Contextual factors of external inspections and mechanisms for improvement in healthcare organizations: A realist evaluation

Einar Hovlid [a,b,*], Gunnar Husabø [a,b], Inger Lise Teig [b], Kjersti Halvorsen [a], Jan C. Frich [c]

[a] *Department of Social Science, Western Norway University of Applied Sciences, P.O. Box 133, 6851, Sogndal, Norway*
[b] *Department of Global Public Health and Primary Care, University of Bergen, P.O. Box 7800, 5020, Bergen, Norway*
[c] *Institute of Health and Society, University of Oslo, P.O. Box 1078, 0316, Oslo, Norway*

A B S T R A C T

External inspections constitute a key element of healthcare regulation. Improved quality of care is one of the important goals of inspections but the mechanisms of how inspections might contribute to quality improvement are poorly understood. Drawing on interviews with healthcare professionals and managers and health record data from inspected organizations, we used a realist evaluation approach to explore how twelve inspections of healthcare providers in x= Norway influenced quality improvement. We found that for inspections to contribute to quality improvement, there must be contextual structures present supporting accountability and engaging staff in improvement work. When such structures are present, inspections can contribute to improvement by creating awareness of gaps between desired and current practices, which leads to readiness for change and stimulates intra-organizational reasoning around quality improvement. We discuss our findings using the theory of de- and recoupling, noting how regulators can identify decoupling between intended goals, management systems, practices, and patient outcomes. We further argue that regulators can contribute to a recoupling between these levels by having the capacity to track the providers' clinical performance over time. This will hold the organization accountable for implementing improvement measures and evaluate the effects of the measures on quality of care.

1. Introduction

In many countries, external inspections that assess the quality of care is a key element of the government's regulation of healthcare providers. Such inspections can serve various purposes like promoting transparency and the democratic legitimacy of healthcare services, controlling that providers meet standards of care, and improving the quality of care (Shaw et al., 2019). Regulatory regimes combine setting standards, assessing performance in relation to standards, and enforcement (Hood et al., 1999). All these elements are present during inspection processes. The inspection authorities must decide which criteria or standards should serve as a basis for the inspection and evaluate the quality of care against these standards. If the healthcare provider fails to meet the standards, the inspection authorities can hold the provider accountable and enforce necessary actions to improve quality.

While some studies have found that external assessment may lead to improvement in care, other studies have found no such effects, or even adverse effects (Allen et al., 2020; Castro-Avila et al., 2019; Flodgren et al., 2016; Husabø, Nilsen, Solligård, et al., 2020a, 2020b). We think that these mixed findings in the research literature regarding the effects of inspections reflect that inspections are complex interventions used in varying contexts, and that the underlying mechanisms of change are poorly understood. Still, inspections are widely employed, and governments and healthcare providers spend considerable resources on conducting and participating in them (Shaw et al., 2019).

Regulation theory offers general guidance on designing inspections. Advocates of responsive regulation (Ayres and Braithwaite, 1992; Baldwin and Black, 2008) argue that using a diverse set of instruments and responses, grounded in a dialogic and flexible strategy, is preferable. Such a strategy accommodates that the context in which inspections take place may affect how inspections are perceived and acted upon by those being inspected (Hovlid et al., 2020; Hut-Mossel et al., 2021). Furthermore, previous research suggests that interaction between the inspection team and the inspected organization can affect leadership, culture and internal team dynamics (Smithson et al., 2018). Still, there is a need for empirical research that brings further insights into how, why, and

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when external assessment approaches work (Hut-Mossel et al., 2021). Specifically, there is a need for rigorous comparisons of contextual conditions and mechanisms at play between external inspections that lead to positive outcomes and ones that do not.

The purpose of this study is to explore how external inspections influence quality improvement within the inspected organizations. We utilize a realist evaluation approach focusing on the interplay between contexts, mechanisms, and outcomes (Pawson and Tilley, 1997). Our research questions are: (1) What characterizes the context of inspections that led to improvement and those that did not? (2) What underlying mechanisms can explain the outcome of inspections?

1.1. Theoretical framework

Inspections are complex interventions, consisting of a variety of intervention components introduced into varying organizational contexts that involve independent actors like healthcare providers, inspection authorities, and policy makers.

We needed an analytical approach that accounted for the possibility that multiple mechanisms can be at work during inspections, and that multiple contextual factors can impinge on their success or failure. We also needed a research framework that systematically ties together evidence related to mechanisms and outcome, and that goes beyond merely exploring and describing experiences with inspections. We therefore chose a realist evaluation approach for this study.

Realist evaluations seek to offer explanations for how interventions work through identifying mechanisms that work within specific contexts (Pawson and Tilley, 1997). In this approach, the context of an intervention includes the characteristics and capacities of the individuals involved in the intervention, and the relationship between them. The context also includes the norms, values, and institutional settings of the organization and its surroundings (Pawson, 2013; Pawson and Tilley, 1997). The outcomes of the intervention are not determined solely by the intervention but are contingent on individuals' actions and reactions. Thus, merely observing correlations between variables is insufficient. Understanding a mechanism requires us to explore how the intervention influences and stimulates responses from the individuals and organizations involved. Following Dalkin et al. (2015), we chose to operationalize the concept of "mechanism" as consisting of the mutually constitutive elements "resources", which are the components introduced by the intervention, and the "reasoning" of those involved in the intervention.

Realist evaluation is theory-driven (Pawson and Tilley, 1997). It posits that interventions are underpinned by theories of how they contribute to change, and urges evaluators to ground their explanations in program theories (Pawson, 2013). Program theories of inspections are seldom made explicit in governing documents. We have formulated an initial program theory based on previous research and theoretical contributions. Our initial program theory consisted of two interconnected parts. First, the inspection affects internal quality improvement efforts positively through highlighting gaps between actual practice and desired practice. When the organization is made aware of such systematic weaknesses, this fuels the members' intrinsic motivation for improvement. Second, the inspection teams hold the leaders of the inspected organization accountable for making such improvements, thus forcing quality improvement onto the agenda of the organization. Using a typology developed by Smithson et al. (2018) describing how inspections can impact organizational changes, we can hypothesize four types of direct linkages between the inspections and internal quality improvement efforts. First, the announcement of the inspection can have an anticipatory effect where the service provider tries to meet the regulator's expectations in advance of an upcoming inspection. Second, the inspection can have a directive impact if the regulator requires the organization to take specific actions. Third, the inspection can have an organizational impact through influencing how leaders and staff reflect on and approach their work. Fourth, the social dynamics in the course of

an inspection can lead to a relational impact, for instance when the inspection team communicates "soft signals" to the healthcare provider (cf. Kok et al., 2020).

Developing this program theory, we drew on theory about organizational readiness for change, and applied a system perspective when exploring how inspections may contribute to organizational change. Organizational readiness for change is considered a critical prerequisite for an organization's ability to successfully implement change, and it can be defined as: "the extent to which organizational members are psychologically and behaviorally prepared to implement organizational change" (Weiner et al., 2008, p. 381). Two key constructs in this theory are awareness of a performance gap between current practice and a desired practice along with an organizational commitment that change is necessary to improve current practice (Holt and Vardaman, 2013).

Through assessing provider performance, inspections can contribute to create an awareness of the inspected organization's current practice and performance gaps, and thereby strengthen commitment to change (Hovlid et al., 2020; Smithson et al., 2018). By holding leaders accountable for implementing change, inspections can contribute to facilitate the planning and implementation of improvement measures. Moreover, our program theory rests on a system perspective, assuming that quality of care is more dependent on how the clinical system delivering care works together as a whole, than on how individuals perform separately (Berwick, 1998). Consequently, the improvement efforts following an inspection need to be designed in a way that target and alter the clinical system of care delivery (Plsek and Wilson, 2001).

Our analyses draw on organizational theory about decoupling and recoupling. Decoupling refers to a situation where gaps are created and maintained between formal structures and actual practices (Meyer and Rowan, 1977). Recoupling refers to the opposite process, trying to link the gap between the policy articulated in the formal structures and the organization's practice (Hallett, 2010). De Bree and Stoopendaal, 2020 have expanded on this theory and applied it to a regulatory context dealing with healthcare inspections. They propose three forms of decoupling: between goals and the management system, between the management system and practice, and between practice and the real outcomes. The latter refers to the deviation of the real outcome produced by the practice, i.e., the "safety and quality experienced by patients, doctors and nurses in the real world" (p. 497), from the outcome the practice was intended to produce. De Bree and Stoopendaal argue that inspections using a system-based regulation approach can potentially facilitate recoupling through recognizing the different forms of decoupling in the inspected organization.

2. Material and methods

2.1. Setting

In Norway, inspections of healthcare are the joint responsibility of Y= The Norwegian Board of Health Supervision and Z= The County Governors. Y is tasked with planning and overseeing proactive inspections of care providers, and the inspections are carried out by Z.

This study includes inspections of providers of primary and specialized healthcare during the years 2014–2018. All inspections followed the ISO guidelines for system based quality audit (International Organization for Standardization, 2012), which require organizations to have a quality management system in place to continuously asses and improve quality. In line with the principles of system-based audits, the standard used during inspections is based on two pillars incorporated into the national legislation: (1) healthcare services should be safe and effective and provided in accordance with sound professional practice and (2) to ensure that their services meet these requirements, healthcare providers are obligated to establish and maintain a quality management system. The top management is responsible for implementing and revising the quality management system. In this way, inspections can hold the management accountable for improving sub-standard

performance and for revising the quality management system so that it becomes an expedient tool for sustaining improvements.

During the planning stages, Norwegian Board of Health Supervision develops audit criteria against which the providers' services will be assessed. The criteria operationalize "adequate care", which is the minimum standard of care quality that the providers are mandated to meet. The providers are notified of the upcoming inspection. During the inspection, the team collects relevant audit evidence, which may include, among other things, governing documents, incident reports, results of user surveys, interviews, and data from health records. They then write up a report that is sent to the provider for review before being published. The report gives an overall assessment and notes any non-conformities that the providers will be required to remedy. Afterwards, the inspection authorities will follow up the provider until they deem that adequate remedial actions are implemented.

2.2. Design and data collection

This study included 12 cases from an ongoing research project into the effects and workings of inspections. Data has been collected from five different inspection programs: use of coercion in dementia care (one inspection), assessment of suicide risk at hospitals for patients with psychiatric disorders (two inspections), nutrition for elderly patients receiving primary care (two inspections), treatment of patients with stroke in hospitals (one inspection), and sepsis care in hospital emergency departments (six inspections).

The cases were selected using a comparison-focused sampling strategy (Patton, 2015), with the goal of comparing inspections that resulted in clinical improvement with cases that did not. We operationalized "outcome" as change in the quality of care delivery for patients. For each inspection, we identified key care processes related to the theme of the inspection and assessed any reports of change using information provided in the interviews. For the cases related to the inspection program of sepsis treatment, we compared average time to key care processes before and after inspection. For the 12 cases included, we found clear evidence of either improved or unaltered quality of care for the patient group targeted by the inspection.

Realist evaluations take their starting point in stating explicit program theories, and the process of collecting and analyzing data is aimed at refining these program theories (Wong et al., 2016). The research project was not initially designed as a single, comprehensive realist evaluation, and some of the data have been analyzed in previous studies. The quantitative data from the sepsis inspections have been included in previous studies analyzing baseline care and average effects of inspections for a group of hospitals (Husabø, Nilsen, Flaatten, et al., 2020a; Husabø, Nilsen, Solligård, et al., 2020b). Interviews from four of the inspections have been analyzed in a previously published study (Husabø, Teig, Frich, Bondevik and Hovlid, 2020c). In the present study, we have reexamined this material, along with new data from eight other inspections, in a more in-depth study, using the lens of realist evaluation. The data have been analyzed to identify contexts, mechanisms, and outcomes related to the inspections' effect on improvement. Table 1 provides an overview of the data collected. Table 1.

The study draws on interviews with clinicians and managers from the inspected healthcare organizations. Sampling interviewees from the healthcare providers who had experiences from recent inspections offered a valuable perspective on how undergoing an inspection may lead to intraorganizational changes in policies and work practices. All interviews were performed as focus group interviews, with each focus group consisting of three to seven interviewees. We recruited interviewees via the management or via quality consultant staff at the healthcare organizations and asked to include leaders from different levels of management and clinicians of varying backgrounds, both in terms of professions and years of experience. The participants were informed about the purpose of the interviews and they signed consent forms before the interviews. The interviews were semi-structured and

Table 1
Number of interviewees and health records per case.

Case number	Interviews with clinicians, number of interviewees	Interviews with managers, number of interviewees	Number of health records
1	3	4	–
2	6	3	–
3	4	4	–
4	4	4	131
5	3	4	127
6	4	3	127
7	4	5	131
8	7	6	–
9	6	7	–
10	4	4	–
11	4	6	132
12	3	3	131

based on interview guides (supplement file) developed on the basis of previous research on inspections (Benson et al., 2006; Walshe and Boyd, 2007). One of the interviewers (EH) was employed by Norwegian Board of Health Supervision, though at the time not in a capacity as inspector, and had prior experience from conducting inspections as an Assistant county physician. The other three interviewers (KH, ILT, and GH) were not employed by the inspection authorities and had no previous experience from inspections.

For the six cases related to the inspection program for sepsis care in emergency departments, we collected additional information about time to diagnostic and treatment processes from electronic health records. The data were collected from four time periods specific to each hospital, two before inspection and two after. Eligible patients were identified using a complete list of patients with ICD-10 codes used to diagnose sepsis and infection. For each hospital, a predefined number of patients from each time period was included into the study after an assessment of individual health records to determine if the patients met the study's inclusion criteria for sepsis. The data collection process and inclusion criteria are described in a separate study protocol (Hovlid et al., 2017).

2.3. Analysis

First, we analyzed each case with regard to whether the quality of care delivery had improved after the inspections. Healthcare quality is a multifaceted and contested concept. One of the most influential frameworks for assessing healthcare quality is the Institute of Medicine's six dimensions stating that healthcare should be: safe, effective, patient-centered, timely, efficient, and equitable (Institute of Medicine, 2001). The inspections in our study primarily addressed the dimensions "safe" and "effective". For cases 1–3 and 8–10 we did a thematic analysis of the interviews, identifying passages describing how the quality of care had been affected by the inspections. For cases 4–7 and 11–12 we analyzed the quantitative data about care delivery obtained from the electronic health records using logistic regression. We obtained odds ratio for the change from before inspection to after inspection in the rate of patients receiving antibiotic treatment within 1 h after admission. Patient sex, age, presence of organ dysfunction, and Charlson comorbidity index were included as adjustment variables.

Second, we conducted a thematic content analysis of context, mechanism, and outcome (CMO configurations) for each case through careful analysis of health record data, interviews, and documentation. The interviews were analyzed using a thematic approach where we identified patterns of information and developed these into themes that were used as a basis for interpretation (Boyatzis, 1998).

Third, we performed a cross-case analysis investigating similarities, differences, and patterns across the different cases, and we developed and refined CMO configurations. EH and GH created a working paper describing possible CMO configurations. Afterwards, these were discussed with the coauthors, refined, and included in the article (see

Table 2
Overview of cases, outcome and supporting evidence.

Case number	Improved clinical care after inspection	Outcome	Evidence supporting change in clinical care. Illustrative quotes from interview data (6 cases) and change in odds ratio for ratio of patients receiving antibiotics within 1 h after the inspection (6 cases)	CMO configurations identified
1	Yes	More thorough assessment and improved preventive measures to avoid coercive treatment in patients with cognitive deficiencies.	"I think the assessment was more detailed than if we had done it in August before the inspection. And I think we were able to implement it … we have implemented it more widely than what we would have been able to without the supervisory agencies."	1,2
2	Yes	More thorough assessment of suicide risk amongst patients with psychiatric disorders	"Yes, I think that measures regarding assessment of suicidal risk have become better, absolutely." "When I read patient records now after the inspection, read the assessments, I find them much more detailed, I think".	2
3	Yes	Improved screening to detect patients at risk of malnutrition and improved measures to follow up malnutrition in primary care.	"Now, the new patients are being screened systematically. And an assessment of what measures we should instigate are being made based on the assessment. And it could be checking checking the weight, tracking tracking the weight, sending a note to the general practitioner, consulting the patient and the family about what they are interested to take part in. So this is much more	2

Table 2 (*continued*)

Case number	Improved clinical care after inspection	Outcome	Evidence supporting change in clinical care. Illustrative quotes from interview data (6 cases) and change in odds ratio for ratio of patients receiving antibiotics within 1 h after the inspection (6 cases)	CMO configurations identified
			systematic than it used to be."	
4	Yes	Earlier antibiotic treatment	Odds ratio for administration of antibiotics within 1 h: 2.94 ($p < .01$)	1,2,3
5	Yes	Earlier antibiotic treatment	Odds ratio for administration of antibiotics within 1 h: 2.50 ($p = .02$)	1,2,3
6	Yes	Earlier antibiotic treatment	Odds ratio for administration of antibiotics within 1 h: 4.01 ($p = .03$)	2,3
7	Yes	Earlier antibiotic treatment	Odds ratio for administration of antibiotics within 1 h: 4.35 ($p < .01$)	1,2,3
8	No	Revised written guidelines for stroke treatment. The revision had no implications for actual clinical care for patients.	"They (management) stress very much that all procedures need to be in place and in order. And, then I feel a bit aggressive, because it's something with … I think that the care and what you do is as important as … papers. I think that if the inspection had not been so positive maybe the leaders would have allocated more resources to what they found, but as long as everyone was happy, there is nothing to improve in a way."	4
9	No	Revised written guidelines for screening patients with risk of malnutrition. The revision had no implications for actual clinical care for patients.	"It's the written procedure, which we lacked, that we have gotten now." "Is it better to be a patient here with regards to nutrition compared with 6 months ago? I	4

Table 2 (*continued*)

Case number	Improved clinical care after inspection	Outcome	Evidence supporting change in clinical care. Illustrative quotes from interview data (6 cases) and change in odds ratio for ratio of patients receiving antibiotics within 1 h after the inspection (6 cases)	CMO configurations identified
			think it's just the same."	
10	No	Revised written guidelines for assessment of psychiatric patients before transfer between to departments within the same hospital. The revision had no implications for actual clinical care for patients	"Change forfor for us? No, because we were … we disagreed with what they pointed out, and we have given our response in writing." "As doctors we have talked about it, but we have not done anything concrete (with the findings)."	5
11	No	Revised written guidelines. Educational measures and reminders that individual staff should comply with the guidelines. No significant improvement in time to treatment with antibiotics.	Odds ratio for administration of antibiotics within 1 h: 1.60 (p = .3)	6
12	No	Revised written guidelines. Educational measures and reminders that individual staff should comply with the guidelines. No significant improvement in time to treatment with antibiotics.	Odds ratio for administration of antibiotics within 1 h: 1.73 (p = .2)	4

Table 2). Including several researchers in both the data collection and thematic analysis phases ensured greater consistency of observations and interpretations, and thus increased the reliability of our findings (Patton, 2015).

The analyses of the qualitative material were aided by the research software Nvivo Qualitative Data Analysis Software V.12 (QSR International Pty), and the quantitative analyses were conducted in Stata/IC, V.16.0 (StataCorp, College Station, TX, USA).

2.4. Ethics approval

The data used in this study were collected with the approval of the xxx Centre for Research Data (project number 39234), the Regional Comittee for Medical Research Ethics Northern Norway (2015/2195/REK nord), and the Norwegian Board of Health Supervision Data Protection Authority (15/01559).

3. Findings

In seven of the 12 included cases we found that care delivery had improved during the inspection process. In the remaining five there were no convincing evidence to support that care delivery had been improved. Table two provides an overview of the cases, the outcomes of the inspections, and the supporting evidence.

We identified three CMO configurations describing how inspections can contribute to improving care delivery and three configurations describing how inspections fail to contribute to improvement. We present these configurations in the following.

3.1. External attention can increase awareness of clinical practice (CMO number one)

External attention can contribute to facilitate multi-professional communication in which clinical practice is articulated, thereby creating awareness and acceptance for change.

3.1.1. Resources
The healthcare organization was notified of an upcoming inspection, along with information concerning the relevant standards and regulation pertaining to the theme of the inspection.

3.1.2. Context
The organization to be inspected had leaders who were committed to the goal of improvement, and who worked together with clinical staff on a regular basis to improve care delivery. There were institutional structures in place to support such improvement work, i.e., structures for meetings, communication, and prioritizing of improvements efforts. The theme of the planned inspection aligned with ongoing improvement work and the organization had quality deficiencies in the care process that the planned inspection would address.

"… it's a fairly competent group of people we got here, so it's a nice group to work with and easy to make things work, and people are aware of their responsibilities, and they make a huge effort to learn new things and make things work." (Case 1).

3.1.3. Reasoning
Leaders recognized the planned inspection as an opportunity to improve care delivery. The clinical staff was involved in self-review and multi-professional reflection on the organization's current clinical practice in relation to the standard that would be used during the planned inspection. By starting in advance of the planned inspection, the leaders saw the scheduled inspection as a way of getting feedback and input on their ongoing improvement work.

"The inspection has emphasized the importance of discussing it. I don't know if we had sat down with surgeons and orthopedics and internist to discuss how we work in the emergency room. What is the process like? What do we do in the emergency room? You know, the whole agenda for for the emergency room has been … emphasized in a very different way, I think, than if we had not been for the inspection." (Case 5).

3.1.4. Outcome
The organization planned and implemented improvement measures that improved care delivery in the areas that were within the scope of the inspection. When the inspection was undertaken it provided feedback on the ongoing work and gave directions for how the organization could improve further.

3.2. Demonstrating need for system improvement (CMO number two)

The inspection can demonstrate care quality's dependency on the performance of the clinical system, and thereby facilitate system improvement that benefits patients.

3.2.1. Resources

The inspection provided feedback to the inspected organization about shortcomings in their clinical system and how it affected care delivery, and it pointed out a more desirable clinical practice. Leaders were held accountable for implementing changes.

3.2.2. Context

The inspected organization delivered substandard care in the area the inspection addressed. There were institutional structures in place to support improvement work and structures for accountability that made leaders take responsibility for substandard care. The leaders facilitated involvement of clinical staff and multi-professional reflection on how to proceed with the improvement work.

"Before [the inspection] then … patients came and they remained in the emergency room. Well, we really did not have the same focus on fast and early diagnostics […] After the inspection […] our approach became more focused. It was nice because in a way … we received a fresh outside gaze on what we knew, and afterwards we focused on the work in a completely different way." (Case 4).

3.2.3. Reasoning

Leaders and clinical staff reasoned that the quality problems revealed by the inspection led to substandard care and leaders felt responsible for initiating improvement efforts within their organization. The inspection thus contributed to create an institutional context of readiness and acceptance for change. Moreover, leaders and clinical staff reasoned that the substandard performance was caused by dysfunction of the clinical system delivering care, and that they needed to improve the clinical system as a whole in order to improve care delivery for the patients.

"I think that the inspection provides a detailed view of what we do in the emergency room across specialties and clinical problems, not only sepsis. But sepsis illustrates many aspects of our challenges. Organization, management, it's a system with many components, it's communication, implementation, professional standards and everything alike. So … I think it's a good example of something that needs a system approach and not just the will of an individual ." (Case 4).

3.2.4. Outcome

The organization planned and implemented improvement measures that changed the clinical system in a way that improved care delivery for the patients.

3.3. Accountability structures for continuous improvement (CMO number three)

By demonstrating need for persistent performance monitoring of clinical practice, the inspection can contribute to create sustained accountability structures that support continuous improvement.

3.3.1. Resources

The inspection provided insight into how clinical performance could be measured and monitored over time and how effects of improvement measures could be evaluated effectively. Leaders were held accountable for developing and maintaining a functional quality management system that could monitor clinical performance.

3.3.2. Context

The inspected organization lacked a functional quality management system that could continuously monitor the clinical performance in the area that the inspection addressed. Their performance was substandard, and they had not been able to detect this by themselves. Moreover, they also lacked a reliable way to evaluate the effect of the improvement measures that they initiated to improve care.

"This [collection of performance data] is also something the inspection team imposed on us. And now we actually do this. And it takes an effort to do it, but we do it. And we do this also for the sake of the patient and for our own sake, to be able to … to be able to say something about how sepsis is managed here. Because we did not really know before the inspection." (Case 6).

3.3.3. Reasoning

Leaders felt responsible for introducing changes to their organization's quality improvement systems. They realized that they needed to continuously monitor their performance and evaluate effects of improvement measures. In order to avoid slipping back to substandard practices, the inspected organization started gathering relevant performance data and used them to monitor progress of improvement efforts and secure sustainability of improvements.

"So we have improvement meetings at Thursdays where we review performance indicators […] and doctors and nurses discuss to find solutions and measures to make things work based on the indicators. And we have had this focus for a year." (Case 7).

3.3.4. Outcome

Monitoring performance contributed to continuous improvement efforts and sustained improvement of care delivery.

3.4. Incongruous focus of inspection (CMO number four)

When the inspection focused on support processes and structural elements it accentuated reasoning and compliance efforts that did not impact on delivery of clinical care.

3.4.1. Resources

The inspection identified substandard practice with regard to support processes, documentation, and written guidelines, but failed to make evident how non-compliance in these processes affected care delivery and clinical care for patients.

3.4.2. Context

The inspected organization had quality problems in care delivery that the inspection failed to address. The cases varied in the degree of ongoing improvement work in the area being inspected in advance of the inspection, and in the maturity of their organizational structures for improvement work. (Two cases had no ongoing work and limited structures for improvement, and one case had ongoing improvement work and some structures for improvement work, i.e., multi-professional meeting places.) There were no structures in place for evaluating the effects of the improvement measures.

"I know that the management has made written procedures regarding screening of nutritional status for new patients and patients who have been admitted for a while. And besides this, I don't know. It is above my pay grade." (Case 9).

3.4.3. Reasoning

Leaders in the inspected organization felt responsible for improving the organization's practices, and they perceived the inspection findings as relevant and useful for improvement. Thus, they addressed the issues raised by the inspection by for instance updating written guidelines and improving documentation. Leaders did not involve nor engage clinical staff in improving care delivery after the inspection, and there was no multi-professional reflection on clinical practice nor the inspection findings. There was no deliberate reasoning or strategy regarding how to improve care delivery. The leaders informed clinical staff about the updated guidelines, and reasoned that by doing so, clinical practice would change and become compliant with the written guidelines. In one

case, the clinical staff were frustrated because the improvement measures did not affect clinical care.

"They (the management) stress very much that the written procedures shall be in place and be in order. And, then I feel a bit aggressive, because there is something with … I think that what you do at the stroke ward is more important than having […] papers." (Case 8).

3.4.4. Outcome

Leaders in the inspected organization implemented changes, but these change measures were not suited to affect care delivery. Leaders believed that clinical practice had improved due to updated written guidelines, and educational activities, but did not evaluate effects of improvement measures on the clinical level. Clinical staff did not make changes in how care was actually delivered.

3.5. Insufficient knowledge challenges legitimacy and fosters opposition to accountability (CMO number five)

Lack of clinical competence and context knowledge in the inspection team can create challenges for the legitimacy and relevance of the inspection findings and divert focus away from clinical improvement.

3.5.1. Resources

The inspection team identified what they regarded as substandard practice but failed to demonstrate for the inspected organization how their findings had relevance for actual care delivery for patients.

3.5.2. Context

The inspected organization delivered substandard care in the area the inspection addressed. The theme of the planned inspection aligned with ongoing improvement work and the organization had institutional structures in place to support the improvement work. The inspected organization had leaders who were committed to the goal of improvement, and who worked together with clinical staff on a regular basis to improve care delivery.

"The whole group (leaders and clinicians) work together. Our department is divided into two teams that meet once a week. And during these meetings we all work together, we discuss patients and we update treatment plans." (Case 10).

3.5.3. Reasoning

The inspected organization experienced that the inspection team lacked necessary knowledge about care delivery and understanding of clinical practice. The communication between the inspection team and inspected organization about required change became demanding due to disagreement about the inspection findings' practical implication for patient care. The inspected organization reasoned that the inspection team did not understand clinical practice and lacked practical knowledge about how care should be delivered. Consequently, they reasoned that there was no need to implement change to improve care delivery. Instead, they sought "quick fixes" that would not change the care processes but could placate the inspection authorities.

"And not having the dialogue – very demanding and frustrating. Because one thing is to discover that this is an area we have to work with, we need improved systems, and there are always areas for improvement. But it feels somewhat frustrating and unfair to be presented with descriptions you feel are wrong." (Case 10).

3.5.4. Outcome

The inspected organization implemented changes that, while formally closing the identified nonconformities, did nothing to affect care delivery. The disagreement about the relevance of the inspection findings for clinical care challenged the legitimacy of the inspection authorities.

3.6. Individualizing the quality problems hinders improvement of the clinical system (CMO number six)

Introducing interventions on the individual level instead of targeting insidious interdependencies in the clinical system makes it harder to achieve substantial quality improvement.

3.6.1. Resources

The inspection provided feedback to the inspected organization about shortcomings in the clinical system and how it affected care delivery, and pointed out a more desirable clinical practice. Leaders were held accountable for implementing change.

3.6.2. Context

The inspected organization had substandard care in the area the inspection addressed. There were deficient structures for engaging and involving clinical staff in improvement work, and leaders did not facilitate multi-professional reflection on inspection findings. The inspected organization lacked a functional quality management system that could evaluate performance of their clinical system, and they did not systematically use data to evaluate effects of improvement measures.

"Well, the management decides procedures and so on, but I feel they are a bit distant, I really feel it, even if consultants and others are involved in decisions. It's a bit […] it's the mail you get from the director, you know. Now it's an inspection on sepsis, and 'beware' in a way, 'our performance is substandard, beware'." (Case 11).

3.6.3. Reasoning

The organization lacked a shared understanding of how the clinical system as a whole needed to be changed in order to improve care delivery. Leaders reasoned that care needed to be improved and their improvement strategy was to target individuals by for instance reminding them to comply with newly updated written guidelines. Moreover, the leaders did evaluate effects of improvement measures on a clinical level.

"But it's about how we work together, that having a challenge, when substandard performance is pointed out, that we actually implement necessary change. And with regards to this, I think we do not go far enough. Maybe we impose a new layer of tasks on top of the rest for the individual to complete. We do another additional thing rather than exploring how we may do things in another way that may make things simpler." (Case 11).

3.6.4. Outcome

Implemented change did not lead to improved care for patients. Improvement measures targeted support processes and individuals but failed to address the shortcomings of the whole clinical system delivering care and clinical performance did therefore not improve. Leaders believed that clinical performance had improved due to these measures, but they did not evaluate the effect of their improvement measures and therefore failed to recognize lack of improvement.

4. Discussion

This study produced six configurations of context, mechanism, and outcome that offer insight into how external inspections might or might not contribute to improve patient care.

Consistent with our initial program theory and the typology proposed by Smithson et al. (2018), we found evidence of directive, anticipatory, organizational and relational impact. In some instances, the inspection exerted directive impact, requiring the healthcare providers to take specific actions. We found that if a context was in place to facilitate collaborative improvement efforts and discussions about quality improvement between clinicians and leaders, the inspections could influence the reasoning within the organization by identifying discrepancies between current practice and a more desirable practice.

Awareness of such discrepancies, along with an organizational commitment to the necessity of change, are two key constructs in the theory of organizational change (Holt and Vardaman, 2013). In line with this theory, and in accordance with the initial program theory developed for this study, awareness of subpar care and commitment to change stand out as key factors, present in all the mechanisms that we have identified as leading to improvement of care quality. The announcement of an inspection can trigger an anticipatory impact through a multi-professional reflection in which current clinical practice is articulated and evaluated. During the assessment, the inspection can have an organizational impact through making evident the discrepancy between the current clinical practice and a more desirable practice. Our findings also demonstrate the importance of the inspection teams having sufficient knowledge about care delivery and the context of the inspected organization to exert relational impact that alters clinical practice and not merely changes aimed at placating the regulator. When the inspection exclusively focused on deficient written guidelines, competence, and documentation, i.e., the structural elements in Donabedian's (1988) model, the subsequent organizational reasoning dealt with ways to improve these structural elements, without sufficiently linking improvements to care delivery.

These findings broadly support those described in the realist review undertaken by Hut-Mossel et al. (2021) of how and why audits work in improving quality of hospital care. They found that externally mandated audits could have an organizational impact through creating awareness of the need to improve quality of care in hospitals. Our study adds to their findings by expanding the empirical evidence supporting these explanations beyond the hospital care setting. Furthermore, we provide insight into how inspections can contribute to create structures for accountability and into the mechanisms of how such structures work. The inspection places the responsibility for following up nonconformities and subpar care at a managerial level. Our findings indicate that if this accountability is to work, there needs to be a context that is conducive for translating accountability into systemic improvement work. This cannot happen if managers merely respond to the inspection with reiterating the moral obligation of clinicians to follow guidelines. As shown in CMO 6, overall care delivery to patients was not improved even though leaders were held accountable, because problems tended to be individualized and improvement measures mainly targeted individuals instead of addressing the performance of the clinical system.

Accountability can rest on formal authority, for instance on the inspection authorities' statutory power to enforce compliance from healthcare providers. Additionally, individuals in organizations can feel accountable due to informal norms and social expectations related to their roles, and this accountability is not only directed towards principals but also towards colleagues, employees, and the society at large (Overman and Schillemans, 2022). We argue that in the case of external inspections, accountability should be understood as encompassing both the formal and informal elements. The informal elements of accountability rely on the same contextual structures that facilitate collaborative improvement efforts, as these structures also act as structures of accountability that hold both managers and clinicians accountable for making concerted efforts of improvement. The desire to close discrepancies between current and more desirable practice act part in conjunction with and is in part determined by the felt obligation to close such gaps.

The mechanisms we have described can be interpreted as cases of decoupling and recoupling, in accordance with the theory proposed by De Bree and Stoopendaal, 2020. The inspection teams in our study identified deficiencies indicating decoupling at all three potential points mentioned by de Bree and Stoopendaal: between goals and management system, between management system and practice, and between practice and real outcome. The inspected organizations' attempts to improve the quality of care can be understood as attempts at recoupling.

Our analyses show that which criteria the inspection authorities set down and how they choose to operationalize quality of care are decisive aspects of the resource provided by the inspection. These can be understood as boundary-drawing regulatory activities of delimiting and demarcating a regulatory object (Lezaun, 2006). The process of making quality assessable by the inspection is not neutral, and can be considered a "call to quality" that mobilizes a certain group of people around a certain notion of quality (Dahler-Larsen, 2019; de Kam, 2020). From a patient perspective, what truly matters in terms of the quality of care delivery, are the real outcomes. In cases of sub-standard care quality, recoupling between practice and the real outcomes, i.e., identifying and remedying changes in practice that have not led to desired outcomes, is thus important, and recoupling between goal, management system and practice can be a prerequisite for recoupling between practice and real outcome.

When the inspection teams in our study focused their analysis and feedback to the inspected organization on decoupling between goal and management system and management system and practice, the subsequent organizational reasoning dealt with ways to recouple these deficiencies, without sufficiently linking improvements to care delivery and the real outcomes.

The inspections identified that a key deficit of the organizations' management systems was that they lacked the capacity to sufficiently evaluate their own clinical performance. Consequently, the organizations were not able to identify decoupling between their own actual practice and their real outcomes. Moreover, they were neither able to evaluate how and to what extent their improvement efforts affected the real outcomes for the patients. We found that a key resource facilitating recoupling between practice and real outcomes was the ability to hold the organization accountable for incorporating continuous assessment of their clinical performance and their real outcomes into their management system. Having thus altered their management systems, managers and staff were able to identify decoupling on their own, and, therefore, they were increasingly equipped for reasoning over insufficient recoupling and the necessity to revise improvement efforts.

Proponents of responsive regulation have argued that regulation needs to be responsive by means of assessing performance (Baldwin and Black, 2008). Previous research shows mixed effects of external inspections (Flodgren et al., 2016), and inspections sometimes fail to contribute to improved care delivery for patients despite facilitating organizational change. Deficient recoupling between practice and real outcomes may provide an explanation for this discrepancy. Our findings demonstrate how performance assessment can contribute to facilitate recoupling. The regulator needs to plan and conduct the inspection in a way that enables them to identify decoupling. Their analysis should address the different types of decoupling and how these affect the quality of care, and they should communicate the findings in a way that affects the reasoning within the organization about how the quality of care can be improved. Our findings show that inspection teams' insufficient knowledge about care delivery and context can lead to perfunctory improvement efforts that do not affect clinical care.

Moreover, we found that holding the organizations accountable for initiating organizational change and improvement measures could facilitate recoupling between practice and real outcomes. If we fail to recognize the contextual importance of structures of accountability, we risk that our program theory of inspection lacks a key element. In keeping with a more responsive regulatory approach and a more systemic understanding of quality improvement, we want to emphasize that accountability is not synonymous with blaming individuals. A critical element of the structures of accountability is having a system for continuously monitoring and acting on data about system performance (Goodwin, 2018). Such a mechanism can counteract individualization of quality problems by altering the reasoning within the organization over time when the leaders held accountable for implementing improvement realize that their current approach fails to improve care. We therefore argue that the inspection resource should include the capacity to track development of system performance, understood as the outcome experienced by the patients, over time. Such a resource is paramount for truly

being able to hold not only leaders but the entire inspected organization accountable for measuring, evaluating system performance, and acting on the findings.

4.1. Strengths and limitations

To the best of our knowledge, this is the first study linking empirical data about resources provided by the inspection, the context in which it takes place and reasoning within the inspected organizations to changes in care delivery on the patient level. This robust research design has produced new knowledge about how inspections might work or fail to improve care delivery for patients.

This study is centered on a specific conception of quality of care that is related to the safety and effectiveness of the services provided to patients. Thus, the study deemphasizes other important quality dimensions, such as patient-centeredness and equity, and it does not engage with other regulatory aims, such as securing democratic legitimacy of healthcare. Our study is further limited in that its focus has been on the direct impact of an inspection on the quality of care for specific patient groups. We have not been able to explore more indirect forms of impact, like how healthcare providers learn from other organizations that have been inspected (lateral impact, cf. Smithson et al., 2018) or the possibility of declining quality of care in areas not prioritized by the inspection.

Wanting to focus our research on what happens within the healthcare organizations being inspected, we have not included data from the perspective of the inspection teams, although we acknowledge that such data could shed light on how regulators adapt their strategies according to the organizations' contexts. Moreover, our study has been conducted in one specific country, and thereby within one specific overall regulatory context. Further research could provide a better understanding of how regulators adapt their strategies according to context and how different strategies enacted in different contexts impact quality improvement within the inspected organizations.

5. Conclusion

The effects of inspections on quality of care are contingent on the resource provided during the inspection, the context it is provided in, and how it affects the reasoning within the inspected organization. Inspections seem to work best when the provided resource addresses performance of the clinical system and stimulates reasoning on how the system can be changed in a context with structures for accountability and structures to engage and involve staff in improvement work.

Deficient recoupling between practice and intended outcomes as experienced by the patients may be a key to understand why inspections sometimes fail to contribute to improved care delivery for patients despite facilitating organizational change. The regulator needs to be responsive to the improvement measures that are implemented following an inspection. Consequently, the inspections should include the capacity to track and follow up actual care delivery as experienced by the patients over time. This way, the regulatory body can hold the inspected organization accountable for implementing change that improves care delivery. Moreover, the regulatory body should hold the inspected organizations accountable for continuously assessing whether care is delivered in a way that produces the intended outcomes for the patients. This can enable the organizations themselves to identify decoupling, initiate activities that promote recoupling, and evaluate and adjust such activities when necessary.

Disclaimer

Data from the Norwegian Patient Registry have been used in this publication. The interpretation and reporting of these data are the sole responsibility of the authors. No endorsement by the Norwegian Patient Registry is intended nor should be inferred.

Author statement and contribution

Einar Hovlid: Conceptualization, Methodology, Formal analysis, Project administration, Data collection, Writing – original draft, Writing – review & editing. Gunnar Husabø: Conceptualization, Methodology, Formal analysis, Project administration, Data collection, Writing – original draft, Writing – review & editing. Inger Lise Teig: Methodology, Formal analysis, Data collection, Writing – review & editing. Kjersti Halvorsen: Methodology, Data collection, Writing – review & editing. Jan C Frich: Conceptualization, Methodology, Formal analysis, Writing – review & editing.

Appendix A. Supplementary data

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References

Allen, T., Walshe, K., Proudlove, N., Sutton, M., 2020. The measurement and improvement of maternity service performance through inspection and rating: an observational study of maternity services in acute hospitals in England. Health Pol. https://doi.org/10.1016/j.healthpol.2020.08.007.

Ayres, I., Braithwaite, J., 1992. Responsive Regulation: Transcending the Deregulation Debate. Oxford University Press, Oxford.

Baldwin, R., Black, J., 2008. Really responsive regulation. Mod. Law Rev. 71 (1), 59–94. https://doi.org/10.1111/j.1468-2230.2008.00681.x.

Benson, L.A., Boyd, A., Walshe, K., 2006. Learning from regulatory interventions in healthcare: the Commission for Health Improvement and its clinical governance review process. Clin. Govern. Int. J. 11 (3), 213–224.

Berwick, D., 1998. Crossing the boundary: changing mental models in the service of improvement. Int. J. Qual. Health Care 10 (5), 435–441. https://doi.org/10.1093/intqhc/10.5.435.

Boyatzis, R.E., 1998. Transforming Qualitative Information: Thematic Analysis and Code Development. Sage Publications, Thousand Oaks.

Castro-Avila, A., Bloor, K., Thompson, C., 2019. The effect of external inspections on safety in acute hospitals in the National Health Service in England: a controlled interrupted time-series analysis. J. Health Serv. Res. Pol. 24 (3), 182–190. https://doi.org/10.1177/1355819619837288.

Dahler-Larsen, P., 2019. Quality: from plato to performance. https://doi.org/10.1007/978-3-030-10392-7.

Dalkin, S.M., Greenhalgh, J., Jones, D., Cunningham, B., Lhussier, M., 2015. What's in a mechanism? Development of a key concept in realist evaluation. Implement. Sci. 10 (1), 49. https://doi.org/10.1186/s13012-015-0237-x.

De Bree, M., Stoopendaal, A., 2020. De- and recoupling and public regulation. Organ. Stud. 41 (5), 599–620. https://doi.org/10.1177/0170840618800115.

de Kam, D., 2020. Through The Regulator's Eyes: On The Effects of Making Quality and Safety of Care Inspectable (PhD thesis). Erasmus University, Rotterdam.

Donabedian, A., 1988. The quality of care. How can it be assessed? JAMA 260 (12), 1743–1748. https://doi.org/10.1001/jama.1988.03410120089033.

Flodgren, G., Goncalves-Bradley, D.C., Pomey, M.P., 2016. External inspection of compliance with standards for improved healthcare outcomes. Cochrane Database Syst. Rev. 12 https://doi.org/10.1002/14651858.CD008992.pub3. Cd008992.

Goodwin, D., 2018. Cultures of caring: healthcare 'scandals', inquiries, and the remaking of accountabilities. Soc. Stud. Sci. 48 (1), 101–124. https://doi.org/10.1177/0306312717751051.

Hallett, T., 2010. The myth incarnate: recoupling processes, turmoil, and inhabited institutions in an urban elementary school. Am. Sociol. Rev. 75 (1), 52–74. https://doi.org/10.1177/0003122409357044.

Holt, D.T., Vardaman, J.M., 2013. Toward a comprehensive understanding of readiness for change: the case for an expanded conceptualization. J. Change Manag. 13 (1), 9–18. https://doi.org/10.1080/14697017.2013.768426.

Hood, C., Scott, C., James, O., Jones, G., Travers, T., 1999. Regulation inside Government: Waste Watchers, Quality Police, and Sleaze-Busters. Oxford University Press, Oxford.

Hovlid, E., Braut, G.S., Hannisdal, E., Walshe, K., Bukve, O., Flottorp, S., Frich, J.C., 2020. Mediators of change in healthcare organisations subject to external assessment: a systematic review with narrative synthesis. BMJ Open. https://doi.org/10.1136/bmjopen-2020-038850.

Hovlid, E., Frich, J.C., Walshe, K., Nilsen, R.M., Flaatten, H.K., Braut, G.S., Harthug, S., 2017. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. BMJ Open 7 (9), e016213. https://doi.org/10.1136/bmjopen-2017-016213.

Husabø, G., Nilsen, R.M., Flaatten, H., Solligård, E., Frich, J.C., Bondevik, G.T., Hovlid, E., 2020a. Early diagnosis of sepsis in emergency departments, time to treatment, and association with mortality: an observational study. PLoS One 15 (1), e0227652. https://doi.org/10.1371/journal.pone.0227652.

Husabø, G., Nilsen, R.M., Solligård, E., Flaatten, H., Walshe, K., Frich, J.C., Hovlid, E., 2020b. Effects of external inspections on sepsis detection and treatment: a stepped-

wedge study with cluster-level randomisation. BMJ Open 10 (10), e037715. https://doi.org/10.1136/bmjopen-2020-037715.

Husabø, G., Teig, I.L., Frich, J.C., Bondevik, G.T., Hovlid, E., 2020c. Promoting leadership and quality improvement through external inspections of management of sepsis in Norwegian hospitals: a focus group study. BMJ Open *10* (11). https://doi.org/10.1136/bmjopen-2020-041997 e041997.

Hut-Mossel, L., Ahaus, K., Welker, G., Gans, R., 2021. Understanding how and why audits work in improving the quality of hospital care: a systematic realist review. PLoS One 16 (3), e0248677. https://doi.org/10.1371/journal.pone.0248677.

Institute of Medicine, 2001. Crossing the Quality Chasm: A New Health System for the 21st Century. Committee on Quality of Health Care in America, Washington DC.

International Organization for Standardization, 2012. Conformity Assessment – Requirements and Recommendations for Content of a Third-Party Audit Report on Management Systems (ISO/IEC TS 17022:2012).

Kok, J., Wallenburg, I., Leistikow, I., Bal, R., 2020. "The doctor was rude, the toilets are dirty." Utilizing 'soft signals' in the regulation of patient safety. Saf. Sci. 131, 104914. https://doi.org/10.1016/j.ssci.2020.104914.

Lezaun, J., 2006. Creating a new object of government: making genetically modified organisms traceable. Soc. Stud. Sci. 36 (4), 499–531.

Meyer, J.W., Rowan, B., 1977. Institutionalized organizations: formal structure as myth and ceremony. Am. J. Sociol. 83 (2), 340–363. https://doi.org/10.1086/226550.

Overman, S., Schillemans, T., 2022. Toward a public administration theory of felt accountability. Publ. Adm. Rev. 82 (1), 12–22. https://doi.org/10.1111/puar.13417 n/a(n/a).

Patton, M.Q., 2015. Qualitative Research & Evaluation Methods: Integrating Theory and Practice, fourth ed. Thousand, Oaks, California (SAGE Publications, Inc).

Pawson, R., 2013. The Science of Evaluation: A Realist Manifesto. SAGE Publications, London.

Pawson, R., Tilley, N., 1997. Realistic Evaluation. SAGE Publications, London.

Plsek, P.E., Wilson, T., 2001. Complexity, leadership, and management in healthcare organisations. BMJ 323 (7315), 746–749. https://doi.org/10.1136/bmj.323.7315.746.

Shaw, C.D., Groene, O., Berger, E., 2019. External institutional strategies: accreditation, certification, supervision. In: Busse, R., Klazinga, N., Panteli, D., Quentin, W. (Eds.), Improving Healthcare Quality in Europe. World Health Organization, pp. 203–231.

Smithson, R., Richardson, E., Roberts, J., Walshe, K., Wenzel, L., Robertson, R., Proudlove, N., 2018. Impact of the care quality commission on provider performance: room for improvement? Retrieved from. https://www.kingsfund.org.uk/publications/impact-cqc-provider-performance.

Walshe, K., Boyd, A., 2007. Designing regulation: a review. https://www.escholar.manchester.ac.uk/uk-ac-man-scw:118421.

Weiner, B.J., Amick, H., Lee, S.Y., 2008. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Med. Care Res. Rev. 65 (4), 379–436. https://doi.org/10.1177/1077558708317802.

Wong, G., Westhorp, G., Manzano, A., Greenhalgh, J., Jagosh, J., Greenhalgh, T., 2016. RAMESES II reporting standards for realist evaluations. BMC Med. 14 (1), 96. https://doi.org/10.1186/s12916-016-0643-1.