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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 explore hospital managers’ perspectives on implementation efforts and work practices, to understand if, and how the Norwegian regulatory framework called *the Quality Improvement Regulation* influences quality and safety improvement activities. Research question: How do hospital managers work to improve quality and what are their experiences with implementing the new regulatory framework?

Design A multi-level case study. Data was analyzed by content analysis. Collected by interviews.

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

Participants Twenty hospital managers or quality advisers selected from different levels of hospital organizations.

Results Participants revealed no change in clinical practice due to the new Quality Improvement Regulation. However, we did discover recent structural and cultural changes to, and development of, quality improvement systems in hospitals. Findings indicated that hospital managers are legally responsible for quality improvement implementation and participants described several benefits with the new Quality Improvement Regulation. This related to adaptation and flexibility to local context, and clinical autonomy as an inevitable element in hospital practice. Trust and a safe work environment were described as key factors to achieve adverse event reporting and support learning processes.

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 regulatory requirements to have any relevant impact on hospital practice.

Article summary

Article focus

Exploration of hospital managers’ perspectives on quality improvement implementation efforts and work practices.

Strengths and limitations of this study

- This study was part of a multi-level case study, involving stakeholders across system-levels.
- Most participants had substantial clinical experience and/or stilled worked in the clinic environment, in addition to having management responsibilities.
- The study did not include all four regional health trusts in its data and interviews focus on managers own reflections – no actual study of practice / implementation / change.

INTRODUCTION

After years of regulatory interventions, management strategies and policymaking, improving quality and safety of healthcare systems remain high on the political agendas. And rightly so

because globally, patient harm is listed as the world's fourteenth biggest health burden along with illnesses such as malaria and tuberculosis [1-5]. Traditionally, the process of quality improvement involves different dimensions which, if addressed, seek to achieve an optimal healthcare system [6] (See Table 1 for details). Moreover, efforts to improve patient outcomes, system performance and professional development (learning), have taken a system perspective on quality improvement and involvement of stakeholders at different levels [7, 8]. Hospital managers are stakeholders situated in the middle of governmental expectations and requirements, administrative demands and clinical practice, making their viewpoints important to explore. Countrywide hospital supervision in Norway have identified challenges to quality improvement as lack of leadership responsibilities, and non-compliance with governmental requirements associated with hospital managers' attitudes, values and organizational culture for learning [9-14]. Internationally, increased attention has been brought to involvement of clinicians in management roles [15, 16]. In Norway, as hospital organizations are required to ensure their employees have relevant competences and training, leadership programs and training regularly include learning about quality improvement methods and systematics [5, 17, 18]. Yet, 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 [19].

Prior research on regulatory activities in healthcare has shown inconsistent outcomes in terms of effectiveness of regulation [20-25]. Many studies have explored healthcare organizations' capacity of adaptation, but to date few multi-level studies link adaptive capacities with regulatory activities [26-35]. As for linking quality improvement and adaptive capacity, others have highlighted that actively engaged participants from all levels in healthcare are important, stressing how active improvement depends on leadership, also in the sense of recognizing conditions that require flexibility [7, 36]. Moreover, attention should be paid to the processes of designing rules that enable adaptive behavior, specifying preferences or goals, especially since this may lead to a bottom-up perspective rather than top-bottom [20, 35-39].

With interest in managers’ perspectives on quality improvement in hospitals, this study explores how hospital managers work to improve quality and how they experience the implementation of a reasonably new Norwegian regulatory framework for quality improvement. This framework, the *Regulation on Management and Quality Improvement in the Healthcare Services* from 2017 (referred to as *the Quality Improvement Regulation*) focuses on developing the capacity of healthcare organizations to continually improve quality and safety by constructing non-detailed goals for risk management [17]. By the Norwegian Ministry of Health and Care Services and the Norwegian Directorate of Health it is considered one of the most important governmental tools to support local quality and safety efforts in hospitals (see Table 2 for details about the regulatory objectives) [5, 40-41]. Its impact on healthcare services is still unknown from all perspectives (inspectors, hospital managers, health personnel). In this study, the aim was to investigate 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. The following research question guided the current study:

- How do hospital managers work to improve quality and what are their experiences with implementing the new regulatory framework?

Table 1 *Definitions and Concepts*

Quality	We adopt the conceptualization introduced by the Institute of Medicine defining quality through six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness, and equity [6, 82].
Regulation	We define the phenomenon of regulation generally as a governmental mechanism (including inspection; supervision) and specifically as the Norwegian regulatory framework; regime referred to in this paper as the Quality Improvement Regulation with a capital “R” in “regulation”.
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 [83]. 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” [84].
Safety	We understand safety as one dimension of quality [85]. 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 [86].

Table 2 *Context, key numbers, quality challenges, and regulatory response in the Norwegian specialist healthcare system*

Key numbers
• Four regional health trusts are set to implement the national policies, plan, organize, govern and coordinate all subordinated local health trusts; hospitals in their region [87, 88].

<ul style="list-style-type: none"> • 1,987,263 million patients treated and/or hospitalized in 2019 [89]. • 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 [90].
Management structure
<ul style="list-style-type: none"> • Hospitals should be organized with a responsible manager at all levels [18]. • For each organizational unit in the hospital (e.g. clinic (division or similar), department or equivalent, and sections), there shall be one manager with overall responsibility for the unit, both administratively and professionally [91].
Quality challenges*
<ul style="list-style-type: none"> • Lack of adequate management responsibility and competencies. • Lack of familiarity with- and implementation of the previous regulatory framework for quality and safety management [92] "ICR", 2002). <p>*[9-13, 93].</p>
Regulatory response- the Quality Improvement Regulation
<ul style="list-style-type: none"> • Through the Quality Improvement Regulation, the regulators require hospital organizations to establish a system for risk management- and responsibility. • 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 [70]. • The Quality Improvement Regulation 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 managers in risk management and quality improvement increased significantly with the new Quality Improvement Regulation, specifying managers responsibility for improvement activities.

METHODS

Study design and setting

This study is part of a qualitative, multi-level case study, performed in the Norwegian specialist hospital system. It involves three levels of stakeholders: macro level (governmental bodies of regulation), meso-level (County Governor-regional supervision) and micro-level (hospital management). This article presents the micro-level sub study, which included semi-structured interviews with 20 Norwegian hospital managers and quality advisers.

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 organizations, e.g. head of clinic, head of department, divisional manager. Eighteen out of twenty participants had authorization 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.

Table 3 *Participants’ characteristics**

**M.D.: Medical Doctor, R.N.: Registered Nurse, D.D.S: Doctor of Dental Surgery, P.T: Physiotherapist*

Participant	Educational background*	Position	Organization & 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

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 in the study. Relevant participants were contacted by e-mail; 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 recorded all interviews face-to-face, at the participants’ workplace. Each interview had a duration of approximately 1 hour to 1 hour and 30 minutes. Based on the preplanned semi-structured interview guide (see Supplementary 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 sharp end. Prior to the interviews, the participants received an information sheet informing them about the study's topic, methods and data protection, and were subsequently requested to give their written consent. No pre-existing relationship with any of the participants existed.

Analysis

Researcher SFO analyzed the interview transcripts manually, using content analysis influenced by Graneheim & Lundman [42]. After organizing and analyzing all transcripts into a matrix, 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 [43]. Our data were relatively rich, and we reached saturation during the analysis, justifying the number of participants [44, 45]. We approached the data inductively, and findings were explained and interpreted by using theory linked to adaptive capacity [46-50].

Patient and public involvement

Patients were not involved in this research. However, co-author GSB has a triple-involvement role, having substantial professional governance experience from the Norwegian Board of Health Supervision in addition to currently being senior adviser at a major university hospital, and a university professor. This gives unique insight into the study field and may be considered public involvement both from a national stakeholder- and a hospital perspective.

RESULTS

From our data of twenty interviews, we identified four themes (see Table 4 and Table 5 for illustration of the analytical process and illustrative quotes): (1) Adaptive capacity in hospital management and practice, (2) Implementation efforts and challenges with quality improvement, (3) Systemic changes, (4) Learning for quality improvement and supervision.

Theme I Adaptive capacity in hospital management and practice

Participants agreed on the Quality Improvement Regulation's flexible design, 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 (e.g. postoperative complications, team

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coordination, complex procedures) of variation and uncertainty. Risk-based management was thus characterized as one of the favorable advantages with the new Quality Improvement Regulation, as it encourages managers to asses risks according to specifics and hallmarks in the relevant unit, department, and clinic.

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 will 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 standardizing 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. And 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.

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 to the nursing profession, participants claimed. 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 (e.g. 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).

201 **Theme II Implementation efforts and challenges with quality improvement**

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

207
208 Although PDSA as a method was familiar to the hospitals prior to introducing the Quality
209 Improvement Regulation, several participants argued that the systematic four phase process
210 is not embedded in health personnel's work practice. They described all four phases as equally
211 important but stressed that evaluation and restoring/returning to a normal state are the most
212 demanding to operationalize into reality.

213
214 Participants believed that the Quality Improvement Regulation did not lead to change in
215 clinical practice. Lack of understanding of what was referred to as "internal jargon" in quality
216 improvement and patient safety was believed to add to the burden and responsibilities of
217 managers. However, several quality improvement measures were described, such as double-
218 check of medications, focus on communication in teamwork, reducing the number of hallway
219 patients, questionnaire for patients' satisfaction, preoperative marking, and surgical
220 checklists. The latter was described as the most difficult, yet most successful implementation
221 measure.

222
223 Several participants referred to what they experienced to be a common, yet a false claim: that
224 physicians are not concerned about or involved in quality improvement. A lot of the
225 improvement methodology is present although it is not stated clearly or written down and
226 most physicians do work unconsciously in accordance with the quality improvement
227 methodology, participants reported.

228 **Theme III Systemic changes**

229 Findings revealed both structural and cultural changes to, and development of, quality
230 improvement systems in the hospitals. The structural quality improvement elements were

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described in terms of 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 management levels in hospitals. 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 was felt to be overwhelmingly, and sometimes routines and procedures overlapped or were outdated. 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.

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. 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.

Theme IV Learning for quality improvement and supervision

In order 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 to in previous supervision activities, contributing to the needed sense of confidence to openly discuss adverse events and risks.

In general, organizational 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. And since it is difficult to learn from adverse events, and the time is lacking – they argued that it is difficult to learn from successful outcomes too.

As a response to questions about the interplay between hospitals and supervisory bodies, most participants emphasized 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.

Table 4 *Theme 1 & 2 and categories with illustrative participants' quotes*

THEME	CATEGORY	ILLUSTRATIVE QUOTES FROM PARTICIPANTS
Adaptive capacity in hospital management and practice	The room for maneuver	<p>Medical doctor, head of department (13): The Quality Improvement Regulation gives you room to maneuver because it has a generic design.</p> <p>Medical doctor, head of clinic (11): 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.</p>
	Perceived benefits with adaptation and flexibility to local context	<p>Medical doctor, head of department (12): 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.</p> <p>Medical doctor, adviser in quality and patient safety (18): 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.</p>

	Risk-based management	<p>Oral surgeon, head of clinic (10): I do put quite an amount of responsibility on the unit managers, because they are in the midst of it all and they know where the risks are, and the risks will vary.</p> <p>Medical doctor, head of clinic (4): Sometimes during a review (of an adverse event) things come up that we did not discover prior to the adverse event, so it is important that the analysis team somehow understands the mission of uncovering elements that <i>might</i> be risks. And that is where the competences; skills come into play, because it is great to attend courses; training, but you must really apply it (practically) to become good at it.</p>
	Autonomy	<p>Medical doctor, head of department (12): In any situation, there is usually a captain. And at the end of the day, someone must make a decision.</p> <p>Medical doctor, head of clinic (15): 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 to do this and that”, that approach will not do, they will boycott it.</p> <p>Nurse, head of department (14): 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.</p> <p>Medical doctor, adviser in quality and patient safety (18): 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.</p>
	Variation, uncertainty and risk	<p>Medical doctor, head of clinic (15): What did Schwartzkopf, the general during the Gulf War say? You must always have a plan, and what happens when the war begins? You throw the plan overboard.</p> <p>Medical doctor, head of department (12): I will defend my employees if it turns out that their choice was not right, because it was the best choice based on what they knew at the time of their decision.</p>
THEME	CATEGORY	ILLUSTRATIVE QUOTES FROM PARTICIPANTS
Implementation efforts and challenges with quality improvement	Managers responsibility for implementation	<p>Medical doctor, adviser in quality and patient safety (18): 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”.</p> <p>Nurse, quality adviser (2): Personally, I have always been concerned with- and interested in risk assessments and risk-based management. So, I am very happy that this new Quality Improvement Regulation is somehow clearer with respect to that.</p>
	PDSA- methodology	<p>Oral surgeon, head of clinic (10): We use PDSA a lot in our work, and I just feel that it is another way of looking at the Quality Improvement Regulation.</p> <p>Medical doctor, head of research (9): The extent to which these (PDSA) circles work according to the intention: there are measures</p>

		implemented, and then there is no follow-up of the decisions. There is a total lack of it, I would almost say.
		Nurse, head of quality (6): 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.
	No change in (clinical) practice	Nurse, quality coordinator (5): Some things have been done by the executive level, but the clinic managers have not addressed it.

Table 5 Theme 3 & 4 and categories with illustrative participants' quotes

THEME	CATEGORY	ILLUSTRATIVE QUOTES FROM PARTICIPANTS
Systemic changes	Structural development	<p>Nurse, Head of Quality (20): 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's to the point, 3 pages and it's kind of "this is how we should do it".</p> <p>Medical Director (8): 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.</p> <p>Lawyer, legal adviser in quality and patient safety (3): We have built a new structure of quality and patient safety units.</p> <p>Lawyer, deputy head of clinic (7): 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.</p>
	Cultural development	<p>Medical doctor, head of clinic (15): (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.</p> <p>Medical doctor, adviser in quality and patient safety (18): Today, managers can hardly speak without having to mention the word patient safety. So, it's been an interesting development.</p> <p>Medical doctor, head of department (19): I have experienced a generational shift compared to when I started twenty years ago, and now the hierarchy and structures are less strict and we have more respect for patients as human beings (...) than just fixing technical issues so to speak.</p>
THEME	CATEGORY	ILLUSTRATIVE QUOTES FROM PARTICIPANTS
Learning for quality improvement and supervision	Organizational trust and interpersonal confidence	<p>Medical doctor, head of clinic (15): We are an intellectual organization, right, that is what drives us forward. After all, it is about our minds, so to be able to change things you must get all these minds on board. Otherwise, everything stops.</p> <p>Medical doctor, head of department (19): And I think that in doing quality improvement and patient safety work, we need to recognize 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.</p>

	Challenges with internal- and cross-sectional learning	Head nurse (17): 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.
	Perceptions of external supervision	Medical doctor, head of clinic (15): If you have a written procedure and something happens, then they (red. inspectors) ask: "But why didn't you do that?" Because the anatomy indicated differently (red. physician answers). "But it says in your written procedure that you should do it, right?" That is how a lawyer speaks compared to a physician... Medical doctor, head of department (19): Nothing is better than having someone from the outside looking in. They assess us and we may disagree with their opinions, but we should not disagree with their opinions, we should look for what they evaluate as an adverse event. Not that we made a poor judgment and if we did, they often justify why we made that mistake or where it went wrong. We should learn from it, and that is where the process starts to get exciting.

DISCUSSION

The principal findings

According to the Quality Improvement Regulation, managers are responsible for implementation efforts- and for the use of PDSA-methodology, but participants described no change in (clinical) practice due to this new regulatory framework. However, we did discover structural and cultural changes to, and development of, quality improvement systems in hospitals in recent years, that the Quality Improvement Regulation appears to be part of. Participants described several benefits with 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.

Strengths and limitations of this study

The main strength with the current study is that it is part of a multi-level designed study investigating regulatory quality improvement implementation and work across a healthcare system. It is 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. Here, main attention is given to managers who both legally and practically are responsible for quality improvement. This is a strength when seeking knowledge about practical implications of regulatory changes. An additional strength is that most participants

had substantial clinical experience and/or still worked in the clinic environment, in addition to having management responsibilities. A limitation with this study is that interviews focus on managers own reflections – no actual 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 [42, 51].

Implementation and the capacity to adapt

How the government chooses to tailor healthcare regulation depends on the area: some sectors are strictly governed by prescriptive rules (e.g. medication related issues). The idea with the Quality Improvement Regulation's design 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. As our data revealed, improvisation and local adaptation is viewed as essential, along with an acceptance that healthcare situations such as patient treatment, diagnosis, surgery can develop into unforeseen scenarios which cannot be planned for. Regulatory measures that are too standardized or prescriptive could adversely reduce the autonomy of 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 [50], 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 organizations this 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 [52]. Hence,

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3 331 our study found a paradox in the systemic development of meetings, councils and committees
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5 332 at the administrative- and management levels in hospitals to comply with regulatory
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7 333 requirements for quality and safety, while managers reported few changes at the sharp end.
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9 334 It is reasonable to think that there is a disparity in hospital manager support across different
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11 335 hospitals. Thus, having autonomous responsibility for competences and management
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13 336 training, could in turn lead to different priorities in different regions and hospitals. Variation
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15 337 in support systems and routines was nevertheless reflected in our results.
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19 339 Moreover, previous research has emphasized skills and support to manage conditions of
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21 340 unexpected events, and that managers (due to prioritization struggles) need guidance to
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23 341 understand what is operationally needed [53-55]. Indeed, lack of knowledge and skills is
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25 342 perceived a significant barrier to quality improvement [56, 57]. We argue that our current
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27 343 study demonstrates that the Quality Improvement Regulation’s non-detailed regulatory
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29 344 design, leaving implementation decisions to managers, could complicate managers’
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31 345 understanding of governmental expectations. Especially since the requirements need to be
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33 346 translated before practically applied (e.g. how to define specific hospital-conduct as
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35 347 reasonable; safe; prudent, what is adequate documentation). As successful implementation
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37 348 requires more than a change in regulatory rhetoric, and our study indicates that support tools
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39 349 for managers to achieve the goals in a systematic way, have not been developed. The
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41 350 disjunction between rhetoric and reality, or theory versus practice, is a familiar one in research
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43 351 on implementation of rules and regulations in healthcare. It is often referred to as a dichotomy
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45 352 of work as imagined versus work as done [49, 58]. This applies particularly to how
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47 353 requirements are trickled down the system to get resonance with those who do the actual
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49 354 implementation [35, 38, 39, 59, 60]. When lower level managers fail to implement efforts
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51 355 because they are difficult to convert into practice or that the policies being implemented have
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53 356 a weak relationship with the core clinical tasks, a process of “decoupling” has occurred [38,
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55 357 39]. The study of van de Bovenkamp et al. 2017 [61] revealed that hospitals needed to do a
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57 358 lot of interpretive work to make use of regulation, however autonomy enabled this strategic
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59 359 work. Other studies have shown that additional resources and systems sometimes are needed
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61 360 in order to interpret and implement regulatory requirements [62]. As detailed rules and
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361 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 operationalization 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 [16, 63-67]. 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 [16, 67]. Moving forward, it will be crucial to develop management practices that encourage quality improvement efforts, and encourage health personnel to participate [19, 68]. 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 behavior firsthand [15, 16, 36]. Thus, the “hybrid professional manager” might bridge professional management, clinical identity and engagement, constituting an important system factor underpinning successful quality improvement and implementation [65, 66, 69].

PDSA – government favored methodology for quality improvement

Although the Quality Improvement Regulation manifested the PDSA-logic [70], it did not fully explain why managers should put quality and safety high up on the agenda. Our findings indicated that clinicians worked with quality improvement, but they did not necessarily follow the PDSA-logic nor were familiar with the Quality Improvement Regulation. Moreover, several participants described that measuring improvement efforts was challenging. This may be because PDSA assumes that everything is measurable [71]. In that sense, and alike our study, prior research has found some drawbacks in using PDSA in hospitals' quality improvement work [72-74]. Although the PDSA methodology encourages learning and supports adaptation of interventions, its efficient use requires considerable training and organizational and managerial support [73]. If PDSA is to remain the core of regulatory design, then issues of organizational support and training need to be accounted for by regional health trusts and government budgets. Several alternative quality improvement methodologies exist. For

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3 394 instance *Six Sigma* (define, measure, analyze, improve, control), *Lean* (identify waste;
4 395 activities that do not add value), *Root Cause Analysis* (RCA) (identify the underlying causes;
5 396 reactive in its approach), *Failure Modes and Effect Analysis* (FMEA) (identify potential adverse
6 397 events, failures and hazards; proactive in its approach) [75]. Commonly amongst these
7 398 approaches is that they presuppose identification of a specific problem area or cause(es)
8 399 before the next steps of action might be implemented. This could possibly make one overlook
9 400 certain areas that are not obviously apparent. Thus, based on the contextual reality of hospital
10 401 managers, reflected in our findings about resources and lack of time, we argue that complex,
11 402 non-linear processes are challenged by these methodologies. Moreover, systemic risk factors
12 403 such as resources and time are embedded and often linked and interrelated when an adverse
13 404 event occurs [76-79]. Other organizational design considerations also seem important,
14 405 beyond specific improvement methods. For instance, the inclusion of short, daily breaks to
15 406 facilitate learning episodes may assist in improvement efforts [80]. Organizational adaptations
16 407 such as this could address some of the challenges identified by participants in this study,
17 408 where systematic quality improvement in line with the Quality Improvement Regulation's
18 409 PDSA-logic, was viewed as too time-consuming to justify full scale implementation.

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35 411 **Implications for clinicians and policy makers - and future research**
36 412 This study is of relevance to both regulatory bodies and the management level within
37 413 hospitals, and important for development and implementation of future regulatory
38 414 amendments in a Norwegian and international context. Our results may contribute to
39 415 theoretical development of macro-level regulation, by implying how inclusive governance can
40 416 add value to fill in the gap between work as imagined and work as done and support adaptive
41 417 capacity as a positive element in quality improvement work [50]. Additionally, our study
42 418 highlights regional variation in management training and programs for leadership
43 419 development, which fuels the idea that it will be important to provide a minimum level of
44 420 training to all hospital managers, regardless of organizational level and regional affiliation. Yet,
45 421 there are some unanswered questions that speaks for future research, for instance:

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55 422 • How to provide additional management support for implementation through adding
56 423 “practice facilitators” [53].
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58 424 • How to improve the collaboration between inspectors and hospital managers [81].
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- 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 their experiences in with implementing a new regulatory framework to support quality improvement. Lack of time, competence and/or motivation, appears to limit the implementation of quality improvement efforts. While quality improvement work is not solely dependent on a specific regulatory framework, the Quality Improvement Regulation may be an instrument that, over time, leads to structural and cultural change, and a shift in strategic learning focus and resource allocations. Ultimately, hospital managers' autonomy, adaptive capacity and ability to tailor quality improvement efforts to local circumstances were key for regulatory requirements to have any relevant impact on hospital practice.

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Competing Interests

None declared.

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Contributors

SFO, GSB, CM, and SW designed the study. SFO conducted all interviews and transcribed 11 of these. 9 interviews were transcribed by a consultant. SFO analyzed 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.

Patient and public involvement
Patients were not involved in this research.

Patient consent for publication
Not applicable.

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 participant signed informed consent ahead of the interview.

Data availability statement

Data retrieved from the interviews is not publicly available due to the risk of identification but may be available from the corresponding author upon reasonable request and with permission from the participant(s).

References

1. Francis R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: executive summary: Stationery Office, 2013.

2. Kirkup, B. The Report of the Morecambe Bay Investigation. 2015.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf
3. Slawomirski, L., Auraen, A., Klazinga, N. The economics of patient safety. Strengthening a value-based approach to reducing patient harm at national level. OECD; 2017. <https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf>. Accessed July 9, 2020.
4. Gandhi, T.K., Kaplan, G.S., Leape, L., et al. Transforming concepts in patient safety: a progress report. *BMJ Qual Saf* 2018;27:1019–1026. DOI: 10.1136/bmjqs-2017-007756
5. Norwegian Directorate of Health. In Norwegian: Nasjonal handlingsplan for pasientsikkerhet og kvalitetsforbedring 2019-2023. In English: National action plan for patient safety and quality improvement 2019-2023. Oslo; 2019.
6. Institute of Medicine. To Err is human: building a safer health system. Edited by Kohn L, Corrigan J, Donaldson M. Washington, DC: Institute of Medicine; 2000.
7. Batalden PB, Davidoff F. What is “quality improvement” and how can it transform healthcare? *BMJ Qual Saf* 2007;16:2-3. <https://doi.org/10.1136/qshc.2006.022046>
8. Wears, R. L., Sutcliffe, K. M. Still Not Safe: Patient Safety and the Middle-Managing of American Medicine 1st Edition. Oxford University Press; 2020.
9. Norwegian Board of Health Supervision. In Norwegian: «Mens vi venter» – forsvarlig pasientbehandling i akuttmodtakene? Rapport fra Helsetilsynet 2/2008. In English: Report.
10. Norwegian Board of Health Supervision. In Norwegian: Krevende oppgaver med svak styring. Rapport fra Helsetilsynet 5/2011. In English: Demanding tasks concerning weak management. Report.
11. Norwegian Board of Health Supervision. In Norwegian: Spesialisthelsetjenestens håndtering av henvisninger og utredning av pasienter med tykk- og endetarmskreft. Rapport fra Helsetilsynet 4/2013. In English: Report.
12. Norwegian Ministry of Health and Care Services. Meld. St. 10 (2012–2013) God kvalitet – trygge tjenester. God kvalitet – trygge tjenester — Kvalitet og pasientsikkerhet i helse- og omsorgstjenesten. Ministry of Health and Care Services; 2012.
13. Norwegian Ministry of Health and Care Services. NOU 2015:11. In Norwegian: Med åpne kort. Forebygging og oppfølging av alvorlige hendelser i helse- og omsorgstjenestene. In English: White Paper 2015:11. Departementenes sikkerhets- og serviceorganisasjon. Oslo: Informasjonsforvaltning; 2015. <https://www.regjeringen.no/contentassets/daaed86b64c04f79a2790e87d8bb4576/no/pdfs/nou201520150011000dddpdfs.pdf>.
14. Wiig, S., Ree, E., Johannessen, T., et al Improving quality and safety in nursing homes and home care: the study protocol of a mixed-methods research design to implement a leadership intervention. *BMJ Open*. 2018;8:e020933; doi: 10.1136/bmjopen-2017-020933.
15. Spehar, I., Frich, J.C. & Kjekshus, L.E. Clinicians’ experiences of becoming a clinical manager: a qualitative study. *BMC Health Serv Res* 2012; 12, 421. <https://doi.org/10.1186/1472-6963-12-421>
16. Spehar, I., Frich, J.C. & Kjekshus, L.E. Clinicians in management: a qualitative study of managers’ use of influence strategies in hospitals. *BMC Health Serv Res* 2014; 14, 251. <https://doi.org/10.1186/1472-6963-14-251>
17. Norwegian Ministry of Health and Care. In Norwegian: Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten. FOR-2016-10-28-1250. In English: Regulation on management and quality improvement in the healthcare services. Oslo: Norwegian Ministry of Health and Care Services; 2016. <https://lovdata.no/dokument/SF/forskrift/2016-10-28-1250>. Accessed July 15, 2020.

18. Norwegian Ministry of Health and Care. In Norwegian: *Lov 2. juli 1999 nr. 61 Lov om spesialisthelsetjenesten m.m. (spesialisthelsetjenesteloven)*. In English: Act of 2 July 1999 No. 61 relating to Specialist Health Care Services. Norwegian Ministry of Health and Care Services; 1999. <https://lovdata.no/dokument/NL/lov/1999-07-02-61>. Accessed July 15, 2020.
19. Drew J. R., Pandit, M. Why healthcare leadership should embrace quality improvement. *BMJ* 2020;368:m872 <https://doi.org/10.1136/bmj.m872>
20. Brennan, T. The role of regulation in Quality Improvement. *Milbank Q* 1998;76,4. <https://doi.org/10.1111/1468-0009.00111>
21. Walshe, K. Regulating Healthcare: A Prescription for Improvement? McGraw-Hill Education; 2003.
22. Flodgren, G., Pomey, MP, Taber, SA & Eccles MP. Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes). *Cochrane Database Syst Rev* 2011 Nov 9;(11)
23. Healy, J. Improving Health Care Safety and Quality: Reluctant Regulators. Routledge; 2016.
24. Schaefer, C., Wiig, S. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. *Saf Health* 2017; 3, 3. <https://doi.org/10.1186/s40886-017-0054-9>
25. Hovlid, E., Frich, J. C., Walshe, K., Nilsen, R. M., Flaaten, H. K., Braut, G. S. ...Harthug, S. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. *BMJ Open* 2017;7:e016213. doi: 10.1136/bmjopen-2017-016213
26. Macrae, C. Reconciling regulation and resilience in health care. In: Hollnagel, E., Braithwaite, J., Wears, R.L. editors. *Resilient Health Care*. Ashgate; 2013.
27. Bal, R. Stoopendaal, A., Van de Bovenkamp, H. Resilience and patient safety: how can health care regulations contribute? *Ned Tijdschr Geneeskd* 2015; 159.
28. Stoopendaal, A., de Bree, M., & Robben, P. Reconceptualizing regulation: Formative evaluation of an experiment with System-Based Regulation in Dutch healthcare. *Evaluation* 2016; 22(4), 394–409. <https://doi.org/10.1177/1356389016667889>
29. Berg, S. H, Akerjordet K., Ekstedt, M. & Aase, K. Methodological strategies in resilient health care studies: An integrative review. *Saf Sci* 2018; 110:300–312. <https://doi.org/10.1016/j.ssci.2018.08.025>.
30. Berg, S. H. & Aase, K. Resilient characteristics as described in empirical studies on health care. In: Wiig, S. & Falbruch, B., editors. *Exploring Resilience. A scientific Journey from Practice to Theory*. Springer Open; 2019.
31. Øyri, S., Wiig, S. Regulation and resilience at the macro-level healthcare system – a literature review. Proceedings of the 29th European Safety and Reliability Conference 2019. Editors: Michael Beer and Enrico Zio. doi: 10.3850/978-981-11-2724-3_0075-cd.
32. Wiig, S., Schibevaag, L., Zachrisen, R. N., Hannisdal, E., Anderson, J., Haraldseid-Driftland, C. Next-of-Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part II The Inspectors' Perspective). *J Patient Saf*, Publish Ahead of Print () October 22, 2019;doi: 10.1097/PTS.0000000000000634.
33. Wiig, Siri PhD, MSc*; Haraldseid-Driftland, Cecilie PhD, RN*; Tvete Zachrisen, Rannveig MSc, RN*; Hannisdal, Einar PhD, MD†; Schibevaag, Lene MSc* Next of Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death, *J Patient Saf*: Publish Ahead of Print () October 22, 2019; doi: 10.1097/PTS.0000000000000630

34. Wiig, S., Aase, K., Billett, S. *et al.* Defining the boundaries and operational concepts of resilience in the resilience in healthcare research program. *BMC Health Serv Res* 2020;**20**, 330. <https://doi.org/10.1186/s12913-020-05224-3>
35. Leistikow I, Bal RA. Resilience and regulation, an odd couple? Consequences of Safety-II on governmental regulation of healthcare quality [published online ahead of print, 2020 Mar 30]. *BMJ Qual Saf* 2020;bmjqs-2019-010610. doi:10.1136/bmjqs-2019-010610
36. Grote, G. Leadership in Resilient Organizations. In: Wiig, S. & Falbruch, B., editors. Exploring Resilience. A scientific Journey from Practice to Theory. Springer Open; 2019.
37. Johannesen, D.T.S., Wiig, S. Why adopt ISO 9001 certification in hospitals? A case study of external triggers and sensemaking in an emergency department in Norway. *Saf Health* 2017;3, 7. <https://doi.org/10.1186/s40886-017-0058-5>
38. van de Bovenkamp, H. M, Stoopendaal, A., van de Bochove, M, Bal, R. Tackling the problem of regulatory pressure in Dutch elderly care: The need for recoupling to establish functional rules. *Health Policy* 2020;124; 275-281.
39. de Bree, M., & Stoopendaal, A. De- and Recoupling and Public Regulation. *Organ. Sci*, 2020; 41(5), 599–620. <https://doi.org/10.1177/0170840618800115>
40. Norwegian Ministry of Health and Care Services. In Norwegian: Klarere krav til ledelse. In English: Clearer Management Requirements, 2016: <https://www.regjeringen.no/no/aktuelt/klarere-krav-til-ledelse/id2518180/>. Accessed July 9, 2020.
41. Øyri, S., 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 Serv Res* (2020) Accepted 6th of July, 2020.
42. Graneheim, U. H & Lundman, B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004;24(2):105-12; DOI:10.1016/j.nedt.2003.10.001
43. Yin, R. K. Case Study Research. Design and Methods. SAGE Publications; 2014 (:88).
44. Braun, V. and Clarke, V., Successful Qualitative Research - a practical guide for beginners, SAGE Publications 2013, Thousand Oaks, CA
45. Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., Burroughs, H., & Jinks, C. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*, 2018;52(4), 1893–1907. <https://doi.org/10.1007/s11135-017-0574-8>
46. Braithwaite, J. The Essence of Responsive Regulation. *UBC Law Review* 2011; 44:3 475-520.
47. Hollnagel, E., Braithwaite, J. & Wears, R. L. Resilient Health Care. Ashgate Publishing Limited; 2013:xxv.
48. Hollnagel, E. Safety-I and Safety-II. The Past and Future of Safety Management. CRC Press, Taylor & Francis Group; 2014.
49. Hollnagel, E. Safety-II in Practice. Developing the Resilience Potentials. Routledge; 2018.
50. Anderson, J.E, Ross, A.J., Macrae, C., Wiig, S. Defining adaptive capacity in healthcare: A new framework for researching resilient performance. *Appl Ergon* 87 2020;103111.
51. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual Health Res*. 2016;26(13):1753-1760. doi:10.1177/1049732315617444

52. Størkersen, K., Thorvaldsen, T., Kongsvik, T., Dekker, S. How deregulation can become overregulation: An empirical study into the growth of internal bureaucracy when governments take a step back. *Saf. Sci* 2020; 128. <https://doi.org/10.1016/j.ssci.2020.104772>
53. Olmos-Ochoa TT, Ganz DA, Barnard JM, *et al* Sustaining effective quality improvement: building capacity for resilience in the practice facilitator workforce. *BMJ Qual Saf* 2019;28:1016-1020.
54. Amalberti R, Vincent C. Managing risk in hazardous conditions: improvisation is not enough. *BMJ Qual Saf* 2020;29:60-63.
55. Pimentel MPT, Austin JM, Kachalia A To improve quality, keep your eyes on the road *BMJ Qual Saf* Published Online First: 11 May 2020. doi: 10.1136/bmjqs-2020-011102
56. Wilkinson, J, Powell, A, Davies, H. Are clinicians engaged in quality improvement? A review of the literature on healthcare professionals' views on quality improvement initiatives. The Health Foundation; 2011. Accessed June 30, 2020. <https://www.health.org.uk/publications/are-clinicians-engaged-in-quality-improvement>
57. Dixon-Woods, M, McNicol, S, Martin, G. Overcoming challenges to improving quality. Lessons from the Health Foundation's improvement programme evaluations and relevant literature. 2012. Accessed June 30, 2020. <https://www.health.org.uk/publications/overcoming-challenges-to-improving-quality>
58. Anderson, J.E., Ross, A.J., Back, J. *et al*. Implementing resilience engineering for healthcare quality improvement using the CARE model: a feasibility study protocol. *Pilot Feasibility Stud* 2016;2, 61. doi:10.1186/s40814-016-0103-x
59. Freeman T, Walshe K. Achieving progress through clinical governance? A national study of health care managers' perceptions in the NHS in England *BMJ Quality & Safety* 2004;13:335-343.
60. van Erp, J, Wallenburg, I, Bal, R. Performance regulation in a networked healthcare system: From cosmetic to institutionalized compliance. *Public Admin.* 2020; 98: 46– 61. <https://doi.org/10.1111/padm.12518>
61. van de Bovenkamp, H. M, Stoopendaal, A. & Bal, R. Working with layers: The governance and regulation of healthcare quality in an institutionally layered system. *Public Policy Adm.* 2017;32:45-65; DOI:10.1177/0952076716652934
62. Simon, M.D. Compliance and High Reliability in a Complex Healthcare Organization. *Front Health Serv Manage.* 2018; 34(4):12–25; DOI: 10.1097/HAP.0000000000000030
63. Mintzberg, H. Towards healthier hospitals, *Health Care Manage Rev*, 1997; 22,4:9-18.
64. Ham, C. Improving the performance of health services: the role of clinical leadership, *Lancet*; 2003; 361:1978-80.
65. Fulop L, Day GE. From leader to leadership: clinician managers and where to next? *Aust Health Rev.* 2010;34(3):344-351. doi:10.1071/AH09763
66. Fulop L. Leadership, clinician managers and a thing called "hybridity". *J Health Organ Manag.* 2012;26(4-5):578-604. doi:10.1108/14777261211256927
67. Spehar I, Frich JC, Kjekshus LE. Professional identity and role transitions in clinical managers. *J Health Organ Manag.* 2015;29(3):353-366. doi:10.1108/JHOM-03-2013-0047
68. Soong C, Cho HJ, Shojania KG Choosing quality problems wisely: identifying improvements worth developing and sustaining *BMJ Qual Saf* Published Online First: 29 April 2020. doi: 10.1136/bmjqs-2020-011054
69. Gauld R, Horsburgh S. Healthcare professionals' perceptions of clinical governance implementation: a qualitative New Zealand study of 3205 open-ended survey comments *BMJ Open* 2015;5:e006157. doi: 10.1136/bmjopen-2014-006157
70. Deming, W. E. Out of the crisis, Massachusetts Institute of Technology Center for Advanced Engineering Study; 1986.

71. Taylor MJ, McNicholas C, Nicolay C, *et al.* Systematic review of the application of the plan-do-study-act method to improve quality in healthcare *BMJ Qual Saf* 2014;**23**:290-298.
72. Curnock, E., Ferguson, J., McKay, J., & Bowie, P. Healthcare Improvement and Rapid PDSA Cycles of Change: A Realist Synthesis of the Literature. 2012. https://nes.scot.nhs.uk/media/1389875/pdsa_realist_synthesis.pdf. Accessed July 8, 2020.
73. Reed JE, Card AJ. The problem with Plan-Do-Study-Act cycles *BMJ Quality & Safety* 2016;**25**:147-152.
74. Knudsen, S.V., Laursen, H.V.B., Johnsen, S.P. *et al.* Can quality improvement improve the quality of care? A systematic review of reported effects and methodological rigor in plan-do-study-act projects. *BMC Health Serv Res* 2019;**19**, 683. <https://doi.org/10.1186/s12913-019-4482-6>
75. Hughes, R.G. (ed.). Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008.
76. Reason, J., Understanding adverse events: the human factor. In: Vincent, C. (Eds.), Clinical risk management: enhancing patient safety, Second Edition. BMJ Books, London, UK; 2001.
77. Reason, J., Combating omission errors through task analysis and good reminders. *Qual Saf in Health Care* 2002;**11** (1), 40-44.
78. Hollnagel, E. Barriers and Accident Prevention. Ashgate Publishing Limited, Aldershot, UK; 2004.
79. Cagliano, A., C., Grimaldi, S., Rafele, C. A systemic methodology for risk management in healthcare sector. *Saf Sci* 2011;**49**,5: 695-708. <https://doi.org/10.1016/j.ssci.2011.01.006>
80. Basheer, H, Allwood, B, Lindsell, C-M, Freeth, D, Vaux, E. Never too busy to learn – How the modern team can learn together in the busy workplace. Royal College of Physicians; 2018. Accessed June 30, 2020. file:///C:/Users/2919684/Downloads/Never%20too%20busy%20to%20learn_report%20FINAL_0_0%20(1).pdf
81. Hovlid, E., Teig, I.L., Halvorsen, K. *et al.* Inspecting teams' and organisations' expectations regarding external inspections in health care: a qualitative study. *BMC Health Serv Res* 2020;**20**, 627. <https://doi.org/10.1186/s12913-020-05475-0>
82. Darzi L, Johnson A. High quality care for all: NHS next stage review final report, vol. 7432. London: The Stationery Office; 2008.
83. Rausand, M. & Utne, I. B. Risikoanalyse- teori og metoder. Fagbokforlaget; 2009.
84. Sollid, S. Risikostyring i klinisk medisin. I: Pasientsikkerhet. Teori og praksis. Karina Aase (red.) Universitetsforlaget; 2015.
85. Sheps, S. & Cardiff, K. Looking at Success versus Looking at Failure: Is Quality Safety? Is Safety Quality? In Hollnagel, E., Braithwaite, J. & Wears, R. L. Resilient Health Care. Ashgate Publishing Limited; 2013:xxv.
86. Aven, T., Boyesen, M., Njå, O., Olsen, K. H., Sandve, K. Samfunnssikkerhet. Universitetsforlaget; 2004.
87. Norwegian Ministry of Health and Care. In Norwegian: Lov 15. juni 2001 nr. 93 Lov helseforetak m.m. (*helseforetaksloven*). In English: Act of 15 June 2001 nr. 93 relating to Health Trusts. Oslo: Norwegian Ministry of Health and Care Services; 2001. https://lovdata.no/dokument/NL/lov/2001-06-15-93#KAPITTEL_1. Accessed July 15, 2020.
88. Norwegian Ministry of Health and Care. Oversikt over landets helseforetak. In English: Display of the country's health trusts. Oslo: Ministry of Health and Care Services; 2019. <https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/innsikt/oversikt-over-landets-helseforetak/id485362/>

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89. SSB. In Norwegian: *Statistikkområde. Helse: Pasienter på sykehus*. In English: *Statistics. Health: Patients in hospitals*. 2020. <https://www.ssb.no/helse/statistikker/pasient>. Accessed on the 9th of July, 2020.

90. Morgan, D., Gmeinder, M., Wilkens, J."An OECD analysis of health spending in Norway", *OECD Health Working Papers*, 2017; No. 91, OECD Publishing, Paris, <https://doi.org/10.1787/63302bbf-en>. Accessed on the 9th of July, 2020.

91. Norwegian Ministry of Health and Care Services. In Norwegian: *Lederansvar i sykehus Rundskriv I-2/2013*. In English: *Circular on management in hospitals*. Oslo: Norwegian Ministry of Health and Care Services; 2013.

92. Norwegian Ministry of Health and Care. In Norwegian: *Forskrift om internkontroll i sosial- og helsetjenesten*. FOR-2002-12-20-1731. In English: Internal Control Regulation in the Healthcare Services. Oslo: Norwegian Ministry of Health and Care Services; 2002. <https://lovdata.no/dokument/LTI/forskrift/2002-12-20-1731>. Accessed July 15, 2020.

93. Norwegian Ministry of Health and Care Services. In Norwegian: *Høringsnotat*. In English: *Hearing Memorandum*. Oslo: Ministry of Health and Care Services; 2015.

Supplementary file

Supplementary file 1," Interview guide".

Interview guide

- Please introduce yourself (name, educational- and professional background, current position).
- Are you familiar with the new Quality Improvement Regulation and its content?
- What are the routines for management in terms of the organization's (the unit, department, clinic) continuous safety- and quality improvement work?
- How do you, as a manager, work with quality improvement and safety measures? What are your responsibilities?
- What is quality improvement to you?
- What kind of mandatory management training/courses for planning- and implementation of risk- and safety measures did you go through as a manager?
- If this type of training/courses was attended, what were the learning outcomes do you think?
- How do you understand the requirements for internal control?
- Have you experienced any challenges regarding the implementation of the new Quality Improvement Regulation, if so, what kind of challenges?
- How do you consider the differences between the new Quality Improvement Regulation and the previous Internal Control Regulations?
- How do you consider the Quality Improvement Regulation to provide you with room to maneuver, if you consider it to facilitate that?
- Seen from your perspective, how do you think the new Quality Improvement Regulation facilitates or hampers/hinders flexibility and adaptation in the local improvement work?
- How does the Quality Improvement Regulation facilitate or hamper/hinder learning, seen from your perspective?
- The concept of resilience focuses on the things that turn out successfully, how do you deal with that in your organization?
- What do you regard as the elements determining if the health services you provide are robust?
- The Quality Improvement Regulation consists of four steps of requirements for the organization's activities (to plan, to act, to evaluate and to correct): how do you work with these requirements and steps?
- Due to the Quality Improvement Regulation, you are obliged to have a management system – how do you document that you have such a system?

- Do you consider any parts or specifics in the Quality Improvement Regulation more important than others, if so, what parts?
- Do you feel that the Quality Improvement Regulation (the document) is accessible and comprehensible? Do you have any examples of terms that are difficult to understand?
- Have you ever experienced uncertainty in how you should work with quality improvement, considering what the regulatory framework implies?
- What do you do if you are uncertain about how to deal with the requirements provided in the regulatory framework?
- Do you have any thoughts about being the subject for supervision/inspection?
- In what ways does the collaboration between national and regional inspectors impact hospital management and quality improvement work?
- How did you experience the communication- and information process (provided by the Ministry, the Directorate, the Inspectorate), prior to the Quality Improvement Regulation went into effect?
- Do you have any suggestions for the government bodies in terms of what they could have done differently during the development and implementation of the Quality Improvement Regulation, if so, which suggestions do you have?
- If you were to give input to changes that could supplement the existing legislation, as a manager, which suggestions would you give the government bodies?
- Have you sensed a change in attitude towards quality improvement following the new Quality Improvement Regulation, if that is the case, what sort of changes?
- Are there any internal documents (to support quality improvement and patient safety work), if so, what sort of documents and what is the content?
- How are guideline- and support documents being applied into the quality improvement work?
- In what ways does the Guidelines document associated with the Quality Improvement Regulation, contribute to ease your work?
- Which specific changes in your work practices has the Quality Improvement Regulation contributed to? (If none, why?)
- Looking ahead – how do you expect the new Quality Improvement Regulation to contribute to improve management of quality in your hospital?
- Is there anything we have not talked about yet, that you feel is important to mention?

Revised Standards for Quality Improvement Reporting Excellence

SQUIRE 2.0

Notes to Authors

- The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare.
- The SQUIRE guidelines are intended for reports that describe [system](#) level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the [intervention\(s\)](#).
- A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these.
- Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.
- The SQUIRE Glossary contains definitions of many of the key words in SQUIRE.
- The [Explanation and Elaboration](#) document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item.
- Please cite SQUIRE when it is used to write a manuscript.

Title and Abstract

1. Title

Indicate that the manuscript concerns an [initiative](#) to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)

“Hospital managers’ perspectives with implementing quality improvement measures and a new regulatory framework - a qualitative case study”

Ref. page 1

2. Abstract

a. Provide adequate information to aid in searching and indexing

b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local [problem](#), methods, interventions, results, conclusions

Ref. page 2

Introduction

Why did you start?

3. Problem Description

Nature and significance of the local [problem](#)

Ref. page 2-3

4. Available Knowledge

Summary of what is currently known about the [problem](#), including relevant previous studies

Ref. page 2-3

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5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem , any reasons or assumptions that were used to develop the intervention(s) , and reasons why the intervention(s) was expected to work Ref. page 4
6. Specific Aims	Purpose of the project and of this report Ref. page 4
Methods	<i>What did you do?</i>
7. Context	Contextual elements considered important at the outset of introducing the intervention(s) Ref. page 4
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it Ref. page 5 b. Specifics of the team involved in the work Ref. page 7
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) c. Approach used to establish whether the observed outcomes were due to the intervention(s) N/A
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s) , including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data N/A
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data ref. page 7 b. Methods for understanding variation within the data, including the effects of time as a variable

12. Ethical Considerations

[Ethical aspects](#) of implementing and studying the [intervention\(s\)](#) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest

Ref. page 20

Results

What did you find?

13. Results

- a. Initial steps of the [intervention\(s\)](#) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project
- b. Details of the [process](#) measures and outcome
- c. Contextual elements that interacted with the [intervention\(s\)](#)
- d. Observed associations between outcomes, interventions, and relevant contextual elements
- e. Unintended consequences such as unexpected benefits, [problems](#), failures, or costs associated with the [intervention\(s\)](#).
- f. Details about missing data

ref. page 6-7

Discussion

What does it mean?

14. Summary

- a. Key findings, including relevance to the [rationale](#) and specific aims
- b. Particular strengths of the project

ref. page 2 and page 14

15. Interpretation

- a. Nature of the association between the [intervention\(s\)](#) and the outcomes
- b. Comparison of results with findings from other publications
- c. Impact of the project on people and [systems](#)
- d. Reasons for any differences between observed and anticipated outcomes, including the influence of [context](#)
- e. Costs and strategic trade-offs, including [opportunity costs](#)

ref. page 15-18

16. Limitations

- a. Limits to the [generalizability](#) of the work

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	<p>b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis</p> <p>c. Efforts made to minimize and adjust for limitations</p> <p>ref. page 14</p>
<p><u>17. Conclusions</u></p>	<p>a. Usefulness of the work</p> <p>b. Sustainability</p> <p>c. Potential for spread to other contexts</p> <p>d. Implications for practice and for further study in the field</p> <p>e. Suggested next steps</p> <p>ref. page 19</p>
<p>Other Information</p>	
<p><u>18. Funding</u></p>	<p>Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting</p> <p>Ref. page 19</p>

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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 A multi-level case study. Data was collected by interviews and analyzed 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 organizations.

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. Participants revealed no change in their practice due to the new Quality Improvement Regulation (2). However, we did discover recent structural and cultural changes to, and development of, quality improvement systems in hospitals (3). 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.

Article summary

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.

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INTRODUCTION

After years of regulatory interventions, management strategies and policymaking, 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 which, if addressed, 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 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 organizations are required to ensure their employees have relevant competences and training. Current leadership programs 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].

Table 1 *Definitions and Concepts*

Quality	We adopt the conceptualization introduced by the Institute of Medicine defining quality through six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness, and equity [6, 16].
Regulation	We define the phenomenon of regulation generally as a governmental mechanism and specifically as the Norwegian regulatory framework; regime referred to in this paper 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 [17, 18].
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 [19]. 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” [20].
Safety	We understand safety as one dimension of quality [21]. 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 [22].

Prior research on healthcare regulation and its relation to improvements in organizational behavior, including conduction of external inspection, has shown inconsistent outcomes in terms of its effectiveness [23-28] (See Table 1 for this study’s conceptualization of ‘regulation’ and regulatory activities). Several previous studies have explored healthcare organizations’ resilience potentials, including their capacity to adapt, but to date few *multi-level* studies link adaptive capacity with regulatory activities [29-38]. Others have highlighted that actively engaged participants from all organizational levels in healthcare are important, stressing how active improvement depends on leadership, also in the sense of recognizing conditions that require flexibility [7, 39]. 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 [23, 38-42].

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 organizations 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, 43-44], its impact on the healthcare services is still unknown from all perspectives (regulatory inspectors, hospital managers, 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. Accordingly, this study aims to investigate hospital managers' perspectives on the regulatory development process, implementation efforts and the following work practices, to understand if, and how, the new Quality Improvement Regulation influences 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 five-year "Patient Safety Program "[45-47]. The latter was launched in 2014, as a broad scale effort to reduce patient injuries [46-47]. This Program (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 [46]. 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 [48-53]:

- Lack of adequate management responsibility and competencies.
- Lack of structure to ensure co-workers 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 [54].

Moreover, hospital managers’ attitudes, values and organizational culture for learning were associated with non-compliance with governmental requirements [48-52]. 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. Through the Quality Improvement Regulation, the regulators require hospital organizations 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 [55]. The Quality Improvement Regulation requires hospitals to plan for and establish systems to minimize 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. 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 [56].

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 to the previous Internal Control Regulations, as it (in a separate provision, cf. § 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 two-fold: by explicitly stating managerial

responsibilities it aims at improving managerial practices, whereas the PDSA-methodology aims at organizing the services in ways that improve clinical care.

Table 2 *Details on the Quality Improvement Regulation's regulatory PDSA design* [56]

PDSA-step	Key areas and improvement tasks	Examples of specific activities
The duty to plan	<ul style="list-style-type: none"> 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. 	<p><i>Example 1:</i> identify and discuss deviances reported to the hospital's system for adverse event reporting.</p> <p><i>Example 2:</i> structured identification and analysis of the last 50 mortalities at the relevant hospital, through medical records.</p>
The duty to implement (do)	<ul style="list-style-type: none"> 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 	<p><i>Example 1:</i> conduct a weekly, 15-minute interdisciplinary meeting to visually display ideas for improving the quality in areas where patient complaints exist.</p> <p><i>Example 2:</i> 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.</p>
The duty to evaluate (study)	<ul style="list-style-type: none"> 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 	<p><i>Example 1:</i> corroborate the implemented efforts by using dashboard indicators.</p> <p><i>Example 2:</i> aggregate data from patient complaints about waiting time, to reduce waiting time.</p>
The duty to correct (act)	<ul style="list-style-type: none"> Correct unsound practice and regulatory violations Ensure implementation of systematic quality improvement efforts Improve necessary procedures, instructions, routines to 	<p><i>Example 1:</i> apply small-scale testing to ensure that recent technology and new treatment is efficient.</p> <p><i>Example 2:</i> conduct a Pareto diagram/chart to uncover what causes certain registered issues at the relevant hospital unit.</p>

	reveal, correct violations	
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The Norwegian specialized healthcare system

Four regional health trusts across Norway are responsible for implementing the national policies and regulations, and planning, organizing, governing and coordinating all subordinated local health trusts; including the hospitals in their region (see Table 3 displaying key numbers in the Norwegian specialist healthcare system) [57, 58]. Every hospital should be organized with a responsible manager at all organizational levels [14]. 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 should be appointed [59].

Table 3 *Key numbers in the Norwegian specialist healthcare system*

Key numbers
<ul style="list-style-type: none">• 1,987,263 million patients treated and/or hospitalized in 2019 [60].• 114,028 thousand people employed in the specialist healthcare services in 2018 [61].• 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 [61].• 2667 EUR (27100 NOK) in operating expenses per inhabitant in 2018 [60].

METHODS

Study design and setting

This study is part of a qualitative, multi-level design single embedded case study, investigating regulatory quality improvement implementation- and work across three levels of the specialized Norwegian healthcare system. 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 organizational levels in two health regions. Specifically, the multi-level study involves three levels of stakeholders: macro level (governmental bodies of regulation), meso-level (County Governors’ inspectors-regional supervision) and micro-level (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 micro-level presented in this article is specifically marked.

Figure 1 *The system-levels involved in the multi-level case study*

According to a multilevel approach, different levels of stakeholders have different impact on the risk management process [62]. 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 [63]. Moreover, a multi-level study design can contribute to reflect healthcare organizations as integrated wholes where the patterns among different stakeholders are a key area of investigation [64]. Accordingly, this article presents the *micro-level* sub study, based on semi-structured interviews with 20 Norwegian hospital managers and quality advisers. Macro-level findings and meso-level findings are presented in two separate research articles [see 44 and 65].

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 organizations, e.g. head of clinic, head of department, divisional manager. 18 out of 20 participants had authorization 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 4 for participants' characteristics.

Table 4 *Participants' characteristics**

*M.D.: Medical Doctor, R.N.: Registered Nurse, D.D.S: Doctor of Dental Surgery, P.T: Physiotherapist

Participant	Educational background*	Position	Organization & 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

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 in the study. Relevant participants were contacted by e-mail; 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 minutes. Based on the preplanned semi-structured interview guide (see Supplementary 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, 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 Supplementary 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 analyzed the interview transcripts manually, using content analysis influenced by Graneheim and Lundman, 2004 [66]. This analytical process consisted of several steps. SFO initially read through all interviews and took notes of immediate thoughts that occurred after reading, before organizing all interview transcripts into a matrix. Thereafter, SFO identified and condensed all meaning units, suggested codes and sub-categories. 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 [67]. Our data were relatively rich, and we reached saturation during the analysis, justifying the number of participants [68, 69].

Resilience in healthcare constitutes a valuable framework that helps to understand how systems can function and improve despite disruptions and adverse events [70]. 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* [71,72]. Findings were therefore explained and interpreted by using resilience theory linked to adaptive capacity [18, 72-75]. The data was partly analyzed inductively by identifying concepts within resilience in healthcare and partly deductively by using predetermined questions explicitly exploring resilience potentials [76].

RESULTS

From our data of 20 interviews, we identified four 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 4).

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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 (e.g. postoperative complications, team coordination, complex procedures) of variation and uncertainty. Risk-based management was thus characterized as one of the favorable advantages with the new Quality Improvement Regulation, as it encourages managers to asses 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 will 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 standardizing 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 to the nursing profession, participants claimed. 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 (e.g. 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 prioritize 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".

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3 340 - Medical doctor, adviser in quality and patient safety (18)
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7 342 Although PDSA as a method was familiar to the hospitals prior to introducing the Quality
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9 343 Improvement Regulation, several participants argued that the systematic four phase process
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11 344 is not embedded in health personnel’s work practice. They described all four phases as equally
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13 345 important but stressed that evaluation and restoring/returning to a normal state are the most
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15 346 demanding to operationalize into reality.

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17 347 The extent to which these (PDSA) circles work according to the intention: there are measures
18 348 implemented, and then there is no follow-up of the decisions. There is a total lack of it, I would almost
19 349 say.

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21 350 - Medical doctor, head of research (9)

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24 352 I do not know if I am able to articulate how I work specifically with the four (PDSA) elements (...) because
25 353 it is quite different from one area to the next.

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27 354 - Nurse, head of quality (6)

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29 355 Participants believed that the Quality Improvement Regulation did not lead to change in their
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31 356 practice. Lack of understanding of what was referred to as “internal jargon” in quality
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33 357 improvement and patient safety was believed to add to the burden and responsibilities of
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35 358 managers. However, several quality improvement measures were described, such as double-
36 359 check of medications, focus on communication in teamwork, reducing the number of hallway
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38 360 patients, questionnaire for patients’ satisfaction, preoperative marking, and surgical
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40 361 checklists. The latter was described as the most difficult, yet most successful implementation
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42 362 measure.

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46 364 Several participants referred to what they experienced to be a common, yet a false claim: that
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48 365 physicians are not concerned about or involved in quality improvement. A lot of the
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50 366 improvement methodology is present although it is not stated clearly or written down and
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52 367 most physicians do work unconsciously in accordance with the quality improvement
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54 368 methodology, participants reported.

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56 369 **Theme III Systemic changes**

57 370 Findings revealed both structural and cultural changes to, and development of, quality
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59 371 improvement systems in the hospitals. The structural quality improvement elements were
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described in terms of 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 management levels in hospitals. 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 was felt to be overwhelmingly, and sometimes routines and procedures overlapped or were outdated. 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's to the point, 3 pages and it's 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. 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)

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406 Today, managers can hardly speak without having to mention the word patient safety. So, it's been an
407 interesting development.

408 - Medical doctor, adviser in quality and patient safety (18)

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410 **Theme IV The potential to learn**

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

420
421 And I think that in doing quality improvement and patient safety work, we need to recognize that the
422 number one priority is to ensure that health personnel are confident that they will be taken care of if
423 they make mistakes, and that they find themselves in a system that reduces the number of adverse
424 events to a minimum.

425 - Medical doctor, head of department (19)

426 In general, organizational and individual learning was described as challenging and even more
427 so learning across departments, clinics and between hospitals. Participants explained that it
428 was difficult to learn from adverse events during normal work operations due to time
429 pressures, nor did health personnel always have the motivation to do it. Since it is difficult to
430 learn from adverse events, and the time is lacking – they argued that it is difficult to learn from
431 successful outcomes too. Implementation of the Quality Improvement Regulation did not
432 change this.

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

438 - Head nurse (17)

As a response to questions about the interplay between hospitals and supervisory bodies, most participants emphasized 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 however described no change in their practice (related to quality and safety activities) due to this new regulatory framework. However, we did discover structural and cultural changes to, and development of, quality improvement systems in hospitals in recent years. The Quality Improvement Regulation appears to be part of that systemic development. 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 [62, 77]. This study investigated hospital managers' perspectives and experiences with practical implications of a specific regulatory change. Lower-level implementation of the new regulatory requirements was given main attention in our study.

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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 still 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 [66, 78]. 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 (e.g. medication related issues) [18]. 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 [18]. 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 standardized 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.

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505 However, a high degree of system adaptive capacity could occasionally represent a
506 disadvantage, for instance when a procedure is adjusted but leads to an unsuccessful or
507 unacceptable outcome [75], or regulatory flexibility combined with a lack of interest in quality
508 improvement work allows regulatees to deliberately ignore quality and safety expectations.
509 Moreover, when choices and decisions are left to hospital organizations it creates
510 considerable demand for internal systems to train managers, to establish systems for
511 implementation support and IT-solutions. This is echoed by past research on the growth of
512 internal bureaucracy due to governmental deregulation of safety management [79]. Hence,
513 our study found a paradox in the systemic development of meetings, councils and committees
514 at the administrative- and management levels in hospitals to comply with regulatory
515 requirements for quality and safety, while managers reported few changes at the sharp end;
516 in clinic. It is reasonable to think that there is a disparity in hospital manager support across
517 different hospitals. Thus, having autonomous responsibility for competences and
518 management training, could in turn lead to different priorities in different regions and
519 hospitals. Variation in support systems and routines was nevertheless reflected in our results.

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521 Moreover, previous research has emphasized skills and support to manage conditions of
522 unexpected events, and that managers (due to prioritization struggles) need guidance to
523 understand what is operationally needed [80-82]. Indeed, lack of knowledge and skills is
524 perceived a significant barrier to quality improvement [83, 84]. We argue that our current
525 study demonstrates that the Quality Improvement Regulation's non-detailed regulatory
526 design, leaving implementation decisions to managers, could complicate managers'
527 understanding of governmental expectations. This resonates especially since the
528 requirements need to be translated before practically applied (e.g. how to define specific
529 hospital-conduct as reasonable; safe; prudent or what is adequate documentation). As
530 successful implementation requires more than a change in regulatory rhetoric or design, our
531 study indicates that support tools for managers to achieve the goals in a systematic way have
532 not been fully developed yet. The disjunction between rhetoric and reality, or theory versus
533 practice, is a familiar one in research on implementation of rules and regulations in healthcare.
534 It is often referred to as a dichotomy of work as imagined versus work as done [74, 85]. This

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3 535 applies particularly to how requirements are trickled down the system to get resonance with
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5 536 those who do the actual implementation [38, 41, 42, 86, 87]. When lower level managers fail
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7 537 to implement efforts because they are difficult to convert into practice or that the policies
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9 538 being implemented have a weak relationship with the core clinical tasks, a process of
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11 539 “decoupling” has occurred [41, 42]. The study of van de Bovenkamp and colleagues, 2017 [88]
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13 540 revealed that hospitals needed to do a lot of interpretive work to make use of regulation,
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15 541 however autonomy enabled this strategic work. Other studies have shown that additional
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17 542 resources and systems sometimes are needed to interpret and implement regulatory
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19 543 requirements [89]. As detailed rules and regulations may often be perceived as barriers to
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21 544 implementation, focusing regulatory attention on defining the quality of processes and
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23 545 outcomes could potentially make regulatory expectations more feasible for practical
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25 546 implementation. On the other hand, some hospital managers may find less details less helpful,
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27 547 because most of the responsibility, decisions and operationalization are left with them. What
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29 548 can be drawn from this is that it will be important to consider how regulatory expectations
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31 549 are designed in ways that enable hospital managers to put efforts into practical reality. This
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33 550 implementation gap may also partly be explained by the type of managers who oversee
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35 551 implementation efforts. With different leadership approaches debated in the literature, prior
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37 552 research has identified how clinical managers’ sometimes struggle with role and identity [12,
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39 553 90-94]. Thus, to become interested in management there ought to be awareness of meaning
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41 554 and purpose in management training, as it is first and foremost clinical work that is perceived
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43 555 meaningful to them [12, 94]. Moving forward, it will be crucial to develop management
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45 556 practices that encourage quality improvement efforts, and encourage health personnel to
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47 557 participate [15, 95]. Putting clinicians in management roles, provided with adequate
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49 558 leadership and quality improvement training, is key to making improvement an embedded
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51 559 and inclusive activity in everyday clinical work—especially since clinical managers often have
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53 560 experienced the importance of flexible and adaptive behavior firsthand [11, 12, 39]. Thus, the
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55 561 “hybrid professional manager” might bridge professional management, clinical identity, and
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57 562 engagement, constituting an important system factor underpinning successful quality
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59 563 improvement and implementation [92, 93, 96].

57 564 **PDSA – government favored methodology for quality improvement**
58 565 Although the Quality Improvement Regulation manifested the PDSA-logic [55], it did not fully
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60 566 explain why managers should put quality and safety activities high up on the 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 [97]. In that sense, and alike our study, prior research has found some drawbacks in using PDSA in hospitals' quality improvement work [98-100]. Although the PDSA methodology encourages learning and supports adaptation of interventions, its efficient use requires considerable training and organizational and managerial support [99]. If PDSA is to remain at the core of regulatory design, then issues of organizational 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, analyze, improve, control), *Lean* (identify waste; activities that do not add value), *Root Cause Analysis* (RCA) (identify the underlying causes; reactive in its approach), *Failure Modes and Effect Analysis* (FMEA) (identify potential adverse events, failures and hazards; proactive in its approach) [101]. Commonly amongst 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 [102-105]. Other organizational 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 [106]. Organizational 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 macro-level 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 macro-level 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 [75]. Additionally, our study highlights regional variation in management training and programs 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 organizational 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” [80].
- How to improve the collaboration between inspectors and hospital managers [107].
- 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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Competing Interests

None declared.

Contributors

SFO, GSB, CM, and SW designed the study. SFO conducted all interviews and transcribed 11 of these. 9 interviews were transcribed by a consultant. SFO analyzed 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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18 661 Patient and public involvement
19 662 Patients were not involved in this research. However, co-author GSB has a triple-involvement
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21 663 role, having substantial professional governance experience from the Norwegian Board of
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23 664 Health Supervision in addition to currently being senior adviser at a major university hospital,
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25 665 and a university professor. This gives unique insight into the study field and may be considered
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27 666 public involvement both from a national stakeholder- and a hospital perspective.
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31 668 Patient consent for publication
32 669 Not applicable.
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35 671 Ethics approval and consent to participate
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38 672 The study did not collect specific patient information, thus no approval from The Regional
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40 673 committees for medical and health research ethics was required. Personal data derived from
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42 674 the study's interviews was notified to the Norwegian Centre for Research Data (NSD) (REF.
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44 675 NO: 381276, October 1. 2018), as required in line with the agreement between the University
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46 676 of Stavanger and the NSD. Every participant signed informed consent ahead of the interview.
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51 678 Data availability statement
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54 679 Data retrieved from the interviews is not publicly available due to the risk of identification but
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56 680 may be available from the corresponding author upon reasonable request and with
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58 681 permission from the participant(s).
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References

1. Francis R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: executive summary: Stationery Office, 2013.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf Accessed October 21, 2020.
2. Kirkup, B. The Report of the Morecambe Bay Investigation. 2015.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf Accessed October 21, 2020.
3. Slawomirski, L., Auraaen, A., Klazinga, N. The economics of patient safety. Strengthening a value-based approach to reducing patient harm at national level. OECD; 2017. <https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf>. Accessed July 9, 2020.
4. Gandhi, T.K., Kaplan, G.S., Leape, L., et al. Transforming concepts in patient safety: a progress report. *BMJ Qual Saf* 2018;27:1019–1026. DOI: 10.1136/bmjqs-2017-007756
5. Norwegian Directorate of Health. In Norwegian: Nasjonal handlingsplan for pasientsikkerhet og kvalitetsforbedring 2019-2023. In English: National action plan for patient safety and quality improvement 2019-2023. Oslo; 2019. https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf Accessed October 21, 2020.
6. Institute of Medicine. To Err is human: building a safer health system. Edited by Kohn L, Corrigan J, Donaldson M. Washington, DC: Institute of Medicine; 2000.
7. Batalden PB, Davidoff F. What is “quality improvement” and how can it transform healthcare? *BMJ Qual Saf* 2007;16:2-3. <https://doi.org/10.1136/qshc.2006.022046>
8. Wears, R. L., Sutcliffe, K. M. Still Not Safe: Patient Safety and the Middle-Managing of American Medicine 1st Edition. Oxford University Press; 2020.
9. Botwinick, L., Bisognano, M., Haraden, C. Leadership Guide to Patient Safety. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2006.
https://pasientsikkerhetsprogrammet.no/om-oss/innsatsomrader/ledelse-av-pasientsikkerhet/_attachment/inline/b314ed6c-3767-46c5-a8a8-fc445aa94f68:1ded2e5d159678cf61b9ebb357af4936a3d37c81/ihl-leadership-guide-to-patient-safety.pdf Accessed October 21, 2020.
10. Künzle, B., Kolbe, M., Grote, G. Ensuring patient safety through effective leadership behaviour: A literature review, *Saf Sci*. 2010; 48:1:1-17; doi.org/10.1016/j.ssci.2009.06.004.
11. Spehar, I., Frich, J.C. & Kjekshus, L.E. Clinicians’ experiences of becoming a clinical manager: a qualitative study. *BMC Health Serv Res* 2012; 12, 421. <https://doi.org/10.1186/1472-6963-12-421>
12. Spehar, I., Frich, J.C. & Kjekshus, L.E. Clinicians in management: a qualitative study of managers’ use of influence strategies in hospitals. *BMC Health Serv Res* 2014; 14, 251. <https://doi.org/10.1186/1472-6963-14-251>
13. Norwegian Ministry of Health and Care. In Norwegian: Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten. FOR-2016-10-28-1250. In English: Regulation on management and quality improvement in the healthcare services. Oslo: Norwegian Ministry of Health and Care Services; 2016.
<https://lovdata.no/dokument/SF/forskrift/2016-10-28-1250>. Accessed July 15, 2020.

14. Norwegian Ministry of Health and Care. In Norwegian: *Lov 2. juli 1999 nr. 61 Lov om spesialisthelsetjenesten m.m. (spesialisthelsetjenesteloven)*. In English: Act of 2 July 1999 No. 61 relating to Specialist Health Care Services. Norwegian Ministry of Health and Care Services; 1999. <https://lovdata.no/dokument/NL/lov/1999-07-02-61>. Accessed July 15, 2020.
15. Drew J. R., Pandit, M. Why healthcare leadership should embrace quality improvement. *BMJ* 2020;368:m872 <https://doi.org/10.1136/bmj.m872>
16. Darzi L, Johnson A. High quality care for all: NHS next stage review final report, vol. 7432. London: The Stationery Office; 2008.
17. Hood, C., Rothstein, H. & Baldwin, R. The Government of Risk: Understanding Risk Regulation Regimes. Oxford University Press, 2001.
18. Braithwaite, J. The Essence of Responsive Regulation. *UBC Law Review* 2011; 44:3 475-520.
19. Rausand, M. & Utne, I. B. Risikoanalyse- teori og metoder. Fagbokforlaget; 2009.
20. Sollid, S. Risikostyring i klinisk medisin. I: Pasientsikkerhet. Teori og praksis. Karina Aase (red.) Universitetsforlaget; 2015.
21. Sheps, S. & Cardiff, K. Looking at Success versus Looking at Failure: Is Quality Safety? Is Safety Quality? In Hollnagel, E., Braithwaite, J. & Wears, R. L. Resilient Health Care. Ashgate Publishing Limited; 2013:xxv.
22. Aven, T., Boyesen, M., Njå, O., Olsen, K. H., Sandve, K. Samfunnssikkerhet. Universitetsforlaget; 2004.
23. Brennan, T. The role of regulation in Quality Improvement. *Milbank Q* 1998;76,4. <https://doi.org/10.1111/1468-0009.00111>
24. Walshe, K. Regulating Healthcare: A Prescription for Improvement? McGraw-Hill Education; 2003.
25. Flodgren, G., Pomey, MP, Taber, SA & Eccles MP. Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes). *Cochrane Database Syst Rev* 2011 Nov 9;(11)
26. Healy, J. Improving Health Care Safety and Quality: Reluctant Regulators. Routledge; 2016.
27. Schaefer, C., Wiig, S. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. *Saf Health* 2017; 3, 3. <https://doi.org/10.1186/s40886-017-0054-9>
28. Hovlid, E., Frich, J. C., Walshe, K., Nilsen, R. M., Flaaten, H. K., Braut, G. S. ...Harthug, S. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. *BMJ Open* 2017;7:e016213. doi: 10.1136/bmjopen-2017-016213
29. Macrae, C. Reconciling regulation and resilience in health care. In: Hollnagel, E., Braithwaite, J., Wears, R.L. editors. Resilient Health Care. Ashgate; 2013.
30. Bal, R. Stoopendaal, A., Van de Bovenkamp, H. Resilience and patient safety: how can health care regulations contribute? *Ned Tijdschr Geneeskd* 2015; 159.
31. Stoopendaal, A., de Bree, M., & Robben, P. Reconceptualizing regulation: Formative evaluation of an experiment with System-Based Regulation in Dutch healthcare. *Evaluation* 2016; 22(4), 394–409. <https://doi.org/10.1177/1356389016667889>
32. Berg, S. H, Akerjordet K., Ekstedt, M. & Aase, K. Methodological strategies in resilient health care studies: An integrative review. *Saf Sci* 2018; 110:300–312. <https://doi.org/10.1016/j.ssci.2018.08.025>.
33. Berg, S. H. & Aase, K. Resilient characteristics as described in empirical studies on health care. In: Wiig, S. & Falbruch, B., editors. Exploring Resilience. A scientific Journey from Practice to Theory. Springer Open; 2019.

34. Øyri, S., Wiig, S. Regulation and resilience at the macro-level healthcare system – a literature review. Proceedings of the 29th European Safety and Reliability Conference 2019. Editors: Michael Beer and Enrico Zio. doi: 10.3850/978-981-11-2724-3_0075-cd.
35. Wiig, S., Schibevaag, L., Zachrisen, R. N., Hannisdal, E., Anderson, J., Haraldseid-Driftland, C. Next-of-Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part II The Inspectors' Perspective). *J Patient Saf*, Publish Ahead of Print () October 22, 2019;doi: 10.1097/PTS.0000000000000634.
36. Wiig, Siri PhD, MSc*; Haraldseid-Driftland, Cecilie PhD, RN*; Tvete Zachrisen, Rannveig MSc, RN*; Hannisdal, Einar PhD, MD[†]; Schibevaag, Lene MSc* Next of Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death, *J Patient Saf*: Publish Ahead of Print () October 22, 2019; doi: 10.1097/PTS.0000000000000630
37. Wiig, S., Aase, K., Billett, S. *et al.* Defining the boundaries and operational concepts of resilience in the resilience in healthcare research program. *BMC Health Serv Res* 2020;**20**, 330. <https://doi.org/10.1186/s12913-020-05224-3>
38. Leistikow I, Bal RA. Resilience and regulation, an odd couple? Consequences of Safety-II on governmental regulation of healthcare quality [published online ahead of print, 2020 Mar 30]. *BMJ Qual Saf* 2020;bmjqs-2019-010610. doi:10.1136/bmjqs-2019-010610
39. Grote, G. Leadership in Resilient Organizations. In: Wiig, S. & Falbruch, B., editors. Exploring Resilience. A scientific Journey from Practice to Theory. Springer Open; 2019.
40. Johannesen, D.T.S., Wiig, S. Why adopt ISO 9001 certification in hospitals? A case study of external triggers and sensemaking in an emergency department in Norway. *Saf Health* 2017;3, 7. <https://doi.org/10.1186/s40886-017-0058-5>
41. van de Bovenkamp, H. M, Stoopendaal, A., van de Bochove, M, Bal, R. Tackling the problem of regulatory pressure in Dutch elderly care: The need for recoupling to establish functional rules. *Health Policy* 2020;124; 275–281.
42. de Bree, M., & Stoopendaal, A. De- and Recoupling and Public Regulation. *Organ. Sci*, 2020; 41(5), 599–620. <https://doi.org/10.1177/0170840618800115>
43. Norwegian Ministry of Health and Care Services. In Norwegian: Klarere krav til ledelse. In English: Clearer Management Requirements, 2016: <https://www.regjeringen.no/no/aktuelt/klarere-krav-til-ledelse/id2518180/>. Accessed July 9, 2020.
44. 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 Serv Res* **20**, 762 (2020). <https://doi.org/10.1186/s12913-020-05513-x>
45. Norwegian Directorate of Health. In Norwegian: *Nasjonal strategi for kvalitetsforbedring i sosial- og helsetjenesten ...Og bedre skal det bli! (2005-2015)*. In English: National Strategy for Quality Improvement in Health and Social Services (2005 - 2015). Oslo: Norwegian Directorate of Health; 2005. https://www.helsedirektoratet.no/veiledere/oppfolging-av-personer-med-store-og-sammensatte-behov/metoder-og-verktoy-for-systematisk-kvalitetsforbedring-for-helhetlige-og-koordinerte-tjenester/de-seks-dimensjonene-for-kvalitet-i-tjenestene-er-sentrale-sjekkpunkter-i-forbedringsarbeidet/Og-bedre-skal-det-bli-nasjonal-strategi-for-kvalitetsforbedring-i-sosial-og-helsetjenesten-2005-2015-IS-1162-bokmal.pdf/_/attachment/inline/985d47ad-c5cc-47e4-8e4d-2d3ae1a05bbe:cdbc34628eed68ec59098b3a2f41e0f8a28a44ee/Og-bedre-skal-det-bli-nasjonal-strategi-for-kvalitetsforbedring-i-sosial-og-helsetjenesten-2005-2015-IS-1162-bokmal.pdf Accessed October 25, 2020.
46. Norwegian Ministry of Health and Care Services. In Norwegian: Pasientsikkerhetsprogrammet I trygge hender 24-7. In English: Program for Patient Safety. In Safe Hands 24-7.

- 809 <https://www.regjeringen.no/no/dokumenter/Pasientsikkerhetsprogrammet-I-trygge-hender-24-7/id2005291/>
810 Accessed October 10, 2020.
- 811 47. Deloitte. In Norwegian: Sluttrapport 2019. In English: Evaluation of Program for Patient Safety.
812 [file:///C:/Users/2919684/Downloads/Sluttrapport_Pasientsikkerhetsprogrammet%20\(1\).pdf](file:///C:/Users/2919684/Downloads/Sluttrapport_Pasientsikkerhetsprogrammet%20(1).pdf) Accessed October
813 21, 2020.
- 814 48. Norwegian Board of Health Supervision. In Norwegian: «Mens vi venter» – forsvarlig pasientbehandling i
815 akuttmodtakene? Rapport fra Helsetilsynet 2/2008. In English: Report. <https://www.helsetilsynet.no/historisk-arkiv/rapport-fra-helsetilsynet/2008/forsvarlig-pasientbehandling-oppsummering-landsomfattende-2007-akuttmottak-somatisk-spesialisthelsetjeneste/> Accessed October 21, 2020.
- 818 49. Norwegian Board of Health Supervision. In Norwegian: Krevende oppgaver med svak styring. Rapport fra
819 Helsetilsynet 5/2011. In English: Demanding tasks concerning weak management. Report.
820 <https://www.helsetilsynet.no/publikasjoner/rapport-fra-helsetilsynet/2011/krevende-oppgaver-med-svak-styring-samlerapport-tilsyn-2010/> Accessed October 21, 2020.
- 822 50. Norwegian Board of Health Supervision. In Norwegian: Spesialisthelsetjenestens håndtering av henvisninger
823 og utredning av pasienter med tykk- og endetarmskreft. Rapport fra Helsetilsynet 4/2013. In English: Report.
824 <https://www.helsetilsynet.no/publikasjoner/rapport-fra-helsetilsynet/2013/spesialisthelsetjenestens-handtering-av-henvisninger-og-utredning-av-pasienter-med-tykk--og-endetarmskreft-oppsummering-av-landsomfattende-tilsyn-2012/> Accessed October 21, 2020.
- 827 51. Norwegian Ministry of Health and Care Services. In Norwegian: Meld. St. 10 (2012–2013) God kvalitet –
828 trygge tjenester — Kvalitet og pasientsikkerhet i helse- og omsorgstjenesten. In English: Good quality – safe
829 services – Quality and Patient Safety in the Health and Care Services.
830 <https://www.regjeringen.no/no/dokumenter/meld-st-10-20122013/id709025/> Accessed October 21, 2020.
- 831 52. Norwegian Ministry of Health and Care Services. In Norwegian: *NOU 2015:11. Med åpne kort. Forebygging*
832 *og oppfølging av alvorlige hendelser i helse- og omsorgstjenestene*. In English: *White Paper 2015:11.*
833 Departementenes sikkerhets- og serviceorganisasjon. Oslo: Informasjonsforvaltning; 2015.
834 <https://www.regjeringen.no/contentassets/daaed86b64c04f79a2790e87d8bb4576/no/pdfs/nou201520150011000dddpdfs.pdf> Accessed October 21, 2020.
- 836 53. Norwegian Ministry of Health and Care Services. In Norwegian: *Høringsnotat*. In English: *Hearing*
837 *Memorandum*. Oslo: Ministry of Health and Care Services; 2015.
838 https://www.regjeringen.no/contentassets/5a7d16bae77f4efe8f91af796c6f4b9c/horingsnotat_forskrift_styrin-gssystem-l945587.pdf Accessed October 21, 2020.
- 840 54. Norwegian Ministry of Health and Care. In Norwegian: *Forskrift om internkontroll i sosial- og helsetjenesten*.
841 FOR-2002-12-20-1731. In English: Internal Control Regulation in the Healthcare Services. Oslo: Norwegian
842 Ministry of Health and Care Services; 2002. <https://lovdata.no/dokument/LTI/forskrift/2002-12-20-1731>.
843 Accessed July 15, 2020.
- 844 55. Deming, W. E. Out of the crisis, Massachusetts Institute of Technology Center for Advanced Engineering
845 Study; 1986.
- 846 56. Norwegian Directorate of Health. In Norwegian: *Veileder til forskrift om ledelse og kvalitetsforbedring i*
847 *helse- og omsorgstjenesten*. In English: *Guidelines to Regulation on management and quality improvement in*
848 *the healthcare services*. Oslo: Norwegian Directorate of Health; 2017.
849 <https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten>
850 Accessed October 21, 2020.
- 851 57. Norwegian Ministry of Health and Care. In Norwegian: *Lov 15. juni 2001 nr. 93 Lov helseforetak m.m.*
852 *(helseforetaksloven)*. In English: Act of 15 June 2001 nr. 93 relating to Health Trusts. Oslo: Norwegian Ministry
853 of Health and Care Services; 2001. https://lovdata.no/dokument/NL/lov/2001-06-15-93#KAPITTEL_1. Accessed
854 July 15, 2020.

58. Norwegian Ministry of Health and Care. In Norwegian: Oversikt over landets helseforetak. In English: Display of the country's health trusts. Oslo: Ministry of Health and Care Services; 2019. <https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/innsikt/oversikt-over-landets-helseforetak/id485362/> Accessed October 21, 2020.
59. Norwegian Ministry of Health and Care Services. In Norwegian: *Lederansvar i sykehus Rundskriv I-2/2013*. In English: *Circula on management in hospitals*. Oslo: Norwegian Ministry of Health and Care Services; 2013. Accessed October 21, 2020.
60. SSB. In Norwegian: *Statistikkområde. Helse: Pasienter på sykehus*. In English: *Statistics. Health: Patients in hospitals*. 2020. <https://www.ssb.no/helse/statistikker/pasient>. Accessed July 9, 2020.
61. Morgan, D., Gmeinder, M., Wilkens, J."An OECD analysis of health spending in Norway", *OECD Health Working Papers*, 2017; No. 91, OECD Publishing, Paris, <https://doi.org/10.1787/63302bbf-en>. Accessed July 9, 2020.
62. Rasmussen, J. Risk management in a dynamic society: a modelling problem. *Saf Sci*. 1997;27:183-213; [https://doi.org/10.1016/S0925-7535\(97\)00052-0](https://doi.org/10.1016/S0925-7535(97)00052-0).
63. Diez-Roux, A. V. (2002): A glossary for multilevel analysis. In *J Epidemiol Community Health* 2002;56:588–594.
64. Anderson, R. A., Crabtree, B. F., Steele, D. J., & McDaniel, R. R. (2005): Case Study Research: The View From Complexity Science. In *Qual Health Res*, 15(5), 669–685.
65. 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*. Accepted October 12, 2020.
66. Graneheim, U. H & Lundman, B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004;24(2):105-12; DOI:10.1016/j.nedt.2003.10.001
67. Yin, R. K. Case Study Research. Design and Methods. SAGE Publications; 2014 (:88).
68. Braun, V. and Clarke, V., *Successful Qualitative Research - a practical guide for beginners*, SAGE Publications 2013, Thousand Oaks, CA
69. Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., Burroughs, H., & Jinks, C. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*, 2018;52(4), 1893–1907. <https://doi.org/10.1007/s11135-017-0574-8>
70. Furniss D, Barber N, Lyons I, *et al*. Unintentional non-adherence: can a spoon full of resilience help the medicine go down? *BMJ Qual Saf* 2014;**23**:95-98.
71. Hollnagel, E., Woods, D.D., Leveson, N. editors. *Resilience Engineering: Concepts and Precepts*. Ashgate, Aldershot; 2006.
72. Hollnagel, E., Braithwaite, J. & Wears, R. L. *Resilient Health Care*. Ashgate Publishing Limited; 2013:xxv.
73. Hollnagel, E. *Safety-I and Safety-II. The Past and Future of Safety Management*. CRC Press, Taylor & Francis Group; 2014.
74. Hollnagel, E. *Safety-II in Practice. Developing the Resilience Potentials*. Routledge; 2018.
75. Anderson, J.E, Ross, A.J., Macrae, C., Wiig, S. Defining adaptive capacity in healthcare: A new framework for researching resilient performance. *Appl Ergon* 87 2020;103111.
76. Blaikie, N. *Designing Social Research*. Cambridge: Polity Press; 2010.

1
2
3 894 77. Engen, O. A., Lindøe, P. H. Coping with Globalisation: Robust Regulation and Safety in High-Risk Industries.
4 895 In Jean-Christophe Le Coze. (2020). Safety Science Research: Evolution, Challenges and New Directions. CRC
5 896 Press.
6
7 897 78. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information
8 898 Power. *Qual Health Res.* 2016;26(13):1753-1760. doi:10.1177/1049732315617444
9
10 899 79. Størkersen, K., Thorvaldsen, T., Kongsvik, T., Dekker, S. How deregulation can become overregulation: An
11 900 empirical study into the growth of internal bureaucracy when governments take a step back. *Saf. Sci* 2020; 128.
12 901 <https://doi.org/10.1016/j.ssci.2020.104772>
13 902 80. Olmos-Ochoa TT, Ganz DA, Barnard JM, *et al* Sustaining effective quality improvement: building capacity for
14 903 resilience in the practice facilitator workforce. *BMJ Qual Saf* 2019;28:1016-1020.
15
16 904 81. Amalberti R, Vincent C. Managing risk in hazardous conditions: improvisation is not enough. *BMJ Qual*
17 905 *Saf* 2020;29:60-63.
18
19 906 82. Pimentel MPT, Austin JM, Kachalia A To improve quality, keep your eyes on the road *BMJ Qual Saf* Published
20 907 Online First: 11 May 2020. doi: 10.1136/bmjqs-2020-011102
21
22 908 83. Wilkinson, J, Powell, A, Davies, H. Are clinicians engaged in quality improvement? A review of the literature
23 909 on healthcare professionals' views on quality improvement initiatives. The Health Foundation; 2011. Accessed
24 910 June 30, 2020. <https://www.health.org.uk/publications/are-clinicians-engaged-in-quality-improvement>
25
26 911 84. Dixon-Woods, M, McNicol, S, Martin, G. Overcoming challenges to improving quality. Lessons from the Health
27 912 Foundation's improvement programme evaluations and relevant literature. 2012. Accessed June 30, 2020.
28 913 <https://www.health.org.uk/publications/overcoming-challenges-to-improving-quality>
29
30 914 85. Anderson, J.E., Ross, A.J., Back, J. *et al*. Implementing resilience engineering for healthcare quality
31 915 improvement using the CARE model: a feasibility study protocol. *Pilot Feasibility Stud* 2016;2, 61.
32 916 doi:10.1186/s40814-016-0103-x
33
34 917 86. Freeman T, Walshe K. Achieving progress through clinical governance? A national study of health care
35 918 managers' perceptions in the NHS in England *BMJ Quality & Safety* 2004;13:335-343.
36 919 87. van Erp, J, Wallenburg, I, Bal, R. Performance regulation in a networked healthcare system: From cosmetic to
37 920 institutionalized compliance. *Public Admin.* 2020; 98: 46– 61. <https://doi.org/10.1111/padm.12518>
38
39 921 88. van de Bovenkamp, H. M, Stoopendaal, A. & Bal, R. Working with layers: The governance and regulation of
40 922 healthcare quality in an institutionally layered system. *Public Policy Adm.* 2017;32:45-65;
41 923 DOI:10.1177/0952076716652934
42
43 924 89. Simon, M.D. Compliance and High Reliability in a Complex Healthcare Organization. *Front Health Serv*
44 925 *Manage.* 2018; 34(4):12–25; DOI: 10.1097/HAP.0000000000000030
45 926 90. Mintzberg, H. Towards healthier hospitals, *Health Care Manage Rev*, 1997; 22,4:9-18.
46
47 927 91. Ham, C. Improving the performance of health services: the role of clinical leadership, *Lancet*;
48 928 2003; 361:1978-80.
49
50 929 92. Fulop L, Day GE. From leader to leadership: clinician managers and where to next? *Aust Health Rev.*
51 930 2010;34(3):344-351. doi:10.1071/AH09763
52
53 931 93. Fulop L. Leadership, clinician managers and a thing called "hybridity". *J Health Organ Manag.* 2012;26(4-
54 932 5):578-604. doi:10.1108/14777261211256927
55
56 933 94. Spehar I, Frich JC, Kjekshus LE. Professional identity and role transitions in clinical managers. *J Health Organ*
57 934 *Manag.* 2015;29(3):353-366. doi:10.1108/JHOM-03-2013-0047
58
59 935 95. Soong C, Cho HJ, Shojania KG Choosing quality problems wisely: identifying improvements worth developing
60 936 and sustaining *BMJ Qual Saf* Published Online First: 29 April 2020. doi: 10.1136/bmjqs-2020-011054

96. Gauld R, Horsburgh S. Healthcare professionals' perceptions of clinical governance implementation: a qualitative New Zealand study of 3205 open-ended survey comments *BMJ Open* 2015;5:e006157. doi: 10.1136/bmjopen-2014-006157
97. Taylor MJ, McNicholas C, Nicolay C, *et al.* Systematic review of the application of the plan-do-study-act method to improve quality in healthcare *BMJ Qual Saf* 2014;**23**:290-298.
98. Curnock, E., Ferguson, J., McKay, J., & Bowie, P. Healthcare Improvement and Rapid PDSA Cycles of Change: A Realist Synthesis of the Literature. 2012. https://nes.scot.nhs.uk/media/1389875/pdsa_realist_synthesis.pdf. Accessed July 8, 2020.
99. Reed JE, Card AJ. The problem with Plan-Do-Study-Act cycles *BMJ Quality & Safety* 2016;25:147-152.
100. Knudsen, S.V., Laursen, H.V.B., Johnsen, S.P. *et al.* Can quality improvement improve the quality of care? A systematic review of reported effects and methodological rigor in plan-do-study-act projects. *BMC Health Serv Res* 2019;**19**, 683. <https://doi.org/10.1186/s12913-019-4482-6>
101. Hughes, R.G. (ed.). Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008.
102. Reason, J., Understanding adverse events: the human factor. In: Vincent, C. (Eds.), Clinical risk management: enhancing patient safety, Second Edition. BMJ Books, London, UK; 2001.
103. Reason, J., Combating omission errors through task analysis and good reminders. *Qual Saf in Health Care* 2002;11 (1), 40-44.
104. Hollnagel, E. Barriers and Accident Prevention. Ashgate Publishing Limited, Aldershot, UK; 2004.
105. Cagliano, A., C., Grimaldi, S., Rafele, C. A systemic methodology for risk management in healthcare sector. *Saf Sci* 2011;49,5: 695-708. <https://doi.org/10.1016/j.ssci.2011.01.006>
106. Basheer, H, Allwood, B, Lindsell, C-M, Freeth, D, Vaux, E. Never too busy to learn – How the modern team can learn together in the busy workplace. Royal College of Physicians; 2018. file:///C:/Users/2919684/Downloads/Never%20too%20busy%20to%20learn_report%20FINAL_0_0%20(1).pdf Accessed June 30, 2020.
107. Hovlid, E., Teig, I.L., Halvorsen, K. *et al.* Inspecting teams' and organisations' expectations regarding external inspections in health care: a qualitative study. *BMC Health Serv Res* 2020;**20**, 627. <https://doi.org/10.1186/s12913-020-05475-0>

Supplementary file

Supplementary file 1," Interview guide".



Figure 1 *The system-levels involved in the multi-level case study*

Interview guide

- Please introduce yourself (name, educational- and professional background, current position).
- Are you familiar with the new Quality Improvement Regulation and its content?
- What are the routines for management in terms of the organization's (the unit, department, clinic) continuous safety- and quality improvement work?
- How do you, as a manager, work with quality improvement and safety measures? What are your responsibilities?
- What is quality improvement to you?
- What kind of mandatory management training/courses for planning- and implementation of risk- and safety measures did you go through as a manager?
- If this type of training/courses was attended, what were the learning outcomes do you think?
- How do you understand the requirements for internal control?
- Have you experienced any challenges regarding the implementation of the new Quality Improvement Regulation, if so, what kind of challenges?
- How do you consider the differences between the new Quality Improvement Regulation and the previous Internal Control Regulations?
- How do you consider the Quality Improvement Regulation to provide you with room to maneuver, if you consider it to facilitate that?
- Seen from your perspective, how do you think the new Quality Improvement Regulation facilitates or hampers/hinders flexibility and adaptation in the local improvement work?
- How does the Quality Improvement Regulation facilitate or hamper/hinder learning, seen from your perspective?
- The concept of resilience focuses on the things that turn out successfully, how do you deal with that in your organization?
- What do you regard as the elements determining if the health services you provide are robust?
- The Quality Improvement Regulation consists of four steps of requirements for the organization's activities (to plan, to act, to evaluate and to correct): how do you work with these requirements and steps?
- Due to the Quality Improvement Regulation, you are obliged to have a management system – how do you document that you have such a system?

- Do you consider any parts or specifics in the Quality Improvement Regulation more important than others, if so, what parts?
- Do you feel that the Quality Improvement Regulation (the document) is accessible and comprehensible? Do you have any examples of terms that are difficult to understand?
- Have you ever experienced uncertainty in how you should work with quality improvement, considering what the regulatory framework implies?
- What do you do if you are uncertain about how to deal with the requirements provided in the regulatory framework?
- Do you have any thoughts about being the subject for supervision/inspection?
- In what ways does the collaboration between national and regional inspectors impact hospital management and quality improvement work?
- How did you experience the communication- and information process (provided by the Ministry, the Directorate, the Inspectorate), prior to the Quality Improvement Regulation went into effect?
- Do you have any suggestions for the government bodies in terms of what they could have done differently during the development and implementation of the Quality Improvement Regulation, if so, which suggestions do you have?
- If you were to give input to changes that could supplement the existing legislation, as a manager, which suggestions would you give the government bodies?
- Have you sensed a change in attitude towards quality improvement following the new Quality Improvement Regulation, if that is the case, what sort of changes?
- Are there any internal documents (to support quality improvement and patient safety work), if so, what sort of documents and what is the content?
- How are guideline- and support documents being applied into the quality improvement work?
- In what ways does the Guidelines document associated with the Quality Improvement Regulation, contribute to ease your work?
- Which specific changes in your work practices has the Quality Improvement Regulation contributed to? (If none, why?)
- Looking ahead – how do you expect the new Quality Improvement Regulation to contribute to improve management of quality in your hospital?
- Is there anything we have not talked about yet, that you feel is important to mention?

COREQ (Consolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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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 was collected by interviews and analyzed 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 organizations.

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.

Article summary

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.

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INTRODUCTION

After years of regulatory interventions, management strategies and policymaking, 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 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 organizations are required to ensure their employees have relevant competences and training. Current leadership programs 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].

Table 1 *Definitions and Concepts*

Quality	We adopt the conceptualization introduced by the Institute of Medicine defining quality through six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness, and equity [6, 16].
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 [17, 18].
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 [19]. 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” [20].
Safety	We understand safety as one dimension of quality [21]. 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 [22].

Prior research on healthcare regulation and its relation to improvements in organizational behavior, including conduction of external inspection, has shown inconsistent outcomes in terms of its effectiveness [23-28] (See Table 1 for this study’s conceptualization of ‘regulation’ and regulatory activities). Several previous studies have explored healthcare organizations’ resilience potentials, including their capacity to adapt, but to date few *multilevel* studies link adaptive capacity with regulatory activities [29-38]. Others have highlighted that actively engaged participants from all organizational levels in healthcare are important, stressing how active improvement depends on leadership, also in the sense of recognizing conditions that require flexibility [7, 39]. 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 [23, 38-42].

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 organizations 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, 43-44], 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 organizations 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 [45]. The Quality Improvement Regulation requires hospitals to plan for and establish systems to minimize 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 five-year "Patient Safety Program" [46-48]. The latter was launched in 2014, as a broad scale effort to reduce patient injuries [47-48]. This Program (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 [47]. 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

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3 136 these initiatives, previously conducted external hospital supervision across health-regions in
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5 137 Norway have identified several challenges to systematic quality improvement [49-54]:
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8 138 • Lack of adequate management responsibility and competencies.
9 139 • Lack of structure to ensure co-workers have prudent professional qualifications
10 140 • Lack of systematic collecting of- and evaluation of risks, vulnerabilities, and adverse
11 141 events
12 142 • Lack of implementation of planned work tasks
13 143 • Lack of evaluation of improvement efforts, post-implementation
14 144 • Lack of familiarity with- and implementation of the previous regulatory framework for
15 145 quality and safety management “the Internal Control Regulations”, 2002 [55].
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22 147 Moreover, hospital managers’ attitudes, values and organizational culture for learning were
23 148 associated with non-compliance with governmental requirements [49-53]. These challenges
24 149 and issues associated with implementation of quality improvement measures in hospitals
25 150 formed an important backdrop to the questions that were asked in our study.
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32 152 *Content and design of the Quality Improvement Regulation*
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35 153 The development and enactment of the Quality Improvement Regulation was thus the
36 154 Government’s response to these challenges and launched in parallel with some of the other
37 155 initiatives described above. The regulatory focus on the managerial level and the role of
38 156 managers in risk management and quality improvement increased significantly with the new
39 157 Quality Improvement Regulation compared to the previous Internal Control Regulations, as it
40 158 (in a separate provision, cf. § 3) specifies the managerial responsibility to improve quality. The
41 159 obligation to delegate tasks from one management level to another in daily work operations
42 160 was specified. Moreover, one new substantial provision was added cf. § 8 litra f): The
43 161 obligation to systematically evaluate risk management and quality improvement measures
44 162 (yearly). The Quality Improvement Regulation’s purpose is hence two-fold: by explicitly stating
45 163 managerial responsibilities it aims at improving managerial practices, whereas the PDSA-
46 164 methodology aims at organizing the services in ways that improve clinical care. In Table 2 we
47 165 illustrate details on the Quality Improvement Regulation’s regulatory PDSA design. Two
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specific examples of activities are given for each of the steps, all retrieved from the Guidelines document relating to the Quality Improvement Regulation [56].

Table 2 *Details on the Quality Improvement Regulation's regulatory PDSA design* [55, 56]

PDSA-step	Key areas and improvement tasks	Examples of specific activities
The duty to plan	<ul style="list-style-type: none"> 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. 	<p><i>Example 1:</i> identify and discuss deviances reported to the hospital's system for adverse event reporting.</p> <p><i>Example 2:</i> structured identification and analysis of the last 50 mortalities at the relevant hospital, through medical records.</p>
The duty to implement (do)	<ul style="list-style-type: none"> 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 	<p><i>Example 1:</i> conduct a weekly, 15-minute interdisciplinary meeting to visually display ideas for improving the quality in areas where patient complaints exist.</p> <p><i>Example 2:</i> 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.</p>
The duty to evaluate (study)	<ul style="list-style-type: none"> 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 	<p><i>Example 1:</i> corroborate the implemented efforts by using dashboard indicators.</p> <p><i>Example 2:</i> aggregate data from patient complaints about waiting time, to reduce waiting time.</p>
The duty to correct (act)	<ul style="list-style-type: none"> Correct unsound practice and regulatory violations Ensure implementation of systematic quality improvement efforts Improve necessary procedures, instructions, routines to 	<p><i>Example 1:</i> apply small-scale testing to ensure that recent technology and new treatment is efficient.</p> <p><i>Example 2:</i> conduct a Pareto diagram/chart to uncover what causes certain registered issues at the relevant hospital unit.</p>

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The Norwegian specialized healthcare system

Four regional health trusts across Norway are responsible for implementing the national policies and regulations, and planning, organizing, governing and coordinating all subordinated local health trusts; including the hospitals in their region (see Table 3 displaying key numbers in the Norwegian specialist healthcare system) [57, 58]. Every hospital should be organized with a responsible manager at all organizational levels [14]. 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 should be appointed [59].

Table 3 *Key numbers in the Norwegian specialist healthcare system*

Key numbers
<ul style="list-style-type: none">• 1,987,263 million patients treated and/or hospitalized in 2019 [60].• 114,028 thousand people employed in the specialist healthcare services in 2018 [61].• 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 [61].• 2667 EUR (27100 NOK) in operating expenses per inhabitant in 2018 [60].

METHODS

Study design and setting

This article represents one sub-study 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 specialized Norwegian healthcare system [44, 62]. 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 organizational levels in two health regions. Specifically, the multilevel study involves three levels of stakeholders: macro level (governmental bodies of regulation), meso-level (County Governors’ inspectors-regional supervision) and micro-level (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 micro-level presented in this article is specifically marked.

Figure 1 *The system-levels involved in the multilevel case study*

According to a multilevel approach, different levels of stakeholders have different impact on the risk management process [63]. 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 [64]. Moreover, a multilevel study design can contribute to reflect healthcare organizations as integrated wholes where the patterns among different stakeholders are a key area of investigation [65]. Accordingly, this article presents the *micro-level* sub study, based on semi-structured interviews with 20 Norwegian hospital managers and quality advisers. Macro-level findings and meso-level findings are presented in two separate research articles [see 44 and 62].

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 organizations, e.g. head of clinic, head of department, divisional manager. Out of 20 participants, 18 had authorization 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 4 for participants' characteristics.

Table 4 *Participants' characteristics**

*M.D.: Medical Doctor, R.N.: Registered Nurse, D.D.S: Doctor of Dental Surgery, P.T: Physiotherapist

Participant	Educational background*	Position	Organization & 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

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 meso-level in the broader multilevel study. Relevant participants were contacted by e-mail; 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 minutes. Based on the preplanned semi-structured interview guide (see Supplementary 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 Supplementary 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.

244

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

249 Analysis

250 Researcher SFO analyzed the interview transcripts manually, using content analysis influenced
251 by Graneheim and Lundman, 2004 [66]. This analytical process consisted of several steps. SFO
252 initially read through all interviews and took notes of immediate thoughts that occurred after
253 reading, before organizing all interview transcripts into a matrix. Thereafter, SFO identified
254 and condensed all meaning units, suggested codes, and sub-categories. Four themes emerged
255 across the data. Researchers GBS and SW read all interview transcripts and participated in
256 discussions about categories and themes, to ensure the data's reliability [67]. Our data were
257 relatively rich, and we reached saturation during the analysis, justifying the number of
258 participants [68, 69].

259 Resilience in healthcare constitutes a valuable framework that helps to understand how
260 systems can function and improve despite disruptions and adverse events [70]. A core idea is
261 that resilience is *the ability of the healthcare system to adjust its functioning prior to, during,*
262 *or following changes and disturbances, so that it can sustain required performance under both*
263 *expected and unexpected conditions* [71,72]. Findings were therefore explained and
264 interpreted by using resilience theory linked to adaptive capacity [18, 72-75]. The data was
265 partly analyzed inductively by identifying concepts within resilience in healthcare and partly
266 deductively by using predetermined questions explicitly exploring resilience potentials [76].

267

268 RESULTS

269 From our data of 20 interviews, we identified four themes: (1) Adaptive capacity in hospital
270 management and practice, (2) Implementation efforts and challenges with quality
271 improvement, (3) Systemic changes, and (4) The potential to learn. All four themes are
272 discussed below, along with illustrative participants' quotes (numbers in parentheses indicate
273 the link to participants characteristics, cf. Table 4).

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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 (e.g. postoperative complications, team coordination, complex procedures) of variation and uncertainty. Risk-based management was thus characterized as one of the favorable 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 standardizing 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 to 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 (e.g. 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 prioritize systematic quality improvement efforts. Some even reported that many managers simply do

340 not care about professional management and administering of their unit, department, or
341 clinic.

342 I think that the Quality Improvement Regulation is providing managers with an overall description of
343 how a manager should act. You must do all these things that many people believe are obvious. And the
344 Quality Improvement is kind of “stating the obvious”.

345 - *Medical doctor, adviser in quality and patient safety (18)*

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

352 The extent to which these (PDSA) circles work according to the intention: there are measures
353 implemented, and then there is no follow-up of the decisions. There is a total lack of it, I would almost
354 say.

355 - *Medical doctor, head of research (9)*

356
357 I do not know if I am able to articulate how I work specifically with the four (PDSA) elements (...) because
358 it is quite different from one area to the next.

359 - *Nurse, head of quality (6)*

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

362 Some things have been done by the executive level, but the clinic managers have not addressed it.

363 - *Nurse, quality coordinator (5)*

364 Not directly linked (the introduction of the Quality Improvement Regulation and implementation of
365 practical measures into clinical work). I cannot think of (episodes) where it was like “let us take a look
366 at this (the Quality Improvement Regulation) and then start changing things”.

367 - *Nurse, Head of Quality (20)*

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

374
375 Several participants referred to what they experienced to be a common, yet a false claim: that
376 physicians are not concerned about or involved in quality improvement. A lot of the
377 improvement methodology is present although it is not stated clearly or written down and
378 most physicians do work unconsciously in accordance with the quality improvement
379 methodology, participants reported.

380 **Theme III Systemic changes**

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

386 We have built a new structure of quality and patient safety units.

387 - *Lawyer, legal adviser in quality and patient safety (3)*

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

393 It has been one of the most important things, the system for documentation, and we have been working
394 intensely to clear away old routines, revise all routines and get them updated, especially since our new
395 quality adviser started.

396 - *Lawyer, deputy head of clinic (7)*

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

402 We were probably more mature now in order to get that new Quality Improvement Regulation, and
403 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
404 it".

405 - *Nurse, Head of Quality (20)*

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

409 - Medical Director (8)

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

419 (Quality improvement work) is not entirely new, but quite new. When I started as a surgeon, these
420 were things that never came into view, so it's been a remarkable change, especially over the last ten
421 years.

422 - Medical doctor, head of clinic (15)

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424 Today, managers can hardly speak without having to mention the word patient safety. So, it's been an
425 interesting development.

426 - Medical doctor, adviser in quality and patient safety (18)

427
428 **Theme IV The potential to learn**

429 To maintain high quality care, interpersonal trust among health personnel and institutional
430 trust between hospital managers and governmental supervisory bodies is a necessity,
431 participants argued. Explaining why adverse event reporting was still weak, participants
432 highlighted a safe work environment. Participants felt that a healthy reporting regime
433 emerges from a just culture, which in turn leads health personnel to feel confident that they
434 will be taken care of if they make mistakes and if they report adverse events. Some noted that
435 a systems-perspective to adverse events, supported by the Quality Improvement Regulation,
436 was more frequently applied now compared to in previous supervision activities, contributing
437 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 recognize 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, organizational, 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 organization, 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 emphasized 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 (e.g. annual quality and patient safety reports to the Norwegian Parliament, National Strategy for Quality Improvement in Health and Social Services (2005- 2015) [46], “Patient Safety Program” [47]), also included the revision of the previous Internal Control Regulations into a new regulatory framework [55, 13]. 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 [62, 77]. 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 [44, 62]. 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 still 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 [66, 78]. 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 (e.g. medication related issues) [18]. 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 [18]. 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 standardized 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.

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3 537 However, a high degree of system adaptive capacity could occasionally represent a
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5 538 disadvantage, for instance when a procedure is adjusted but leads to an unsuccessful or
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7 539 unacceptable outcome [75], or regulatory flexibility combined with a lack of interest in quality
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9 540 improvement work allows regulatees to deliberately ignore quality and safety expectations.
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11 541 Moreover, when choices and decisions are left to hospital organizations it creates
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13 542 considerable demand for internal systems to train managers, to establish systems for
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15 543 implementation support and IT-solutions. This is echoed by past research on the growth of
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17 544 internal bureaucracy due to governmental deregulation of safety management [79]. Hence,
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19 545 our study found a paradox in the systemic development of meetings, councils and committees
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21 546 at the administrative- and management levels in hospitals to comply with regulatory
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23 547 requirements for quality and safety, while managers reported few changes at the sharp end;
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25 548 in clinic, related to implementation of quality and safety activities. It is reasonable to think
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27 549 that there is a disparity in hospital manager support across different hospitals. Thus, having
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29 550 autonomous responsibility for competences and management training, could in turn lead to
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31 551 different priorities in different regions and hospitals. Variation in support systems and
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33 552 routines was nevertheless reflected in our results.
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37 554 Moreover, previous research has emphasized skills and support to manage conditions of
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39 555 unexpected events, and that managers (due to prioritization struggles) need guidance to
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41 556 understand what is operationally needed [80-82]. Indeed, lack of knowledge and skills is
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43 557 perceived a significant barrier to quality improvement [83, 84]. We argue that our current
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45 558 study demonstrates that the Quality Improvement Regulation's non-detailed regulatory
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47 559 design, leaving implementation decisions to managers, could complicate managers'
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49 560 understanding of governmental expectations. This resonates especially since the
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51 561 requirements need to be translated before practically applied (e.g. how to define specific
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53 562 hospital-conduct as reasonable; safe; prudent or what is adequate documentation). As
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55 563 successful implementation requires more than a change in regulatory rhetoric or design, our
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57 564 study indicates that support tools for managers to achieve the goals in a systematic way have
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59 565 not been fully developed yet. The disjunction between rhetoric and reality, or theory versus
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566 practice, is a familiar one in research on implementation of rules and regulations in healthcare.
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It is often referred to as a dichotomy of work as imagined versus work as done [74, 85]. This

applies particularly to how requirements are trickled down the system to get resonance with those who do the actual implementation [38, 41, 42, 86, 87]. 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 [41, 42]. The study of van de Bovenkamp and colleagues, 2017 [88] 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 [89]. 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 operationalization 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, 90-94]. 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, 94]. Moving forward, it will be crucial to develop management practices that encourage quality improvement efforts, and encourage health personnel to participate [15, 95]. 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 behavior firsthand [11, 12, 39]. Thus, the “hybrid professional manager” might bridge professional management, clinical identity, and engagement, constituting an important system factor underpinning successful quality improvement and implementation [92, 93, 96].

PDSA – government favored methodology for quality improvement

Although the Quality Improvement Regulation manifested the PDSA-logic [45], it did not independently explain if- and why managers decided to put quality and safety activities on

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600 their agenda. Our findings indicated that clinicians worked with quality improvement, but they
601 did not necessarily follow the PDSA-logic nor were they familiar with the Quality Improvement
602 Regulation. Moreover, several participants described that measuring improvement efforts
603 was challenging. This study links this to the assumption that everything is measurable
604 according to the PDSA-logic [97]. In that sense, and alike our study, prior research has found
605 some drawbacks in using PDSA in hospitals' quality improvement work [98-100]. Although the
606 PDSA methodology encourages learning and supports adaptation of interventions, its efficient
607 use requires considerable training and organizational and managerial support [99]. If PDSA is
608 to remain at the core of regulatory design, then issues of organizational support and training
609 need to be accounted for by regional health trusts and Government budgets.

610
611 Several alternative quality improvement methodologies exist. For instance *Six Sigma* (define,
612 measure, analyze, improve, control), *Lean* (identify waste; activities that do not add value),
613 *Root Cause Analysis* (RCA) (identify the underlying causes; reactive in its approach), *Failure*
614 *Modes and Effect Analysis* (FMEA) (identify potential adverse events, failures and hazards;
615 proactive in its approach) [101]. Commonly amongst these approaches is that they
616 presuppose identification of a specific problem area or cause(es) before the next steps of
617 action might be implemented. This could possibly make managers overlook certain areas that
618 are not obviously apparent. Thus, based on the contextual reality of hospital managers,
619 reflected in our findings about resources and lack of time, we argue that complex, non-linear
620 processes are challenged by these methodologies. Moreover, systemic risk factors such as
621 resources and time are embedded and often linked and interrelated when an adverse event
622 occurs [102-105]. Other organizational design considerations also seem important, beyond
623 specific improvement methods. For instance, the inclusion of short, daily breaks to facilitate
624 learning episodes may assist in improvement efforts [106]. Organizational adaptations such
625 as this could address some of the challenges identified by participants in this study, where
626 systematic quality improvement in line with the Quality Improvement Regulation's PDSA-
627 logic, was viewed as too time-consuming to justify full scale implementation.

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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 macro-level 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 macro-level 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 [75]. Additionally, our study highlights regional variation in management training and programs 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 organizational 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” [80].
- How to improve the collaboration between inspectors and hospital managers [107].
- 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

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3 660 circumstances, were key for the new Quality Improvement Regulation to have any relevant
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5 661 impact on hospital practice and for it to influence quality and safety activities.
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9 663 Acknowledgments
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11 664 The authors express special thanks to the participants for sharing their valuable knowledge
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13 665 and reflections.
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37 675 Competing Interests
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39 676 None declared.
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41 677 Contributors
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43
44 678 SFO, GSB, CM, and SW designed the study. SFO conducted all interviews and transcribed 11
45
46 679 of these. 9 interviews were transcribed by a consultant. SFO analyzed the data, and SW and
47
48 680 GSB read the interview transcripts and discussed categories and themes. SFO drafted the
49
50 681 manuscript. All four authors made critical revisions to the manuscript's scientific content.
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54 682 Authors' Information
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695 Patient and public involvement

696 Patients were not involved in this research. However, co-author GSB has a triple-involvement
697 role, having substantial professional governance experience from the Norwegian Board of
698 Health Supervision in addition to currently being senior adviser at a major university hospital,
699 and a university professor. This gives unique insight into the study field and may be considered
700 public involvement both from a national stakeholder- and a hospital perspective.

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702 Patient consent for publication

703 Not applicable.

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705 Ethics approval and consent to participate

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

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5 712 Data availability statement
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7 713 Data retrieved from the interviews is not publicly available due to the risk of identification but
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9
10 714 may be available from the corresponding author upon reasonable request and with
11
12 715 permission from the participant(s).
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15 716 References
16
17 717 1. Francis R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: executive
18 718 summary: Stationery Office, 2013.
19 719 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf)
20 720 [947.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf) Accessed October 21, 2020.
21
22
23 721 2. Kirkup, B. The Report of the Morecambe Bay Investigation. 2015.
24 722 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/4](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf)
25 723 [7487_MBI_Accessible_v0.1.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf) Accessed October 21, 2020.
26
27 724 3. Slawomirski, L., Auraaen, A., Klazinga, N. The economics of patient safety. Strengthening a value-based
28 725 approach to reducing patient harm at national level. OECD; 2017. [https://www.oecd.org/els/health-](https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf)
29 726 [systems/The-economics-of-patient-safety-March-2017.pdf](https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf). Accessed July 9, 2020.
30
31 727 4. Gandhi, T.K., Kaplan, G.S., Leape, L., et al. Transforming concepts in patient safety: a progress report.
32 728 *BMJ Qual Saf* 2018;27:1019–1026. DOI: 10.1136/bmjqs-2017-007756
33
34
35 729 5. Norwegian Directorate of Health. In Norwegian: Nasjonal handlingsplan for pasientsikkerhet og
36 730 kvalitetsforbedring 2019-2023. In English: National action plan for patient safety and quality improvement 2019-
37 731 2023. Oslo; 2019. [https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-](https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf)
38 732 [omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%20201](https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf)
39 733 [9-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-](https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf)
40 734 [4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsi](https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf)
41 735 [kkerhet%20og%20kvalitetsforbedring%202019-2023.pdf](https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf/_attachment/inline/79c83e08-c6ef-4adc-a29a-4de1fc1fc0ef:94a7c49bf505dd36d59d9bf3de16769bad6c32d5/Nasjonal%20handlingsplan%20for%20pasientsikkerhet%20og%20kvalitetsforbedring%202019-2023.pdf) Accessed October 21, 2020.
42 736
43 736 6. Institute of Medicine. To Err is human: building a safer health system. Edited by Kohn L, Corrigan J, Donaldson
44 737 M. Washington, DC: Institute of Medicine; 2000.
45
46 738 7. Batalden PB, Davidoff F. What is “quality improvement” and how can it transform healthcare? *BMJ Qual*
47 739 *Saf* 2007;16:2-3. <https://doi.org/10.1136/qshc.2006.022046>
48
49 740 8. Wears, R. L., Sutcliffe, K. M. Still Not Safe: Patient Safety and the Middle-Managing of American Medicine 1st
50 741 Edition. Oxford University Press; 2020.
51
52 742 9. Botwinick, L., Bisognano, M., Haraden, C. Leadership Guide to Patient Safety. IHI Innovation Series white
53 743 paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2006.
54 744 [https://pasientsikkerhetsprogrammet.no/om-oss/innsatsomrader/ledelse-av-](https://pasientsikkerhetsprogrammet.no/om-oss/innsatsomrader/ledelse-av-pasientsikkerhet/_attachment/inline/b314ed6c-3767-46c5-a8a8-fc445aa94f68:1ded2e5d159678cf61b9ebb357af4936a3d37c81/ihi-leadership-guide-to-patient-safety.pdf)
55 745 [pasientsikkerhet/_attachment/inline/b314ed6c-3767-46c5-a8a8-](https://pasientsikkerhetsprogrammet.no/om-oss/innsatsomrader/ledelse-av-pasientsikkerhet/_attachment/inline/b314ed6c-3767-46c5-a8a8-fc445aa94f68:1ded2e5d159678cf61b9ebb357af4936a3d37c81/ihi-leadership-guide-to-patient-safety.pdf)
56 746 [fc445aa94f68:1ded2e5d159678cf61b9ebb357af4936a3d37c81/ihi-leadership-guide-to-patient-safety.pdf](https://pasientsikkerhetsprogrammet.no/om-oss/innsatsomrader/ledelse-av-pasientsikkerhet/_attachment/inline/b314ed6c-3767-46c5-a8a8-fc445aa94f68:1ded2e5d159678cf61b9ebb357af4936a3d37c81/ihi-leadership-guide-to-patient-safety.pdf)
57 747 [Accessed October 21, 2020.](https://pasientsikkerhetsprogrammet.no/om-oss/innsatsomrader/ledelse-av-pasientsikkerhet/_attachment/inline/b314ed6c-3767-46c5-a8a8-fc445aa94f68:1ded2e5d159678cf61b9ebb357af4936a3d37c81/ihi-leadership-guide-to-patient-safety.pdf)
58
59
60

10. Künzle, B., Kolbe, M., Grote, G. Ensuring patient safety through effective leadership behaviour: A literature review, *Saf Sci.* 2010; 48:1:1-17; doi.org/10.1016/j.ssci.2009.06.004.
11. Spehar, I., Frich, J.C. & Kjekshus, L.E. Clinicians' experiences of becoming a clinical manager: a qualitative study. *BMC Health Serv Res* 2012; 12, 421. <https://doi.org/10.1186/1472-6963-12-421>
12. Spehar, I., Frich, J.C. & Kjekshus, L.E. Clinicians in management: a qualitative study of managers' use of influence strategies in hospitals. *BMC Health Serv Res* 2014; **14**, 251. <https://doi.org/10.1186/1472-6963-14-251>
13. Norwegian Ministry of Health and Care. In Norwegian: *Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten*. FOR-2016-10-28-1250. In English: Regulation on management and quality improvement in the healthcare services. Oslo: Norwegian Ministry of Health and Care Services; 2016. <https://lovdata.no/dokument/SF/forskrift/2016-10-28-1250>. Accessed July 15, 2020.
14. Norwegian Ministry of Health and Care. In Norwegian: *Lov 2. juli 1999 nr. 61 Lov om spesialisthelsetjenesten m.m. (spesialisthelsetjenesteloven)*. In English: Act of 2 July 1999 No. 61 relating to Specialist Health Care Services. Norwegian Ministry of Health and Care Services; 1999. <https://lovdata.no/dokument/NL/lov/1999-07-02-61>. Accessed July 15, 2020.
15. Drew J. R., Pandit, M. Why healthcare leadership should embrace quality improvement. *BMJ* 2020;368:m872 <https://doi.org/10.1136/bmj.m872>
16. Darzi L, Johnson A. High quality care for all: NHS next stage review final report, vol. 7432. London: The Stationery Office; 2008.
17. Hood, C., Rothstein, H. & Baldwin, R. The Government of Risk: Understanding Risk Regulation Regimes. Oxford University Press, 2001.
18. Braithwaite, J. The Essence of Responsive Regulation. *UBC Law Review* 2011; 44:3 475-520.
19. Rausand, M. & Utne, I. B. Risikoanalyse- teori og metoder. Fagbokforlaget; 2009.
20. Sollid, S. Risikostyring i klinisk medisin. I: Pasientsikkerhet. Teori og praksis. Karina Aase (red.) Universitetsforlaget; 2015.
21. Sheps, S. & Cardiff, K. Looking at Success versus Looking at Failure: Is Quality Safety? Is Safety Quality? In Hollnagel, E., Braithwaite, J. & Wears, R. L. Resilient Health Care. Ashgate Publishing Limited; 2013:xxv.
22. Aven, T., Boyesen, M., Njå, O., Olsen, K. H., Sandve, K. Samfunnssikkerhet. Universitetsforlaget; 2004.
23. Brennan, T. The role of regulation in Quality Improvement. *Milbank Q* 1998;76,4. <https://doi.org/10.1111/1468-0009.00111>
24. Walshe, K. Regulating Healthcare: A Prescription for Improvement? McGraw-Hill Education; 2003.
25. Flodgren, G., Pomey, MP, Taber, SA & Eccles MP. Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes). *Cochrane Database Syst Rev* 2011 Nov 9;(11)
26. Healy, J. Improving Health Care Safety and Quality: Reluctant Regulators. Routledge; 2016.
27. Schaefer, C., Wiig, S. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. *Saf Health* 2017; 3, 3. <https://doi.org/10.1186/s40886-017-0054-9>
28. Hovlid, E., Frich, J. C., Walshe, K., Nilsen, R. M., Flaaten, H. K., Braut, G. S. ...Harthug, S. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. *BMJ Open* 2017;7:e016213. doi: 10.1136/bmjopen-2017-016213

29. Macrae, C. Reconciling regulation and resilience in health care. In: Hollnagel, E., Braithwaite, J., Wears, R.L. editors. *Resilient Health Care*. Ashgate; 2013.
30. Bal, R. Stoopendaal, A., Van de Bovenkamp, H. Resilience and patient safety: how can health care regulations contribute? *Ned Tijdschr Geneeskd* 2015; 159.
31. Stoopendaal, A., de Bree, M., & Robben, P. Reconceptualizing regulation: Formative evaluation of an experiment with System-Based Regulation in Dutch healthcare. *Evaluation* 2016; 22(4), 394–409. <https://doi.org/10.1177/1356389016667889>
32. Berg, S. H, Akerjordet K., Ekstedt, M. & Aase, K. Methodological strategies in resilient health care studies: An integrative review. *Saf Sci* 2018; 110:300–312. <https://doi.org/10.1016/j.ssci.2018.08.025>.
33. Berg, S. H. & Aase, K. Resilient characteristics as described in empirical studies on health care. In: Wiig, S. & Falbruch, B., editors. *Exploring Resilience. A scientific Journey from Practice to Theory*. Springer Open; 2019.
34. Øyri, S., Wiig, S. Regulation and resilience at the macro-level healthcare system – a literature review. *Proceedings of the 29th European Safety and Reliability Conference 2019*. Editors: Michael Beer and Enrico Zio. doi: 10.3850/978-981-11-2724-3_0075-cd.
35. Wiig, S., Schibevaag, L., Zachrisen, R. N., Hannisdal, E., Anderson, J., Haraldseid-Driftland, C. Next-of-Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part II The Inspectors' Perspective). *J Patient Saf*, Publish Ahead of Print () October 22, 2019;doi: 10.1097/PTS.0000000000000634.
36. Wiig, Siri PhD, MSc*; Haraldseid-Driftland, Cecilie PhD, RN*; Tvete Zachrisen, Rannveig MSc, RN*; Hannisdal, Einar PhD, MD†; Schibevaag, Lene MSc* Next of Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death, *J Patient Saf*: Publish Ahead of Print () October 22, 2019; doi: 10.1097/PTS.0000000000000630
37. Wiig, S., Aase, K., Billett, S. *et al*. Defining the boundaries and operational concepts of resilience in the resilience in healthcare research program. *BMC Health Serv Res* 2020;20, 330. <https://doi.org/10.1186/s12913-020-05224-3>
38. Leistikow I, Bal RA. Resilience and regulation, an odd couple? Consequences of Safety-II on governmental regulation of healthcare quality [published online ahead of print, 2020 Mar 30]. *BMJ Qual Saf* 2020;bmjqs-2019-010610. doi:10.1136/bmjqs-2019-010610
39. Grote, G. Leadership in Resilient Organizations. In: Wiig, S. & Falbruch, B., editors. *Exploring Resilience. A scientific Journey from Practice to Theory*. Springer Open; 2019.
40. Johannesen, D.T.S., Wiig, S. Why adopt ISO 9001 certification in hospitals? A case study of external triggers and sensemaking in an emergency department in Norway. *Saf Health* 2017;3, 7. <https://doi.org/10.1186/s40886-017-0058-5>
41. van de Bovenkamp, H. M, Stoopendaal, A., van de Bochove, M, Bal, R. Tackling the problem of regulatory pressure in Dutch elderly care: The need for recoupling to establish functional rules. *Health Policy* 2020;124; 275-281.
42. de Bree, M., & Stoopendaal, A. De- and Recoupling and Public Regulation. *Organ. Sci*, 2020; 41(5), 599–620. <https://doi.org/10.1177/0170840618800115>
43. Norwegian Ministry of Health and Care Services. In Norwegian: Klarere krav til ledelse. In English: Clearer Management Requirements, 2016: <https://www.regjeringen.no/no/aktuelt/klarere-krav-til-ledelse/id2518180/>. Accessed July 9, 2020.

44. 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 Serv Res* **20**, 762 (2020). <https://doi.org/10.1186/s12913-020-05513-x>
45. Deming, W. E. Out of the crisis, Massachusetts Institute of Technology Center for Advanced Engineering Study; 1986.
46. Norwegian Directorate of Health. In Norwegian: *Nasjonal strategi for kvalitetsforbedring i sosial- og helsetjenesten ...Og bedre skal det bli! (2005-2015)*. In English: National Strategy for Quality Improvement in Health and Social Services (2005 - 2015). Oslo: Norwegian Directorate of Health; 2005. https://www.helsedirektoratet.no/veiledere/oppfolging-av-personer-med-store-og-sammensatte-behov/metoder-og-verktoy-for-systematisk-kvalitetsforbedring-for-helhetlige-og-koordinerte-tjenester/de-seks-dimensjonene-for-kvalitet-i-tjenestene-er-sentrale-sjekkpunkter-i-forbedringsarbeidet/Og-bedre-skal-det-bli-nasjonal-strategi-for-kvalitetsforbedring-i-sosial-og-helsetjenesten-2005-2015-IS-1162-bokmal.pdf/_attachment/inline/985d47ad-c5cc-47e4-8e4d-2d3ae1a05bbe:cdbc34628eed68ec59098b3a2f41e0f8a28a44ee/Og-bedre-skal-det-bli-nasjonal-strategi-for-kvalitetsforbedring-i-sosial-og-helsetjenesten-2005-2015-IS-1162-bokmal.pdf Accessed October 25, 2020.
47. Norwegian Ministry of Health and Care Services. In Norwegian: Pasientsikkerhetsprogrammet I trygge hender 24-7. In English: Program for Patient Safety. In Safe Hands 24-7. <https://www.regjeringen.no/no/dokumenter/Pasientsikkerhetsprogrammet-I-trygge-hender-24-7/id2005291/> Accessed October 10, 2020.
48. Deloitte. In Norwegian: Sluttrapport 2019. In English: Evaluation of Program for Patient Safety. [file:///C:/Users/2919684/Downloads/Sluttrapport_Pasientsikkerhetsprogrammet%20\(1\).pdf](file:///C:/Users/2919684/Downloads/Sluttrapport_Pasientsikkerhetsprogrammet%20(1).pdf) Accessed October 21, 2020.
49. Norwegian Board of Health Supervision. In Norwegian: «Mens vi venter» – forsvarlig pasientbehandling i akuttmottakene? Rapport fra Helsetilsynet 2/2008. In English: Report. <https://www.helsetilsynet.no/historisk-arkiv/rapport-fra-helsetilsynet/2008/forsvarlig-pasientbehandling-oppsummering-landsomfattende-2007-akuttmottak-somatisk-spesialisthelsetjeneste/> Accessed October 21, 2020.
50. Norwegian Board of Health Supervision. In Norwegian: Krevende oppgaver med svak styring. Rapport fra Helsetilsynet 5/2011. In English: Demanding tasks concerning weak management. Report. <https://www.helsetilsynet.no/publikasjoner/rapport-fra-helsetilsynet/2011/krevende-oppgaver-med-svak-styring-samlerapport-tilsyn-2010/> Accessed October 21, 2020.
51. Norwegian Board of Health Supervision. In Norwegian: Spesialisthelsetjenestens håndtering av henvisninger og utredning av pasienter med tykk- og endetarmskreft. Rapport fra Helsetilsynet 4/2013. In English: Report. <https://www.helsetilsynet.no/publikasjoner/rapport-fra-helsetilsynet/2013/spesialisthelsetjenestens-handtering-av-henvisninger-og-utredning-av-pasienter-med-tykk-og-endetarmskreft-oppsummering-av-landsomfattende-tilsyn-2012/> Accessed October 21, 2020.
52. Norwegian Ministry of Health and Care Services. In Norwegian: Meld. St. 10 (2012–2013) God kvalitet – trygge tjenester – Kvalitet og pasientsikkerhet i helse- og omsorgstjenesten. In English: Good quality – safe services – Quality and Patient Safety in the Health and Care Services. <https://www.regjeringen.no/no/dokumenter/meld-st-10-20122013/id709025/> Accessed October 21, 2020.
53. Norwegian Ministry of Health and Care Services. In Norwegian: *NOU 2015:11. Med åpne kort. Forebygging og oppfølging av alvorlige hendelser i helse- og omsorgstjenestene*. In English: *White Paper 2015:11. Departementenes sikkerhets- og serviceorganisasjon*. Oslo: Informasjonsforvaltning; 2015. <https://www.regjeringen.no/contentassets/daaed86b64c04f79a2790e87d8bb4576/no/pdfs/nou201520150011000dddpdfs.pdf> Accessed October 21, 2020.
54. Norwegian Ministry of Health and Care Services. In Norwegian: *Høringsnotat*. In English: *Hearing Memorandum*. Oslo: Ministry of Health and Care Services; 2015. https://www.regjeringen.no/contentassets/5a7d16bae77f4efe8f91af796c6f4b9c/horingsnotat_forskrift_styrin_gssystem-l945587.pdf Accessed October 21, 2020.

- 876 55. Norwegian Ministry of Health and Care. In Norwegian: *Forskrift om internkontroll i sosial- og helsetjenesten*.
877 FOR-2002-12-20-1731. In English: Internal Control Regulation in the Healthcare Services. Oslo: Norwegian
878 Ministry of Health and Care Services; 2002. <https://lovdata.no/dokument/LTI/forskrift/2002-12-20-1731>.
879 Accessed July 15, 2020.
- 880 56. Norwegian Directorate of Health. In Norwegian: *Veileder til forskrift om ledelse og kvalitetsforbedring i*
881 *helse- og omsorgstjenesten*. In English: *Guidelines to Regulation on management and quality improvement in*
882 *the healthcare services*. Oslo: Norwegian Directorate of Health; 2017.
883 <https://www.helsedirektoratet.no/veiledere/ledelse-og-kvalitetsforbedring-i-helse-og-omsorgstjenesten>
884 Accessed October 21, 2020.
- 885 57. Norwegian Ministry of Health and Care. In Norwegian: *Lov 15. juni 2001 nr. 93 Lov helseforetak m.m.*
886 *(helseforetaksloven)*. In English: Act of 15 June 2001 nr. 93 relating to Health Trusts. Oslo: Norwegian Ministry
887 of Health and Care Services; 2001. https://lovdata.no/dokument/NL/lov/2001-06-15-93#KAPITTEL_1. Accessed
888 July 15, 2020.
- 889 58. Norwegian Ministry of Health and Care. In Norwegian: Oversikt over landets helseforetak. In English:
890 Display of the country's health trusts. Oslo: Ministry of Health and Care Services; 2019.
891 [https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/innsikt/oversikt-over-landets-](https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/innsikt/oversikt-over-landets-helseforetak/id485362/)
892 [helseforetak/id485362/](https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/innsikt/oversikt-over-landets-helseforetak/id485362/) Accessed October 21, 2020.
- 893 59. Norwegian Ministry of Health and Care Services. In Norwegian: *Lederansvar i sykehus Rundskriv I-2/2013*. In
894 English: *Circula on management in hospitals*. Oslo: Norwegian Ministry of Health and Care Services; 2013.
895 Accessed October 21, 2020.
- 896 60. SSB. In Norwegian: *Statistikkområde. Helse: Pasienter på sykehus*. In English: *Statistics. Health: Patients in*
897 *hospitals*. 2020. <https://www.ssb.no/helse/statistikker/pasient>. Accessed July 9, 2020.
- 898 61. Morgan, D., Gmeinder, M., Wilkens, J. "An OECD analysis of health spending in Norway", *OECD Health*
899 *Working Papers*, 2017; No. 91, OECD Publishing, Paris, <https://doi.org/10.1787/63302bbf-en>. Accessed July 9,
900 2020.
- 901 62. Øyri, S.F., Braut, G.S., Macrae, C., Wiig, S. Investigating hospital supervision: a case study of regulatory
902 inspectors' roles as potential co-creators of resilience. *Journal of Patient Safety*. Accepted October 12, 2020.
- 903 63. Rasmussen, J. Risk management in a dynamic society: a modelling problem. *Saf Sci*. 1997;27:183-213;
904 [https://doi.org/10.1016/S0925-7535\(97\)00052-0](https://doi.org/10.1016/S0925-7535(97)00052-0).
- 905 64. Diez-Roux, A. V. (2002): A glossary for multilevel analysis. In *J Epidemiol Community Health* 2002;56:588–
906 594.
- 907 65. Anderson, R. A., Crabtree, B. F., Steele, D. J., & McDaniel, R. R. (2005): Case Study Research: The View From
908 Complexity Science. In *Qual Health Res*, 15(5), 669–685.
- 909 66. Graneheim, U. H & Lundman, B. Qualitative content analysis in nursing research: concepts, procedures and
910 measures to achieve trustworthiness. *Nurse Educ Today* 2004;24(2):105-12; DOI:10.1016/j.nedt.2003.10.001
- 911 67. Yin, R. K. Case Study Research. Design and Methods. SAGE Publications; 2014 (:88).
- 912 68. Braun, V. and Clarke, V., Successful Qualitative Research - a practical guide for beginners, SAGE Publications
913 2013, Thousand Oaks, CA
- 914 69. Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., Burroughs, H., & Jinks, C. Saturation
915 in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*, 2018;52(4), 1893–
916 1907. <https://doi.org/10.1007/s11135-017-0574-8>
- 917 70. Furniss D, Barber N, Lyons I, et al. Unintentional non-adherence: can a spoon full of resilience help the
918 medicine go down? *BMJ Qual Saf* 2014;23:95-98.

71. Hollnagel, E., Woods, D.D., Leveson, N. editors. *Resilience Engineering: Concepts and Precepts*. Ashgate, Aldershot; 2006.
72. Hollnagel, E., Braithwaite, J. & Wears, R. L. *Resilient Health Care*. Ashgate Publishing Limited; 2013:xxv.
73. Hollnagel, E. *Safety-I and Safety-II. The Past and Future of Safety Management*. CRC Press, Taylor & Francis Group; 2014.
74. Hollnagel, E. *Safety-II in Practice. Developing the Resilience Potentials*. Routledge; 2018.
75. Anderson, J.E, Ross, A.J., Macrae, C., Wiig, S. Defining adaptive capacity in healthcare: A new framework for researching resilient performance. *Appl Ergon* 87 2020;103111.
76. Blaikie, N. *Designing Social Research*. Cambridge: Polity Press; 2010.
77. Engen, O. A., Lindøe, P. H. Coping with Globalisation: Robust Regulation and Safety in High-Risk Industries. In Jean-Christophe Le Coze. (2020). *Safety Science Research: Evolution, Challenges and New Directions*. CRC Press.
78. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual Health Res*. 2016;26(13):1753-1760. doi:10.1177/1049732315617444
79. Størkersen, K., Thorvaldsen, T., Kongsvik, T., Dekker, S. How deregulation can become overregulation: An empirical study into the growth of internal bureaucracy when governments take a step back. *Saf. Sci* 2020; 128. <https://doi.org/10.1016/j.ssci.2020.104772>
80. Olmos-Ochoa TT, Ganz DA, Barnard JM, *et al* Sustaining effective quality improvement: building capacity for resilience in the practice facilitator workforce. *BMJ Qual Saf* 2019;28:1016-1020.
81. Amalberti R, Vincent C. Managing risk in hazardous conditions: improvisation is not enough. *BMJ Qual Saf* 2020;29:60-63.
82. Pimentel MPT, Austin JM, Kachalia A To improve quality, keep your eyes on the road *BMJ Qual Saf* Published Online First: 11 May 2020. doi: 10.1136/bmjqs-2020-011102
83. Wilkinson, J, Powell, A, Davies, H. Are clinicians engaged in quality improvement? A review of the literature on healthcare professionals' views on quality improvement initiatives. The Health Foundation; 2011. Accessed June 30, 2020. <https://www.health.org.uk/publications/are-clinicians-engaged-in-quality-improvement>
84. Dixon-Woods, M, McNicol, S, Martin, G. Overcoming challenges to improving quality. Lessons from the Health Foundation's improvement programme evaluations and relevant literature. 2012. Accessed June 30, 2020. <https://www.health.org.uk/publications/overcoming-challenges-to-improving-quality>
85. Anderson, J.E., Ross, A.J., Back, J. *et al*. Implementing resilience engineering for healthcare quality improvement using the CARE model: a feasibility study protocol. *Pilot Feasibility Stud* 2016;2, 61. doi:10.1186/s40814-016-0103-x
86. Freeman T, Walshe K. Achieving progress through clinical governance? A national study of health care managers' perceptions in the NHS in England *BMJ Quality & Safety* 2004;13:335-343.
87. van Erp, J, Wallenburg, I, Bal, R. Performance regulation in a networked healthcare system: From cosmetic to institutionalized compliance. *Public Admin*. 2020; 98: 46– 61. <https://doi.org/10.1111/padm.12518>
88. van de Bovenkamp, H. M, Stoopendaal, A. & Bal, R. Working with layers: The governance and regulation of healthcare quality in an institutionally layered system. *Public Policy Adm*. 2017;32:45-65; DOI:10.1177/0952076716652934
89. Simon, M.D. Compliance and High Reliability in a Complex Healthcare Organization. *Front Health Serv Manage*. 2018; 34(4):12–25; DOI: 10.1097/HAP.0000000000000030
90. Mintzberg, H. Towards healthier hospitals, *Health Care Manage Rev*, 1997; 22,4:9-18.

91. Ham, C. Improving the performance of health services: the role of clinical leadership, *Lancet*; 2003; 361:1978-80.
92. Fulop L, Day GE. From leader to leadership: clinician managers and where to next? *Aust Health Rev*. 2010;34(3):344-351. doi:10.1071/AH09763
93. Fulop L. Leadership, clinician managers and a thing called "hybridity". *J Health Organ Manag*. 2012;26(4-5):578-604. doi:10.1108/14777261211256927
94. Spehar I, Frich JC, Kjekshus LE. Professional identity and role transitions in clinical managers. *J Health Organ Manag*. 2015;29(3):353-366. doi:10.1108/JHOM-03-2013-0047
95. Soong C, Cho HJ, Shojania KG Choosing quality problems wisely: identifying improvements worth developing and sustaining *BMJ Qual Saf* Published Online First: 29 April 2020. doi: 10.1136/bmjqs-2020-011054
96. Gauld R, Horsburgh S. Healthcare professionals' perceptions of clinical governance implementation: a qualitative New Zealand study of 3205 open-ended survey comments *BMJ Open* 2015;5:e006157. doi: 10.1136/bmjopen-2014-006157
97. Taylor MJ, McNicholas C, Nicolay C, *et al*. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare *BMJ Qual Saf* 2014;**23**:290-298.
98. Curnock, E., Ferguson, J., McKay, J., & Bowie, P. Healthcare Improvement and Rapid PDSA Cycles of Change: A Realist Synthesis of the Literature. 2012. https://nes.scot.nhs.uk/media/1389875/pdsa_realist_synthesis.pdf. Accessed July 8, 2020.
99. Reed JE, Card AJ. The problem with Plan-Do-Study-Act cycles *BMJ Quality & Safety* 2016;25:147-152.
100. Knudsen, S.V., Laursen, H.V.B., Johnsen, S.P. *et al*. Can quality improvement improve the quality of care? A systematic review of reported effects and methodological rigor in plan-do-study-act projects. *BMC Health Serv Res* 2019;**19**, 683. <https://doi.org/10.1186/s12913-019-4482-6>
101. Hughes, R.G. (ed.). Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008.
102. Reason, J., Understanding adverse events: the human factor. In: Vincent, C. (Eds.), Clinical risk management: enhancing patient safety, Second Edition. BMJ Books, London, UK; 2001.
103. Reason, J., Combating omission errors through task analysis and good reminders. *Qual Saf in Health Care* 2002;11 (1), 40-44.
104. Hollnagel, E. Barriers and Accident Prevention. Ashgate Publishing Limited, Aldershot, UK; 2004.
105. Cagliano, A., C., Grimaldi, S., Rafele, C. A systemic methodology for risk management in healthcare sector. *Saf Sci* 2011;49,5: 695-708. <https://doi.org/10.1016/j.ssci.2011.01.006>
106. Basheer, H, Allwood, B, Lindsell, C-M, Freeth, D, Vaux, E. Never too busy to learn – How the modern team can learn together in the busy workplace. Royal College of Physicians; 2018. file:///C:/Users/2919684/Downloads/Never%20too%20busy%20to%20learn_report%20FINAL_0_0%20(1).pdf Accessed June 30, 2020.
107. Hovlid, E., Teig, I.L., Halvorsen, K. *et al*. Inspecting teams' and organisations' expectations regarding external inspections in health care: a qualitative study. *BMC Health Serv Res* 2020;**20**, 627. <https://doi.org/10.1186/s12913-020-05475-0>

Supplementary file

Supplementary file 1," Interview guide".

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For peer review only



Figure 1 *The system-levels involved in the multi-level case study*

Interview guide

- Please introduce yourself (name, educational- and professional background, current position).
- Are you familiar with the new Quality Improvement Regulation and its content?
- What are the routines for management in terms of the organization's (the unit, department, clinic) continuous safety- and quality improvement work?
- How do you, as a manager, work with quality improvement and safety measures? What are your responsibilities?
- What is quality improvement to you?
- What kind of mandatory management training/courses for planning- and implementation of risk- and safety measures did you go through as a manager?
- If this type of training/courses was attended, what were the learning outcomes do you think?
- How do you understand the requirements for internal control?
- Have you experienced any challenges regarding the implementation of the new Quality Improvement Regulation, if so, what kind of challenges?
- How do you consider the differences between the new Quality Improvement Regulation and the previous Internal Control Regulations?
- How do you consider the Quality Improvement Regulation to provide you with room to maneuver, if you consider it to facilitate that?
- Seen from your perspective, how do you think the new Quality Improvement Regulation facilitates or hampers/hinders flexibility and adaptation in the local improvement work?
- How does the Quality Improvement Regulation facilitate or hamper/hinder learning, seen from your perspective?
- The concept of resilience focuses on the things that turn out successfully, how do you deal with that in your organization?
- What do you regard as the elements determining if the health services you provide are robust?
- The Quality Improvement Regulation consists of four steps of requirements for the organization's activities (to plan, to act, to evaluate and to correct): how do you work with these requirements and steps?
- Due to the Quality Improvement Regulation, you are obliged to have a management system – how do you document that you have such a system?

- Do you consider any parts or specifics in the Quality Improvement Regulation more important than others, if so, what parts?
- Do you feel that the Quality Improvement Regulation (the document) is accessible and comprehensible? Do you have any examples of terms that are difficult to understand?
- Have you ever experienced uncertainty in how you should work with quality improvement, considering what the regulatory framework implies?
- What do you do if you are uncertain about how to deal with the requirements provided in the regulatory framework?
- Do you have any thoughts about being the subject for supervision/inspection?
- In what ways does the collaboration between national and regional inspectors impact hospital management and quality improvement work?
- How did you experience the communication- and information process (provided by the Ministry, the Directorate, the Inspectorate), prior to the Quality Improvement Regulation went into effect?
- Do you have any suggestions for the government bodies in terms of what they could have done differently during the development and implementation of the Quality Improvement Regulation, if so, which suggestions do you have?
- If you were to give input to changes that could supplement the existing legislation, as a manager, which suggestions would you give the government bodies?
- Have you sensed a change in attitude towards quality improvement following the new Quality Improvement Regulation, if that is the case, what sort of changes?
- Are there any internal documents (to support quality improvement and patient safety work), if so, what sort of documents and what is the content?
- How are guideline- and support documents being applied into the quality improvement work?
- In what ways does the Guidelines document associated with the Quality Improvement Regulation, contribute to ease your work?
- Which specific changes in your work practices has the Quality Improvement Regulation contributed to? (If none, why?)
- Looking ahead – how do you expect the new Quality Improvement Regulation to contribute to improve management of quality in your hospital?
- Is there anything we have not talked about yet, that you feel is important to mention?

COREQ (Consolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.