 3 - The person who has the overall responsibility for the organization must ensure that systematic management of the organization's activities is established and carried out in accordance with these regulations and that the employees in the organization contribute to this.	The overall responsibility sits with the top management level.	Responsibility could be delegated to managers at subordinate levels in the organization. Rationale: to avoid uncertainty over leadership responsibility in organizations that differ, and to facilitate independent delegation.	The perspective of variation and independence is in line with the system approach to adaptive capacity.
§ 8 - review deviations, including adverse events, so that similar conditions can be prevented.	Does not specify what type of deviation or adverse event it aims at.	Includes all sorts of deviations, and not just severe adverse events. Rationale: to fit different organizations and different deviations.	In a resilience perspective this resonates with the notion of flexibility and adaptive capacity at lower organizational levels.

Legal standards and prudency evaluation

Words, phrases, and expressions in legal documents may require adaptive interpretation or evaluation. To establish rule content of what is called a "legal standard" in a regulation regime, evaluation is needed. To illustrate: all healthcare services are guided and governed by the general principle of sound professional practice and prudent conduct (Norwegian Health Personnel Act, 1999). This principle is referred to as a legal standard, where the content and scope of it changes in line with professional development and current values, determined by current medical standards, ethics and other statutory requirements, context; conditions; risks (Lilleholt, 2003; Lindøe et al., 2015). Legal standards could be considered "functional requirements" as opposed to

explicit norms/detailed requirements. A legal standard is part of the previously described (see chapter 2.4) “de lege lata” approach and should thus not be perceived as a “de lege ferenda” approach. De lege lata judgements for instance, constitute a fundament for supervision as part of the inspectors’ task to evaluate based on the requirement of sound professional practice.

4.4.2 Interviews - analysis

Qualitative content analysis

Interview data was partly analyzed inductively by identifying potentials for resilience in healthcare, and partly deductively by using predetermined questions explicitly mapping resilience potentials (Blaikie, 2010). Data was analyzed inspired by a qualitative content analysis (Graneheim & Lundman, 2004) (see Figure 15). I led the analytic work by initially reading through all interviews and taking notes of immediate thoughts that occurred after reading, before turning to the process of identifying and condensing all meaning units. Thereafter, I suggested codes, sub-categories and themes in a matrix set up for the analysis. During this process, findings were also manually compiled by color marking, where different colors represented different categories in the material. Moreover, findings from sub study I were (by hand, on paper) set up in a matrix across categories. At the latest stage in the analytical process, themes were sorted across participants, partly done by hand on paper (sub study II), partly computer wise (sub study I and III). These category and theme matrices were helpful in looking for patterns across the data. Three of four researchers (Norwegian speaking co-authors) read all the interview material and discussed codes and sub-categories. After the initial phase of analysis, as described above, themes were eventually refined in collaboration among the researchers (i.e., the hermeneutic circle (Ritzer, 2005)). This collaborative analytical process was carried out in all three sub-studies. Examples for each sub study are provided after Figure 15.

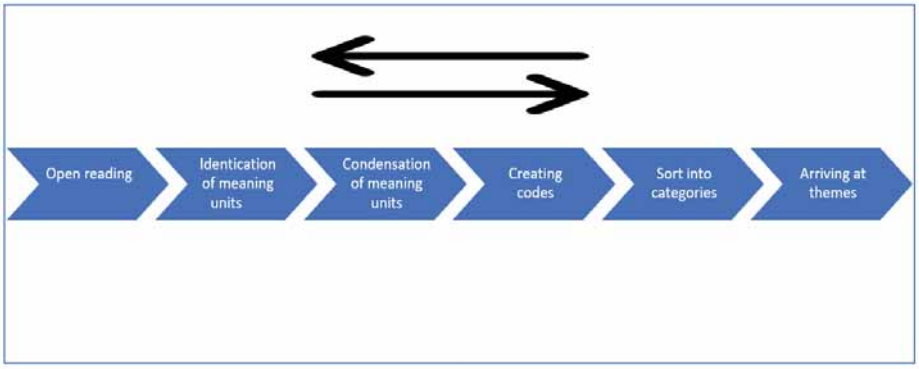

Figure 15: The analytical process as a nonlinear process

Sub study I

Sub-categories were deductively formed in line with the resilience potentials of anticipation, adaptation, and flexibility. Finally, sub-categories were sorted into two themes:

1) Rationale,
2) Expectations.

Table 13: Illustrative examples of original participants' quotes or documents, sub-categories, and themes in sub study I

Original Quote from Participants or documents	**Sub-category**	**Theme**
They did this in an overly bureaucratic and wrong way with a lot of emphasis on written procedures and things like that (…) it seemed very alienating, so you could not get the rationale [of the previous Internal Control Regulation] (...) and selling the idea was very difficult, many who simply did not understand it. - Governmental leader	Adaptation and Flexibility	Rationale
Managers should identify activities or processes in areas where adverse events or breach may occur frequently, and in areas with potentially severe or adverse consequences for patients and users - The Guidelines document	Anticipation	Expectations

Sub study II

In sub study II, 10 sub-categories were identified, partly deductively, partly inductively. They were: 1) Perceptions – the new Quality Improvement Regulation, 2) Supervisory methods, 3) Management, 4) Competence, 5) Variation, 6) Collaboration between the County Governors and the NBHS, 7) Culture, 8) Trust, 9) Hospital strategy, 10) Resilience in Healthcare; positive feedback. The analysis resulted in five themes:

1) Changes in Supervisory Work due to the new Quality Improvement Regulation,
2) Inspectors' Work to Apply Regulation and Facilitate Adaptive Capacities,
3) Learning from Supervision,
4) Supervisory Impact on Hospital Performance,
5) Improvement Potentials in Supervisory Practice.

Table 14: Illustrative examples of original participants' quotes, sub-categories, and themes in sub study II

Original Quote from Participants	**Sub-category**	**Theme**
I have not noticed any change because of the new Quality Improvement Regulation, at the level that I work. However, 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	Perceptions – the new Quality Improvement Regulation	Changes in Supervisory Work due to the new Quality Improvement Regulation
The Quality Improvement Regulation accommodates everything, and it accommodates our opportunity to look at their entire system and conclude that they do not secure their services well enough. Also, if things were very precise, then you can deviate from aspects that are not important, that do not really consider the complexity. Thus, very precise legislation is a little scary. - Individual interview	Supervisory methods	Inspectors' work to apply regulation and facilitate adaptive capacities

The group processes in the first focus group were potentially suffering from the presence of the Chief County Medical Officer. In turn, that may have influenced the data. Hence, while listening to the recorded tapes and reading the transcripts during the analytical process, this was paid attention to in terms of aspiring to bring clarity about the intra hierarchical structures. Additional notes taken directly after the conducted interview also assisted in sorting out these reflections. Individual interviews and focus group interviews were analyzed in separate matrices in the first round of analysis. Sub-category findings across all interviews were thereafter traced manually on paper. Lastly, sub-categories in both focus groups and the two individual interviews were integrated into themes. The integration of data enhanced the description of the five themes (Lambert & Loiselle, 2008).

Sub study III

In sub study III, inductively formed sub-categories were identified and linked to the following elements: quality improvement, PDSA, collaboration between hospitals and supervisory authorities, culture and trust, economy; resources, variation and uncertainty, risk, procedures and standardization, the management responsibility, autonomy, monitoring, work as imagined versus work as done. Four themes were identified:

1) Adaptive capacity in hospital management and practice,
2) Implementation efforts and challenges with quality improvement,
3) Systemic changes,
4) The potential to learn.

Table 15: Illustrative example of original participants' quotes, sub-categories, and themes in sub study III

Original Quote from Participants	**Sub-category**	**Theme**
I do put quite an amount of responsibility on the unit managers because they are in the middle of it all and they know where the risks are, and the risks will vary. - Head of Clinic	Risk-based management	Adaptive capacity in hospital management and practice
Some things have been done by the executive level, but the clinical managers have not addressed it. - Quality coordinator	No change in (clinical) practice	Implementation efforts and challenges with quality improvement

(Quality improvement work) is not entirely new, but quite new. When I started as a surgeon, these were things that never came into view, so it has been a remarkable change, especially over the last ten years. - Head of clinic	Cultural development	Systemic changes

In qualitative content analysis, Graneheim and Lundman (2004) stress the importance of describing the meaning unit in full. Condensation of the meaning unit helps in shortening the text while preserving the core, however there is always a degree of interpretation upon approaching a text. This may represent both a challenge and a strength when the researcher is seeking to clarify the participants' responses (Graneheim et al., 2017). On one hand the interpretative process can be tainted by the researcher's prejudices, on the other hand the same prejudices may lead to a deeper understanding of the objectives and meanings. Accordingly, self-reflexivity and preconditions are explicated in chapter 4.6 "The researcher's role".

4.5 Trustworthiness

The aim of trustworthiness is to ensure that the findings are worth paying attention to (Lincoln & Guba, 1985). Normally, four to five criterions are applied for the assessment of trustworthiness in qualitative research traditions: credibility, dependability, conformability, transferability, authenticity (Lincoln & Guba, 1985). Graneheim and Lundman (2004) on the other hand focus on the concepts of credibility, dependability, and transferability. This thesis rests on these concepts, but includes reflections based on perspectives from other scholars too, including for instance Elo and colleagues (2014) and Bowen (2009).

Credibility is connected to the aim of the study, sample size and how the researcher deals with participants (Graneheim & Lundman, 2004; Elo et al., 2014). There is no optimal sample size, it depends on the study aim, the research questions, and data richness (Elo et al., 2014). Furthermore, in qualitative content analysis it is important to choose meaning units wisely (Elo et al., 2014). Meaning units were consciously selected in the matrix set up for the analysis, but the size varied. Wordy meaning units were occasionally necessary

to avoid fragmented meaning. Moreover, credibility relates to self-awareness (Koch, 1994). Hence, the researcher should ask oneself: "Did I ask too broad questions?" "Did I ask too narrow questions?" "Did I manipulate or (mis)lead the participants?" (Elo et al., 2014). I reflected about these self-critical questions together with the supervisory team. Besides, interview transcriptions were checked for methodological quality in accordance with the consolidated criteria for reporting qualitative research (Tong et al., 2007). Paper III was additionally checked in accordance with the BMJ Open checklist that was required upon submission. Findings (translated and summarized into Norwegian) along with the published papers, were also presented to parts of the sample in sub studies I and II, as a "member check" (Lincoln & Guba, 1985).

Triangulation of data in sub studies I and II enhanced the thesis' trustworthiness and was chosen due to several reasons:

1. *To enrich the study of the phenomenon.* The examination, evaluation and interpretation of documents contributed to build an understanding of the overall process, initiatives, rationale, and objectives within the governmental bodies, which in turn provided me with valuable information and suggestions for questions that needed to be asked during the interviews (e.g., background information (Bowen, 2009)).
2. *The value of documents in the case study.* Documents, such as the Guidelines document, White Papers, and propositions, policy, hearing, and discussion documents (in addition to the Quality Improvement Regulation), were key sources of data in terms of being the foundation of the Quality Improvement Regulation. Moreover, the documents displayed the progress of the design, development, and implementation process.
3. *To anticipate the possible anti credibility accusations against the study's findings* (Bowen, 2009). Conducting the document analysis prior to the interviews helped refrain from "overreliance" on documents as the sole data source (Bowen, 2009). It was also useful to return to the documents post interview to seek out the missing details when participants did not remember certain aspects about the process (due to the long timespan of the process). Some of the documents were referred to by the researcher during the interviews as well, where it was relevant for the follow up of the participant's response or in cases where it was suitable to make references to policies and reports. This moving back and forth activity is in line with

the understanding and interpretation process described in the hermeneutical circle.

4. Using multiple methods was an advantage to *identify the different objectives and values* held by various stakeholders at the different levels, to understand, interpret and operationalize different concepts in the data.

The latter relates to both internal and external validity. Although the value of validity within qualitative research is disputed, triangulation is reckoned a validity procedure of merging different information sources to identify themes or categories (Creswell & Miller, 2000). The case study design presented in this thesis could contribute to ensure *internal* validity, because it connects embedded units of analysis and thus hampers data from being fractioned. In terms of *external* validity, analyzation limited to *one* level could lead to the field of practice having less confidence in the produced research. Thus, exploring different levels could have an antifragmentation effect by contributing to shrink the gap between science and practice (Costa et al., 2013; Johnson et al., 2017).

Dependability is referred to by Elo and colleagues (2014) as data stability over time and under different conditions, typically related to how easy it is for other researchers to follow the initial researcher's trail of decisions. Participants in this study were carefully selected to gain dependable outcomes (Elo et al., 2014). Characteristics are described in this thesis' methods section as well as in the three related papers, with emphasis on educational backgrounds and current positions. In addition, the description of the analytical process for each sub study speaks for dependability.

Transferability in qualitative studies is complicated and perhaps not recommendable with regards to generating knowledge from a specific context to broader contexts (Whittemore et al., 2001). The aim with case study research is not *statistical* generalization of data (Yin, 2014). However, could *analytical* generalization emerge from the case: findings may contribute to cast new light on some of the theoretical perspectives applied in the research (Yin, 2014). Since one of the future directions retrieved from this thesis' findings is related to theory development and theorization in the context of macro-level regulation and supervision, extrapolation of stakeholder collaboration across system levels may be relevant to consider in disciplines outside health sciences too. The

transferability is in that sense based on how this thesis' researcher has described context and study setting, in a way that enable others to assess whether the findings may have external relevance. It was thus key in this thesis to explain study context and the analytical process, as it may enable others to assess whether the findings would be applicable to their context. Adding to the process of ensuring transferability, I was careful when picking quotations for each of the three sub studies' manuscripts, striving to choose those which connected with the main themes and concepts (Elo et al., 2014). Lastly, it is also crucial to explicitly address the study's limitations (Elo et al., 2014). All three sub studies therefore included a separate section in each published paper, addressing methodological limitations and strengths, presented accordingly in a separate sub chapter in this thesis (see 6.2).

Regardless of all efforts to ensure trustworthiness in this study, all research is nevertheless a representation by the author (Elo et al., 2014). This applies certainly in qualitative research where subjectivity and creativity are present factors (Whittemore et al., 2001). The research presented in this thesis is therefore only valid to the extent that my bias and interpretive subjectivity are considered part of my findings. Further reflections on my role as a researcher, are provided in the next chapter.

4.6 The researcher's role

The researcher's position, in this case my patterns of understanding, perspectives and attributes will influence what the researcher sees, explores, and addresses, hence shaping interpretations. To ignore my own presuppositions, bias, and subjective prejudices as a qualitative researcher, would thus potentially influence the data and the analytical process (Whittemore et al., 2001). To stand back on oneself as in self-reflexivity, is a fundamental prerequisite for free reflection (Koch, 1994; Gadamer, 2004). Human understanding as dependent on preconception recognizes that it is impossible to overlook that the researcher and the study's participants are all connected to their surroundings and context (Merleau-Ponty, 1994; Taylor, 2001; Gadamer, 2004). As preconditions formed a backdrop in the context of interpretation, the process of clarifying my preconditions for preunderstanding, was an important step in this thesis' critical reflections upon data collection and

the analytical process. This process, in line with the essence of the hermeneutic circle, related specifically to interpretation of both written documents in the document analysis and transcribed text withdrawn from the interviews. Preunderstanding, presuppositions, and context constituted my "glasses"; "frame of reference"; "horizon of expectation" (Kuhn, 1962; Popper, 1963; Gilje & Grimen, 1993, 1995; Aadland, 1997). To illustrate: my interdisciplinary background of Master of Laws (LL.M.) and MSc in Risk Management and Societal Safety, provided me with a set of conceptual frameworks for interpretation and understanding, especially in terms of interpretation of legal sources. My interest into law, risk and safety, and political science, was also decisive in how I communicated questions, and interpreted participants' expressions (Kuhn, 1962; Popper, 1963; Gilje & Grimen, 1993, 1995; Aadland, 1997). Likewise, the participants' "glasses" and insights shaped their expectations of questions posed and their perceptions about this thesis' scope and purposes (Gadamer, 1987; Skjervheim, 1976, 2001). Hence, I had to acknowledge that the participants' interpretations of the interview questions perhaps were influenced by what they had read about the PhD project in the information sheet, and what sort of facts, thoughts, and perspectives they believed the project could benefit from. Moreover, knowledge about the participants' cultural and educational background; their "horizon", was a prerequisite for interview questions to be understood as intended. Thus, prior to the interview, each participant was handed a background sheet to fill out, with requested information about age, gender, education, previous and current position. Throughout the entire study research process, the supervisors contributed to discussions about participant selection, and potential bias related to the positioning and understanding of the researcher-participant role.

The process of understanding and interpretation in the thesis' work has also included phenomena associated with misunderstanding and communication (Gadamer, 1987). I might have failed to understand the participants during parts of the conducted interviews. Opposite, the participants may have understood some aspects better than the researcher, and may "actually be right" (Gadamer, 1996:82). In cases of ambiguous response, for instance, participant answers were followed up by me, to clarify meaning. Being conscious about how interview questions were designed, appropriately adapting communication and responses, was therefore important reflexivity work in my research role. Since

participants' backgrounds and roles varied, it was also considered useful to adapt terminology and rhetoric accordingly during the interviews. For instance, *performance-based regulation* was a term that the researcher explained to non-legal participants. Likewise, *resilience* was to most participants explained as linked with the ability to adapt and be flexible to context. I believe that clarification of these two key terms was sensible, to ensure common ground for further communication and discussion between the researcher and the participant.

My position in the study field

Some of the Paper III participants, and readers of this thesis, might have questioned my credibility as a researcher due to my lack of clinical experience in the research field investigated. I did not bring any pre knowledge and practical experiences about how it is to work with patient related tasks. Regardless, this thesis has brought along valuable insight into how different stakeholders perceive regulation, influence risk management in hospitals, and how these system levels alongside contribute to adaptive capacity. Perhaps I was fortunate to get hold of these insights due to my position in the field as a safety science researcher in the healthcare context. It sometimes felt like the participants in Paper III were talking to me like I was some sort of a "speaker" that finally paid attention to their views, hoping that their experiences would reach Government officials and regulators. My professional, interdisciplinary background added value to the macro and meso level investigation with thorough understanding of governmental design and enactment processes. Regardless of my lack of healthcare professional experience, my co-author team held professional experience from clinical, medical hospital practice. This contributed to increase awareness of hospital perspective's thinking into this thesis.

4.6.1 Ethical considerations

The study did not collect specific patient information, thus no approval from The Regional Committees for Medical and Health Research Ethics was required. Personal data derived from the interviews was notified to the Norwegian Centre for Research Data (NSD) (REF. NO: 381276, October 1., 2018), as required in line with the agreement between the University of

Stavanger and the NSD. Every participant signed informed consent ahead of the interview, with information about the option of withdrawal from the study. All interview data was anonymized. 10 of the interviews were transcribed by an external consultant, who signed a non-disclosure agreement, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Documents retrieved from online sources are publicly available. Documents exempted from public disclosure are not available. Data retrieved from the interviews is available upon reasonable request and only with permission from the participant(s).

5 Findings

Each of this thesis' three sub studies holds one published paper, of which all three papers contribute to answer the overall aim. A summary of the main findings from each paper and the relationship between the papers are presented in the following.

5.1 Paper I

Paper I, titled *Exploring links between resilience and the macro-level development of healthcare regulation- a Norwegian case study*, aimed at exploring the macro-level, governmental rationale, and expectations towards hospital management. Two research questions were investigated:

1) What was the regulatory rationale for developing a management focused regulatory framework (the Quality Improvement Regulation) for quality and safety improvement in healthcare?
2) How do the regulatory bodies expect the new Quality Improvement Regulation to influence resilience in hospitals?

Two themes emerged from the analysis: "Governmental Rationale for Revising the Quality Improvement Regulation" and "Expectations of Resilient Capacities". The governmental rationale for developing a management focused regulation for quality and safety improvement in healthcare was linked to implementation issues with the previous Internal Control Regulations, lack of management competencies and responsibilities in the healthcare services, and the need for promoting quality improvement as a managerial responsibility. A flexible, nondetailed regulatory framework was identified as developed into having a more instructive PDSA design which intended to support local adaptation.

Hospital managers were expected to *adapt* risk management and quality improvement measures to their specific context, activities, and risk conditions. The Quality Improvement Regulation was considered to have the potential of being a catalyst for hospital managers to gain a bird's eye perspective on the conditions and activities in their unit; department; clinic, facilitating the ability

to anticipate local risks. However, most participants did not have a clear vision of how hospital managers would adapt it to their practical day to day work. Adding to this, the Government did suspect a disconnection between what the top-level managers prioritize and what is done at the level where clinical work unfolds. The generic and flexible regulatory design was described as essential for it to fit any organizational context, as well as challenging to make it relevant for the right clinical level. Also, lack of instructive details about the expected level of effort and measures according to the regulatory framework, was considered a possible challenge to healthcare professional's comprehension.

5.2 Paper II

Paper II, titled *Investigating hospital supervision: a case study of regulatory inspectors' roles as potential co-creators of resilience*, aimed at investigating the meso-level changes in supervisory approach and inspectors' work to facilitate adaptive capacity and learning in hospitals. Two research questions were investigated:

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

The content analysis resulted in five themes: "Changes in Supervisory Work due to the new Regulation", "Inspectors' Work to Apply Regulation and Facilitate Adaptive Capacities", "Learning from Supervision", "Supervisory Impact on Hospital Performance", "Improvement Potentials in Supervisory Practice". No substantial change in the inspectors' approach due to the new Quality Improvement Regulation was found. Although the Norwegian Board of Health Supervision at the national level, occasionally provides guidance, supervision was normally adapted to specific contexts and inspectors balanced trade-offs daily. Trade-offs were typically described as balancing between system and individual responsibility and causality in the inspectors' assessments of adverse event-based supervision.

Participants expressed a general concern about the impact of supervision on hospital performance. Benefits and disadvantages with positive feedback from inspectors were debated, whereas some believed they had improved their practice of giving positive feedback to hospital managers during the concluding supervision meeting. One County Governor acknowledged that they had yet to practice the latter. One important issue with positive feedback was stressed by several participants: as supervision does not shine a light on every matter, positive feedback could mislead hospitals to believe that everything with their system is fine. However, inspectors could nurture learning by improving their follow up, use expert inspectors, and add more hospital self-assessment activities.

5.3 Paper III

Paper III, titled *Hospital managers' perspectives with implementing quality improvement measures and a new regulatory framework - a qualitative case study*, aimed at exploring micro-level hospital implementation efforts and the regulatory influence on quality and safety. One research question was investigated:

1) How do hospital managers work to improve quality and what are their experiences with implementing the Quality Improvement Regulation?

Four themes were identified across the data: "Adaptive capacity in hospital management and practice", "Implementation efforts and challenges with quality improvement", "Systemic changes", "The potential to learn". The Quality Improvement Regulation's flexible design was agreed on as essential, partly due to the complexity in the hospital system, including different risks and elements of variation and uncertainty. Participants argued that having a one size fits all solution is not easy, as improvising will always be necessary at a local level where new situations occur. The latter implied that it is impossible to anticipate every possible event. Autonomy was described as a key flexibility feature in everyday hospital work. However, autonomy could influence physicians' willingness to actively participate in systematic quality improvement work as well as leaving the hospitals with the decision to implement adverse event reporting systems of their own choosing. Too many obligations being left with managers and a lack of time to prioritize systematic

PDSA methodology and quality improvement efforts, were reported as challenges to the regulatory implementation of quality and safety related requirements. The Quality Improvement Regulation's legal basis solely did not lead to change in the managers' work practices related to quality and safety activities, neither did it lead to changes in clinic. Reports although revealed implementation of several measures to improve quality and safety over the past few years. Most physicians worked unconsciously in accordance with the quality improvement methodology, participants reported.

Structural changes were found as in the establishment of different types of meetings, councils, and committees (e.g., patient safety and quality councils, network meetings, internal audit meetings) at the administrative and managerial levels in the hospitals. According to participants, a cultural shift had occurred in attitudes towards the importance of continuous quality improvement and the systematic approach to it. Courses and training that used to be ignored by physicians, had gained attention, and increased in popularity, however support systems and routines varied.

Interpersonal trust among health personnel and institutional trust between hospital managers and governmental supervisory bodies were described as a necessity to maintain high quality care. Participants explained that it was difficult to learn from adverse events during normal work operations due to time pressure. In addition, health personnel did not always have the motivation to deal with it. Since it was difficult to learn from adverse events, it appeared difficult to learn from successful outcomes too. Most participants emphasized that supervision could be useful but noted that some recommendations from inspectors were difficult or impossible to implement in practice. However, a system-based perspective to adverse events was more frequently applied recently compared to in previous supervision activities, contributing to the needed sense of confidence to openly discuss adverse events and risks.

5.4 Relationship between papers

The three papers in this thesis are interrelated: each paper represents one system level in the overall multilevel case study. Each unit of analysis thus reports findings from either micro, meso, or macro-level. Altogether the findings report

the larger unit of analysis (the Quality Improvement Regulation), and its link to adaptive capacity.

Findings in Paper I about regulatory bodies' rationale for revising the regulatory framework highlighted expectations towards hospital management and thus formed a foundation for Paper III. Document analysis in Paper I contributed to identify the objectives in Paper II focusing on a stronger and explicit management focus in the supervisory approach towards Norwegian hospitals. In turn, findings about supervisory activity and methods applied in external hospital inspection in Paper II, informed the data collection for Paper III.

All three papers interrelate in the sense that to achieve a regulatory change set out in a practical hospital context, adaptive capacity, with more collaboration, is needed across three system levels. The thesis identified that to move forward, it requires a demanding systemic adaptive process. Paper II focused on learning and improvement perspectives whilst Paper III displayed how managers experienced supervision. Both Paper I and III showed how change was requested and needed. The aim with the revised regulatory framework was to make a flexible regulation (Paper I) and Paper III findings indicated that managers experienced it to be flexible due to its context sensitive design. Findings across all system levels highlighted contextual flexibility. The new Quality Improvement Regulation did however not lead to changes in the inspectors' work practices (Paper II) nor in the managers' work related to quality improvement activities (Paper III). Through integration of macro, meso, and micro findings, it came to light that there was a mismatch between the new Quality Improvement Regulation and the need to accordingly develop a new supervisory approach. Relevant support, training, and implementation efforts were lacking, to achieve fundamental changes in hospital management due to a single regulatory framework (Papers I, II, III). Nevertheless, Paper I findings and the need for change held together with Paper III findings did show that several changes have happened in recent years, with regards to structural and cultural aspects in hospitals' quality improvement systems and approaches (Paper III).

Findings retrieved from the multilevel approach in this thesis illustrate that the embedded units in Papers I, II and III have interrelated system wide impact, making way for further discussions about how design, enactment, and

implementation of healthcare regulation best links with adaptive capacity across system levels.

6 Discussion

The avenue for the discussion is to examine how resilience is linked across system levels and whether regulatory action taken at one level undermines or supports abilities for resilient performance at another. Complex adaptive systems are dynamic; therefore, the perspective is that organizational levels need to *continuously create* safety, viewed as an *activity* rather than a property (Hollnagel, 2018 a; Bergström & Dekker, 2019; Wears & Sutcliffe, 2020). The discussion aims at deepening the critical perspective about whether resilience and regulation are useful. Overall, it grapples with a bigger perspective uniting adaptive capacity and resilience with regulatory regimes. Herby, it contributes to theory development in bridging responsive risk regulation with resilience perspectives, including what role regulators *could* play. By designing the overall case study to start its investigation at the top (macro-level), prior to lower system levels, also contributes to methodological development in the field of resilience in healthcare (Berg et al., 2018).

6.1 Conflicts and reconciliation: implementation, interaction, and integration across macro, meso, and micro-levels

The interpretive work in the integration of this thesis' three sub studies focuses on possible gaps or conflicts in the relationship between the system of formal regulations and the way these norms unfold in practical hospital context. These gaps are essentially demonstrated by cases of governmental requirements designed regardless of complicated reality (Walshe, 2003). In the literature, such conflicts are often called work as imagined versus work as done, or a "sharp end" – "blunt end" dichotomy (Hollnagel, 2014; 2018; Anderson et al., 2020; Haavik 2020). By comparing data stemming from three different system levels, this thesis could contribute to unite the different perspectives, and thus reduce tension between work as imagined and work as done. By facilitating a more adapted, real-world take on developing and implementing new regulation, the outcome of knowledge from this research could be relevant and informative for stakeholders at all levels in the healthcare system. Contributions and implications are described and discussed in the forthcoming chapters.

6.1.1 Macro-level "gap reducing" initiative

Macro-level findings showed how the regulators adjusted and replaced the previous Internal Control Regulations with the new Quality Improvement Regulation (Paper I). Due to lack of adequate management responsibility and competencies and other revelations retrieved from external inspections, the macro-level hence recognized issues with compliance and practicality of the previous regulatory framework (the Internal Control Regulations). Their response was to amplify the management responsibility and design a context sensitive regulation (Paper I). This type of regulatory response to micro-level challenges, as reported in this thesis, does not appear to have been the subject of any prior studies. The present findings confirmed that hospital managers were expected to *adapt* management of risk and remedies applied to increase quality, to their specific context, activities, and risk conditions. Moreover, Paper I data demonstrated that the Quality Improvement Regulation provided hospital managers with a potential to gain an overview of their contextual conditions: resources, competences, and activities. The ability to anticipate local risks was hence incorporated into governmental expectations, countering with a traditional clinician viewpoint seeing regulation as a necessary evil (Macrae, 2013; Wears & Sutcliffe, 2020). Earlier research has highlighted an "unfortunate negative focus" on the consequences of regulation and the burdens of compliance, in opposition to a positive outlook on compliance with regulation as a means that could lead to avoidance of losses and the gaining of benefits (Quick, 2017). Still, the findings of this study suggested a gap between hospitals and governmental bodies in terms of work as imagined and work as done (Hollnagel, 2018 a). The regulators in Paper I acknowledged that healthcare is complex and that hospitals are complex organizations. However, compared to managers in Paper III, macro-level regulators seemed to believe in the instrument of regulation *per se*. In addition, Paper III managers at various hospital levels indicated that important issues and obstacles to implementation were related to time pressure, lack of resources and finances. Lack of time to do evaluations of new projects was similarly mirrored as hampering to learning in a recent published study (Hedsköld et al., 2021). Aspects of resources and finances however appeared to not play an equally important part in the governmental "equation" when macro-level participants in Paper I reported about quality improvement and patient safety in hospitals.

6.1.2 The regulatory craft

If the assumption is that there is a gap that needs to shrink, how and why does regulation play a role? According to Sparrow (2000), the *regulatory craft* plays a big role in bringing regulation closer to practical reality. The imperative task for regulators is to "pick important problems and fix them" (Sparrow, 2000:9). Elements such as public protection from harm, pressure to improve services due to variation of quality, and accountability pressure, are often applied to explain why regulation is important (Healy, 2011). In the context of quality and patient safety, regulation has thereby its paramount in contributing to reduce risks and improve the services (Walshe, 2003; Macrae, 2013). How to fix problems, however, depends on the initial problem description and thus different problems require different problem-solving techniques, different risk assessment and control, and various administrative and organizational structures. This strategy is in line with the objective in responsive regulation (Braithwaite, 2011). Sparrow (2000) draws the analogy to what is commonly referred to as the *hammer and nail pathology:* "when the only tool you know how to use is a hammer, every problem looks like a nail". This illustrates that the *intention* of a regulatory strategy could very well be sensible to the practical field, but if the problem description from the start is not shared by all stakeholders, the intention is left irrelevant. In that case, there is a gap between formal introduction and actual world implementation which needs to be met (Meyer & Rowan, 1977; de Bree & Stoopendaal, 2020; van de Bovenkamp et al., 2020). This aspect relates to how the Quality Improvement Regulation was formally introduced to the Norwegian hospital systems as a policy and regulatory strategy, but where partly Paper II findings and mainly Paper III findings demonstrated how it lacked comprehensive implementation. As the previous Internal Control Regulations lacked guidance on implementation, which was a major issue, the macro-level sought to reduce the implementation gap by adjusting the Internal Control Regulations into the Quality Improvement Regulation (Paper I). Hence, Paper I findings indicated that the Government's work was led by the *intention* of trying to accommodate the needs of the regulatees by redesigning an unpopular and "alienated" previous regulatory framework. Hospital participants however implicated that the Government's intention was partly unsuccessful (Paper III). In contrast to past research, enforced self-regulation based on a performance-based regulatory regime was

according to this thesis' findings not sufficient to minimize the gap between the formal and the actual world (de Bree & Stoopendahl, 2020). The regulatory craft reported in the thesis therefore demonstrated an untapped regulator-regulatee collaboration potential.

Regulatory strategies and regimes are generally designed according to *models of* the healthcare system, (cf. Weber's "ideal type"), but could in *reality* be more, or less correct (Weber, 1949; Crotty, 1998). They can be too simple, or too complicated to grapple with for the regulatees (Weber, 1949; Crotty, 1998). Despite different views on *how* to regulate and the *degree* of regulation that should be present, regulation was affirmed to play a role to quality and safety across macro, meso, and micro participants in all three sub studies. This aspect of the reported research could presumably relate to the regulatory strategy that the macro-level based their development process on. Having the characteristic of *an ideal type* of the healthcare system, the regulatees reckoned the strategy as too complicated to grapple with. International studies suggest that a debate about regulation's origin and functionality is needed, followed by the right implementation measures and support tools (van de Bovenkamp et al., 2020). Odds are otherwise low when it comes to lower-level implementation. To this thesis' research problem this applied particularly in two matters:

1) The development process leading up to the Quality Improvement Regulation displayed that regulators appeared to adjust the previous Internal Control Regulations with the rationale of bringing regulation more into line with experiences of the work on the "front line".
2) There was lots of work to develop the Quality Improvement Regulation, but little work to support the implementation of it, leading to less implementation efforts at the micro-level.

As described through previous countrywide external inspections (NBHS, 2008, 2011, 2013; MHCS, 2012, 2015, 2016), and reported elsewhere in this thesis, it was considered paramount to explicitly target the top management level as responsible for improving quality in hospital settings. It was however left with the different health regions and local health trusts to instruct and encourage hospital managers to get engaged with systematic quality improvement courses and training. In turn, support systems and routines varied across different hospitals (Paper III). As past research has stressed, lack of knowledge and skills

are significant barriers to quality improvement in the healthcare setting (Dixon-Woods et al., 2012; Wilkinson et al., 2011). One of the questions to this thesis was thus to what extent the Quality Improvement Regulation incorporated and embodied both the responsive regulatory strategy of escalating sanctions, and escalating support (Braithwaite, 2011). Moreover, it investigated into what kind of support was needed to go alongside the objectives of requiring local level management of quality and safety. Although it may be a complicated task, regulators with regulation as their instrument, could play a part in reducing the possible conflict between macro-level objectives defined by performance-based regulation and practical, lower-level implementation. If the intention of adjusting the Quality Improvement Regulation was followed by increased budget allocations specifically targeting support systems and management training, *and* more direct involvement of clinicians, regulators could have accommodated the macro-level objectives *and* micro-level implementation (both rationale and expectations). Due to a lack of these aspects, the Government did not achieve full scale implementation at the hospital management level. The responsive elements of increasing the "positive" aspects that are needed (training, knowledge, resources), was signaled by Paper I findings. In addition, attention to reduction of the "negative" aspects by anticipatory, risk reduction planning and actions, should be considered part of the "regulatory craft". These findings highlight that little is known about this dual craft, and how to achieve both elements. By stimulating "comfort zones" or "reflexive spaces" for debate among regulators and regulatees, not just blaming the regulatory pressure itself, could positively enhance the link between defining what good quality entails, and the role regulation should play (van de Bovenkamp et al., 2020; Wiig et al, 2020 a; Kok et al., 2020). Further studies are needed to address adjacent implications.

Expectations of adaptive capacity and the link to "translation" of regulation

As argued in the theory chapter, investigating into adaptive capacity is a key feature in the concept of resilience in healthcare (Hollnagel et al., 2006, 2013; Vincent & Amalberti, 2016; Berg & Aase, 2019; Wiig et al., 2020 b). This thesis demonstrates unprecedented ways of linking flexibility and adaptive capacity to regulatory activity by giving attention to regulatory design processes which enable or support adaptive capacity. This link demonstrates to

be especially key since a well-known issue is the clash between top-down regulatory control and the "leave me alone and let me deal with real work here" bottom-up perspective (Ayres & Braithwaite, 1992; Hollnagel et al., 2013; Braithwaite et al., 2016). A performance-based regime by specifying preferences or objectives, thus possibly supports a bottom-up perspective rather than top-bottom (Brennan, 1998; Grote, 2019; Johannesen et al., 2017; Leistikow & Bal, 2020; van de Bovenkamp et al., 2020; de Bree & Stoopendaal, 2020). This type of regulatory approach may even support what Weick, and Sutcliffe (2007) denote as being *mindful to context*, for instance increase awareness about how deviations differ from expectations. Resilience theories emphasize sensitivity to context yet acknowledge initial structures and frames that form expectations (McDonald, 2006, Hollnagel et al., 2013; Hollnagel, 2014; Bergström & Dekker, 2019). This thesis argues that the bigger the regulatory slack is, i.e., flexibility to choose and tailor appropriate actions and efforts, the more it supports the idea of hospitals' adaptive capacity (Schulman, 1993). It does not, however, ignore that flexibility also could encourage less fortunate behavior, expose managers to too many choices and not increase performance and/or outcome quality. This balance between autonomy and risk of too much creativity was recently mirrored in Hedsköld and colleagues (2021).

As different organizational levels are not static in their positions and external conditions influence these processes; it is important to have flexibility and adaptation in the system for it to change accordingly (Rasmussen, 1997). Hence, as organizational resilience constitutes nonlinear, dynamic capacities measured by the ability to create foresight and anticipate errors and risks, flexibility in different organizational layers is interesting to investigate (Vincent & Amalberti, 2015; Berg et al., 2018; Bergström & Dekker, 2019; Woodward, 2019; Wiig et al., 2020 b). However, the potential to be flexible does not exist in isolation in complex hospital systems. If flexibility ought to be profitable, it presupposes a certain amount of competence, knowledge, and resources. To illustrate by this thesis' regulatory context: the legal standard of professional sound practice and prudent conduct (described previously in chapter 4.4.1), is the underpinning principle in the Norwegian healthcare services. Consequently, regardless of whether the adaptation is triggered by an adverse event or not, or simply done in the setting of adjusting and improving

normal work mode, it should always remain in line with professional sound practice. Likewise, what constitutes professional sound practice shifts with clinical development of knowledge and competence (Lindøe et al., 2018). In turn, this implies that flexibility and adaptation are embedded in the legal standard of which the Quality Improvement Regulation supports. Looking at the analysis in the light of legal dogmatic, it is worth questioning the governmental expectations towards the meso and micro-levels' skills to interpret the content of legal standards such as this. What Paper II findings indicated was that when the County Governors were set to evaluate hospital conduct, they based their assessments on certain criteria for risk management, that in turn the hospitals were expected to manage to operationalize. Participants from both meso and micro-levels reported on hospital organizational variations when it came to these assessments (Papers I and II). They argued that it sometimes related to different descriptions of reality.

Having the multilevel perspective in mind, the latter is key (Bouwman et al., 2017). For instance, the Guidelines document associated with the Quality Improvement Regulation appears to have the potential to be instructive, with examples of how legal standards in the context of the Quality Improvement Regulation should be interpreted. For managers and clinicians that may find flexibility and nondetailed requirements difficult, the Guidelines document could be particularly helpful. Along with specific clinical guidelines, routines, procedures, and standards, it is in place to make managers and clinicians feel supported with more detailed expectations and more operationalized determinations, if, and when specifications are needed. The document explicates the provisions in the Quality Improvement Regulation with comments about how national and professional guidelines are not legally binding, yet it emphasizes the desirable and recommendable choices of action (for instance connected to QIR §§6c and 7c) (NDH, 2017). It stresses that these types of national and professional guidelines describe what the authorities have defined as professional sound practice with support to how regulations ought to be interpreted (NDH, 2017). It however also emphasizes that assessments in every choice of action, are supposed to be individually based (NDH, 2017). The responsiveness is thus integrated in the regulatory system by different means (e.g., strategies such as self-regulation and acts of laws, and sanctions such as notifications or warnings *after* dialogue), to accommodate different operational

levels (Braithwaite 2011, 2017). Regulators (Paper I findings) however indicated that the Guidelines document became large and comprehensive, which was expected to reduce its utility and practicality. Managers and advisors at the hospital level (Paper III) were divided in their responses and did not emphasize the document's role in their work of operationalizing the Quality Improvement Regulation, unless directly asked about it. Positive answers indicated that the document was a good support by providing examples or explanations to unclear terminology.

Previous research has described how hospitals needed to do a lot of interpretive work to make use of regulation, with additional resources and systems occasionally required to implement regulatory requirements (van de Bovenkamp et al., 2017; Simon, 2018). This aspect applies particularly to hospital managers because they rarely possess pre knowledge about the legal skills needed for them to read and implement regulatory texts into practical settings. The shortcomings regarding hospital manager training and support portrayed in Paper II and III, indicated that the support for "translation of" legal standards was crucial if managers were to find the regulatory framework instructive. At the same time, autonomy was characterized as an enabling aspect to any activity or quality enhancing effort. This "double fitting" process aligns with results from a previous study of the global regulation of HIV treatment where regulations on one hand were fitted to practice and on the other hand practice was fitted to the regulations (Heimer, 2013; Øyri & Wiig, 2019). Future research on how hospital managers practice their autonomy may extend the explanations of how they are supported, or not, by quality advisors and guidelines to enhance and improve quality. It remains to see how this link unfolds in the Norwegian hospital setting.

6.1.3 Trade-offs at all the system levels

Different types of gaps and thereby trade-offs, could be present between:

- Bureaucrats, policymakers, and regulators in the same governmental body
- Governmental levels, such as the ministry level and the supervisory level
- Governmental level and regional healthcare authorities
- Regional healthcare authorities and local health trusts
- Administrative management levels in hospital and clinical managers

- Hospital managers and clinicians at the "front line"
- Clinicians and other professional groups

All these possible gaps related to understanding, expectations, communication, knowledge, competence, respect, and trust, make up a whole constellation of aspects that contribute to organizational and managerial complexity in the healthcare system (Braithwaite, et al., 2016). They are therefore all key to understand resilience in healthcare (Hollnagel, 2014). The present findings provide information about some of the complexity aspects.

Various roles and system levels' influence on decision-making

Gaps could be both good and bad, either as representing assets to innovation and development of new strategies and solutions, as well as appearing as conflicts between power relations (Mintzberg, 1984). Stakeholders at different levels have various roles, tasks, and responsibilities, whereupon different "system logics" influence how they describe and deal with issues (Engen & Lindøe, 2019; Lindøe & Baram, 2019). In Paper III, managers at the hospital level in general argued for autonomy to handle varying demands, as they acted on little information and short time and therefore sometimes needed to discard procedures. Paper I and II indicated governmental expectations of anticipatory capacity, conduction of risk analysis and hospital self-assessment, tasks that require longer time spans and complex analysis.

Past research has outlined how different dimensions to the understanding of quality vary with inspected organizations, hospitals and among managers (Doyle et al., 2013; Wiig et al., 2014; Schaefer & Wiig, 2017; Hovlid et al., 2020 a, b). Bouwman and colleagues (2017) found for instance a mismatch between regulators' tendency to emphasize clinical aspects of harm and safety, and patient reports with emphasis on nonclinical aspects such as organizational elements. In contrast, findings across this thesis' Paper I and II, indicated that the regulators and inspectors in the Norwegian context, included managerial and organizational elements in their regulatory activities and demands. This thesis hence argues that the Government acknowledged and expected that *work as imagine* sometimes needs to be adapted to be more in line with *work as don*e. Specifically, it is illustrated by the option of delegation in the Quality Improvement Regulation, that allows informal delegation of tasks between different hospital levels (cf. QIR § 3). Managers are indeed encouraged by the Quality Improvement Regulation to adapt decisions to context, to meet

circumstances such as adverse events and staffing issues with the adequate response. This perspective is sometimes described as thoroughness versus efficiency and relates to cases where people must make considerations between time and effort spent on preparations, and time and effort spent on *practically* carrying something out (cf. the ETTO principle (Efficiency-thoroughness Trade-off): Hollnagel, 2009). In the Guidelines document associated with the Quality Improvement Regulation it was similarly recognized that managers close to clinical work often are the ones who *practically* implement quality improvement measures in large hospital organizations. This view aligns with lower-level responsiveness to context, found in responsive regulation pyramids (Braithwaite, 2011). The aspect of delegation, in terms of *who* gets delegated the task of identifying and evaluating risks, could however impact evaluation outcomes and in turn be decisive for the choice of risk reducing measures (Rae & Alexander, 2017). Thus, macro-level data (Paper I) indicated that Safety II "thinking" was introduced into governmental practice, with trade-offs recognized as inevitable.

With respect to this thesis' system approach, the governmental level has the overall responsibility of facilitating safe and sound healthcare practices, moreover, to set "constraints" or "environmental stressors" to the activities (Rasmussen, 1997; Leveson et al., 2005, 2006). As ensuring safety is a public obligation, and ensuring patient safety is a public health concern, regulating patient safety involves "looking beyond the profession for solutions" (Quick, 2017:52). This implies that the governmental level must recognize and balance the "big picture" in their decision-making process. Lindøe and Baram (2019) refer to it as the regulator's role as "orchestrator" in safety management. Whilst clinical managers on the other hand have more specific patient related tasks and responsibilities, which do not require that holistic approach. County level inspectors in Paper II partially confirmed that the maturity regarding, and implementation of systematic improvement efforts, varied with the hospital managers involved (as reported in Paper III).

Also, adaptive capacity looks and works differently in regulatory bodies with "system wide responsibilities" compared to lower levels (Anderson et al., 2020). Interestingly, the County Governors (Paper II) at the regional level described somewhat different "modus operandi": they reported different interpretations of prudent conduct, and various ascriptions of management

responsibilities. Some of the daily trade-offs that were made by the inspectors were related to their adverse event-based assessments of balancing system versus individual responsibility and causality.

This makes up an inescapable conflict about priorities, resources, and efforts to improve quality at the different system levels. Trade-off examples in Paper III for instance, linked to the PDSA logic, as managers viewed it as too time consuming to justify full scale implementation. Others flagged how autonomy sometimes could complicate their work in the sense that they requested more strict support and correctives from their senior managers. The latter is interesting both in a responsive regulation perspective (Braithwaite, 2011) and to how resilience in healthcare (Hollnagel, 2018 a; Wiig et al., 2020 b) values lower-level flexibility. It portrays how regulation cascades through the system and sometimes results in different responses in practice. Broadly translated, all trade-offs are therefore relative to the specific role and system level, and sometimes considerations vary in between system levels (Paper II). Thus, this thesis argues that trade-offs as part of the different system levels' adaptive capacity, recognize that considerations made in practice depend on the people making them.

Pitfalls with adaptive capacity and regulatory flexibility

This thesis' micro-level findings indicated that resilience as in daily adaptation, was part of an overall trade-off between what hospital managers perceived to be administrative and governmental requirements, and what daily work at the clinical level required from a hospital management perspective in terms of resources, time, and engagement. Adaptation to context was sometimes associated with the ability to perform the necessary tasks, procedures, and patient treatment. On the other hand, it indicated that adaptation could hamper quality improvement initiatives that were traded off because of resources, time, and engagement, resulting in unwanted variation between units, clinics, hospitals, and regions (Hollnagel, 2009). Based on the integrated findings, adaptive capacity will therefore not always lead to quality and safety enhancement (Wears & Hettinger, 2014; Anderson et al., 2020). A high degree of adaptive capacity at the micro-level could occasionally lead to drawbacks, for instance when a medical or technical procedure is adjusted but leads to an unsuccessful or unacceptable outcome (Anderson et al., 2020). Regulatory flexibility supported by a performance-based regime (Braithwaite, 2011;

Lindøe et al., 2018), combined with a lack of interest in quality improvement work, allows regulatees to deliberately ignore quality and safety expectations. In the long run, if such an unfortunate trade-off concerning adaptive capacity results in biased quality for patients, it has the potential to weaken the core idea with contextual regulatory flexibility as a favorable asset to hospital practice.

6.1.4 *Learning from everyday work: a focus for improving quality?*

Many scholars have encouraged more attention to success in healthcare and "normal" or "regular" work modes, but it is not yet clear *how* it feasibly could add to the current regulatory regime (Lawton et al., 2014; Dieckmann et al., 2017; Ellis et al., 2019; Woodward, 2019; Wiig et al., 2020 b; Hegde et al., 2020). Previous reports illustrate difficulties with using positive deviances to achieve learning outcomes, due to lack of reliable parameters for what safe care is (Lawton et al., 2014). One of the hospital findings (Paper III) addressed learning from positive experiences as: "this is just regular work for us". The point drawn from this was that if daily hospital work went along as expected, without deviances and adverse events, it was considered normal practice and not worth paying extra attention to. Although knowledge about the concept of resilience varied among regulators and inspectors (Paper I and II), they all expected that hospital managers were concerned about learning from incident reporting and actively engaged in learning from supervision. This contradicted some of the Paper III descriptions from hospital managers and their advisors, who admittedly reported it difficult to learn from adverse events under the current reporting regime, during normal work operations. In turn, it was reported even more difficult to learn from successful outcomes, and clinicians sometimes lacked motivation.

Perhaps the "regular work" response found among hospital managers (Paper III) can be attributed to a disapproving judgment of the positivity perspective within the resilience concept (Lawton et al., 2014; Dieckmann et al., 2017; Ellis et al., 2019; Wiig et al., 2020 b; Hegde et al., 2020). Whereas the underpinning theoretical assumption is that resilience is useful, that it makes organizations safer, critiques may argue that good, sound, and successful practice equals normal practice. In resilience literature this is referred to as "habituation", a

psychological reference to "non associative learning" (Hollnagel et al., 2013). Regular situations are disregarded, leading to reduced attention simply because they are *the norm* (Hollnagel et al., 2013; Wears & Sutcliffe, 2020). Both perspectives are acknowledged in this thesis, but it highpoints one finding in particular: the lack of positive focus in supervisory reports to promote learning from regular, sound hospital practice. Some of the managers in Paper III wished that external supervision aimed at more than negative aspects, whilst inspectors in Paper II expressed concern for such an approach. They argued that if positive aspects were to be described in supervisory reports, it could mislead hospitals to think their entire system for quality and patient safety related work was completely fine. This view could be related to the assumption in resilience theories that safety is about "seeing what is not there" (Hollnagel et al., 2013; Wears & Sutcliffe, 2020:171). The assumption implies that if inspectors gave hospital managers a "stamp of approval" it would contribute to reinforce their "habituation" (Hollnagel et al., 2013; Wears & Sutcliffe, 2020).

Documentary evidence in Paper II exposed a general lack of references in governmental documents to include positive elements in hospital supervision methods. Likewise, documentary evidence in Paper I displayed lack of discussion about including positive elements to the existing regulatory regime. One exception was however displayed: The Ministry signaled that organizational culture was a key element in sharing of results and experiences within and cross sector (MHCS, 2015 b). These findings are broadly in line with previous findings addressing how regulators have a core task in applying knowledge retrieved from existing incident reports in a way that also includes positive learning outcomes, resources, success factors and challenges in supervision reports (Lawton et al., 2014; Hegde et al., 2020). Based on integrated findings, this thesis suggests that to overcome seeing "regular work" as an irrelevant improvement factor, it is key to define what resilience in healthcare values in processes that "goes right" (Leveson, 2020). Is regular work reserved successful outcomes or does regular work include failed outcomes that turned out "bad" despite well performed work operations? These questions need answers and adjacent boundaries to better inform hospital improvement work in a resilience perspective. It is certainly needed if regulators should step up the perspective of resilience in their guidance documents, and equally important for inspectors, as it could contribute to their

understanding and evaluations of successful practices in hospital activities. Lastly, it seems key to answer these questions to meet hospital level skepticism towards the resilience in healthcare perspective of valuing "learning from success" (Nemeth et al., 2008; Hollnagel et al., 2013, Hollnagel, 2018 a; Sujan, 2018; Sujan et al., 2019; Wiig & Fahlbruch, 2019; Hegde et al., 2020). This is argued to be best done with "hard facts" (retrieved from for instance Functional Resonance Analysis Method (FRAM)) rather than theoretical assumptions (Hollnagel, 2018 b; Leistikow & Bal, 2020). Some monitoring tools have however shown to have bias in terms of poor reporting and added administrative burdens (Leistikow & Bal, 2020). By developing a monitoring tool that includes both quantitative and qualitative measurements and codes for successful practices, it would nevertheless provide stakeholders with "benchmarks" for their evaluations of regular work and modes of normal work operations. Given that supervision as a governmental monitoring tool has deviation and adverse events as its main target, a new type of monitoring tool could have a much more nuanced and in-depth scope than offered in today's supervisory regime. It could also contribute to collaborative reflection, along with supervision reports (Wiig et al., 2020 a; Kok et al., 2020). In return, "codes" for adaptive capacity could be considered a resource to quality and safety in complex healthcare systems.

The integrative analysis indicated how crucial it is that local health trusts and regional health authorities, inspectors, and regulators, gain awareness about what hospital managers close to clinical practice perceive as critical questions to their practical application of quality enhancing efforts. Previous research has demonstrated a relationship between physician burnout and quality, related to both safety and acceptability (Dewa et al., 2017). Others have suggested connections between burnout, emotional resilience, and increased regulation and workload (McKinley et al., 2020). As past research has shown, governmental regulation of quality often comes with administrative burdens for healthcare organizations (Leistikow & Bal, 2020). These results may signal how Norwegian healthcare authorities, regional health authorities and local health trusts could facilitate implementation of new requirements aiming at improving the quality of care, without just adding to the burden of managers and clinicians. Managerial assistance to recognize and reward those who initiate changes leading to improvement is recommended (Lawton et al., 2014).

Learning: a combined Safety I and Safety II effort

Based on this thesis' findings, individual and organizational learning was portrayed as difficult, and adverse event reporting was still weak (Papers II and III). Despite past research demonstrating an increased system perspective in external inspection in the Norwegian supervisory context, this thesis' Paper II findings did nevertheless indicate that it has not been sufficiently emphasized in supervision reporting (Wiig & Lindøe, 2009; Wiig et al., 2018). Backed up with evidence from a recent Swiss study suggesting an unfulfilled potential in learning from "never event" outcomes (Schwappach & Pfeiffer, 2020), the present findings suggest that a system perspective to adverse events and planned external inspection needs to be thoroughly implemented in Norwegian supervisory methods. In turn, that may encourage an open incident reporting culture. A system perspective may also contribute to encourage inspectors to put emphasis on the complexity issues leading to adverse events (e.g., postoperative complications). Medication related issues, team coordination, complex procedures, everyday workload, lack of good quality indicators, lack of personnel and time, information overload, lack of coordinated data systems, are all system elements forming a spider's web of complexity. In a resilience in healthcare perspective, one cannot understand adverse events processes, how and why work unfolds, without looking at all system levels, including complex interaction between stakeholder levels (Gao & Dekker, 2017; Wiig et al., 2020 b). Hence, this thesis sees learning from serious adverse events as a remaining issue that needs a more systematic and inclusive approach in hospital reporting regimes. Such an approach is required before the Government can expect systematic internal learning retrieved from successful practices (in line with resilience perspectives).

Near misses and unanticipated consequences do probably have several "take home" learning points. Afterall, a patient related injury was registered in roughly 12 % of hospital stays during 2019 (Norwegian hospitals) (NDH, 2020 a). This speaks for a reduction, and close attention to underlying causes, to learn in line with a Safety I perspective. However, it also implies that 88 % of hospital stays were "injury free". The latter demonstrates that "what goes right" is regular mode and worth highlighting, in line with a Safety II (resilience) perspective. The broad implication of the present research is thus that learning from adverse events must work efficiently if implementation of learning from

what goes right should work efficiently too. Ergo, Safety I and Safety II have interdependent impact to quality and safety (Hollnagel, 2018 a). A promising aspect with the findings in this thesis is that it can provide a basis for the understanding of how a specific regulatory regime in healthcare may accommodate both learning aspects.

6.1.5 Bridging levels by choosing the "right" regulatory regime – suggestions for theorization

In the application of responsive regulation to this thesis' findings, it was crucial to remain sensitive to the setting of which the theory was developed. Given that the setting was Australian based, where the regulatory system builds on British Common Law, application of some of the strategies and sanctions may apply differently to a Norwegian setting. Differences could typically relate to the associations between private and public governance in healthcare, for instance through systems of financing and health insurance coverage. Also, addressing regulation in general and its impact on healthcare performance, brings along some methodological challenges. According to Walshe (2003), it is challenging to evaluate regulatory interventions due to two elements:

1) it is not possible to compare "unregulated" and "regulated" healthcare organizations because regulation to some degree is involved,

2) to compare regulatory interventions before and after is difficult, due to difficulties in determining if changes in performance are because of the regulatory intervention per se or because of the collection of data.

These two aspects were of relevance to this thesis's approach of analyzing the revision of the previous Internal Control Regulations into the new Quality Improvement Regulation. It was however not in this thesis' scope to measure or compare performance in hospital practice and/or management of quality and safety efforts before and after the regulatory regime change. Future research with such an approach in mind, will have to be consciously aware of these challenges of application and methodology.

Within any regulation regime however, several strategies and options of sanctions exist along with different types of motivations and principles, and or

pragmatic foundations (Ayres & Braithwaite, 1992; Graver, 2006). Governments choose to tailor their healthcare regulation regimes differently, and some sectors and systems are strictly governed by prescriptive rules. In contrast to prescriptive, detailed regulation, some governmental regulations aim at securing a certain level of performance. In the Norwegian healthcare regime, the Government applies a range of different strategies and sanctions. The Specialized Health Services Act (1999) is comprehensive and quite detailed in its regulatory approach. In the broadest sense it regulates responsibilities, the regional health authorities' tasks in general, more specified tasks and requirements, approving processes of institutions and health services, financing, other tasks and duties such as contingency plans, accident and emergency assistance, notification of severe adverse events to the Inspectorate, and the duty to establish quality and patient safety councils. All these requirements and duties are framing the hospitals' room to maneuver. It implies that the legal basis for the Quality Improvement Regulation is already "restrained" (see previous Table 4). Hence, the hospital manager's room to maneuver within the scope of the Quality Improvement Regulation, has several boundaries retained from higher level parts of the responsive pyramids. Also, all sort of self-regulation involves a degree of governmental influence, whereas *enforced* self-regulation (such as internal control) is dependent on previous development of measures and tools for performance and management (Baldwin & Cave, 1999; Gunningham & Sinclair, 2009; Stoopendahl et al., 2016). Performance-based regimes therefore never exist in isolation. Although performance-based regulation supports context sensitivity related to a particular area, it has a broad-scale regulatory backdrop forming a wider regulatory context. Regulations based on a performance-based logic may therefore come across as more "straight forward" at first blush than what really is the case. It is specifically illustrated in this study by the aspect of a wider Norwegian regulatory context that excludes full autonomy in healthcare settings, due to the principle of sound professional practice and prudent conduct.

Evaluations based on prudency and variability are often necessary to meet with unexpected elements, because of healthcare's embedded complexity, whereas acceptable variation remains part of healthcare professionals' "craft" (Braut, 2001; Anderson et al., 2016). Hollnagel (2014) argues that while regulators seek to eliminate variation, they miss out on valuable information about quality.

To this thesis' understanding, the picture is even more nuanced than either one of the perspectives. Data in Paper III reported how managers and their advisors worked on *standardizing* procedures, aiming to reduce some of the *unwanted variation* in their work. Although it was described as very challenging to update procedures, due to constant evolvement in methods of treatment and evidence, it also illustrates that unwanted variation could occasionally benefit from stricter approaches. For instance, regulation targeting infection control measures could benefit from a stricter, more detailed information approach (e.g., Covid-19; NDH, 2020 b). Similarly, it makes more sense to provide less room for individual variation in the application and management of measures, routines, and procedures applying for laboratories, biobanks, and medication related issues. This applies for instance to the checking and cross checking of bags for blood transfusion (Johnson & Lane, 2017). Thus, despite constant shifts in circumstances that add to the original plans, some procedures and regulations would not be *patient safe* to work around or break. Regulatory flexibility in healthcare regimes thus needs careful application.

In the resilience in healthcare literature, standardization as in protocols and checklists has nevertheless been viewed as reducing communication exchange among clinicians, especially in cases of handovers (Chuang, 2013). Past research has also added knowledge about surgical checklists' impact to patient safety, with data reporting about its potential contribution to enhance safety (Haugen et al., 2015; Wæhle et al., 2020). The same two studies however, revealed challenges with "automatic" use of checklists and lacking impact if checklists were not integrated in the preexisting risk management strategies (Haugen et al., 2015; Wæhle et al., 2020). Moreover, a common view is that standardization is a hampering element to decision making which undermines the healthcare professionals' autonomy (Macrae, 2013; Øyri & Wiig, 2019). As the latter is one of the objectives with standardization, it may also *enable* anticipation: healthcare professionals can rather direct attention to uncertainties and variations, than trivial basics in the systems (Macrae, 2013). Illustrated by the inspectors' issues (Paper II) with their standardized work methods in adverse event related supervision (not having freedom to pick one case evaluation over another based on higher risk), adaptive capacity is thus in this setting conflicted. This thesis therefore encourages the resilience in healthcare research field to broadly acknowledge the duality in the concept. Critiques

claiming that regulation in general is a bad fit in healthcare, and that resilience is incompatible with regulatory strategies, should differentiate between various areas in scope and the objectives with regulation. Regulation could be both a source of improvement and a "wasteful distraction" (Macrae, 2013).

Enforcement and sanctions: various modes of operation

Regarding sanctions and deterrence, the Health Supervision Act (2017) lists the specific options of sanctions enforced by the Inspectorate and the County Governors (see previous Figure 9). The different options have different degrees of intrusive impact on the regulatee (Hood et al., 2001). The pyramid of sanctions in the Norwegian supervisory regime therefore syncs with the principles outlined in Braithwaite's pyramid of sanctions (2011). Punitive approaches will nevertheless have to be specified contextually in the relevant healthcare regime. This is a particularly important note as Braithwaite's original work was inspired by the enforcement of the pharmaceutical industry and coal mine safety (Ayres & Braithwaite, 1992; Braithwaite, 2011). Indications based on Paper II findings illustrated that different County Governors cascaded different methods through the supervisory system, which was suspected to impact meso and micro interactions. However, the theoretical constructed pyramids of regulatory strategies and sanctions presume that it is best to start with lower levels of the pyramids, namely the least interventionistic approaches (Ayres & Braithwaite, 1992; Braithwaite, 2011). If these approaches turn out to not have the expected and/or desirable impact, then higher levels; more interventionistic strategies and sanctions that potentially may influence and change organizational behaviour, could be applied by regulators. The evidence from Paper I did indicate that the macro-level manifested the system of localized internal control into the Quality Improvement Regulation, resonating with the pyramid's strategy of enforced self-regulation as a lower-level strategy. If the hospitals fail to fulfil their obligation of self-regulation however, the manifestation of localized internal control may be challenged by higher level sanction options. Supervision is thus one governmental enforcement and sanction strategy, matching with what responsive regime theory describes about regulators moving up the pyramid in cases where lower-level aims are not met. In line with the pyramid's intention, Paper II implied that inspectors were expected to move fluidly between the regulatory pyramid strategies. Based on Paper II findings however, inspectors

appeared to experience difficulties in doing so. In line with this thesis, previous results from hospital and risk regulator interaction have indicated that supervisory authorities struggled to balance enforcement and learning (Wiig & Lindøe, 2009). According to Reason (1997), the struggle to help regulatees in reducing their risks is part of "the regulator´s unhappy lot". Others have highlighted the challenge regulators have in combining control with compliance, and their role as "mentor" (Lindøe & Baram, 2019). Consistent with this perspective and Paper II findings, this thesis indicates that pursuing evaluations along with the Quality Improvement Regulation may be an even more complicated task for inspectors. They will have to combine the role of "command and control", along with the job of facilitating quality and empowering the regulatees (Hood et al., 2001). The latter aligns with what is referred to as "soft approaches" to safety regulation: the requirements set goals but leave the operationalization with the organizations, very much in correspondence with a performance-based regulatory regime (Lindøe & Baram, 2019). This approach also ties well with Dutch regulators' application of "soft signals" during inspection (Kok et al., 2020). Mainly described as reading "between the lines", "soft signals" could for instance be the collection of informal data through informal reports, complaints, and during meetings with managers and healthcare professionals (Kok et al., 2020). To the Dutch inspectors this informal data collection represented "tin openers" or "tin closers", either revealing or reassuring the ways healthcare organizations handled patient safety risks or potential risks (Kok et al., 2020). As Paper II findings displayed inspectors' hesitance about giving *advice* (both during, and outside a formal investigation or inspection), it illustrated their difficulty in combining different "hats" og "modes of operation". How much this tension influences hospital practice, is yet to explore in future studies. Ideally, it may become more important, and a potential mechanism for resilience approaches in regulatory regimes to base supervisory decisions on different kind of information retrieved from the use of soft signals such as informal guidance rather than command and control.

Micro-level involvement in regulation: more freedom, increased burden?

Findings from another recent study on inspecting bodies' expectations of how inspected organizations prepared for inspection, indicated that guidance rather than control *prior* to inspection encouraged more involvement and commitment among hospital managers and health personnel in general, *during* inspection

(Hovlid et al, 2020 b). This sort of bridging expectations at one system level with the experiences of the regulatees, by increased participation, is in line with a resilience perspective too (Hutter, 2001; Macrae, 2010; Berg et al., 2018; Macrae & Wig, 2019; Wiig et al., 2019 a, b). To this thesis, increased participation applies particularly to how the macro and meso-level may support micro-level stakeholders' involvement into development, design, and supervision processes. Holding macro and meso-level findings together illustrates the complex adaptive work that performance-based regulation requires, both from the perspectives of regulators *and* inspectors (Paper I and II). The regulatees on their part, deal with self-regulation and self-assessment, whilst regulators and inspectors evaluate and decide how to sanction the regulatees. Hence, a shift to performance-based regulation creates increased requirements for regulators in terms of their ability to adapt and engage flexibly with those they are regulating. This aligns with previous research on performance-based regulation in a network setting, indicating that performance-based regulation engaged stakeholders at different levels (van Erp et al., 2018). It could also support in reducing the gap between administrative and clinical "logics" (van Erp et al., 2018). These indications may speak for further theoretical development within responsive regulation and resilience theories.

The performance-based regulatory regime design facilitates more freedom to address *potential harms* than other regimes and thereby has the potential to support anticipatory capacity (May, 2007). Its main benefit is therefore presumably linked to whether the hospital managers set to manage the autonomy and freedom, has broad oversight of potential risks or not (Paper I documentary evidence). Paper III findings indicated that managers having a clinical background (many participants still worked clinically) saw it as decisive to improvise and accept that situations can develop into unforeseen scenarios which cannot be planned for. Thus, in their view, strict regulations could hamper the resilience potentials of adaptation and anticipation. The broad implication is that overregulation with too much detailed and standardized regulatory measures could lead to less freedom and less autonomous healthcare professionals. In turn, it could potentially affect quality and patient safety. On the other hand, a performance-based system with nondetailed requirements has the potential side effect of becoming overly simple, putting an increased

demand on managers' and advisors' operationalization (Paper III findings). Despite the potential of imposing a burden on the regulatees, this thesis characterizes the Quality Improvement Regulation as an "autonomy" and "anticipatory" facilitator. The characterization is accounted for based on the analysis of documentary evidence and the Quality Improvement Regulation's lack of specification (Paper I).

Scales of organizational activity

It has been suggested to conceptualize resilience at three scales of organizational activity: situated (readjust), structural (reorganize), and systemic (reforming) (Macrae & Wiig, 2019). These scales address processes of resilience regardless of traditional affiliation with macro, meso, or micro-level activity (Macrae & Wiig, 2019). Relating the scales to findings in Paper II, it implies that inspectors' adaptation to hospital context in their assessments of causal connections between available resources, risks, and managerial responsibility, could be characterized as situated resilience. Systemic changes were found in Paper III, in processes of establishing different types of patient safety and quality councils, network meetings, and internal audit meetings at the administrative and managerial levels in hospitals. A systemic adaptation was represented in Paper I findings, indicating systemic resilience: reformation of the previous regulatory regime (the Internal Control Regulations) to a new, PDSA designed Quality Improvement Regulation. This thesis provides evidence that underpins the view that there is available regulation theory supporting how a regulatory regime can flexibly tailor the managing of quality, and safe healthcare services. It argues that in a multilevel perspective, performance-based regulation and adaptive capacity find common ground by interaction and establishment of processes to support change.

PDSA – Government favored methodology

The regulators' manifestation of the PDSA logic into the Quality Improvement Regulation, might possibly have been at the expense of other established improvement methodologies such as Six Sigma, Root Cause Analysis, Failure Modes and Effect Analysis and Lean (Hughes, 2008). A key characteristic with some of these approaches to risk and safety is that their coping strategies focus on "what went wrong". According to Braithwaite and colleagues (2020), linear thinking unlike complex systems thinking, does not recognize the complexity

in risk evaluations. Application of complex systems' thinking is therefore argued more suitable when the aim is to understand "care as delivered" (Braithwaite et al., 2020). To this thesis' understanding, the PDSA logic and methodology in that sense, *could potentially* be suitable to complex, nonlinear contexts such as healthcare settings. On the other hand, it was initially developed within industrial systems, having small scale testing in scope (Deming, 1986). The PDSA logic may have *looked* like a simple solution to the macro-level (Paper I). However, some scholars have argued that it seems to be a common curse in healthcare improvement to miss the hidden complexity that can lie underneath simple solutions (Macrae & Stewart, 2019).

The further question here is how far improvement methodologies like the PDSA can be incorporated into regulation without conflicting with or complicating the role of regulation at different levels of the healthcare system. Indeed, the PDSA logic manifested in the Quality Improvement Regulation was favored by the governmental bodies studied (Paper I and II). On the other hand, several hospital managers (Paper III) reported that they did not follow the PDSA logic nor were familiar with the new regulatory framework. Perhaps the debate across study levels about PDSA as regulatory design, relates to past research reports on implementation difficulties with the PDSA logic (Curnock et al., 2012; Reed & Card, 2016; Knudsen et al., 2019). Some resilience in healthcare scholars even claim that the PDSA logic potentially underpins "people's belief in standardization for safety", puts attention on organizational prevention of error and has limited impact on improvement resulting from anticipation of risks (Chuang, 2013:178). Others point to the fact that the PDSA methodology assumes that every step of an intervention is measurable (Taylor et al., 2014). Included projects in a quite recent review on PDSA effects on improvement reported improvement but only 27% of the projects met their preplanned aim (Knudsen et al., 2019). Correspondingly, Paper III participants found measuring improvement efforts to be challenging.

All four PDSA steps outlined in the Quality Improvement Regulation have much more nuanced profiles compared to the previous Internal Control Regulations (ICR, 2002; QIR, 2016). The irony of that is that the Internal Control Regulations too was a performance-based regulation based on a PDSA logic. According to regulators and documentary evidence in Paper I, it was however not explicitly designed along with the four PDSA steps and not well

incorporated into hospitals' improvement strategies. The analysis of the regulatory revision revealed that it led to a *more detailed* regulatory design. The Quality Improvement Regulation therefore became "new" in terms of both design and rhetoric (Paper I). Regardless of these novelties, hospital managers and advisors in Paper III described lack of understanding of "internal jargon" in quality improvement and patient safety related documents, meetings, and arenas. The latter added to the burden and responsibilities of hospital managers.

Despite more details, a typical text formulation in the Quality Improvement Regulation has words that need deeper, thorough explanation (NDH, 2017). For example, micro-level participants wondered what it entailed to collect "*enough* information and knowledge to be able to plan and implement the tasks" (QIR, 2016 §6 b). To establish what "enough" meant appeared challenging to the regulatees and the managers that were supposed to comply with this specific requirement. To this thesis' interpretation, it implies that the relevant manager in charge must decide based on his/her experience, competences, resources, existing evidence, and guidelines in the area in scope (Lindøe et al., 2018). This broad-based evaluation presumably makes this specific PDSA requirement difficult to address at the various management levels.

Findings from both the inspector level (Paper II) and the hospital management level (Paper III) reported about recent changes in work practices, although these were not suspected to relate to the PDSA design. Meso-level inspectors revealed the introduction of a new report template, with requirements for more thorough information (Paper II). Several quality improvement measures were described by managers and advisors (Paper III), such as double check of medications, focus on communication in teamwork, reducing the number of hallway patients, questionnaire for patients' satisfaction, preoperative marking, and surgical checklists. Moreover, despite not being stated clearly or written down, the improvement methodology was present, and most physicians worked unconsciously in accordance with the PDSA methodology (Paper III). Broadly translated, this illustrates how fractured regulatory development and expectations can be, and what design issues can lead to in terms of lacking commitment and implementation.

In a responsive regulation perspective, legitimate regulation gains higher likelihood of compliance (Braithwaite, 2011). Previous research has

emphasized the role of managers as key to achieve successful implementation (Mintzberg, 1997; Ham, 2003; Botwinick et al., 2006; Fulop & Day, 2010; Robert et al., 2011; Curnock et al., 2012; Fulop, 2012; Spehar et al., 2014, 2015; Reiman et al., 2015; Reed & Card, 2016; Knudsen et al., 2019; Grote, 2019; Lyons et al., 2020). Hence, this thesis demonstrates that if performance goals designed around a PDSA structure ought to be achieved systematically, better methodology tools for managers are required. Moreover, a regulatory shift to a new set of principles and methods to improvement, needs to be heavily supported by in-depth, broad-based support on how to implement that approach (e.g., new tools, education, and exemplars). As argued elsewhere, Papers I, II, III evidence collectively pointed towards a lacking development of such fundamental tools, despite the present hospital advisors and the Guidelines document. Leaving decisions of regulatory implementation of improvement methodology to managers without sufficient support and efficient systems for it, could complicate managers' understanding of governmental expectations.

Inspectors' impact on the micro-level, and vice versa

This thesis did find a common understanding and passion about improving patient care among macro, meso, and micro participants, as well as in the documentary evidence. The previously reported discussion of the regulatory PDSA design (across study levels), however, spoke for a lack in shared vision for how quality best could be improved in a system perspective (Papers I, II, III). To set out a new start for quality improvement in the Norwegian healthcare system is probably too ambitious, but there is a growing international interest in focusing attention on challenges with integration and collaboration among stakeholders in an entire healthcare system (Macrae & Wiig, 2019; Burgess et al., 2019: Drew & Pandit, 2020). According to Paper III, resilience as local micro-level adaptation was to a large extent determined by the interaction between individuals (managers *and* clinicians) and contextual factors such as resources, time pressure, adverse events, near misses and hick ups in IT systems and medical devices, and team composition (Anderson et al., 2019). By involving hospital managers directly in this thesis' research on regulatory development and implementation, it is reasonable to believe that their practical knowledge about work processes in their specific discipline or level, were brought to the surface (Braun & Clarke, 2013; Molina-Azorin et al., 2019). By involving managers at different hospital levels, variations between professional

levels *within* the micro-level were identified. For instance, Paper III findings revealed differences between physicians and nurses. In general, nurses were described as more interested in applying systematic PDSA methodology. Data suggested that courses and training in continuous quality improvement had traditionally been ignored by physicians but recently gained attention, whereas autonomy was perceived more central to physicians than to the nursing profession.

Paper II findings displayed inspectors' practices and activities to be both reactive (case-based inspections of adverse events) and proactive (planned, system-based inspections). This thesis sees a potential to discover and monitor the system's adaptive capacity through planned system-based inspection directed at the micro-level. By framing risks and safety issues, meso-level inspectors can in that way be part of the micro-level's proactive efforts to improve quality (Kok et al., 2020). Ideally, inspectors may help hospital managers with anticipation, another key resilience potential. The approach chosen by the inspectors could also impact their own expectations of improvement (Schaefer & Wiig, 2017). A recent study reported how inspectors' engagement with clinicians in the evaluations they performed (instead of basing their assessments solely on written guidelines), could positively impact hospital managers to become more successful in initiating improvement (Hovlid et al., 2020 b). Moreover, it indicated that a language of guidance was viewed as having a more constructive impact on the inspected hospitals (Hovlid et al., 2020 b). The latter corresponds with this thesis' micro-level finding of linking inspectors' rhetoric with supervision's impact (Paper III). Moreover, it came to light through Paper III findings that it was essential to have institutional trust between hospital managers and governmental supervisory bodies if inspection was meant to encourage learning. Connecting these findings with Paper II, where inspectors argued for an increased application of expert inspectors, this thesis reflects another recent study showing that for the inspected organization to trust the outcome of the inspection, inspectors needed the appropriate knowledge and skills (Hovlid et al., 2020 a). This is also consistent with research showing that the efficiency of management-oriented regulation may be undermined by the absence of or supported by the presence of organizational trust (Gunningham & Sinclair, 2009). In a responsive regime of supervision, the democratic value of cooperation may impact trust between different

stakeholders (Braithwaite, 2011). Thus, a high level of trust could speak for less regulation whilst a low level of trust could result in more regulation (Quick, 2017).

Macro-level impact on supervision

Adaptations were constantly present at the meso-level according to Paper II findings, in line with the responsive regulation pyramid. Inspectors were on one hand tasked to monitor hospital performance based on strict, detailed regulatory assessments, and guidance provided by the Norwegian Board of Health Supervision. On the other hand, they reported constant, dynamic, adaptive work to specific circumstances (e.g., hospital size, type of personnel, type of patients). This contradicts with previous research claiming that external regulation and supervision often ignore size and context (Walshe, 2003). However, the inspectors' prioritization according to risk were to some extent strained by macro-level influence, as risk-based inspection was not the leading regime as of date. There were indications of missing links between inspectors' current practices and the complexity supervision was supposed to evaluate and support. Inspectors were worried about lack of manpower resources and increased case volume, with implications for their capacity to follow up all the reported adverse events and patient complaints (Paper II). This thesis sees this combination as a basis for a possible undermining of the County Governors' ability to do evaluations elaborately, resulting in severe cases potentially getting swamped by less severe cases.

The micro paradox

This thesis found a paradox in the systemic development of patient safety and quality councils, network meetings, and internal audit meetings at the hospitals' administrative and management levels, while managers reported few changes in their practices as well as at the "front line". This proposed paradox implies that there was increased administrative activity and establishment of new structures around quality but less actual change of practice. It is sensible to think that this paradox could somehow relate to operationalization processes at the management level. Responsive regulation theory suggests that noncompliance to lower-level responsiveness (implementation in this thesis' case), may link with lack of management competence (Braithwaite, 2017). The

literature outlines different leadership approaches, and previous research has identified how awareness of meaning and purpose in management training is key to achieve successful implementation (Mintzberg, 1997; Ham, 2003; Fulop & Day, 2010; Fulop, 2012; Spehar et al., 2014, 2015; Grote, 2019). As clinical work is what managers with healthcare professional backgrounds perceive meaningful, clinical managers sometimes struggle with role and identity (Mintzberg, 1997; Ham, 2003; Fulop & Day, 2010; Fulop, 2012; Spehar et al., 2014, 2015; Grote, 2019). Yet, past research has shown that to get systematic improvement methodology embedded in everyday clinical work, it is crucial to have clinicians in management roles, as they possess firsthand experience with adaptive behavior (Spehar et al., 2012, 2014; Grote, 2019).

As illustrated in Paper III, hospital advisors were set to accompany hospital managers in their daily struggles of interpreting higher level requirements and expectations. The advisors were part of the systemic contribution to reduce hospital managers' administrative workload. Paper III findings highlighted that managers perceived it as quite easy to ask for assistance if they were uncertain about terminology in governmental documents. Some hospital managers (Paper III) however described interpretation struggles, despite the presence of councils, committees, meetings, and hospital advisors. Besides, they adjusted and improved *in clinic* regardless of their ability to interpret and operationalize the Quality Improvement Regulation. This thesis therefore sees adaptive capacity at the hospital level as a very nuanced quality, with hospital advisors and administrative managers on one hand having *regulatory* adaptive capacity. Whereas clinical managers and clinicians on the other hand have an implicit capacity to adapt their *professional* behaviour and actions. The managerial role as a "juggler" between higher level requirements and expectations, and lower-level activity may in that sense have a potential to contribute to fill in some of the gap between work as imagine and work as done (Johansen and Lane, 2017). This thesis' investigation of the managerial role sees an untapped potential in accompanying managers with competency development and in-house support.

A performance-based regime that emphasizes a bottom-up perspective can nevertheless, and ironically, lead to an increase of internal self-regulation systems. Consequently, leaving choices and decisions to hospital organizations creates considerable demand for internal systems to train managers, to establish systems for implementation support and IT-solutions. An ironic system trade-

off described in the study, was for instance the response to the high number of documents in hospital management support systems (Paper III). Some of the hospital managers and some of the advisors reported over 20.000 documents available. That amount was not portrayed helpful, partly because the high number implied an impossible task in gaining oversight, partly because routines and procedures occasionally overlapped or were outdated. This thesis argues that the regional health authorities and local health trusts may be "caught in the middle": not accountable if documents are lacking, too disorganized and overwhelming if documents are too many. Based on its finding, this thesis encourages a more stringent approach to the organizing and self-regulating parts of the hospitals' document support system, with common cross regional grounds for what to include and what to exclude.

The ironic association between self-regulation and increased demand for support systems, illustrated in this thesis, is echoed by past research on the growth of internal bureaucracy due to governmental deregulation of safety management (Størkersen et al., 2020). Accordingly, on one hand it is crucial to facilitate training and support for managers while at the other hand it seizes resources, manpower and budgetary allocations that could be spent otherwise. The Quality Improvement Regulation and the generation of new hospital advisory structures, patient safety and quality councils, and network meetings with the objective of facilitating context sensitive adaptation of regulation as in line with resilience, thus appear with a paradox. It has increased the attention towards the system and its attenuation of risk, whilst the required need for new structural elements have not yet manifested into practical changes.

6.1.6 Moving ahead - closer to regulator-regulatee interaction and integration?

Based on this thesis' reflections, resilience in healthcare as a theoretical concept still lacks conceptual clarifications on what a broad scale multilevel approach to adaptive capacity looks like. However, by revising and replacing an ineffective regulatory framework (the Internal Control Regulations) with the new regulatory framework (the Quality Improvement Regulation), this thesis argues that there was an *initial* potential to reconcile the gap between macro expectations and micro implementation. Integration from a theoretical

perspective indicates that there are similarities in the PDSA model, the resilience in healthcare concept and responsive regulation theory. The models' "flow charts" or "modus operandi" have reminding features in terms of three steps:

1) an initial design, then
2) the application of checking or monitoring activity accordingly to the design, and lastly
3) the process of adaptation if expectations are not met.

However, this thesis reveals that there still is too much dissonance between how expectations were outlined and how they were put into practical application (Paper I versus Paper III findings). Based on that, responsive regulation theory lacks reflections about the governmental construction needed to meet with the task of moving up a pyramid of strategies. This task relates to how the regulatory system in a particular country is built (van de Bovenkamp et al., 2017). In turn, it relates to the democratic distance between institutions, for instance how regulatory bodies are connected to supervisory bodies and if governmental ties are regionally based or locally based, or both. It is likely to think that the closer regulators are to the subject under external inspection, the more context-based inspectors' evaluations are. Also, the closer interaction between inspector level and inspected level, the more likely it is to gain mutual trust.

This thesis upholds that regulators, inspectors and regulatees will all together benefit from a regulatory system of *checks and balances.* In a resilience perspective, stakeholders are interdependent in creating and maintaining quality and safe performance under varying circumstances and conditions (Hollnagel, 2013). However, as argued earlier, resilience in healthcare still lacks explanations on how regular/normal/successful hospital performance is constructed and interpreted into a practical toolkit for hospital management. Sorting out ideas about these constructions needed, could positively contribute to unite different stakeholder perspectives. This thesis has a potential to move the current regulatory healthcare regime and its stakeholders into a more systematic collaboration with dialogue-based approaches. The outcomes imply that the Quality Improvement Regulation counters with previous descriptions

of regulation as an external approach to quality improvement that treats healthcare organizations with little regard to their unique characteristics. As the Quality Improvement Regulation supports a broad, system-based outlook on specifics such as size, context, competence, skills, and resources, it also aligns with facilitation of resilient performance. By building structures for collaboration in regulatory development and implementation processes, regulators, inspectors, managers, and clinicians may find more common ground than as of today.

Lastly, as this thesis has urged to explain, resilience in healthcare is more than the sum of its stakeholders. A key "take home point" is that researchers and research as such would benefit from acknowledging that complex phenomenon are difficult to fully grasp, and that macro, meso, and micro are interdependent in healthcare. Neither one of the levels are more valuable than another, not in this thesis nor in real life. The relative dichotomy of "sharp" end versus "blunt" end roles in the healthcare system illustrates this point: a system is only resilient if it is complete (Johnson & Lane, 2017). The issue is therefore that all stakeholders in the complex adaptive system need to gain understanding for the unique roles different stakeholders play in obtaining resilience in healthcare (Johnson & Lane, 2017; Braithwaite et al., 2020). Despite inevitable trade-offs, gaps, and conflicts between macro regulation, meso supervision and micro implementation, this thesis suggests moving ahead towards closer integration between regulators and regulatees. Accordingly, this thesis adds to some of the gap in knowledge and casts a new light on macro, meso, and micro integration processes by three main areas:

- It reconciles regulation and resilience by pointing towards how performance-based regulation relates to adaptive capacity,
- It seeks out what influence the Quality Improvement Regulation has at different system levels, and whether resilience is part of that,
- It adds to theory development of stakeholder collaboration across system levels, by highlighting how regulatory processes and strategies can contribute to adaptive capacity in hospital contexts.

6.2 Methodological Considerations

6.2.1 Strengths

This thesis has three key strengths:

1) Its multilevel design, involving three levels of stakeholders in the healthcare system.

2) Application of multiple methods, combining traditional empirical material and legal sources, and document analysis in merge with qualitative interviews.

3) Theorizing adaptive capacity in regulatory regimes

Multilevel design and multiple methods
The multilevel designed case study investigated regulatory quality improvement implementation across three levels of the Norwegian healthcare system. Although challenges exist (see chapter 6.2.2), it is assumed essential to include different types of stakeholders in complex adaptive systems involved in risk management. Ranging from regulators, inspectors, managers, to "system operators" (e.g., clinical staff), a system-oriented approach is pinpointed by aspects of complexity, uncertainty, and variation.

Moreover, the aim in any conducted research should play a dominant role in what methodological approach the researcher chooses (Blaikie, 2010). The use of multiple methods in the data collection process is regarded a strength because it helps to see reality in different ways (Johnson et al., 2017). This was key to the topic under scrutiny in this thesis, as the complex phenomenon of risk and safety, and resilience associated with regulation and supervision, are concepts viewed differently in different disciplines (Bergström & Dekker, 2019). This conceptual element was considered important with regards to gaining a broad selection of participants with different professional backgrounds and a diversity in the management level of which they operated. The consideration also applied during the interpretation process of participants' responses. To illustrate: most participants in Paper III had substantial clinical experience and/or stilled worked in the clinic environment, in addition to having management responsibilities. Since this thesis pursued knowledge about practical

implications of regulatory changes, main attention was given to managers who both legally (by delegation) and practically, were responsible for quality improvement.

Even though resilience is considered a system ability, different "narratives" or "notions" of resilience may exist in the data (Bakhtin, 1984; Bergström & Dekker, 2019). Presented in the literature, resilience could be understood as *found*, *made* and/or as *unfinished* (Aranda et al., 2012). Drawn from this thesis, macro-level resilience could be labeled as the expected, meso-level resilience constitutes what is inspected/discovered (found by supervision) and micro-level resilience is produced (made by practical hospital management activities). Due to these three levels of stakeholders from several academic disciplines, the different notions of resilience were displayed as descriptions of different objectives and values (Rasmussen, 1997). My interdisciplinary background (Master of Laws (LL.M.) and MSc in Risk Management and Societal Safety) was therefore an advantage in the identification of the various objectives and values among the participants. It may be considered a further validation of the identification process to have involved multiple methods of both document analysis and interviews (individual and focus groups) to mirror policy with practice. The process of breaking down and operationalize the data according to the different narratives, required both a preunderstanding of my own capabilities and knowledge about the theoretical concepts that were applied in the analysis.

Theorizing adaptive capacity in regulatory regimes

Adaptive capacity, and various strategies for adaptation and flexibility, are essential to the resilience in healthcare perspective (Hollnagel, 2018 a; Wiig et al., 2020 b). This thesis contributes to a novel understanding of adaptive capacity at three system levels in healthcare, by adding knowledge about the system boundaries of regulation and supervision and its potential embodiment of flexibility and contextual application into hospital management (Eurocontrol, 2013; Hybinette et al., 2021). By seeing adaptive capacity as the underlying and unifying aspect in performance-based regulatory regimes and risk management, this thesis adds to the resilience in healthcare perspective (see chapter 3.3).

6.2.2 Challenges and Reflections

Linguistic challenges

"Resilience" is not in the Norwegian vocabular, neither exists a relevant translation of the term. It is fair to think that the participants used "robustness" as a way of describing anticipatory capacity, in lack of familiarity with "resilience". The term "robustness" was therefore kept in the relevant quotations. Presuming that it is the operationalization of a term that really defines its content, and my interpretation was that "resilience" and "robust" targeted similar aspects, it might nevertheless not have been the case: exactly because one of the terms is present in English and not in Norwegian. This uncertainty about content and interpretation of "resilience" was inevitably present throughout this thesis. Similarly, the Norwegian legal term "forskrift" has no equivalent term in English. The terminology that seemed closest was "regulation" although it has a broad specter of meanings in the English vocabulary (see further clarification in the theory section).

Challenges in multilevel research

One of the first practical challenges that arose in the PhD project was to obtain access to the different stakeholders at all three levels. It is presumed difficult to gain access to the top decision maker or executive level (macro-level) compared to positions lower in the hierarchy (Monahan & Fischer, 2015). In my experience however, it was quite easy to gain access and to find relevant and interested participants at all three levels. Le Coze (2019) claims that the issue of access represents a connection between a methodological challenge and a theoretical one. In turn, the researcher may experience some time-consuming issues, both in getting familiar with the paradigms of other disciplines, and the process of getting to appreciate the complexity in the vast number of interactions between all levels (Rasmussen, 1997; Le Coze, 2019). Due to scope, this thesis limited its system perspective to the following public institutions in the Norwegian healthcare system: The Ministry of Health and Care Services, The Norwegian Board of Health Supervision, The Norwegian Directorate of Health, three County Governors and three local health trusts (hospitals) selected from two regional health authorities. Consequently, selecting these units naturally excluded other variables, for instance the boards

of regional health authorities and top executive levels in local health trusts (Costa et al., 2013).

The researcher that pursues multilevel research must consider various bottom-up and top-down processes in parallel with analyzing multilevel processes (Aguinis & Molina-Azorin, 2015). In the present thesis, the parallel process involved looking into normative practice developed at the macro-level (e.g., the regulatory framework), simultaneously with descriptions given at the meso and micro-levels of supervision activities and hospital management experiences. Therefore, both a bottom-up perspective and a top-down perspective were nurtured in this thesis. In line with Bartlett and Vavrus (2017), this thesis assumed that integration could emerge from tracing the stakeholders' notions of the *rationale* behind the adjusted regulatory regime, in addition to actively looking for *resilience potentials* in the different descriptions and responses given. Moreover, macro-level and micro-level often mean dissimilar things in different scientific domains, whereas certain methodological approaches lead to variety in the way phenomenon are perceived, conceptualized, and analyzed (Costa et al., 2013). Thus, sensemaking from one level to another may add to the challenge in cases where answers at the individual micro-level do not make sense at a higher (macro or meso) level (Costa et al., 2013). My interdisciplinary background was a methodological strength, it however offered a limited knowledge base centered around risk regulation and management in a societal safety perspective.

Finally, choosing a multilevel approach is suggested relevant only in cases where it adds substantial value to the theoretical field, ensuring that appropriate theory supports the multilevel analysis (Costa et al., 2013). The latter resonates with this thesis' aim of developing new knowledge about feasible design of an inclusive regulation regime in the context of quality, patient safety and resilience (Macrae, 2008, 2010, 2013; Braithwaite, 2011; Leistikow & Bal, 2019; Wiig et al., 2020 a).

Sample size and recruitment

Despite the possible limitation of a sample size of seven interviews in Paper I, data held enough information power due to the strategic participants' in-depth knowledge of the Quality Improvement Regulation development process and the governmental expectations in the area (Malterud et al., 2016). Macro-level

participants were strategically selected to highlight and elaborate on the documentary evidence. As documents were the main source of data in Paper I, acting as the foundation of the Quality Improvement Regulation, the sample size of seven participants was therefore a considerable *supplement*.

The number of three focus groups and the sample size of 12 participants in Paper II could also be considered a limitation. However, the narrow study aim required fewer participants, and was supported by documents being part of the empirical foundation (Malterud et al., 2016). The three County Governors were chosen because the counties they represented were matched with the third unit of analysis: the three included hospitals. However, a larger sample could have strengthened the findings from each county.

Awareness about the selection of hospitals at the micro-level was focused around selecting hospitals with similar organizational structure. All three hospitals were characterized as large, university hospitals. Selection was however, not limited to identical clinics, departments, or units. Nor was it limited to either specialized somatic healthcare or psychiatry. The risk management principles based in the Quality Improvement Regulation apply for all sorts of organizational structures (QIR, §§2 and 5). Accordingly, and since *the case* was the phenomenon of the Quality Improvement Regulation by itself, it was not to this thesis' object to limit its investigation to restricted hospital areas. Paper III did not include all four regional health authorities in the Norwegian specialized healthcare system. This may have hampered valuable information about the implementation process and geographical variations since the support systems and routines for training managers differed from region to region. Guided by the information power, however, the sample size of 20 participants was adequate and supported our effort to ensure trustworthiness (Graneheim & Lundman, 2004; Malterud et al., 2016). Besides, three hospitals were included, providing cross regional perspectives.

Although triangulation of methods was applied, a survey in sub study III and/or observation of inspectors in sub study II, could added potentially relevant knowledge and insights into the case under investigation. I encourage future research on regulatory interventions, to involve and apply these types of methods.

Stakeholder involvement

Patients were not included as stakeholders in this thesis. Recent years have shown an increased governmental interest in patient, user, and next of kin perspectives, indicated by several references in the Quality Improvement Regulation to this type of involvement (e.g., the QIR §§6-8). With regards to that, patients with experiences from Hearings and/or patient safety and quality councils, network meetings and the like, could potentially contribute positively to future studies about implementation efforts. Also, it could have beneficial impact to hospital improvement (Vennik et al., 2016). This study included stakeholders at regulatory and policymaking levels that often are not represented in resilience in healthcare research (Berg et al., 2018; Wiig et al., 2019 a, b).

Face value

The participants' selective memory may have compromised the trustworthiness of interview data, but their self-reported data had to be taken at face value (Labaree, 2009; Kvale & Brinkmann, 2009). To illustrate; the Chief County Medical Officer was present in the first focus group interview in sub study II, of which the "power balance" possibly constrained the other participants. As a result, the Chief County Medical Officer represented at the second County Governor, was interviewed separately from the inspectors. This displays how group dynamic and intra hierarchical structures can influence data in a potentially unfortunate way.

The national five-year "Patient Safety Program" was a broad scale patient injury reducing effort, effective across the Norwegian healthcare system (MHCS, 2014 a). Many of the initiatives and activities stemming from this Program were launched in parallel with the development process and enactment of the Quality Improvement Regulation. Likewise, some initiatives and activities were ongoing during this thesis' data collection phase (e.g., Safe Surgery, Treating Strokes, Safe Discharge). It is not unlikely that participants' responses regarding structural and cultural development were inspired by or linked to this Program specifically. Thus, it could implicitly or explicitly have impacted participants' views and experiences with quality improvement and in turn potentially have influenced findings.

7 Conclusion

This thesis has explored the rationale, expectations, implementation, and management of the Quality Improvement Regulation. The overall and leading research question was: How does a new healthcare regulation implemented across three system levels contribute to adaptive capacity in hospital management of quality and safety?

I investigated this through macro-level rationale and expectations, how meso-level supervision was affected, and how the micro-level managers in hospitals experienced the implementation.

At the **macro-level** (Paper I), the thesis found that the rationale for the Quality Improvement Regulation's design was to make it flexible to hospital context. In turn, the macro-level expected hospital managers to anticipate local risks. However, the study found that the Government expected the generic regulatory design to come across as challenging for hospital managers and clinicians. Hence, it indicated that regulators considered *work as done* to be important when designing the Quality Improvement Regulation, resonating with the resilience in healthcare concept. On the other hand, limited involvement of clinicians in the regulatory development process and a lack of reflexive spaces could hamper quality improvement efforts. Importantly, the findings demonstrate that a regulatory regime *open for* context sensitive implementation by the regulatees, exists as a foundation, but this does not guarantee *actual* adaptive capacity in hospital practice and/or management of quality and safety efforts.

At the **meso-level** (Paper II), the thesis showed that the nondetailed regulatory framework provided hospitals with room to maneuver, and that case prioritization according to risk could potentially reduce resource pressure at the County Governors. Despite that supervision was adapted to specific hospital contexts and the inspectors balanced trade-offs in their evaluations, there was a general concern about the impact of supervision on hospital performance. The thesis shows that there still is an unrealized potential to increase learning outcomes from external hospital inspection. Inspectors could nurture learning

by improving their follow up, use expert inspectors, and add more hospital self-assessment activities in regulatory enforcement strategies.

At the **micro-level** (Paper III), the thesis found no changes in management practices or in clinical practice related to quality improvement due to the new regulatory framework. These findings were identified despite recent structural and cultural changes to quality improvement in hospitals. However, participants described the Quality Improvement Regulation as a more relevant regulatory framework, more suitable to variation and different contexts compared to the previous Internal Control Regulations. Broadly translated, micro-level findings indicated that a lack of time, competence and/or motivation/disinterest impacted hospital implementation. The thesis showed that hospital managers' autonomy and adaptive capacity to tailor quality improvement efforts were imperative for the regulatory requirements to have any relevant impact on hospital practice.

The **integrated findings** across macro-meso-micro system levels (Papers I, II, III) contributed to map the complex everyday reality in a regulatory regime in healthcare. Overall, the thesis' integrated findings demonstrated that healthcare regulation could be sensible if it is inclusive of those who are responsible to implement the strategies, objectives, and requirements. Likewise, resilience in regulatory regimes could be favorable to practice, if the adaptive capacity is applied wisely into hospital context, without compromising the expectations of active attention to quality improvement. The latter may be compromised due to lack of resources, and lack of in-house interpretation support or competences in the administrative and advisory hospital systems. This is an important finding in the understanding of the thorough efforts needed at all system levels to improve quality and safety.

In **conclusion**, and responding to the overall research question, the core regulatory challenge is to provide healthcare professionals, clinicians, and their managers, with the relevant level of freedom to tailor quality improvement to local conditions and contexts (Leistikow & Bal, 2020). The present findings indicated that the Quality Improvement Regulation facilitates a balance between two ideals: 1) central oversight, as in providing hospitals with governmental requirements, versus 2) local adaptation, as in room to independently decide measures accordingly with hospital risks. Thus, this

multilevel study revealed a breach with a long-established assumption claiming that the macro-level does not consider work as done at lower system levels when drafting new regulations (Rasmussen, 1997; Hutter, 2011; Macrae, 2013). This aspect of the research suggests that current practice is much more nuanced, with indications pointing at Safety II being implicitly introduced into governmental thinking in the Norwegian healthcare system. From review of extant literature, this is the first report where adaptive capacity is united with a specific regulatory framework for quality and safety in a multilevel healthcare context.

7.1 Implications for macro-meso-micro practice

Overall outputs from this thesis may benefit and have implications for regulatory and supervisory bodies, and management levels within hospitals. The integrated findings are important for development and implementation of future regulatory amendments, nationally and internationally. Several implications from the research can assist in reducing gaps between governmental expectations, supervision, and hospital management practices. These aspects are suggested below and represent a step forward in encouraging changes in regulators', inspectors', and hospital managers' practices (Braun & Clarke, 2013).

7.1.1 Governmental regulatory processes

Outputs from this study may influence how governmental bodies develop, design, and enforce regulations.

- Performance-based regulation as a regulatory instrument, requiring certain outcomes (achieved or avoided) without specifying any solutions, could have positive implications for resilience. In general, the Government expects all activities and practices in the Norwegian healthcare system to meet with the overall aim of safe and high-quality care, corresponding to the principle for sound professional practice that exists regardless of adaptive capacity. As *unconditional* flexibility potentially would compromise this overall aim, a too "loose" or "wide" regulatory framework, followed by little or next to no option of sanctioning, implies a

pitfall: it could give the hospitals "a free pass". A responsive regime, therefore, accommodates this design challenge by encouraging a scale of different options, both in strategies and sanctions (Braithwaite, 2011). Based on Paper III findings, a responsive regime nonetheless requires company of guidance and ongoing development of competences and skills to implement it with efficiency to context and with constructive functionality for both regulatees and regulators.

- Gaps between legal terminology, rhetoric, and practical hospital context and challenges could sometimes be necessary because the healthcare system consists of different positions, roles and professional groups with different skills, goals, perceptions, and responsibilities. Nevertheless, these groups are expected to work together in today's system. Hence, it is desirable to strive for a low level of conflict. Based on this thesis, there is a potential to reduce misunderstandings and misinterpretation of governmental aims and expectations by developing a more responsive regime of support systems for hospital managers, by two means: 1) foster advisors that are skilled in both legal terminology and clinical perspectives, 2) invite different categories of clinicians into the regulatory development process. Thus, it is recommended that the governmental bodies co create a plan for involvement that exceeds the current regime of Hearings.
- Regulators should crave feedback about the performance of their regulatory system to adjust accordingly, and to maintain or increase "political accountability", (May, 2007). Hence, the Norwegian Government should map implementation efforts and activities and evaluate the long-term impact of the Quality Improvement Regulation. By doing this broad scale, across all four regional health authorities, it may bring awareness about how the regulatory framework has influenced quality improvement in hospitals in general and gain systematic knowledge from how managers and clinicians have experienced these activities.

7.1.2 Inspectors' practices and collaboration with the hospital level

Paper II and III findings spoke for several improvement potentials in external inspection.

- The Government could contribute to bridge Safety I and Safety II by recommending the County Governors to actively reflect on and communicate positive experiences from and smart adaptations in hospital practice. Recognizing the complexity and nuances in any adverse event, or patient complaint, may increase learning about the fine lines of coincidences, preventable and non-preventable circumstances.
- Documentary evidence in Paper II showed that during concluding inspection meetings, inspectors should strive to involve all relevant hospital participants and come to an agreement about the facts. Agreement was amplified to be the best basis for further improvement. The relationship between inspectors and the service they are set to be quality and safety contributors for, are best served when trust and confidence are in place. It is likely that by introducing more dialogue between inspectors and hospitals, it could remedy issues with respect and trust, and contextual elements that otherwise would not be revealed, may surface.

7.1.3 Hospital management and clinical level

Paper III highlighted regional variation in management training and development.

- A minimum level of training to all hospital managers, regardless of organizational level and regional affiliation could contribute to increase managers' interest and competences in improvement methodologies and systematics.
- Support systems and quality advisors could ask hospital managers to explicate the advantages and challenges they face in their job to tailor and implement quality improvement activities. This may contribute to increase the relevance in the support provided to managers.
- A key component in future attempts to overcome differences in the existing perceptions of quality improvement work, may be to establish arenas for reflection among regulators and regulatees. Deliberation could focus on i) what is high quality care, ii) how do hospitals work to improve their services, iii) how can regulators and inspectors contribute to set constructive boundaries and opportunities for hospital management, iv) what key examples may contribute to highlight challenges with

implementation, and finally, v) what nuances are present when clinical work *goes* right, and events *turn out* successfully in patient care. Governmental bodies, regional health authorities and local heath trusts should put this on their agenda.

- Managerial support and training could benefit from having focus on balancing clinical perspectives with management tasks. Managers should be given support to recognize and reward those who initiate changes at the clinical level (Lawton et al., 2014).
- Leaving more of the assessment processes with internal hospital audit teams could increase larger hospitals' sense of responsibility and commitment and reduce County Governors' resource demands (although it will require increased resources at the hospital level).

7.2 Implications for future research

This thesis inspires future studies to explore, and answer questions related to several aspects.

- Future investigations are necessary to better understand the role of how hospital size and context impacts the use of regulatory flexibility in practical operationalization. Flexibility is primary to both performance-based regulatory regimes and a core potential in resilience in healthcare. Due to limited knowledge, it is therefore a question of future research to investigate further how a performance-based healthcare system links flexibility with regulatee recognition, compared to a more detailed, prescriptive regulatory system.
- Interesting research questions for future research can be derived from investigating into how to add more direct engagement of clinicians at all stages of regulatory processes (prior to, during and post implementation).
- Future research should focus on attention to time pressure, lack of resources and finances, as these were described as obstacles to implementation. As support systems and routines varied across different hospitals, it provides a good starting point for discussion and further research to look at increased budget allocations specifically targeting support systems and management training.

- Further studies should investigate how quality advisors support hospital managers to enhance and improve quality (or not), as well as how (if) they assist with interpretation of legal expectations and translation of legal standards.
- Innovation in supervisory methods has been suggested by others, for instance by involving next of kin and/or use reflexive spaces (Wiig et al, 2019 a, b; Wiig et al., 2020 a). This thesis however points to the potential of using planned system-based inspections as a platform to frame risks and thus assist hospital managers' capacity to monitor and anticipate risks. It would therefore be an interesting topic for future work to explore how using inspectors with educational and professional backgrounds directly linked to the area in scope for inspection, could nurture collaboration between inspectors and hospital managers (Hovlid et al., 2020 a, b).
- It will be important that future research investigates how resources, success factors and challenges could be included in supervision reports to better inform hospital improvement work in a resilience perspective (Hegde et al., 2020). This includes studies of how collaboration between inspectors and hospital managers (and their clinicians) may benefit from acknowledging successful practices in hospital activities and include positive elements such as examples of smart adaptations and helpful technology into hospital supervision reports. This could add to the future task of defining what resilience in healthcare values in processes of "what goes right". Future studies should be aware of not excluding potential drawbacks with adaptive capacity, such as adjustments of medical or technical procedures that result in unsuccessful or unacceptable outcomes (Anderson et al., 2020).
- Future research should integrate theoretical frameworks from implementation science to investigate risk regulation and resilience in healthcare, as well as to explore implementation challenges.
- Future cross-country comparative studies could investigate the association between different regulatory regimes and how they value healthcare professionals' autonomy in regulatory strategies for quality improvement and patient safety. In addition, how different governmental approaches include clinicians during regulatory design processes may prove an important area for future research.

7.3 Implications for theory

Overall, this thesis represents a rare glimpse into regulatory implementation efforts across three system levels, set out in a resilience in healthcare context. Held together with suggestions of a need to incorporate ideas and contextual factors into a common understanding in the research field of resilience in healthcare, findings from this thesis may contribute to theoretical development of macro-level regulation (Wears & Sutcliffe, 2020).

- It provides insight into how regulators can develop a regulation regime for quality and safety management with emphasis on nondetailed regulatory design, and how it may impact inspectors' supervisory approach and operationalization and interpretation at hospital levels. The findings about the Quality Improvement Regulation's regulatory design align with resilience potentials due to its emphasis on risk-based management, context sensitivity and flexible application of resources, competences, quality indicators, routines, and procedures (Wiig et al., 2020 b). It thus constitutes a significant contribution to knowledge about how resilience in healthcare theory may apply to regulatory regimes, by uniting nondetailed regulation design, with sensitivity to flexible application to context.
- It provides knowledge about how a responsive regulation regime may support the implementation of governmental demands, by providing mechanisms for the escalation of support and the involvement of stakeholders across system levels. This inclusive collaboration can address gaps between work as imagined and work as done. As such, this thesis views performance-based regulation as supportive of adaptive capacity and a potentially positive element in quality improvement work (Anderson et al., 2020). Such theorization may have a field of appeal beyond the health sciences, thus adding to interdisciplinary relevance in safety science.
- It may contribute to reflections and learning across system levels, by increasing the understanding of the different roles, responsibilities, and trade-offs that regulators, inspectors, and hospital managers possess and display. These outcomes could therefore be regarded as beneficial to the resilience in healthcare perspective on multilevel complexity.

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PART 2

List of Papers

Paper I

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RESEARCH ARTICLE Open Access

Exploring links between resilience and the macro-level development of healthcare regulation- a Norwegian case study

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Abstract

Background: The relationship between quality and safety regulation and resilience in healthcare has received little systematic scrutiny. Accordingly, this study examines the introduction of a new regulatory framework (the Quality Improvement Regulation) in Norway that aimed to focus on developing the capacity of hospitals to continually improve quality and safety. The overall aim of the study was to explore the governmental rationale and expectations in relation to the Quality Improvement Regulation, and how it could potentially influence the management of resilience in hospitals. The study applies resilience in healthcare and risk regulation as *theoretical perspectives*.

Methods: The *design* is a single embedded case study, investigating the Norwegian regulatory healthcare regime. Data was collected by approaching three regulatory bodies through formal letters, asking them to provide internal and public documents, and by searching through open Internet-sources. Based on this, we conducted a document analysis, supplemented by interviews with seven strategic informants in the regulatory bodies.

Results: The *rationale* for introducing the Quality Improvement Regulation focused on challenges associated with implementation, lack of management competencies; need to promote quality improvement as a managerial responsibility. Some informants worried that the generic regulatory design made it less helpful for managers and clinicians, others claimed a non-detailed regulation was key to make it fit all hospital-contexts. The Government expected hospital managers to obtain an overview of risks and to *adapt* risk management and quality improvement measures to their specific context and activities.

Conclusions: Based on the rationale of making the Quality Improvement Regulation flexible to hospital context, encouraging the ability to anticipate local risks, along with expectations about the generic design as challenging for managers and clinicians, we found that the regulators did consider work as done as important when designing the Quality Improvement Regulation. These perspectives are in line with ideas of resilience. However, the Quality Improvement Regulation might be open for adaptation by the regulatees, but this may not necessarily mean that it promotes or encourages adaptive behavior in actual practice. Limited involvement of clinicians in the regulatory development process and a lack of reflexive spaces might hamper quality improvement efforts.

Keywords: Quality improvement, Patient safety, Resilient performance, Adaptive capacity, Quality improvement regulation, Performance-based regulatory regimes, Governmental bodies, Regulators, Management, Implementation, Involvement

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Background

International studies show that despite significant efforts, quality and safety in healthcare remains a major challenge, and adverse events rates among hospitalized patients are still high [1, 2]. Some of the fundamental challenges in quality and safety are related to how organizations are led and managed, particularly in relation to improvement activities, with a recent progress report calling for stronger leadership commitment and acknowledgment of quality and safety as integral to the operational culture of healthcare organizations [3]. Investigations into major healthcare failures, such as the Mid Staffordshire and Morecambe Bay inquiries in the UK, found issues with poor management and organizational oversight of safety [4, 5]. One important issue is therefore how regulators should try and address issues of organizational leadership, engagement and management of patient safety [6, 7].

Previous research from the British National Health Service reveals a vast number of guidelines and standards that clinicians are expected to comply with, which can create practical challenges and difficulties in identifying the most relevant or essential rules [8]. Equally, there are concerns that the complexity and demands of external regulation might distract organizations rather than support them in efforts to improve quality and safety [7]. Therefore, it is important to explore how regulators seek to shape and co-opt organizational activities to effectively manage and improve quality and safety. The complexity and variation in healthcare means it can be challenging—and at times impossible—to provide detailed rules and regulations that adequately fit every context. Thus, regulatory approaches that support flexibility and local adaptation can be useful, if not essential [9–12]. Understanding flexibility and adaptive capacities is a central concern of the field of resilience in healthcare, where much recent work has attempted to conceptualize the adaptive processes and resilient capacities that underpin quality and safety in complex settings (see Table 1 for conceptual clarifications) [3, 21, 22].

However, the traditional focus in research on quality and safety in healthcare has been on work done at the sharp-end, and less research effort has examined the detailed relationship between regulatory activities and quality and safety improvement [23–29]. Likewise, there has been limited macro-level research exploring how regulatory activities at a national level relate to resilience in healthcare. Studies on the mechanisms of resilience across multiple levels of the healthcare system are relatively rare [28–33]. Accordingly, this study seeks to explore the link between risk regulation and resilience. Specifically, it examines the assumptions and rationale that lie behind the development of a new regulatory regime in the Norwegian healthcare system, which seeks to encourage the organizational management and leadership of quality and safety improvement. This new regulatory regime is defined within the *Regulation of management and quality improvement in the healthcare services* [34], and in this paper referred to as "the Quality Improvement Regulation" (see Table 2).

Table 1 Conceptual Clarifications

The relationship of Quality, Safety and Resilience

- Different paradigms exist when it comes to resilience. This paper relies on a resilience engineering tradition that has been applied in healthcare [13].
- There is not always a clear distinction between the concepts of quality and safety in healthcare.
- According to the Institute of Medicine, and the Norwegian adoption of the conceptualization of quality, quality consists of six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness, and equity [14, 15, 16, 17].
- Some definitions view safety as an "attribute of quality", and successful healthcare outcomes as results from quality efforts [18]. According to Sheps & Cardiff [18] this view misses that tradeoffs, complexity and variability are important elements in healthcare.
- *In this paper,* we argue that there are different quality *dimensions* with safety as one dimension. Resilience is about creating and obtaining high quality services (Safety-II). We thus apply a wider definition compared to traditional literature focusing on risk and safety (Safety-I). Our perspective is in line with the ongoing Resilience in Healthcare Research Program (2018–2023) [12].
- We define resilience as "the capacity to adapt to challenges and changes at different system levels, to maintain high quality care" [12].

Resilient *Performance*

- According to Hollnagel [19], any organization that manages to respond to, monitor, learn from and anticipate both expected and unexpected events would in a strict sense have *potential* for resilient performance. Performance, however, is complicated to study and to measure theoretically because it depends on context and local circumstances.
- *In this paper,* the potential for resilient performance is explored as the potential to adapt regulatory requirements into daily work practices.

Regulation

- Legal and regulatory matters are primarily developed, applied and disputed within national borders. This makes legal terminology and regulatory activities multifaceted and not easy to interconnect on an international scale.
- *This paper* defines the phenomenon of regulation generally and specifically:

1. as a general governmental mechanism/instrument (including inspection; supervision).
2. as one specific Norwegian regulatory framework; regime referred to in this paper as *the Quality Improvement Regulation* with a capital "R" in "regulation".

- *In this paper* a regulatory system of *Internal Control* is defined as *enforced self-regulation* characterized by the organization's individual responsibility to apply systematic measures to ensure that all organizational activities are planned, organized, carried out and maintained in accordance with governmental requirements- and health legislation [20].
- We define *performance-based* regulation as a regulatory instrument that requires certain outcomes (achieved or avoided) without specifying any solutions [9].

Aim

The overall aim of this study was to explore:

1) how one particular country (Norway) developed a new Quality Improvement Regulation that aimed to

Table 2 The Norwegian Regulatory Context*

Size and Scale of the Norwegian Specialized Health System	• 1,967,758 million people were treated in hospital units in 2018. • 114,028 thousand people employed in the specialist healthcare services in 2018. • 2667 EUR (27,100 NOK) in operating expenses per inhabitant in 2018.
Governmental Regulatory and Policy-making Bodies	• The *Ministry of Health and Care Services* directs health and care services through comprehensive legislation, annual budgetary allocations and by means of various governmental institutions such as the *Norwegian Board of Health Supervision* and the *Norwegian Directorate of Health*.
Quality and Safety Challenges in the Norwegian Healthcare Services	• Indications of an 11,9% adverse event rate in 2018, against 13,7% in 2017 in the hospital context. • Lack of adequate management responsibility and competencies. • Lack of competence and implementation of the *Internal Control Regulations in the Healthcare Services* developed to ensure sound professional practice and service quality and safety in the Norwegian healthcare system. • Areas of non-compliance with governmental requirements are believed to be related to hospital managers' attitudes, values and the development of organizational culture with emphasize on learning.
Governmental Regulatory Response to these Challenges	• Regulators adjusted and replaced the former *Internal Control Regulation in the Healthcare Services* with the new *Regulation for management and quality improvement in the healthcare services* (hereafter referred to as: the Quality Improvement Regulation), effective from January 1st 2017. • This Quality Improvement Regulation embodies the overall aim of contributing to professionally sound practice, quality improvement and patient- and user safety, and compliance with other requirements. • It requires hospitals to plan and establish barriers in order to discover failure before it has consequences for the patients, and to handle, correct and evaluate adverse events and failures. • The focus on the managerial level and the role of leaders in risk management and quality improvement increased significantly with the new Quality Improvement Regulation. • The Ministry of Health and Care Services requests knowledge about how the hospitals comply with- and implement the new Quality Improvement Regulation.

* [1, 20, 34–41]

co-opt organizational capacity to manage and improve quality and safety, and

2) in what ways regulators expected this new Quality Improvement Regulation to relate to the capacity for resilience in hospitals.

Theoretical framework

This study drew on theories of risk regulation to explore the development and implementation of the new Quality Improvement Regulation, as well as theories of resilient healthcare, which emphasize adaptive capacities, to understand how regulators expect the new Quality Improvement Regulation to influence hospitals' work on quality and safety.

Risk regulation

Laws and regulations are an essential part of how society manages risks [42]. The idea of a "risk regulation regime" seeks to explain and analyze the interacting ideas, rules and practices associated with the regulation of risks, such as the relationship between regulators and people at the front-line [43], and the role of different stakeholders such as policy makers, regulators and managers [44]. Different forms of regulatory activity can be conceptualized as a pyramid of regulatory strategies that are responsive to different degrees and forms of risk [45], with less coercive strategies at the bottom (such as self-regulation independent of government activity, see Table 1 for clarification) and more interventionistic strategies at the top (for instance, prosecution).

According to Vincent and Amalberti [46], different approaches to quality and safety can vary due to the need for standardization and control on the one hand *and* adaptability on the other. Because healthcare is complex with different types of activities and clinical settings it is not possible to rely on one "primary model" [46]. It is a demanding task to develop detailed rules and regulations that would fit many different organizational contexts, so regulators commonly leave details and specific decisions on how to manage safety and quality up to the regulatee [47]. Whereas the American regulatory system has a tradition of governing by prescriptive rules and regulations, the Norwegian system is performance-based with functional requirements, also referred to as a system of "Internal Control" (see Table 1 for detailed definition). A degree of trust is therefore required between the regulator and the regulatee, and risks are mainly handled based on norms and legal standards [9, 10, 47, 48]. The Quality Improvement Regulation we explored in this study represents such a system of enforced self-regulation and internal control, implying a performance-based approach to

regulation that makes hospital management responsible for clinical performance and quality and safety.

Resilience in healthcare

Resilience in healthcare constitutes a valuable framework that helps to explain how systems are improved and can function despite disruptions and adverse events [49]. A core idea is that resilience is "the ability of the healthcare system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required performance under both expected and unexpected conditions" [13, 50]. Two approaches to safety have recently been delineated in the resilience literature. "Safety I" views safety as the absence of adverse events and failures and builds on linear processes and reactive measures [51]. In contrast, "Safety II" emphasizes the importance of focusing on what makes things go right, and that it can be hard to precisely predict and anticipate future events. The assumption is therefore that people must continually adjust and adapt to variability. Resilience is therefore regarded a key priority in healthcare [13, 50, 52] and capacities of *anticipation* (know what to expect; anticipate future developments), *adaptation* and *flexibility*, are key to understanding how healthcare organizations are capable of delivering services when challenges or disruptions occur [13, 22, 29, 53].

In this study, we specifically considered that adaptation to variation is a necessary component of safety, and that efforts to manage and improve quality depend on adaptation to local conditions and context. The degree and type of adaptation that may be required depends on the specific hospital setting and quality challenges that are being faced [46]. Berg and Aase [54] identify empirical studies of adaptive capacities at different levels. At the level of individual clinicians, adaptive capacities included dealing with unexpected situations, developing rules and procedures and improvising [54]. The ability to anticipate was found to be closely related to the ability to adapt. At the management level, "anticipatory regulation" was described as the ability to anticipate the need for resources, such as staffing levels, in line with patient demand [54].

Resilient Healthcare – Work as Imagined versus Work as Done.

According to Hollnagel [19] it is a crucial question to explore why people act the way they do: in the planning phase of work operations, the managing phase of actual work and in the phase of analysis after work has taken place (regardless of the outcome). The planned work phase is characterized by Work As one Imagine it do be (WAI), while the phase of actual work, is labeled Work As Done (WAD). Design of laws and regulations, management of quality and safety efforts including supervision, are all considered WAI. There is often an alignment challenge between WAI and WAD, that we need to explore and address to understand resilience in healthcare [19, 55].

Research questions

The following research questions guided this study:

- What was the regulatory rationale for developing a management-focused regulatory framework (the Quality Improvement Regulation) for quality and safety improvement in healthcare?
- How do the regulatory bodies expect the new Quality Improvement Regulation to influence resilience in hospitals?

Methods

A single embedded case study design was chosen to explore the phenomenon of resilience associated with regulation and supervision in its real-world context [56]. The *case* was defined as the regulatory design and implementation of the *Regulation on management and quality improvement in the healthcare services* and its impact on hospital managers quality and safety improvement, including the nurturing and/or hampering of resilience potentials in hospitals. The study examined three levels of healthcare oversight: governmental bodies of regulation (macro-level), regional supervision (County Governors), and hospital managers. In this article, we report on the analysis of macro-level governmental regulatory bodies.

Data collection and recruitment

Methodological multiplicity is useful when researching complex phenomenon such as resilience associated with regulation and supervision. The data collection consisted of documents and semi-structured qualitative interviews, illustrated in Table 3.

The three key national policymaking- and regulatory bodies in charge of developing and stimulating implementation of new healthcare regulation in Norway are the Ministry of Health and Care Services (hereafter referred to as: the Ministry), the Norwegian Directorate of Health (hereafter referred to as: the Directorate) and the Norwegian Board of Health Supervision (hereafter referred to as: the Inspectorate). Through formal letters, we requested these bodies to provide internal and public documents on the development- and implementation process of the new Quality Improvement Regulation. Internal documents, several of them exempted from public disclosure, and public documents were retrieved. These are considered legitimate sources of law [67]. Additionally, we accessed federal documents by search through open Internet sources. The documents formed the main data material in exploring the regulatory bodies' rationale; motives and purposes for adjusting the Internal

Table 3 Empirical Foundation of the Study

Documents identified, selected, read and analyzed:

2002 • Internal Control Regulations in the Healthcare Services (hereafter referred to as: Internal Control Regulation) [20] (2 pages)

2013 • Circula on management in hospitals, provided by the Ministry of Health and Care Services (the Ministry) [57] (5 pages)
• Assignment letter of drafting a new Quality Improvement Regulation, sent from the Ministry to the Norwegian Directorate of Health (the Directorate) [58] (3 pages)
• Project plan sent from (the Directorate to relevant stakeholders [59] (8 pages)

2014 • Invitation to give input to the Directorate's draft of the new Quality Improvement Regulation [60] (2 pages)
• Draft of the Hearing Memorandum sent to the Ministry, provided to them by the Directorate in cooperation with the Norwegian Board of Health Supervision (the Inspectorate) [61] (47 pages)

2015 • Final Hearing Memorandum submitted to relevant stakeholders, by the Ministry [37] (41 pages)
• White Paper (NOU) [36] (344 pages, with exceptions)

2016 • Hearing Comments [62] (38 pages)
• The Prerogative document for the Quality Improvement Regulation on management and quality improvement in the healthcare services, which stated the narrative of the facts and circumstances of its policies. Formal approval was given in Royal Assent [65] (4 pages)

2017 • Regulation on management and quality improvement in the healthcare services [34] (3 pages)
• Guidelines relating to the Regulation on management and quality improvement in the healthcare services [66] (57 pages)

Individual Interviews (in total 7):

2018 • 3 interviews at the Ministry of Health and Care Services
• 2 interviews at the Norwegian Directorate of Health
• 2 interviews at the Norwegian Board of Health Supervision

Control Regulation into a new management-focused regulatory framework for quality and safety improvement (the Quality Improvement Regulation).

After reviewing the documents, we conducted semi-structured interviews with seven informants positioned at the Ministry, the Directorate and the Inspectorate. These informants were chosen because they were recommended by our contacts in the organizations as key figures in the development process of the Quality Improvement Regulation (see the informants' characteristics in Table 4). We recruited them to explore their considerations on the rationale and their expectations. Their educational backgrounds were a mix of economics, management, sociology, law, medicine and engineering. Informants were contacted by e-mail, informed about this study's focus area of the specialist healthcare services, and proposed participation. Five of the interviews took place at the workplace of the interviewed person, whilst two were conducted by phone. Semi-structured interviews were conducted to explore informants' experiences of their "world of the case" [56]. Thus, we developed a semi-structured interview guide based on theoretical perspectives on resilience and risk regulation regimes and based on information retrieved from the documents (see Supplementary file 1). The topics included: rationale, experiences of stakeholder involvement and information processes, expectations regarding implementation and capacity for regulatory flexibility. Moreover, the semi-structured interview guide enabled the researcher to ask additional questions based on the informant's answers. Interview duration varied between 1 h and 1 h and 30 min. Author SFO conducted, tape-recorded and transcribed all seven interviews.

Data analysis

Prior to conducting the interviews, SFO read and inductively analyzed the documents, to gain an overview of the regulatory process [68]. Due to SFO's cross-disciplinary background (Master in Law and MSc in Risk Management and Societal Safety), documents were read in terms of both directed content analysis [69] and legal dogmatic [70]. The latter aims for identifying the legislator's meaning through textual- and contextual interpretation. The interview data was partly analyzed inductively by identifying concepts within resilience in healthcare [71], and partly deductively by using predetermined questions explicitly exploring resilience capacities. The interview transcriptions were checked for methodological quality in accordance with the consolidated criteria for reporting qualitative research [72]. We analyzed the interview data inspired by a qualitative content analysis [73]. We identified all meaning units, condensed these, identified codes and sub-categories. Sub-categories were formed in line with the resilience capacities of anticipation, adaptation,

Table 4 Informants' Characteristics

Informant	Background	Governmental Role
Informant 1	Economy, Quality Improvement in Healthcare	Leader
Informant 2	Health Professional, Administration in Healthcare, Quality Improvement in Healthcare	Advisor
Informant 3	Quality and Safety in Healthcare	Advisor
Informant 4	Legal Professional, Administration in Healthcare	Leader
Informant 5	Health Professional	Leader
Informant 6	Engineering, Administration in Healthcare	Leader
Informant 7	Health Professional	Leader

flexibility. Finally, we sorted the sub-categories into themes, summarized to reflect the perspectives of "rationale" and "expectations" according to the research questions. Researcher SFO led the analysis process, while GSB and SW read the interviews and contributed in discussion about the results, developing and refining the categories.

Results

The results from documents and interviews were analyzed separately, but are presented together, and described theme-wise. This structure was chosen because most of the informants played some part in the regulatory development process by either contributing in writing the Quality Improvement Regulation or issuing the Hearing Memorandum (containing suggestions and draft of the Quality Improvement Regulation), the Prerogative document approving the Quality Improvement Regulation [74], Hearing Comments or Guidelines. In Table 5 we summarize the themes, subcategories and main findings.

Table 5 Themes, Sub-Categories and Key "take home" Points

THEME-I RATIONALE	
Sub-Category	**Key Points**
Adaptation & Flexibility	The new Quality Improvement Regulation was elaborated and adapted to meet the needs from the services: • Modernized by adding management and quality improvement • Designed around a PDSA structure • The obligation to delegate tasks in daily work was specified • One new substantial provision was added: The obligation to systematically evaluate risk management and quality improvement measures (yearly) The Quality Improvement Regulation per se is flexible in its non-detailed, regulatory design, because: • The rules can be adapted to any hospital organization
THEME-II EXPECTATIONS	
Sub-Category	**Key Points**
Adaptation & Flexibility	The Government expected hospital managers to: • implement risk reducing- and quality improvement measures based on specific context, size, activities and risk picture Design-wise, the Quality Improvement Regulation may be flexible as it leaves the regulatees to decide on details for implementation, but: • this does not necessarily mean that it encourages adaptive behavior in actual hospital work practices • it is challenging to make the Quality Improvement Regulation relevant for the right clinical level The Government did: • not have a clear vision of how hospital managers would adapt it to their practical work • suspect a disconnection between what the top-level managers prioritize and what is done at the level where clinical work unfolds
Anticipation	The Government expected hospital managers to: • obtain an overview of- and reveal risk factors prior to failure

Theme I - governmental rationale for revising the quality improvement regulation

Modernization - language and appeal

The documents by the Ministry [37, 38] described how a regulatory revision was important due to lack of compliance and a need to unite the previous internal control regime with systematic quality and safety improvement. The interviewed informants highlighted discontent with the former Internal Control Regulation. Overall, they perceived the control component to not sit well within the field of clinical practice. They claimed the term "internal control" was an alienating term that was too technical. Several institutions in the hearing process therefore agreed to exclude the term "internal control" from the new Quality Improvement Regulation. Some informants claimed that the former Internal Control Regulation was bureaucratic, blaming its non-pedagogical design and inaccessible language. All informants pointed to a need for modernization, adaptation, simplification and better explanation in the Quality Improvement Regulation. Informants believed there had been limited success in making the former Internal Control Regulation a "living document". Governmental documents listed risk management and leadership requirements, coordination of services and causal analysis of adverse events as important areas to clarify in a new Quality Improvement Regulation. Elements of management responsibility, co-worker involvement and quality improvement were specified and promoted in the new Quality Improvement Regulation. Some informants described problems of under-communication to hospital leaders, making the former Internal Control Regulation less known than it could have been.

> "They did this in an overly bureaucratic and wrong way with a lot of emphasis on written procedures and things like that (…) it seemed very alienating, so you couldn't get the rationale [of the former Internal Control Regulation] (…) and selling the idea was very difficult, many who simply did not understand it" –Informant 5

A shift in focus: leaders' responsibility for quality improvement and co-worker involvement

The findings indicated that including "management" in the title of the Quality Improvement Regulation would emphasize the importance of hospital managers in the continuous improvement of quality and patient safety. Some informants noted that management challenges existed in general in the healthcare services, and all highlighted the lack of focus on leadership and management elements in the former Internal Control Regulation. Both the documentation produced by the Inspectorate, and informants referred to their own experiences retrieved from supervision when they argued for a stronger and

specified management-focus. The Quality Improvement Regulation's title words "management" and "quality improvement" appealed to people in the healthcare services, our informants argued.

Several informants described the Quality Improvement Regulation's *mandate* to hospital leaders as an advantage. According to The Prerogative document approving the Quality Improvement Regulation [65], the judicial accountability for implementing and governing a management system for quality and safety lies with the hospital's CEO. The Directorate [64] however, argued against a provision that solely focused on the overall responsible leader and urged the Ministry to consider including a provision that stressed that leaders at every level of healthcare organizations have responsibility to assure compliance and be responsible for the requirements in the Quality Improvement Regulation. However, to avoid uncertainty over the formal, top-level management responsibility, such a provision was not included. Nonetheless, the responsibility to implement certain tasks and make these operational at department- or unit level, may be delegated by the hospital leader, meaning that employees in the entire organization are expected to be involved in the quality improvement process, ref. § 3 in the Quality Improvement Regulation,

> "Anyone who has overall responsibility for the organization shall ensure that systematic management of the organization's activities is established and implemented in accordance with these regulations and that the employees of the organization contribute to this".

Informants considered the term "contribute to" important, because co-workers are familiar with the daily challenges and are often best placed to improve the quality of clinical systems. Indeed, the Guidelines developed for the Quality Improvement Regulation acknowledge that leaders close to clinical work are often the ones who practically implement quality improvement measures in large organizations [66].

Quality improvement in accordance with the systematic PDSA approach

The Quality Improvement Regulation categorizes and explicate the duties of planning, implementation, evaluation and correction in line with Deming's [75] "Plan, Do, Study, Act"- cycle (PDSA). These obligations are extensive, and according to provision §5 all four categories of duties presuppose an overview of the organization's activities, structures, competences and risks, including how to develop and improve routines and tasks. The Directorate's documentation [64] described how they expect that a PDSA structure would give the Quality Improvement Regulation a more educational approach, stressing how the link between the different provisions then would appear clearer (provide more information to support and educate people). Based on positive feedback relating to the inclusion of quality improvement principles drawn from Deming's [75] work that was included in the former Internal Control Regulation, there was agreement on retaining that logic in the new Quality Improvement Regulation, as long as the systematic quality improvement approach was elaborated in more detail. Although the Inspectorate [63] described the PDSA approach as "an exciting idea", they argued that the model would lead to several disadvantages if not every four PDSA steps were distinguished into equivalent four separate provisions in the Quality Improvement Regulation. Informants noted that quality improvement - and patient safety work tend to be for enthusiasts only and supported using Deming's four phases. It would make it easier to remember and relate to, especially for people with no legal background, they argued.

> "… people have started to get used to that way of thinking [PDSA]. So, we thought they might recognize themselves if having these four elements [in the Quality Improvement Regulation]. We tried to write it in a comprehensive way with management focus and enhance or clarify that". ¨
> –Informant 4

Regulatory design adjustments

Overall, the informants expressed the need for new legal adjustments aiming at quality improvement and patient safety measures. Our documents indicated that from a strict legal point of view, the former Internal Control Regulation and the new Quality Improvement Regulation more or less overlap, but one new substantial provision was included: the obligation to evaluate risk management and quality improvement measures systematically once a year.

Regardless of similar legal aims, informants described the new Quality Improvement Regulation as moving away from an Internal Control Regulation they referred to as having a "static" design, towards a more "dynamic" approach. They believed the Quality Improvement Regulation had a better balance between reactive and proactive approaches.

> "The former Internal Control Regulation seemed a little static, seemed a bit like the intention of making a book, "job done", while this (new) one is probably more dynamic, I think that is the idea".
> - Informant 7

Some of the informants described how the Ministry strived in their initial effort to make an integrative

regulation, applicable for both specialist healthcare services (responsible for the hospital sector), and the municipalities (responsible for primary care services: general practitioners, nursing homes, home care, ambulatory care) in Norway. The main challenge was related to making sure that the Quality Improvement Regulation was applicable at all system-levels. Some informants described an internal battle within the government institutions, led by The Ministry of Local Government and Modernization, which did not wish to regulate in detail, but instead wished to have a regulation with the capacity of being adaptable to the size of the individual entity. One informant wished the Quality Improvement Regulation covered even more than it ended up doing, arguing that the lawyers were not willing to accommodate this. According to the documentary evidence, the Quality Improvement Regulation ended up having a relatively broad overall design, to allow it to fit all sorts of healthcare organizations. Several of the informants pointed towards the advantage of underspecifying the Quality Improvement Regulation, because it forces the managers to think about what is applicable and required in their context, adapting the rules to the organization and their entity. One informant argued that while the Quality Improvement Regulation is more detailed than other regulations, it is however "deadly to become too detailed".

> "It is a system for robustness (…) without forcing it on people".
> - Informant 1

On the other hand, informants' supervisory experiences showed that the overall design might lead the organizations to think the Quality Improvement Regulation is too generic: implying that the hospitals wanted the inspectors to tell them how to apply it to their context. Our findings indicated that the government therefore saw the need to provide examples in the Guidelines, to make it comprehensible for people "who do not love regulations".

Theme II - expectations of resilient capacities

Anticipation - risk as a fundamental principle

The Memorandum (containing suggestions and draft of the Quality Improvement Regulation) [37] outlined the obligation for managers: to gain an overview of risk areas, to plan prevention of risks, to reveal risk factors, with an expectation of systematic implementation of improvement measures. Managers should pay special attention to activities or processes in areas where failure or breach may occur more frequently than accepted, and in areas with potentially severe or unfortunate consequences for patients and users [66]. And it was considered important for managers to identify risk in connection with: planned changes; repeated observations of risks in relation to a specific activity; and adverse event in one part of the healthcare service which may be related to other departments or units [66].

Informants described that the new PDSA structure of the Quality Improvement Regulation allowed it to relate to everyday hospital practice, because each step of the PDSA was elaborated in the new regulatory framework. Moreover, the revised language made it much more meaningful compared to the former Internal Control Regulation. This would in turn enable the organizations to uncover real risks, they argued. Informants expected the Quality Improvement Regulation to be a potential catalyst for the hospital managers to gain a bird's eye perspective on the risks, promoting the ability to address local risks. Some pointed out the need for change in how people within the healthcare system perceive quality improvement and for greater congruence between management and healthcare practitioners' perspectives. They worried that the regulatory- and safety management system can become so complicated and complex that it is counterproductive to effective risk management. Some expected the Quality Improvement Regulation to be worthless if not incorporated into- and helped shape the organizational culture and management. In order to create anticipatory systems, time and resources are key, informants argued.

Adaptation to context

In the documentary evidence, the Ministry [37] explained that all four PDSA-steps were supposed to be connected to one another, by incorporating continuous evaluation along with relevant corrections. Both the Hearing Memorandum [37] and the Quality Improvement Regulation (§5) describe that organizations are expected to base their risk management and quality improvement measures on proportionality; that is, their own specific context, size, activities and risk picture. Similar factors should guide how the organizations choose to document and implement their measures. According to the Quality Improvement Regulation, management systems are expected to encompass deviations and adverse events. However, the documents highlighted that the type of follow up should vary according to the type of the deviation or adverse event. The Inspectorate suggested that the Quality Improvement Regulation needed a more thorough specification of how organizations should be obliged to follow-up severe adverse events, while the Ministry argued that increasing the level of detail could actually narrow the scope and applicability of the Quality Improvement Regulation. Ultimately, the final Quality Improvement Regulation did not specify *how* the organizations should comply.

In line with the Memorandum [37], many informants stressed the importance for the rules to be adapted to the hospital's size, complexity and risks. The informants did see more advantages than disadvantages with the Quality Improvement Regulation encouraging these adaptive capacities. The Quality Improvement Regulation provides room for flexibility, depending on how it is adapted to a specific organization. However, there was some concern that top-level hospital managers would solely focus on claims; regulatory details provided by the Ministry which might lead to a lack of local adaptive capacity.

> "whether you have a small organization with few employees or a large hospital with many employees, will make a difference to what risk reducing measures you implement. I do think it is an advantage that the Quality Improvement Regulation is non-detailed because it forces the managers to think about what fits their organization"
> - Informant 6

The practical relevance for healthcare professionals

The Directorate [64] stressed its support for a more pedagogically approach in the Quality Improvement Regulation and suggested an elaboration on the four quality improvement steps (PDSA), as this could work as a checklist for managers. This would make the Quality Improvement Regulation more practically applicable especially when coupled with a set of well-prepared guidelines accompanying the Quality Improvement Regulation.

In its Hearing Comment, the Inspectorate [63] referred to the concept of resilience and research on resilience engineering, emphasizing the lack of focus on positive outcome and well-functioning processes. Thus, the Inspectorate stressed that it would be important and relevant in both the Quality Improvement Regulation and associated Guidelines, to mention the two sets of paradigms of Safety-I and Safety-II. The reasoning was this could encourage the hospitals to refer to successful experiences and activities upon which to develop relevant quality improvement measures. The Ministry [37] highlighted the importance of creating an organizational culture where results and experiences should be shared both within and cross-sector. This suggestion of tying resilience in healthcare to practical learning was not present anywhere else in the governmental documents and informants only tangentially considered this link:

> "I do not remember that the concept of resilience was discussed when we planned the Quality Improvement Regulation. We had heard of resilience in other arenas, but I did not link the two processes together".
> - Informant 7

> "The latest fashion to learn from successful stories, like the concept of resilience: to strengthen what is good. It makes it more proactive than to just repair. I have not thought about until now, but I think there is an improvement potential".
> – Informant 1

All the informants highlighted how demanding it was to relate the former Internal Control Regulations to practice because people across the healthcare system understood and interpreted it in very different ways. There were conflicting expectations regarding the new Quality Improvement Regulation's applicability in practice. Some argued that it should not be difficult to move from the written text, to recognize and apply it in a specific hospital context, without interpretation. Others expected it to be difficult, wondering to what extent the Quality Improvement Regulation would be helpful. They stressed how it is not a given that all managers recognize their own role and obligations in the Quality Improvement Regulation and realize what efforts to put into practice. Interview findings suggested that it could be hard for healthcare professionals to comprehend what an underspecified regulatory design really encompasses, since no one knows the exact level of effort and measures expected. A minimum level of regulatory detail could therefore guide the healthcare service to find its own weaknesses. Some informants were quite negative towards the practical implications. They described that many people were still not fully aware of the new Quality Improvement Regulation and its content, even though governmental expectations were more explicitly expressed now compared to in the former Internal Control Regulation. The Inspectorate informants described experiences from supervision, claiming that the Quality Improvement Regulation aims to become a management tool, but it fails in becoming a *real, practical* tool:

> "I think that from the authorities' point of view, the Quality Improvement Regulation was thought to represent a "living" tool, closer to the clinical environment. I believe that it has not succeeded with that".
> - Informant 7

> "It does seem a little clearer, more visible that the Quality Improvement Regulation in a sense is a management tool, but that does not imply that it is easy to get it into the practical field".
> - Informant 3

Informants confirmed that the Guidelines became a large, comprehensive document, reducing its utility and practicality.

> "What I am a little worried about is that you come up with a new Quality Improvement Regulation, and then there is excitement, this is useful and so on, and then you may not have the good tools to put this into practice. Maybe five years will pass, and the national audit shows that it is not implemented (…). And, then the enthusiasm falls. So, we must work a lot more with enabling managers to meet the requirements".
> - Informant 3

Interviews indicated that high ranked policy makers did get a lot of positive feedback, both in informal and formal settings, indicating that the Quality Improvement Regulation was welcomed and perceived as useful. One informant referred to different lawyers who recounted how well received the Quality Improvement Regulation was, but noted ironically, "I would wait to pop the champagne until I see the effect in real life". Some informants described the challenge of making the Quality Improvement Regulation relevant for the right stakeholder level. They anticipated depressing response from hospital departments if they had asked about the practical effect of the regulatory adjustments. They were curious to see the response and how "alive" the Quality Improvement Regulation was, questioning if the Ministry was too far away from the service to receive any negative response. Some described that there was no need for more rules and regulations.

> "Authorities might become a little too theoretical in relation to those who work in practice and are in the middle of the patient flow and only do their job as best they can, without necessarily thinking that 'yes, this fits section six of that regulation'". – Informant 6

The expectations about the implementation of the Quality Improvement Regulation was the most debated and complicated aspect of the development process. There was agreement in the Prerogative document approving the Quality Improvement Regulation [65] and among informants, that the new Quality Improvement Regulation had greater appeal the way it was designed. However, most informants did not have a clear vision of how people would implement it in their practical work. In line with this, some described how there often is a disconnection between what the top-level managers prioritize and what is actually done at the level where practical work unfolds, and that practice does not change solely due to government information. Based on prior experiences where the complexity of implementation had been underestimated, the Directorate [66] laid out their expectations for the top leader and leaders at every level, to pay special attention to practical implementation efforts.

> "Clinicians never disagree on the measures; it is the implementation that creates discussion and frustration because that is the hard part. (…) There is a major gap between what we do know and what we do. (…) To change practice, that is the difficult bit. (…) Dissemination of knowledge is hard work. Sometimes it happens pro forma, "we have done it", and we can see that they have not done anything at all".
> – Informant 1

Support for implementation

In accordance with governmental task delegation, the Directorate is responsible for administration, information and interpretation of regulations, including the new Quality Improvement Regulation [76]. Our findings however, showed that an implementation plan for the Quality Improvement Regulation, did not exist. Although the Ministry is not set up to develop implementation programs, one informant said that they perhaps paid too little attention. The Quality Improvement Regulation was announced solely to the top management level in hospitals and to the hospital trusts. Findings highlighted that it would be time consuming to announce and voice the regulatory expectations throughout the system and the hospitals, partly because, "it takes a long time to get people to realize what they really should be doing". Although the Quality Improvement Regulation formally was distributed online through the Ministry and the Directorate's websites, there was a lack of further diffusion and practical implementation. We found that the regulators stressed their expectation towards the hospital's *actual, practical* implementation, by specifying that there is an obligation to *accomplish* plans in the Quality Improvement Regulation (§7a), not just state the obligation to plan per se [65, 66].

We found limited involvement of clinicians in the development process and a lack of involving physicians in projects for training prior to the Quality Improvement Regulation implementation. No training was aimed at leaders. Some informants, however, stressed that courses on improvement methodology were *offered* by the Directorate and that leaders were *provided with* a framework and support. The governmental expectation towards the hospitals' ability to be in control of their activities, was described as systematic quality improvement work as part of a long-term implementation process.

Discussions

In this article, we have explored the governmental rationale behind developing the *Regulation on management and*

quality improvement in the healthcare services and expectations to how it relates to resilience. Our findings indicated that it was developed as a response to a perceived lack of adequate management competence and responsibility in the Norwegian healthcare services. One important finding regarding the governmental expectations was that our informants were not sure if there was a *specific, practical effect* from the new Quality Improvement Regulation. This illustrates the challenge in designing regulations that accommodate the gap between work as imagined and work as done. The discussion follows in line with our research questions.

The development and implementation process

WAI/WAD in the regulatory development

Earlier research emphasizes the challenge of having an imbalance between regulation and practical expertise [77]. It is important to engage those working inside complex systems, experienced in recognizing risks [77]. We found little involvement of the hospitals including clinicians in the regulatory development process. There is little evidence that the government engaged with clinicians who disagreed on the suggested quality improvement measures, but who then subsequently experienced implementation challenges. This points to the need for "reflexive spaces" to discuss and align the perspectives of policy makers, regulators, managers, and clinicians [78]. Reflexive spaces provide arenas for the involvement of "clinical, sharp end" healthcare professionals, quality advisors and hospital managers in dialogue and productive conversations about practical experience, processes and activities. In turn, policy makers and regulators are able to learn about the practical challenges of quality improvement. Moreover, by facilitating "communities of practice and storytelling" these arenas can reveal the adaptive capacity that often is present implicitly in daily works practices [79]. Lack of stakeholder involvement could contribute to regulations becoming less useful and applicable in practice, increasing the dissonance between WAI and WAD [13, 19, 80]. Our findings indicated that the government expressed awareness of this gap, which highlights an under-explored potential in designing regulations for complex healthcare environments: to deeply involve clinical managers in the design of regulatory regimes. Such co-regulatory models will provide stakeholders with a greater opportunity to make their voices heard. More broadly, it is important to create spaces for collaboration to improve quality and safety in the healthcare system [12, 78]. It may therefore be beneficial for regulators to invite stakeholders into the development and evaluation process, in both formal and informal settings, enabling knowledge exchange and enhancement between actors at the macro- and micro levels.

The potential for flexibility in the development of a performance-based regulatory regime

As long as the regulatory regime has capacities to adapt to different situations, anticipation is safeguarded [81]. Our analysis indicated that performance based regulatory systems inherently aim to engage with and co-opt the practical expertise of managers (managers determine or delegate specific risk- and quality improvement measures), and by supporting local flexibility and adaptation this creates a space for resilient performance.

Many studies view the gaps between WAI and WAD as a safety-issue, which therefore needs to be tightened or closed [80]. However, the perspective of Safety-II researchers is that adaptation and adjustments to local context is inevitable in healthcare [55]. Our study found that the governmental rationale for a performance-based regulatory approach was based on the assumption that adjustment and flexibility are inevitable elements of managerial and clinical work in hospital settings. This echoes a Safety-II perspective, implying that rules and regulations cannot be fully mapped and specified in advance [55]. According to Carthey et al. [8], the more that rules have a prescriptive design, the less likely workers are to comply. And, since adaptability is considered a natural human factor, full compliance is not realistic [6, 8]. This encourages room for slack and flexibility in the regulatory design. Based on our findings, we argue that the Quality Improvement Regulation supports risk-adaptive capacities by valuing context, which is a key for promoting resilience in healthcare.

One of the objectives with the proportionality principle in the Quality Improvement Regulation's obligation to monitor performance and have oversight over risk areas, is to anticipate needs; risks and thereby adapt and adjust accordingly. Woods [82, 83] points out that data from observations and analysis of how a system adapts to *former* disruptions and adverse events, can be relevant in the assessment of the system's potential for *future* adaptive actions. We further argue that risk analysis is a measure of which anticipation is embedded, because the rationale for analysis is to map potential risks *prior* to adverse events, in line with resilience thinking.

Regulatory expectations

Adaptation

According to previous resilience research, an increased interconnected system of rules in healthcare can lead to less space for local adjustments [84]. Standards and requirements designed with little concern for sharp-end practicality can reduce the capacities of mindful local adaptation to unexpected events [30].

Vincent and Amalberti [85] describe safety as a moving target, constantly shifting with progress in innovation and prevention. Although workarounds are often developed in

relation to problems in hospital environments, there is a need to develop these strategies of adaptation from local and informal improvisation into broader system-wide capacities [46]. We found an expectation of that the Quality Improvement Regulation would contribute to building adaptive capacity into the system it regulates, both prior to and when challenges and changes arise. However, if rules look good on paper, but are impossible or very difficult to translate into practice, the idea of adaptation is compromised [84]. Some informants worried that a too generic regulatory design made it less helpful for the clinicians, yet others claimed it was key to have a non-detailed regulation so it could fit all contexts. As suggested by Leistikow & Bal [11], the core regulatory challenge is thus to provide healthcare professionals with the appropriate "level of freedom to tailor quality management to their local conditions". Further research is needed to better understand the role of hospital size and context and how different organizations use the flexibility in practice. This is an underlying principle in both the design of performance-based regulatory regimes and is core to the resilience perspective.

According to the Quality Improvement Regulation, the hospital's CEO is expected to have formal accountability. Described as central oversight (Safety-I), this is sometimes considered to conflict with the resilient ideal of local adaptation and decentralization [86]. However, there is an option of delegation in the Quality Improvement Regulation, which was related to the capacity to adapt to varying circumstances. More specifically, we argue that the government acknowledged and expected that WAI sometimes need to be adapted to be more in line with WAD. Managers are encouraged by the Quality Improvement Regulation to adapt decisions to context, in order to meet practical circumstances such as adverse events and staffing-issues. Our findings therefore indicated that the Quality Improvement Regulation aims to facilitate a balance between the two ideals of central oversight and local adaptation. Thus, we believe this indicates that Safety-II thinking is introduced into governmental practice. This perspective is not a commonly explored assumption in the resilience- and patient safety literature, as the macro-level usually is assumed to not consider WAD and the field of practice when drafting new regulations [30, 44, 87]. Practice might be much more nuanced, and further research should focus on how other countries and regulatory systems emphasize the role of context and adaptation at the macro level.

Anticipation

The capacity to anticipate is characterized by foresight; to pay attention to what has not happened yet, but potentially will [19, 88]. Woods [82] describes it as looking beyond behavior in compliance with standards and norms: anticipatory aspects of resilient performance involve how people anticipate risks and bottlenecks. Organizations which emphasize proactive measures, such as monitoring, will most likely have a better potential to discover and anticipate weak signals compared to those with a less proactive approach [89]. Previous research from the Dutch healthcare system revealed that despite a complicated relationship between management and regulation of healthcare, hospitals built systems that enabled a more proactive approach to quality and safety work with the potential of facilitating innovative solutions [90]. According to our results, the hospitals have an obligation to identify- and work to uncover risks. The aspiration and intent of the regulators is that this approach will encourage anticipation. In addition, the embedded flexibility in the system could facilitate a proactive approach allowing for improvised solutions, which enables the stakeholders to anticipate these events. The Quality Improvement Regulation might foster practices that support these anticipatory capacities in hospitals and encourages awareness of for instance: risks connected to coordination of tasks and personnel, areas with a high degree of risk for failure and awareness about complaints and statistics retrieved from similar areas of activity. However, further studies are needed to evaluate the long-term effect of the implementation.

In line with Wiig and Lindøe [91], our findings revealed that the regulator has an untapped potential to engage with and obtain information from a broad range of *clinical* stakeholders. Our findings indicated that congruence between management and healthcare practitioners' perspectives is important, which resonates with the concept of "recoupling" between different layers in the organization and the healthcare system [92, 93]. Lack of stakeholder engagement might indicate that the capacity to anticipate on a system level, is hampered. A recent study of the inspectors' perspective on next-of-kin involvement in regulatory investigations, found that the involvement positively informed the investigations [94]. Due to the Quality Improvement Regulation, the organizations are expected to retrieve experiences and complaints from users, patients and next of kin, which can contribute in providing a learning platform for building systems with improved capacity to anticipate risks.

Previous research indicates that in systems where the regulator and the regulatee have very different roles and tasks, prescriptive regulation is even more challenging because it demands a common understanding of "adequate behavior" [6]. As discussed in this article, it seems to be a reasonable assumption that the regulatory intent is to ease that burden because the organizations are thought to possess the best knowledge on how they can improve their performance. Furthermore, it implies that what is adequate behavior in one hospital

department is adequate behavior regardless of the regulator's understanding of it. This type of a risk regulation regime emphasizes a bottom-up perspective rather than the prescriptive regime's top-down perspective. However, we believe that it is unrealistic to expect hospitals to understand and implement legislation without preknowledge or assistance either from internal resources or from governmental bodies [89, 95]. If regulations are perceived as obstacles, rather than guidance, due to time- and resource consuming regulatory compliance and implementation work, regulation can compromise the ability to be flexible [89]. To promote resilience, Grote [6] suggests designing non-rigid rules specifying the underlying goals, priorities or preferred processes. Others have suggested that regulators ask organizations to demonstrate their safety management system, instead of just inspecting processes and standards [96]. By not regulating in detail, and having functional requirements, the Quality Improvement Regulation is designed to fit any healthcare organizational context. This adaptive capacity supports quality improvement measures to be more sufficiently implemented and accepted by the regulatee. Our study therefore indicates that from a resilience perspective, a performance-based healthcare system will probably be better off compared to a prescriptive one. Further exploration of these links is needed due to the limited knowledge about how interaction between system levels in healthcare influences adaptations and improvement efforts. Outputs from this study might influence how governmental bodies design and inspect rules and regulations. And interaction could fuel the goal to unite work as imagined with work as done, which favors and contributes to improve resilience capacities in the healthcare system.

Trustworthiness and limitations

The key strength in this study is the mixed approach of traditional empirical material and legal source material, and document analysis in merge with qualitative interviews. Data was triangulated to enhance trustworthiness. Conducting the document analysis prior to the interviews helped in generating new interview questions and supplying with interviews helped avoiding "over-reliance" on documents as the sole data source [97].

This study has some limitations. The first is linguistic. **1.** "Resilience" is not in the Norwegian vocabular, neither exists a relevant translation of the term. It is fair to think that the informants used "robustness" as a way of describing anticipatory capacity, in lack of familiarity with "resilience". However, we chose to keep the word "robustness" in our quotes from the informants. **2.** The sample size of seven interviews is a limitation but held sufficient information power due to our strategic informants who had in depth knowledge of the Quality Improvement Regulation development process and the expectations from the regulatory bodies in this area [98]. Moreover, documents were the main source of data, acting as the foundation of the Quality Improvement Regulation per se. **3.** Data retrieved from the interviews had to be taken at face value; and so was potentially exposed to the bias of informant-selective memory [99]. **4.** To ensure trustworthiness in the data analysis, three out of four researchers were involved in the analytical process of the interview material and discussed codes and subcategories. We believe this, along with two of the co-authors' substantial professional governance experience from the Norwegian Board of Health Supervision (author GSB) and the Petroleum Safety Authority Norway (author SW), contributed to increase the validity of our findings [56]. **5.** This paper did not aim for a complete analysis of Hollnagel's four potentials [13, 19]. The idea of a performance-based regulatory system is to embed flexibility and as regulatory design is essential in this paper, we looked for and discussed if the regulatory design is flexible enough to facilitate adaptation- and anticipate relevant quality and safety improvement measures based on hospital context. These resilience aspects were also the focus of our predetermined interview questions. We are aware of recent critique about over-reliance on theory-founding authors [100] and partially agree. However, we believe that all Hollnagel-potentials are equally important and monitoring and learning are thus framed and discussed in a later paper (currently in review).

Conclusions

This study's overall aim was to explore the governmental rationale and expectations of the Quality Improvement Regulation, and how it could potentially influence the management of resilience in hospitals. Previous research identified a gap in the literature on the relationship between regulation and resilience, and to our knowledge this study will be the first to operationalize elements of resilience capacities within a regulation for management and quality improvement in healthcare. We identified a double take on adaptation: **1.** The Quality Improvement Regulation itself was adapted because the services asked for revision of the former Internal Control Regulation. This implies adaptive capacity at the macro level. **2.** Our study identified a dynamic, non-detailed regulatory framework that is expected to provide hospital managers with the potential to have risk-oversight and to adapt quality improvement measures to their organizations. Based on the Quality Improvement Regulation's support for risk-anticipation and local adaptation, it accommodates variation in daily clinical work. The governmental rationale of making the Quality Improvement Regulation flexible to hospital context, along with regulators

expectations about the overall design as challenging for healthcare practitioners, we found that the regulators did consider work as done as important when designing the Quality Improvement Regulation. These perspectives are in line with ideas of resilience. However, the Quality Improvement Regulation might be open for adaptation by the regulatees, but as our informants pointed out; this may not necessarily mean that it promotes or encourages adaptive behavior in actual practice.

There was no grand implementation plan and limited involvement of clinicians in the regulatory development process. Quality improvement efforts could benefit from inviting clinical stakeholders into the regulatory development process. Thus, we recommend the governmental bodies to co-create a plan for involvement. Moreover, with large-scale and ambitious regulatory reform such as this, it is important that the government develop an evaluation of the Quality Improvement Regulation, to map implementation efforts and activities, to explore how these have influenced quality improvement in the hospitals and to gain knowledge from how managers and clinicians experienced these activities.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12913-020-05513-x.

Additional file 1. "Interview guide". A semi-structured interview guide based on theoretical perspectives on resilience and risk regulation regimes and based on information retrieved from the documents. The topics included: rationale, experiences of stakeholder involvement and information processes, expectations regarding implementation and capacity for regulatory flexibility.

Abbreviations

The Ministry: The Ministry of Health and Care Services; The Inspectorate: The Norwegian Board of Health Supervision; The Directorate: The Norwegian Directorate of Health; The Quality Improvement Regulation: Regulation on management and quality improvement in the healthcare services; Internal Control Regulation: Internal Control Regulations in the Healthcare Services; WAI: Work as Imagined; WAD: Work as Done

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Authors' contributions

SFO, GSB, CM, and SW designed the study. SFO collected all documents, conducted and transcribed the interviews. SFO analyzed the data, and SW and GSB read the interview material and discussed codes and subcategories. SFO drafted the manuscript. All four authors made critical revisions to the manuscript's scientific content. The author(s) read and approved the final manuscript.

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Availability of data and materials

Documents retrieved from online sources are publicly available. Documents exempted from public disclosure are not available. Data retrieved from the interviews is available from the corresponding author upon reasonable request and with permission from the informant(s).

Ethics approval and consent to participate

The study did not collect specific patient information, thus no approval from The Regional committees for medical and health research ethics was required. Personal data derived from the study's interviews was notified to the Norwegian Centre for Research Data (NSD) (REF. NO: 381276, October 1. 2018), as required in line with the agreement between the University of Stavanger and the NSD. Every informant signed informed consent ahead of the interview.

Consent for publication

Not applicable.

Competing interests

Author Siri Wiig is an associate editor of BMC Health Services Research.

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Publisher's Note

Paper II

OPEN

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 literature[1] 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	• 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	• 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	• Two main categories of supervision conducted by the county governors: 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 prudency • 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
"We make changes all the time, we adjust. We have dealt with this in terms of assigning responsibility." (Focus group 1) "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)	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
"…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) "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) "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)	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 Act[35] 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 devaluate 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 prudency 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 Vandeskog[42] 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 challenges[48] could be included in supervision reports to better inform hospital improvement work in a resilience perspective.

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Paper III

BMJ Open

Hospital managers' perspectives with implementing quality improvement measures and a new regulatory framework: a qualitative case study

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ABSTRACT

A new regulatory framework to support local quality and safety efforts in hospitals was introduced to the Norwegian healthcare system in 2017. This study *aimed* to investigate hospital managers' perspectives on implementation efforts and the resulting work practices, to understand if, and how, the new Quality Improvement Regulation influenced quality and safety improvement activities.

Design This article reports one study level (the perspectives of hospital managers), as part of a multilevel case study. Data were collected by interviews and analysed according to qualitative content analysis.

Setting Three hospitals retrieved from two regional health trusts in Norway.

Participants 20 hospital managers or quality advisers selected from different levels of hospital organisations.

Results Four themes were identified in response to the study aim: (1) adaptive capacity in hospital management and practice, (2) implementation efforts and challenges with quality improvement, (3) systemic changes and (4) the potential to learn. Recent structural and cultural changes to, and development of, quality improvement systems in hospitals were discovered (3). Participants however, revealed no change in their practice solely due to the new Quality Improvement Regulation (2). Findings indicated that hospital managers are legally responsible for quality improvement implementation and participants described several benefits with the new Quality Improvement Regulation (2). This related to adaptation and flexibility to local context, and clinical autonomy as an inevitable element in hospital practice (1). Trust and a safe work environment were described as key factors to achieve adverse event reporting and support learning processes (4).

Conclusions This study suggests that a lack of time, competence and/or motivation, impacted hospitals' implementation of quality improvement efforts. Hospital managers' autonomy and adaptive capacity to tailor quality improvement efforts were key for the new Quality Improvement Regulation to have any relevant impact on hospital practice and for it to influence quality and safety improvement activities.

Strengths and limitations of this study

- The main strength of this study is the novel approach of involving hospital managers' perspectives in healthcare regulation research, as they are both legally and practically responsible for improving quality and safety.
- Most participants had substantial clinical experience and/or still worked in the clinic environment, in addition to having management responsibilities. This provided our study with valuable insight into the complexity in hospital management.
- The study did not include all four regional health trusts in Norway in its data.
- Variations in support systems and routines for training managers differ from region to region and may have implicitly or explicitly impacted participants' views and experiences with quality and safety improvement and in turn potentially influenced findings.
- The individual interviews only focused on hospital managers own reflections and no actual, observational studies of practice, implementation or change where conducted.

INTRODUCTION

After years of regulatory interventions, management strategies and policy-making, improving quality and safety of healthcare systems remain high on political agendas around the world. Still, patient harm is listed as the world's 14 biggest health burden along with illnesses such as malaria and tuberculosis.[1–5] The process of improving quality and safety has traditionally involved different dimensions, for instance clinical effectiveness, patient centeredness and care coordination.[6] If addressed, these dimensions seek to achieve an optimal healthcare system[6] (see table 1 for definitions of 'quality' and 'safety'). A system perspective on quality improvement and involvement of stakeholders at different levels are portrayed as key in efforts to improve patient outcomes, system performance and professional development (learning).[7 8] Moreover, management of and leadership in healthcare is reckoned one of

Table 1 Definitions and concepts

Quality	We adopt the conceptualisation introduced by the Institute of Medicine defining quality through six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness and equity.[6 100]
Regulation	We define the phenomenon of regulation generally as a governmental mechanism and specifically as the Norwegian regulatory framework; regime referred to in this article as the Quality Improvement Regulation with a capital 'R' in 'regulation'. Different regulatory activities exist, with different interventionistic approaches; acts of law, internal control, self-regulation, external inspection; supervision.[64 101]
Risk	We define risk as the consequence of any activity with associated uncertainty; the possibility that an event or human action could negatively affect valuables.[102] For instance: a specific patient injury that possibly can occur during or after surgery, but with uncertainty to whether it will happen, when it will occur and what consequences it will lead to.[103]
Safety	We understand safety as one dimension of quality.[104] And, we apply it as the preventive measures put in place to reduce potential adverse events and the proactive measures that seeks to reduce the negative consequences and maintain its regular performance.[105]

the fundamental elements to quality and safety, particularly related to implementation of improvement activities.[9 10] Inquiries into major healthcare failures, such as the Mid Staffordshire inquiry in 2013 and the Morecambe Bay inquiry in 2015 in the UK, revealed poor management and lack of safety oversight as common contributors to quality failures.[1 2] A progress report from 2018 added to these findings, calling for stronger management commitment in healthcare, amplifying how quality and safety should be incorporated into operational culture.[4] Internationally, increased attention has been brought to involvement of clinicians in management roles and highlighted the key role top managers play in providing support to lower level managers.[11 12] In Norway, hospital organisations are required to ensure their employees have relevant competences and training. Current leadership programmes and training regularly include learning about quality improvement methods and systematics.[5 13 14] Yet, recent research has indicated that to make quality improvement a thriving part of daily management practice, it needs to be supported by a strategic commitment to improvement, time to spend on improvement, and a culture that supports managers and clinicians working together.[15]

Prior research on healthcare regulation and its relation to improvements in organisational behaviour, including conduction of external inspection, has shown inconsistent outcomes in terms of its effectiveness[16–21] (see table 1 for this study's conceptualisation of 'regulation' and regulatory activities). Several previous studies have explored healthcare organisations' resilience potentials, including their capacity to adapt, but to date few *multilevel* studies link adaptive capacity with regulatory activities.[22–31] Others have highlighted that actively engaged participants from all organisational levels in healthcare are important, stressing how active improvement depends on leadership, also in the sense of recognising conditions that require flexibility.[7 32] The latter links management of quality improvement to management of adaptive capacity. Thus, attention should be paid to the development process of designing regulation that enables flexibility and supports adaptive capacity, by requesting non-detailed preferences or performance goals, especially since this may lead to a bottom-up perspective rather than top-bottom.[16 31–35]

In 2017, a new regulatory framework to support local quality and safety efforts was introduced in the Norwegian healthcare system.[13] This framework, the *Regulation on Management and Quality Improvement in the Healthcare Services* (referred to as *the Quality Improvement Regulation*) focuses on developing the capacity of healthcare organisations to continually improve quality and safety by constructing non-detailed goals for risk management[13] (see table 1 for definition of 'risk'). Although the Quality Improvement Regulation is considered one of the most important governmental tools to support local quality and safety efforts in hospitals,[5 36 37] its impact on the healthcare services is still unknown from all perspectives (regulatory inspectors, hospital managers and healthcare personnel). The role of hospital managers is particularly important as they are stakeholders situated in the middle of governmental expectations and requirements, administrative demands and clinical practice.

Through the Quality Improvement Regulation, the regulators require hospital organisations to establish a system for risk management and responsibility. Its design embeds a structure of Plan, Do, Study, Act (PDSA), a four-step management methodology for quality improvement activities developed by Deming.[38] The Quality Improvement Regulation requires hospitals to plan for and establish systems to minimise risks, and to discover adverse events before they have consequences for the patients. Furthermore, it requires hospital managers to handle, correct and evaluate adverse events and failures. Accordingly, this study aims to investigate hospital managers' perspectives on implementation efforts and the resulting work practices, to understand if, and how, the new Quality Improvement Regulation influenced quality and safety improvement activities.

Contextual background of the Norwegian regulatory regime for quality improvement

Several governmental initiatives have been launched in Norway in recent years in order to facilitate the hospitals' continuous attention to patient safety and to increase the overall quality in the healthcare services they offer. The initiatives include annual quality and patient safety reports to the Norwegian Parliament (White Papers), national quality indicators, the previous National

Strategy for Quality Improvement in Health and Social Services (2005–2015), a patient safety campaign (2010–2013), followed by a the national 5-year 'Patient Safety Program'.[39–41] The latter was launched in 2014, as a broad scale effort to reduce patient injuries.[40 41] This programme (2014–2018) aimed at targeting several areas where it was believed to be crucial to increase care quality, including 'Safe Surgery' and 'Management of Patient Safety'. It quantified several objectives—for instance to reduce infections, to improve survival rate and to improve patient safety culture.[40] Specific improvement projects were developed to meet relevant challenges in specific hospital settings, and hospitals were expected to incorporate the different initiatives to their daily work schedules. The recent national action plan for quality and patient safety (2019–2023) maintains attention on structural and cultural dimensions in quality and safety improvement.[5] In addition to these initiatives, previously conducted external hospital supervision across health regions in Norway have identified several challenges to systematic quality improvement[42–47]:

- Lack of adequate management responsibility and competencies.
- Lack of structure to ensure coworkers have prudent professional qualifications.
- Lack of systematic collecting of and evaluation of risks, vulnerabilities and adverse events.
- Lack of implementation of planned work tasks.
- Lack of evaluation of improvement efforts, post implementation.
- Lack of familiarity with and implementation of the previous regulatory framework for quality and safety management 'the Internal Control Regulations', 2002.[48]

Moreover, hospital managers' attitudes, values and organisational culture for learning were associated with non-compliance with governmental requirements.[42–46] These challenges and issues associated with implementation of quality improvement measures in hospitals formed an important backdrop to the questions that were asked in our study.

Content and design of the quality improvement regulation

The development and enactment of the Quality Improvement Regulation was thus the Government's response to these challenges and launched in parallel with some of the other initiatives described above. The regulatory focus on the managerial level and the role of managers in risk management and quality improvement increased significantly with the new Quality Improvement Regulation compared with the previous Internal Control Regulations, as it (in a separate provision, cf. section 3) specifies the managerial responsibility to improve quality. The obligation to delegate tasks from one management level to another in daily work operations was specified. Moreover, one new substantial provision was added (cf. § 8 litra f): the obligation to systematically evaluate risk management and quality improvement measures (yearly). The Quality Improvement Regulation's purpose is hence twofold: by explicitly stating managerial responsibilities it aims at improving managerial practices, whereas the PDSA methodology aims at organising the services in ways that improve clinical care. In table 2, we illustrate details on the Quality Improvement Regulation's regulatory PDSA design. Two specific examples of activities are given for each of the steps, all retrieved from the guidelines document relating to the Quality Improvement Regulation.[49]

The Norwegian specialised healthcare system

Four regional health trusts across Norway are responsible for implementing the national policies and regulations, and planning, organising, governing and coordinating all subordinated local health trusts, including the hospitals in their region (see box 1 displaying key numbers in the Norwegian specialist healthcare system).[50 51] Every hospital should be organised with a responsible manager at all organisational levels.[14] For each organisational unit in the hospital (eg, clinic (division or similar), department or equivalent, and sections), one manager with overall responsibility for the unit, both administratively and professionally should be appointed.[52]

METHODS

Study design and setting

This article represents one substudy that is part of a broader qualitative, multilevel design single embedded case study, investigating regulatory quality improvement implementation and work across three levels of the specialised Norwegian healthcare system.[37 53] The case was defined as the design, implementation and enactment of the Quality Improvement Regulation and its impact on management and quality improvement across three organisational levels in two health regions. Specifically, the multilevel study involves three levels of stakeholders: macrolevel (governmental bodies of regulation), mesolevel (County Governors' inspectors-regional supervision) and microlevel (three hospitals selected from two regional health trusts in Norway). To illustrate, figure 1 outlines the three system levels involved in the overall case study, whereas the microlevel presented in this article is specifically marked.

According to a multilevel approach, different levels of stakeholders have different impact on the risk management process.[54] These levels are interconnected through processes of information and decision-making, thus asking questions within three levels rather than within one single level, might help overcome single-level limitations.[55] Moreover, a multilevel study design can contribute to reflect healthcare organisations as integrated wholes where the patterns among different stakeholders are a key area of investigation.[56] Accordingly, this article presents the *microlevel* substudy, based on semistructured interviews with 20 Norwegian hospital managers and quality advisers. Macrolevel findings and mesolevel findings are presented in two separate research articles.[37 53]

Table 2 Details on the Quality Improvement Regulation's regulatory Plan, Do, Study, Act (PDSA) design[48 49]

PDSA step	Key areas and improvement tasks	Examples of specific activities
The duty to plan	► Plan tasks and activities ► Gain overview of responsibility, laws, regulations, guidelines and of deviations. ► Gain overview of adverse events, risks and areas of significant need for quality improvement ► Plan how to minimise these risks.	*Example 1:* identify and discuss deviances reported to the hospital's system for adverse event reporting. *Example 2:* structured identification and analysis of the last 50 mortalities at the relevant hospital, through medical records.
The duty to implement (do)	► Ensure that activities relevant regulations and guidelines are known ► Develop and implement procedures and routines to reveal, correct and prevent breach and violation of sound professional practice and systematic quality improvement	*Example 1:* conduct a weekly, 15 min interdisciplinary meeting to visually display ideas for improving the quality in areas where patient complaints exist. *Example 2:* relevant department or unit leader conducts a patient safety 'visit' with the objective of identifying risks and possible areas for improvement and to encourage collaboration between the management level and 'front-line' clinicians.
The duty to evaluate (study)	► Assess implementation of activities, plans, including systematic quality improvement efforts ► Evaluate if regulations are met ► Review deviations, adverse events to prevent similar events ► Minimum one annual systematic review of the management system	*Example 1:* corroborate the implemented efforts by using dashboard indicators. *Example 2:* aggregate data from patient complaints about waiting time, to reduce waiting time.
The duty to correct (act)	► Correct unsound practice and regulatory violations ► Ensure implementation of systematic quality improvement efforts ► Improve necessary procedures, instructions, routines to reveal, correct violations	*Example 1:* apply small-scale testing to ensure that recent technology and new treatment is efficient. *Example 2:* conduct a Pareto diagram/chart to uncover what causes certain registered issues at the relevant hospital unit.

Participants

The inclusion criteria were participants who currently worked as hospital managers or advisers to hospital managers, preferably with clinical experience, situated at all levels within the hospital organisations, for example, head of clinic, head of department, divisional manager. Out of 20 participants, 18 had authorisation and license as health personnel and clinical experience from hospital practice. Several of them still worked clinically. Four out of five advisers had previous hospital manager experience and were chosen to highlight the support system for managers in the selected hospitals. Gender balance: 11 men and 9 women. See table 3 for participants' characteristics.

Recruitment

Participants were recruited from three different hospitals. Hospital one and two belonged to the same regional health trust, while hospital three belonged to a different regional health trust. These three hospitals were selected as they were affiliated with the three County Governors offices recruited at the mesolevel in the broader multilevel study. Relevant

Box 1 Key numbers in the Norwegian specialist healthcare system

Key numbers

- 1 987 263 million million patients treated and/or hospitalised in 2019.[106].
- 114 028 thousand people employed in the specialist healthcare services in 2018.[107].
- The overall level of staffing by higher level health personnel is relatively high, with more than 50% of hospital employees being either physicians or nurses/midwives.[107].
- €2667 (Kr27 100 Norway) in operating expenses per inhabitant in 2018.[106].

Figure 1 The system levels involved in the multilevel case study.

Table 3 Participants' characteristics

Participant	Educational background*	Position	Organisation and region
1	M.D., specialist, PhD	Divisional manager	A-1
2	R.N., MSc in risk management	Adviser, quality and patient safety	A-1
3	Lawyer	Legal adviser, quality and patient safety	A-1
4	M.D.	Head of clinic	A-1
5	R.N., MSc in risk management	Adviser, quality; clinical coordinator	B-1
6	R.N., specialist	Head of quality	B-1
7	Lawyer	Deputy head of clinic	B-1
8	M.D., PhD	Medical director	B-1
9	M.D., PhD	Head of research	C-2
10	D.D.S., PhD	Head of clinic	A-1
11	M.D., specialist, MSc in health management	Head of clinic	A-1
12	M.D., specialist; surgeon, PhD, management courses	Head of department	B-1
13	M.D., PhD, management courses	Head of department	B-1
14	R.N., specialist	Head of department	B-1
15	M.D., specialist; surgeon	Head of clinic	C-2
16	P.T., MSc in management	Adviser, quality	C-2
17	R.N., specialist	Head nurse	B-1
18	M.D.	Senior adviser, quality and patient safety	C-2
19	M.D., PhD	Head of department	C-2
20	R.N., MSc in health management	Head of quality	C-2

*M.D., medical doctor, R.N., registered nurse, D.D.S, doctor of dental surgery, P.T, physiotherapist.

participants were contacted by email; proposed participation in the study, of which all (except one) accepted the invitation to participate.

Data collection

All interviews were conducted during the spring of 2019, then transcribed. SFO conducted and audio recorded all interviews face to face, at the participants' workplace. Each interview had a duration of approximately 1 hour to 1 hour and 30 min. Based on the preplanned semistructured interview guide (see online supplemental file 1), open-ended questions focused on areas of responsibility, work practices, training, implementation of quality improvement measures, regulatory flexibility, the role of supervision in improvement work and learning, experiences connected to structural development and attitudes, cooperation among different levels of government, management levels in hospitals and clinical, front-line personnel.

More specifically, questions were asked to determine if and how the Quality Improvement Regulation addressed some of the issues and challenges described in previous external inspections. The questions included for instance whether non-detailed risk management goals in the new regulatory framework facilitated flexibility in practical application and how managers experienced the systematic PDSA methodology (see preplanned questions in the online supplemental file 1). In addition, questions relating to communication and interaction among different system levels were asked to give insight into the regulator–regulatee interaction. The latter was particularly important to ascertain how hospital managers viewed the role of regulators and the new regulation, and the extent to which possible conflicts were reduced between government-level expectations and local-level, practices of managing quality improvement and safety.

Prior to the interviews, the participants received an information sheet informing them about the study's topic, methods and data protection, and the researcher's (SFO) credentials and occupation at the time of the study. Participants were subsequently requested to give their written consent. No pre-existing relationship with any of the participants existed.

Analysis

Researcher SFO analysed the interview transcripts manually, using content analysis influenced by Graneheim and Lundman.[57] This analytical process consisted of several steps. SFO initially read through all interviews and took notes of immediate thoughts that occurred after reading, before organising all interview transcripts into a matrix. Thereafter, SFO identified and condensed all meaning units, suggested codes and subcategories. Four themes emerged across the data. Researchers GBS and SW read all interview transcripts and participated in discussions about categories and themes, to ensure the data's reliability.[58] Our data were relatively rich, and we reached saturation during the analysis, justifying the number of participants.[59 60]

Resilience in healthcare constitutes a valuable framework that helps to understand how systems can function and improve despite disruptions and adverse events.[61] A core idea

is that resilience is *the ability of the healthcare system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required performance under both expected and unexpected conditions.*[62 63] Findings were therefore explained and interpreted by using resilience theory linked to adaptive capacity.[63–67] The data were partly analysed inductively by identifying concepts within resilience in healthcare and partly deductively by using predetermined questions explicitly exploring resilience potentials.[68]

RESULTS

From our data of 20 interviews, we identified 4 themes: (1) adaptive capacity in hospital management and practice, (2) implementation efforts and challenges with quality improvement, (3) systemic changes, and (4) the potential to learn. All four themes are discussed below, along with illustrative participants' quotes (numbers in parentheses indicate the link to participants characteristics, cf. table 3).

Theme I adaptive capacity in hospital management and practice

Participants agreed that the Quality Improvement Regulation was designed in a way that supported flexibility, enabling managers to determine and adapt implementation efforts and quality improvement measures to their local context. This was portrayed as essential, partly due to the complexity in the system including different risks and elements (eg, postoperative complications, team coordination, complex procedures) of variation and uncertainty. Risk-based management was thus characterised as one of the favourable advantages with the new Quality Improvement Regulation, as it encourages managers to assess risks according to specifics and hallmarks in the relevant unit, department and clinic.

> The Quality Improvement Regulation gives you room to maneuver because it has a generic design.
>
> *- Medical doctor, head of department (13)*

> After all, you are completely dependent on close dialogue with those who work (at the sharp end) and we as managers need to move closer to find out where we need to adjust and to discover the areas where things are not working.
>
> *- Medical doctor, head of clinic (11)*

Participants argued that having a one size fits all solution is not easy, as improvising will always be necessary at a local level. They continued with describing that in a hospital you are not in control of your day because new situations occur, implying that it is impossible to anticipate every possible event. This is one of the main reasons for why implementation of new routines and procedures are challenging, participants claimed. They believed that the embedded risks would remain risks regardless of new regulatory requirements, illustrated by the fact that adverse events still occur despite new, improved routines and procedures. Adding to this, participants described how they worked on standardising procedures aiming to reduce some of the unwanted variation in their work but noted that methods of treatment and evidence evolve so quickly that procedures need constant updates. While the government sometimes presents a black and white solution, a procedure is only valid until good reasons exist to deviate from it, they noted.

> There are so many different things that come up and occur, that it is not always easy to have a one size fits all solution. There is some improvisation sometimes, in how to approach a problem.
>
> *- Medical doctor, head of department (12)*

> For a very detailed procedure to work well, you must be able to predict all types of situations that the different medical practitioners may come across, and we do not always manage to predict that.
>
> *- Medical doctor, adviser in quality and patient safety (18)*

Autonomy was described as a key flexibility feature in everyday hospital work, especially for physicians. However, high degrees of autonomy may sometimes compromise physicians' willingness to actively participate in systematic quality improvement work compared with the nursing profession, participants claimed.

> They must get the impression of being involved in- and to influence their daily work. To give a purely administrative order, like: "Now you must pull yourself together, you should do this and that", that approach will not do, they will boycott it.
>
> *- Medical doctor, head of clinic (15)*

They also reported that the flexibility leaves the hospitals with the choice to implement whatever adverse event reporting system they choose. Furthermore, adaptive capacity to handle risks and challenges implies that hospitals are influenced by their own competences in terms of having the right personnel and training. Some participants even requested more strict support and correctives from their senior managers because that would indicate that their manager knew what sort of challenges they struggled with in their everyday work (eg, quality improvement efforts are added on top of their everyday workload, lack of good quality indicators, lack of personnel and time, information overload, lack of coordinated data systems).

> I feel that we are free to express it (further up the hierarchy) if we experience that some efforts do not make sense to our work practices.
>
> *- Nurse, head of department (14)*

> Physicians hate to be controlled. At the same time, they write to the Ministry "we got to have some clear guidelines", so physicians both love and hate rules. And it's a schizophrenia that physicians have always had.
>
> *- Medical doctor, adviser in quality and patient safety (18)*

Theme II implementation efforts and challenges with quality improvement

Our participants all agreed about the advantage and necessity of highlighting management responsibility in the new Quality Improvement Regulation. However, participants reported that most managers already have too many obligations and do not have time to prioritise systematic quality improvement efforts. Some even reported that many managers simply do not care about professional management and administering of their unit, department or clinic.

> I think that the Quality Improvement Regulation is providing managers with an overall description of how a manager should act. You must do all these things that many people believe are obvious. And the Quality Improvement is kind of "stating the obvious".
>
> *- Medical doctor, adviser in quality and patient safety (18)*

Although PDSA as a method was familiar to the hospitals prior to introducing the Quality Improvement Regulation, several participants argued that the systematic four phase process is not embedded in health personnel's work practice. They described all four phases as equally important but stressed that evaluation and restoring/returning to a normal state are the most demanding to operationalise into reality.

> The extent to which these (PDSA) circles work according to the intention: there are measures implemented, and then there is no follow-up of the decisions. There is a total lack of it, I would almost say.
>
> *- Medical doctor, head of research (9)*

> I do not know if I am able to articulate how I work specifically with the four (PDSA) elements (…) because it is quite different from one area to the next.
>
> *- Nurse, head of quality (6)*

Participants believed that the Quality Improvement Regulation did not lead to change in their practice.

> Some things have been done by the executive level, but the clinic managers have not addressed it.
>
> *- Nurse, quality coordinator (5)*

> Not directly linked (the introduction of the Quality Improvement Regulation and implementation of practical measures into clinical work). I cannot think of (episodes) where it was like "let us take a look at this (the Quality Improvement Regulation) and then start changing things".
>
> *- Nurse, Head of Quality (20)*

Lack of understanding of what was referred to as 'internal jargon' in quality improvement and patient safety was believed to add to the burden and responsibilities of managers. However, several quality improvement measures were described, such as double check of medications, focus on communication in teamwork, reducing the number of hallway patients, questionnaire for patients' satisfaction, preoperative marking, and surgical checklists. The latter was described as the most difficult, yet most successful implementation measure.

Several participants referred to what they experienced to be a common, yet a false claim: that physicians are not concerned about or involved in quality improvement. A lot of the improvement methodology is present although it is not stated clearly or written down and most physicians do work unconsciously in accordance with the quality improvement methodology, participants reported.

Theme III systemic changes

Findings revealed both structural and cultural changes to, and development of, quality improvement systems in the hospitals. The structural quality improvement elements were described in terms of the establishment of different types of meetings, councils and committees (eg, patient safety and quality councils, network meetings, internal audit meetings) at the administrative and management levels in hospitals.

> We have built a new structure of quality and patient safety units.
>
> *- Lawyer, legal adviser in quality and patient safety (3)*

Furthermore, systems of adverse event reporting and systems for documentation of procedures, routines, guidelines were introduced, and constantly evaluated and improved. The latter was described as extremely challenging in everyday work, as the number of available documents felt overwhelming, and sometimes routines and procedures overlapped or were outdated.

> It has been one of the most important things, the system for documentation, and we have been working intensely to clear away old routines, revise all routines and get them updated, especially since our new quality adviser started.
>
> *- Lawyer, deputy head of clinic (7)*

In addition to hospital internal structural changes, participants described an increased governmental spotlight on patient safety in general and on managers' roles in reducing risks and enabling their employees to work safely and provide high quality care to patients. As a legal document, the Quality Improvement Regulation manifested this development, the participants explained.

> We were probably more mature now in order to get that new Quality Improvement Regulation, and what I think is very nice is that it is to the point, three pages and it is kind of "this is how we should do it".
>
> *- Nurse, Head of Quality (20)*

> We are obliged to do an annual risk review, which we have never done before, and we believe that the (Quality Improvement) Regulation has helped us in turning the spotlight on that.
>
> *- Medical Director (8)*

All participants reported a cultural shift in improvement work over recent years. They described a change in attitudes towards the importance of continuous quality improvement and the systematic approach to it. Courses and training that used to be ignored by physicians, had gained attention, and increased its popularity, however support systems and routines varied among the study sites. Several participants also had experienced and expected a further shift with new generations of physicians approaching the field. This was explained partly due to the renewed curriculum introducing the methodology of systematic planning, acting, restoring and evaluation early on in their education.

> (Quality improvement work) is not entirely new, but quite new. When I started as a surgeon, these were things that never came into view, so it's been a remarkable change, especially over the last ten years.
>
> *- Medical doctor, head of clinic (15)*

> Today, managers can hardly speak without having to mention the word patient safety. So, it's been an interesting development.
>
> *- Medical doctor, adviser in quality and patient safety (18)*

Theme IV the potential to learn

To maintain high quality care, interpersonal trust among health personnel and institutional trust between hospital managers and governmental supervisory bodies is a necessity, participants argued. Explaining why adverse event reporting was still weak, participants highlighted a safe work environment. Participants felt that a healthy reporting regime emerges from a just culture, which in turn leads health personnel to feel confident that they will be taken care of if they make mistakes and if they report adverse events. Some noted that a systems-perspective to adverse events, supported by the Quality Improvement Regulation, was more frequently applied now compared with in previous supervision activities, contributing to the needed sense of confidence to openly discuss adverse events and risks.

> And I think that in doing quality improvement and patient safety work, we need to recognise that the number one priority is to ensure that health personnel are confident that they will be taken care of if they make mistakes, and that they find themselves in a system that reduces the number of adverse events to a minimum.
>
> *- Medical doctor, head of department (19)*

In general, organisational, and individual learning was described as challenging and even more so learning across departments, clinics and between hospitals. Participants explained that it was difficult to learn from adverse events during normal work operations due to time pressures, nor did health personnel always have the motivation to do it.

> We are part of an intellectual organisation, right, that is what drives us forward. After all, it is about our minds. To be able to change things you must get all these minds on board. Otherwise, everything stops.
>
> *- Medical doctor, head of clinic (15)*

Since it is difficult to learn from adverse events, and the time is lacking—participants argued that it is difficult to learn from successful outcomes too. Implementation of the Quality Improvement Regulation did not change this.

> We do have regular meetings within the clinic and across departments, so we learn a lot and it is our responsibility to somehow pass it on to our department. I don't think there is a good system for that, but I don't know how it could be resolved. The challenge is the amounts of information which I must communicate further down the system, to my employees, but they work shifts and are not necessarily checking their email every day.
>
> *- Head nurse (17)*

As a response to questions about the interplay between hospitals and supervisory bodies, most participants emphasised that supervision could be useful and help the managers to focus on certain risk areas or challenging work practices. However, participants gave examples of less helpful episodes, such as inspectors having different views on certain rules and regulations, adding that some recommendations from inspectors were difficult or impossible to implement in practice. Some noted that supervision focuses primarily on negative aspects of improvement and felt that internal audits were more relevant and useful than governmental supervision, because the hospitals are leading their own problem solving.

> If you have a written procedure and something happens, then they (red. inspectors) ask: "But why did you not do that?" Because the anatomy indicated differently (red. physician answers). "But it states in your written procedure that you should do it, right?" That is how a lawyer speaks compared to a physician…
>
> *- Medical doctor, head of clinic (15)*

DISCUSSION

The main findings

According to the Quality Improvement Regulation, managers are responsible for implementation efforts and for the use of PDSA methodology. Our participants nevertheless described no change in their practice (related to quality and safety activities) solely due to this new regulatory framework. The introduction of the Quality Improvement Regulation was thus perceived by the participants as having no direct link with how they performed their work. Despite that, this study discovered structural and cultural changes to, and development of, quality improvement systems in hospitals in recent years. We argue that the structural and cultural changes that have happened (eg, annual quality and patient safety reports to the Norwegian Parliament, National Strategy for Quality Improvement in

Health and Social Services (2005–2015),[39] 'Patient Safety Program'[40]), also included the revision of the previous Internal Control Regulations into a new regulatory framework.[13 48] Hence, the governmental development of the Quality Improvement Regulation appears to be part of that systemic change. Participants described several benefits with the Quality Improvement Regulation in terms of adaptation and flexibility to local context, and clinical autonomy as an inevitable element in hospital practice. Trust and a safe work environment were considered key factors to support adverse event reporting and learning processes in general. The latter was crucial if collaboration with external supervisory inspectors should positively influence hospital quality enhancement.

Strengths and limitations of this study

It is assumed essential to involve different types of stakeholders when researching the system-level phenomenon of risk-based management, where complexity, uncertainty and variation are key concepts.[53 69] This study investigated hospital managers' perspectives and experiences with practical implications of a specific regulatory change. Lower level management implementation of the new regulatory requirements was given main attention in our study. It is thus a limitation that it only reports the perspectives of managers and no other stakeholders from different levels in the system, such as patients, full-time clinicians, regulators. The perspectives of regulators and inspectors are presented in two separate research articles.[37 53] The main study strength is the uncommon approach of involving hospital managers in healthcare regulation research, as they both legally and practically are responsible for improving quality and safety. An additional strength is that most participants had substantial clinical experience and/or stilled worked in the clinic environment, in addition to having management responsibilities, which provided the study with valuable insight into the complexity in hospital management. A limitation with this study is that the interviews focused on hospital managers own reflections and did not include any observational study of practice/implementation/change. Another limitation is that two out of four regional health trusts in the Norwegian specialist healthcare system were not included. This may have hampered valuable information about the implementation process and geographical variations since the support systems and routines for training managers differ from region to region. Guided by the information power, however, the sample size of 20 participants was adequate and supported our effort to ensure trustworthiness.[57 70] We did nevertheless not discuss potential differences among participants belonging to the three different local health trusts (which could be viewed as a limitation), as we did not fully map resources, size and context of their quality advising units. However, all hospitals had established committees, boards and units related to quality improvement, and the structural and cultural changes reported in theme 3 reflected that overall systemic development.

Implementation, the capacity to adapt and the link to support systems

Healthcare regulation is tailored in various ways by the government, depending on the area. Some sectors are strictly governed by prescriptive rules (eg, medication-related issues).[64] The idea with the Quality Improvement Regulation's design on the other hand was to provide managers with non-detailed goals for risk management-based implementation. With a non-detailed regulatory framework, the government does not specify *how* hospital managers should 'get there', built on ideas of local autonomy and context sensitivity.[64] As our data revealed, improvisation and local adaptation is viewed as essential to hospital management, along with an acceptance that healthcare situations such as patient treatment, diagnosis or surgery can develop into unforeseen scenarios which cannot be planned for. Regulatory measures that are too standardised or prescriptive could adversely reduce the autonomy of managers and health personnel. Our findings illustrated that managers acknowledged that strict regulations could potentially affect and hamper patient safety in cases where flexibility could be beneficial to the outcome.

However, a high degree of system adaptive capacity could occasionally represent a disadvantage, for instance when a procedure is adjusted but leads to an unsuccessful or unacceptable outcome,[67] or regulatory flexibility combined with a lack of interest in quality improvement work allows regulatees to deliberately ignore quality and safety expectations. Moreover, when choices and decisions are left to hospital organisations it creates considerable demand for internal systems to train managers, to establish systems for implementation support and IT solutions. This is echoed by past research on the growth of internal bureaucracy due to governmental deregulation of safety management.[71] Hence, our study found a paradox in the systemic development of meetings, councils and committees at the administrative and management levels in hospitals to comply with regulatory requirements for quality and safety, while managers reported few changes at the sharp end; in clinic, related to implementation of quality and safety activities. It is reasonable to think that there is a disparity in hospital manager support across different hospitals. Thus, having autonomous responsibility for competences and management training could in turn lead to different priorities in different regions and hospitals. Variation in support systems and routines was nevertheless reflected in our results.

Moreover, previous research has emphasised skills and support to manage conditions of unexpected events, and that managers (due to prioritisation struggles) need guidance to understand what is operationally needed.[72–74] Indeed, lack of knowledge and skills is perceived a significant barrier to quality improvement.[75 76] We argue that our current study demonstrates that the Quality Improvement Regulation's non-detailed regulatory design, leaving implementation decisions to managers, could complicate managers' understanding of governmental expectations. This resonates especially since the requirements need to be translated before practically applied (eg, how to define

specific hospital-conduct as reasonable; safe; prudent or what is adequate documentation). As successful implementation requires more than a change in regulatory rhetoric or design, our study indicates that support tools for managers to achieve the goals in a systematic way have not been fully developed yet. The disjunction between rhetoric and reality, or theory versus practice, is a familiar one in research on implementation of rules and regulations in healthcare. It is often referred to as a dichotomy of work as imagined versus work as done.[66 77] This applies particularly to how requirements are trickled down the system to get resonance with those who do the actual implementation.[31 34 35 78 79] When lower level managers fail to implement efforts because they are difficult to convert into practice or that the policies being implemented have a weak relationship with the core clinical tasks, a process of 'decoupling' has occurred.[34 35] The study of van de Bovenkamp *et al*[80] revealed that hospitals needed to do a lot of interpretive work to make use of regulation; however, autonomy enabled this strategic work. Other studies have shown that additional resources and systems sometimes are needed to interpret and implement regulatory requirements.[81] As detailed rules and regulations may often be perceived as barriers to implementation, focusing regulatory attention on defining the quality of processes and outcomes could potentially make regulatory expectations more feasible for practical implementation. On the other hand, some hospital managers may find less details less helpful, because most of the responsibility, decisions and operationalisation are left with them. What can be drawn from this is that it will be important to consider how regulatory expectations are designed in ways that enable hospital managers to put efforts into practical reality. This implementation gap may also partly be explained by the type of managers who oversee implementation efforts. With different leadership approaches debated in the literature, prior research has identified how clinical managers' sometimes struggle with role and identity.[12 82–86] Thus, to become interested in management, there ought to be awareness of meaning and purpose in management training, as it is first and foremost clinical work that is perceived meaningful to them.[12 86] Moving forward, it will be crucial to develop management practices that encourage quality improvement efforts, and encourage health personnel to participate.[15 87] Putting clinicians in management roles, provided with adequate leadership and quality improvement training, is key to making improvement an embedded and inclusive activity in everyday clinical work—especially since clinical managers often have experienced the importance of flexible and adaptive behaviour firsthand.[11 12 32] Thus, the 'hybrid professional manager' might bridge professional management, clinical identity and engagement, constituting an important system factor underpinning successful quality improvement and implementation.[84 85 88]

PDSA—government favoured methodology for quality improvement

Although the Quality Improvement Regulation manifested the PDSA logic,[38] it did not independently explain if and why managers decided to put quality and safety activities on their agenda. Our findings indicated that clinicians worked with quality improvement, but they did not necessarily follow the PDSA-logic nor were they familiar with the Quality Improvement Regulation. Moreover, several participants described that measuring improvement efforts was challenging. This study links this to the assumption that everything is measurable according to the PDSA logic.[89] In that sense, and alike our study, prior research has found some drawbacks in using PDSA in hospitals' quality improvement work.[90–92] Although the PDSA methodology encourages learning and supports adaptation of interventions, its efficient use requires considerable training and organisational and managerial support.[91] If PDSA is to remain at the core of regulatory design, then issues of organisational support and training need to be accounted for by regional health trusts and Government budgets.

Several alternative quality improvement methodologies exist. For instance, *Six Sigma* (define, measure, analyse, improve, control), *Lean* (identify waste; activities that do not add value), *root cause analysis* (identify the underlying causes; reactive in its approach), *failure modes and effect analysis* (identify potential adverse events, failures and hazards; proactive in in its approach).[93] Commonly among these approaches is that they presuppose identification of a specific problem area or cause(es) before the next steps of action might be implemented. This could possibly make managers overlook certain areas that are not obviously apparent. Thus, based on the contextual reality of hospital managers, reflected in our findings about resources and lack of time, we argue that complex, non-linear processes are challenged by these methodologies. Moreover, systemic risk factors such as resources and time are embedded and often linked and interrelated when an adverse event occurs.[94–97] Other organisational design considerations also seem important, beyond specific improvement methods. For instance, the inclusion of short, daily breaks to facilitate learning episodes may assist in improvement efforts.[98] Organisational adaptations such as this could address some of the challenges identified by participants in this study, where systematic quality improvement in line with the Quality Improvement Regulation's PDSA logic, was viewed as too time consuming to justify full-scale implementation.

Implications for clinicians and policy-makers—and future research

This study is of relevance to both regulatory bodies and the management levels within hospitals. It adds some useful insights to development and implementation of future regulatory amendments in a Norwegian and in an international context. Moreover, the study highlights the importance of ensuring that any macrolevel quality improvement initiatives and regulatory requirements are accompanied by appropriate resourcing, support, and advanced preparation to ensure that it has the best possible chance of being implemented effectively. Our results therefore may contribute to theoretical

development of macrolevel regulation, by implying how inclusive governance can add value to fill in the gap between work as imagined and work as done and support adaptive capacity as a positive element in quality improvement work.[67] Additionally, our study highlights regional variation in management training and programmes for leadership development, which fuels the idea that it will be important to provide a *minimum level* of training to all hospital managers, regardless of organisational level and regional affiliation. Yet, there are some unanswered questions that speaks for future research, for instance:

- How to provide additional management support for implementation through adding 'practice facilitators'.[72]
- How to improve the collaboration between inspectors and hospital managers.[99]
- It would also be valuable to engage in cross-country comparative research to investigate how different regulatory regimes value flexibility in regulatory strategies for quality improvement and patient safety.

CONCLUSION

In this study, we explored how hospital managers work to improve quality and investigated their experiences with implementing the new Quality Improvement Regulation, provided to support management of quality improvement. The study showed that lack of time, competence and/or motivation, appears to limit the implementation of quality improvement efforts. While managers' work to improve quality does not solely depend on a specific regulatory framework, the Quality Improvement Regulation may be an instrument that over time, leads to structural and cultural change. In turn, it can push managers towards a shift in strategic learning focus and resource allocations. Ultimately, hospital managers' autonomy and their adaptive capacity and ability to tailor quality improvement efforts to local circumstances were key for the new Quality Improvement Regulation to have any relevant impact on hospital practice and for it to influence quality and safety activities.

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Contributors All authors designed the study. SFO conducted all interviews and transcribed 11 of these. Nine interviews were transcribed by a consultant. SFO analysed the data, and SW and GSB read the interview transcripts and discussed categories and themes. SFO drafted the manuscript. All four authors made critical revisions to the manuscript's scientific content.

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Patient consent for publication Not required.

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Appendices

Appendix 1: Notification to the Norwegian Centre for Research Data (NSD)

NSD NORSK SENTER FOR FORSKNINGSDATA

NSD sin vurdering

Prosjekttittel

Resilience and Regulation in Healthcare – mechanisms, challenges and opportunities

Referansenummer

381276

Registrert

01.10.2018 av Sina Furnes Øyri - sina.f.oyri@uis.no

Behandlingsansvarlig institusjon

Universitetet i Stavanger / Det helsevitenskapelige fakultet

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Sina Furnes Øyri, sina.f.oyri@uis.no, tlf: 93660803

Type prosjekt

Forskerprosjekt

Prosjektperiode

20.09.2018 - 01.08.2021

Status

28.10.2018 - Vurdert

Vurdering (1)

28.10.2018 - Vurdert

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet med vedlegg 28.10.2018. Behandlingen kan starte.

MELD ENDRINGER
Dersom behandlingen av personopplysninger endrer seg, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. På våre nettsider informerer vi om hvilke endringer som må meldes. Vent på svar før endringer gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle alminnelige kategorier av personopplysninger frem til 01.08.2022.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er

at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 og 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse som kan dokumenteres, og som den registrerte kan trekke tilbake. Lovlig grunnlag for behandlingen vil dermed være den registrertes samtykke, jf. personvernforordningen art. 6 nr. 1 bokstav a.

PERSONVERNPRINSIPPER
NSD finner at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om:
- lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke behandles til nye, uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

NSD vurderer at informasjonen om behandlingen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13. Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

Det kan være aktuelt å benytte en transkriberingsassistent som databehandler i prosjektet. NSD legger til grunn at behandlingen oppfyller kravene til bruk av databehandler, jf. art 28 og 29.

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og/eller rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp behandlingen underveis (hvert annet år) og ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet og om behandlingen pågår i tråd med det som er dokumentert.

Lykke til med prosjektet!

Kontaktperson hos NSD: Belinda Gloppen Helle
Tlf. Personverntjenester: 55 58 21 17 (tast 1)

Appendix 2: Informasjonsskriv og samtykkeerklæring (information sheet and informed consent)

Vil du delta i forskningsprosjektet

"Resilience and Regulation in Healthcare – mechanisms, challenges and opportunities"?

Formålet med dette forskningsprosjektet er å utforske grunnlaget for, forventningene til og operasjonaliseringen av den nye internkontrollforskriften, *forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten.* Vi ønsker også å undersøke hvordan denne legger til rette for eller hindrer resiliens («robusthet») i sykehuset. Resiliente helsetjenester innehar evnen til å tilpasse sine systemfunksjoner i forkant av, underveis eller i etterkant av endringer og forstyrrelser. Målet er at systemet kan gjenopprette den nødvendige ytelsen/aktiviteten under både forventede og overraskende forhold. Resiliens er den norske oversettelsen av det engelske begrepet «resilience».

Vi tror at du kan ha viktig og nyttig informasjon å bidra med. Derfor ønsker vi å intervjue deg. I dette skrivet gir vi deg informasjon om målene for prosjektet og hva deltakelse vil innebære for deg. Deltakelsen er basert på frivillighet. Du kan også velge å trekke deg i løpet av prosjektet, selv om du i utgangspunktet har sagt deg villig til å delta.

Formål
Prosjektet søker å få kunnskap om myndighetenes vurderings- og beslutningsgrunnlag for ny forskrift, og hvordan Helse- og omsorgsdepartementet, Helsedirektoratet og Statens helsetilsyn forventer at den nye forskriften tilrettelegger for eller hindrer resiliens og forbedrer kvaliteten i sykehusenes arbeid. Videre ønsker vi å få kunnskap om hvordan tilsynsmyndighetene endrer, tilpasser og forbedrer sin tilsynspraksis etter forskriftsendringene samt undersøke hvordan ledere på sykehusavdelinger erfarer dette i sykehuspraksis.

Hvem er ansvarlig for forskningsprosjektet?
Universitetet i Stavanger er faglig ansvarlig for forskningsprosjektet, som ledes av PhD-stipendiat Sina Furnes Øyri, jurist med mastergrad i samfunnssikkerhet, og utføres i samarbeid med hovedveileder professor Siri Wiig og biveilederne professor II Geir Sverre Braut og Senior Visiting Associate Carl Macrae.

Hvorfor får du spørsmål om å delta?
Du er forespurt om å delta i forskningsprosjektet fordi du er leder eller ansatt i departement, direktorat, tilsyn eller i et sykehus.

Hva innebærer det for deg å delta?
I prosjektet vil data samles inn på flere måter, både gjennom dokumentanalyse, individuelle intervju og gruppeintervjuer. Du, som leder eller ansatt, blir forespurt om å delta i individuelle intervju eller gruppeintervju:

- Individuelle intervju med lydopptak varer i ca. 45 minutter. Intervjuet inneholder spørsmål om hvilke forventninger du har til ny forskrift, hvilke utfordringer du opplever i arbeidet med kvalitet og sikkerhet, hvordan du opplever forskriftsendringen i praksis, hvordan det arbeides med denne endringen i din enhet/avdeling, om det har skjedd endringer over tid og hvordan disse endringene oppfattes og oppleves, eventuelt hvilke endringer i regelverk samt i praksis relatert til kvalitet og sikkerhetsarbeidet som *burde* foretas.
- Gruppeintervju med lydopptak varer i ca. 90 minutter. Intervjuet omfatter diskusjon omkring forståelse av kvalitet og sikkerhet, tilsynsoppgaver, hvilke forventninger du har til ny forskrift, hvordan forskriftsendringen har vært arbeidet med i organisasjonen, om det har skjedd

endringer i tilsynspraksis over tid og hvorfor, eventuelt hvilke endringer i regelverk samt i tilsynspraksis relatert til kvalitet og sikkerhetsarbeidet som *burde* foretas.

Det er frivillig å delta
Det er frivillig å delta i prosjektet. Hvis du velger å delta, kan du når som helst trekke samtykke tilbake uten å oppgi noen grunn. Alle opplysninger om deg vil da bli anonymisert. Det vil ikke ha noen negative konsekvenser for deg hvis du ikke vil delta eller senere velger å trekke deg.

Ditt personvern – hvordan vi oppbevarer og bruker dine opplysninger
Vi vil bare bruke opplysningene om deg til formålene vi har fortalt om i dette skrivet. Vi behandler opplysningene konfidensielt og i samsvar med personvernregelverket. Alle opplysningene vil bli behandlet uten navn eller andre direkte gjenkjennbare opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste, og betyr at opplysningene er avidentifisert. Det er kun prosjektteamet ved Universitetet i Stavanger som har adgang til navnelisten og kan finne tilbake til deg. Informasjonen som registreres om deg skal kun brukes som beskrevet i formålet over. Lydbåndopptakene vil bli overført til en datamaskin og slettes like etter at intervjuet er transkribert. Det vil ikke være mulig å identifisere deg når resultatene fra studien publiseres. PhD-stipendiat Sina Øyri har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte.

Hva skjer med opplysningene dine når vi avslutter forskningsprosjektet?
Prosjektet skal etter planen avsluttes 1. august 2022. Datamaterialet anonymiseres ved prosjektslutt ved at navnelisten som kopler navn til resultater blir makulert.

Hva gir oss rett til å behandle personopplysninger om deg?
Vi behandler opplysninger om deg basert på ditt samtykke.
På oppdrag fra Universitetet i Stavanger har NSD – Norsk senter for forskningsdata AS vurdert at behandlingen av personopplysninger i dette prosjektet er i samsvar med personvernregelverket.
Studien er meldt til Universitetet i Stavanger sitt Personvernombud NSD – Norsk senter for forskningsdata AS, epost (personvernтjenester@nsd.no), telefon: 55 58 21 17.
Referansenummer 381276, 1. oktober 2018.

Hvor kan jeg finne ut mer?
Hvis du har spørsmål til studien, eller ønsker å benytte deg av dine rettigheter, ta kontakt med:
Sina Furnes Øyri, ved Universitetet i Stavanger, på tlf. 93660803 eller e-post: sina.f.oyri@uis.no.

Med vennlig hilsen

Sina F. Øyri

Prosjektansvarlig

Samtykkeerklæring

Jeg har mottatt og forstått informasjonen om prosjektet *Resilience and Regulation in Healthcare – mechanisms, challenges and opportunities*, og har fått anledning til å stille spørsmål. Jeg samtykker til:

☐ å delta i intervju

Jeg samtykker til at mine opplysninger behandles frem til prosjektet er avsluttet, ca. 1. august 2022.

(Signert av prosjektdeltaker, dato)

Appendix 3: Intervjuguidene (interview guides)

INTERVJUGUIDE MAKRONIVÅ

- Presenter deg selv med alder, utdanning, fag- og erfaringsbakgrunn og nåværende stilling.
- Hva var rasjonalet bak myndighetenes tilpasning av internkontrollregelverket til en ny kvalitetsforbedringsforskrift med et eksplisitt lederfokus?
- Hvordan representerer det nye lederfokuset en nødvendig endring for kvalitetsforbedring innen helsetjenesten?
- Hva legger dere i begrepet «kvalitetsforbedring»?
- Hvordan forventer dere at den nye forskriften skal kunne tilrettelegge for kvalitetsforbedring, pasientsikkerhet og trygg pasientbehandling (ref. resiliens) og derigjennom forbedre sykehusenes prestasjoner/ytelser?
- På hvilke måter har praktikerne innen sykehusledelse vært involvert i utviklingen av den nye forskriften?
- Hvordan kommuniserte og informerte dere (Helsedirektoratet) om tilpasningene/endringene til spesialisthelsetjenesten?
- Hva var kommunikasjonsstrategien når ikrafttredelsen av forskriften skulle formidles?
- I retroperspektiv/ i etterkant: hva ville dere ha gjort annerledes når det gjelder utviklingen og implementeringen av forskriften?
- Når vi betrakter internkontroll som myndighetsregulert egenkontroll av risiko- hva er årsakene til en slik funksjonsbasert reguleringsstrategi (at formål angis, men detaljkrav utelates)?
- Hvilke typer forventninger har dere (Helse- og omsorgsdepartementet; Helsedirektoratet; Statens helsetilsyn) til sykehusleders kunnskap om og skolering innen sikkerhetssystemer for kvalitetsforbedring?
- Hva er fordelene med den nye lederforskriften?
- Hvilke ulemper med regelverket kan forventes?

1

- Hvilke tilbakemeldinger har dere mottatt i etterkant – positive og negative?

- Tenk 5 år frem i tid – hvilke endringer forventer myndighetene skal skje?

- Sluttkommentar: Nå tror jeg at vi har vært igjennom det jeg har ønsket å stille spørsmål om. Det kan hende at det utover dette er forhold vi ikke har fått belyst, men som likevel er viktige tema. Er det noe du føler vi ikke har dekket som du har lyst til å si noe om?

Åpne tilleggsspørsmål (noe overlapp med de øvrige):

- Debatt i høringsrunden omkring navnet: fortell litt om det.
- Hvordan opplevde du arbeidet med å utvikle forskriften, dertil høringsrunden?
- Kan du si noe om hvilke utfordringer du opplever i dag, i arbeidet med kvalitet og sikkerhet?
- Fortell om hvordan det arbeides med å følge opp endringene i din enhet/avdeling.
- Forskriften er delt inn i fire tema av plikter som påhviler ansvarlig leder. Kan du si noe om hvor inspirasjonen bak forskriftens oppbygging ble hentet fra?
- Spørsmål om veilederen. Du har jobbet en del med utarbeidelse av veileder til forskrift- fortell litt om dette arbeidet.
- Innledningsvis i veilederen stilles to spørsmål: Er veilederen et godt verktøy for helse- og omsorgstjenesten i arbeidet med ledelse og kvalitetsforbedring? Hvordan kan veilederen forbedres? Hvordan vil du svare på disse spørsmålene?
- Det finnes en brukerundersøkelse fra internkontrollforskriftens veileder «Hvordan holde orden i eget hus». Finnes det en tilsvarende undersøkelse for lederforskriften?
- Hvordan vurderer du virkningene av forskriftsendringene som har blitt gjort?
- Kan du si noe om hvilke endringer i regelverket relatert til kvalitet og sikkerhetsarbeid som *burde* foretas?

2

INTERVJUGUIDE MESONIVÅ (enkeltintervju)

- Presenter deg selv med alder, utdanning, fag- og erfaringsbakgrunn og nåværende stilling.
- Hvordan vil du karakterisere og tolke den nye forskriften?
- Hva legger du i begrepet «kvalitetsforbedring»?
- Kan du si noe kort om tilsynsvirksomheten dere utøver? Si gjerne noe om forventningene du har til arbeidet du utfører.
- Kan du si noe om rolleforventningene du opplever til deg som tilsynsfører i møte med ledere i sykehus? (Hvordan opplever du grensene mellom uformelle og formelle prosedyrer og rutiner? Kan du si noe om fordeler og ulemper med måten arbeidet ditt kommuniseres til tilsynsobjektet?)
- Kan du beskrive hvilke føringer dere får fra sentralt hold ved endringer i regelverket som det skal føres tilsyn med?
- Kan du si noe om hvordan dere forholdt dere til departement og direktorat når de nye forskriftsbestemmelsene ble utarbeidet og iverksatt?
- Hvordan tilpasser du ditt arbeid til forskriftsendringene, slik at arbeidet/praksisen som tilsynsførere og regelverksiverksettere forbedres?
- Sammenlignet med tidligere interkontrollforskrift- på hvilke måter er den nye forskriften implementert/iverksatt i tilsynsaktivitetene?
- På hvilke måter har tilsynsarbeidet endret seg med implementeringen av det nye forskriftsregelverket?
- Hvilke endringer i praksis forventes den nye forskriften å føre til?
- Har du opplevd noen kvalitetsforbedringer som en konsekvens av /avledet av den nye forskriften?
- Hva er fordelene med den nye forskriften?
- Hvilke ulemper erfarer du?
- Forskriften består av 4 bolker av plikter: Hvordan jobber dere med tilsyn ut i fra disse pliktene?:
  - plikten til å planlegge virksomhetens aktiviteter
  - plikten til å gjennomføre virksomhetens aktiviteter
  - plikten til å evaluere virksomhetens aktiviteter
  - plikten til å korrigere virksomhetens aktiviteter
- Er det noen deler/noen spesifikke forhold i forskriften som du tenker er viktigere enn andre? I så fall, hva da?
- Hvordan tilrettelegger eller hindrer du i ditt tilsynsarbeid fleksibilitet og tilpasning i sykehus?
- Hvordan tilrettelegger eller hindrer du i ditt tilsynsarbeid læring i sykehus?

1

- Hvilken type kompetanse vurderer du som avgjørende å besitte for sykehusledelsen, for å tilfredsstille forskriftens krav og plikter?

- Hvilke veiledende dokumenter eksisterer for tilsynspraksis etter at den nye forskriften trådte i kraft?

- Bakgrunnsdokumenter-interne dokumenter: hvordan brukes veiledende dokumenter/støttedokumenter i tilsynsarbeidet?

- Hvis det kom forespørsel fra lovgiver om å gi input- hvilke forslag ville du ha kommet med som kunne ha supplert eksisterende lovgivning (den nye forskriften)?

- Kan du si noe om hva du mener burde vært sterkere vektlagt i arbeidet med forskriftsoppfølging?

- Hvis du ser litt fram i tid – hvilke endringer antar du vil forekomme pga. ny forskrift? Hvis ikke endringer, hvorfor?

- Be om sluttkommentar: Nå tror jeg at vi har vært igjennom det jeg har ønsket å stille spørsmål om. Det kan hende at det utover dette er forhold vi ikke har fått belyst, men som likevel er viktige tema. Er det noe du føler vi ikke har dekket som du har lyst til å si noe om?

2

INTERVJUGUIDE MESONIVÅ (fokusgrupper)

- Presenter dere selv med alder, utdanning, fag- og erfaringsbakgrunn og nåværende stilling.
- Kan dere si noe om tilsynsarbeidet dere utfører/beskrive hva det viktigste i arbeidet er?
- Forholdet mellom dere og sykehuset dere fører tilsyn med:
  Hvilke rolleforventninger foreligger? Hvordan er skillet mellom uformelle og formelle prosedyrer og rutiner? Hvordan opplever dere kommunikasjonen mellom dere som tilsynsførere og tilsynsobjektet? Rådgivning vs. føre tilsyn: hva er grenseoppgangene i dette?
- Hvilke endringer opplever dere fra internkontrollforskriften til lederforskrift?
- Hvordan vil dere karakterisere og tolke den nye forskriften?
- Hvordan påvirker forskriften arbeidet til Fylkesmennene, mener dere?
- Hva legger dere i begrepet «kvalitetsforbedring»?
- Hvordan tilpasser dere arbeidet deres til forskriftsendringene, slik at arbeidet/praksisen som tilsynsførere og regelverksiverksettere forbedres?
- På hvilke måter har tilsynsarbeidet endret seg med implementeringen av det nye forskriftsregelverket?
- Sammenlignet med tidligere interkontrollforskrift- på hvilke måter er den nye forskriften implementert i tilsynsaktiviteter på regionalt nivå og på nasjonal nivå?
- Hva er fordelene med det nye lederfokuset i forskriften?
- Hvilke ulemper erfarer dere med forskriften?
- Er det noen deler av forskriften som dere tenker er viktigere enn andre? I så fall, hva?
- Forskriften består av 4 bolker av plikter (planlegge- gjennomføre- evaluere- korrigere): Hvordan jobber dere med tilsyn ut i fra disse pliktene?
- Har dere opplevd noen kvalitetsforbedringer som en konsekvens av/avledet av den nye forskriften? Kan dere gi eksempler/forklare/utdype.
- Hvordan tilrettelegger eller hindrer dere som fører tilsyn, fleksibilitet, tilpasning og læring i sykehusenes lokale forbedringsarbeid?
- Hvilken type kompetanse vurderer dere som avgjørende å besitte for sykehusledelse, for å tilfredsstille forskriftens krav og plikter?
- Hvis det kom forespørsel fra lovgiver om å gi input- hvilke forslag ville dere ha kommet med som kunne ha supplert eksisterende lovgivning (den nye forskriften)?
- Hvilke veiledende dokumenter eksisterer for tilsynspraksis etter at den nye forskriften trådte i kraft?
- Bakgrunnsdokumenter-interne dokumenter: hvordan brukes veiledende dokumenter/støttedokumenter i tilsynsarbeidet?

1

- Hva har dere av erfaring med hvilken kompetanse Fylkesmannsembetene har i forhold til å følge opp det nye regelverket?
- Kan dere beskrive hvilke føringer dere får fra sentralt hold ved endringer i regelverket som det skal føres tilsyn med?
- Kan dere si noe om hvordan dere forholdt dere til departement og direktorat når de nye forskriftsbestemmelsene ble utarbeidet og iverksatt?
- Kan dere si noe om hva dere mener burde vært sterkere vektlagt i arbeidet med forskriftsoppfølging?
- Hvis dere ser litt fram i tid – hvilke endringer antar dere vil skje pga. ny forskrift? Hvis ikke endringer, hvorfor?
- Sluttkommentar: er det noe dere tenker er viktig å nevne eller si noe om som vi ikke har snakket om?

2

INTERVJUGUIDE MIKRONIVÅ

- Presenter deg selv (alder, utdanning, fag- og erfaringsbakgrunn og nåværende stilling).
- Kjenner du til den nye forskriften *Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten* og innholdet i den?
- Hva er ledelsesrutinene for oppfølging av organisasjonens (avdelingens) kontinuerlige sikkerhets- og kvalitetsforbedringsarbeid?
- Hvordan arbeider du som leder med kvalitetsforbedring og sikkerhetstiltak i organisasjonen? Hva er ditt ansvar?
- Hva legger du i begrepet «kvalitetsforbedring»?
- Hvilken opplæring/kursing når det gjelder planlegging- og iverksetting av risiko- og sikkerhetstiltak har vært obligatorisk for ledere å gjennomføre/for deg som leder?
- Dersom slik opplæring har blitt gjennomført av deg: hva har læringsutbyttet vært?
- Hvordan forstår du kravene til internkontroll?
- Hvordan opplever du forskjellene mellom den nye forskriften sammenlignet med tidligere forskrift?
- Opplever du utfordringer med implementering av ny forskrift, i så fall hvilke utfordringer?
- Hvordan oppfatter du handlingsrommet forskriften gir? (hvis du mener den gir et handlingsrom)
- Hvordan legger den nye forskriften til rette for eller hindrer fleksibilitet og tilpasning i det lokale forbedringsarbeidet, sett fra ditt perspektiv?
- Hvordan legger forskriften til rette for eller hindrer læring, sett fra ditt perspektiv?
- Resiliens har søkelys på det som går godt. Hvordan forholder man seg til dette i virksomheten?
- Hvilke faktorer tenker du er med på å avgjøre om helsetjenestene dere leverer er robuste?
- Forskriften består av 4 bolker av plikter for virksomhetens aktiviteter (planlegge, gjennomføre, evaluere og korrigere): Hvordan jobber du/dere med disse pliktene?
- Ifølge forskriften plikter dere å ha et styringssystem - hvordan dokumenterer dere at dere har dette?
- Er det noen deler/noen spesifikke forhold i forskriften som du tenker er viktigere enn andre? I så fall, hva da?

1

- Opplever du at det som står i forskriften er lett tilgjengelig og forståelig? Har du eksempler på begreper som er vanskelige å få fatt på/forstå i teksten?
- Har du opplevd å være usikker på hvordan du skal jobbe med kvalitetsforbedring ut i fra det som står i regelverket?
- Hva gjør du om du står fast/er usikker på hvordan du skal forholde deg til det regelverket legger opp til av krav og plikter?
- Har du noen tanker omkring det å være den som det føres tilsyn med?
- På hvilke måter påvirker og eventuelt forbedrer samhandlingen mellom nasjonale og regionale tilsynsførere sykehusenes ledelse og kvalitetsforbedringsarbeid?
-
- Hvordan erfarer du kommunikasjons- og informasjonsprosessen (fra departement, direktorat og tilsyn) som har vært før forskriften trådte i kraft?
- Har du forslag til hva myndighetsinstansene kunne ha gjort annerledes i utviklingen og implementeringen av forskriften, og i så fall hvilke forslag?
- Hvis du skulle gi innspill til endringer som kunne supplere eksisterende lovgivning: hvilke forslag ville du som leder gi til myndighetsinstansene?
- Merkes det endringer i holdningen til kvalitetsforbedring etter at den nye forskriften trådte i kraft, i så fall hvilke holdningsendringer?
- Finnes det bakgrunnsdokumenter/interne dokumenter, hvilke dokumenter er det i så fall og hva inneholder disse?
- Hvordan brukes veiledende dokumenter/støttedokumenter i kvalitetsforbedringsarbeidet?
- På hvilke måter bidrar veilederen fra Helsedirektoratet til å gjøre arbeidet ditt/deres lettere?
- Hvilke konkrete endringer i måten dere jobber på har ny lederforskrift medført? (Dersom dere ikke mener det medfører endring- hvorfor?)
- Litt frem i tid- hvordan vil ny forskrift bidra til bedre styring av kvalitet i ditt sykehus? Hva forventes?
- Åpen post- sluttkommentar? Noe vi ikke har dekket, men som er viktig å si noe om?

2