# Rethinking regulation and its effects

In the introduction of this thesis, I described how regulators are increasingly called to account for the impact of their regulatory practices and are regularly confronted with uncertainty about how to (best) regulate particular issues (Gilad, 2010; Leistikow, 2018; Sabel et al., 2018). In the classic 'command and control' regulatory approach, a regulator monitors the compliance of regulatees with prescribed standards. Regulation, as an activity, occurs in cases of non-compliance and serves to ensure future compliance (Baldwin et al., 2012). Today, society expects regulators to be able to do more than have regulatees comply with standards and it is recognised that 'good performance' is not just adherence to standards (Gilad, 2010; Gunningham, 2012). Accordingly, our ideas about what prescriptive regulation can accomplish have changed. Gilad describes how "regulators in different countries and domains are experimenting with regulatory arrangements that allow regulated organizations flexibility to tailor regulation to their individual circumstances, while holding them accountable for the adequacy and efficacy of their internal control systems" (Gilad, 2010, p. 485). In such process-based regulatory arrangements, prescriptive standards might still feature, but regulators also assess (the quality of) the systems and processes regulatees have in place that allow them to comply with said standards. This means that regulatees can do well or not on more than one level. Gilad's multi-tiered take on regulation helps to understand the work of contemporary regulators and some of the challenges they might face, but it also leaves some questions unanswered. It sidesteps the question of how a regulator constructs the 'quality issues' it focuses on in the first place. Also, it does not speak of the regulatory instruments that enable a regulator to inspect regulatee performance along the lines of a given quality issue.

To understand how a regulator comes to regulate a (multi-tiered) quality issue, I developed the argument that regulation can be thought of as unfolding by and through the construction of *regulatory objects*. A regulatory object transforms a particular quality issue into the (legitimate) object of regulation. For a regulator monitoring food safety, hygiene might constitute such an object. What a regulatory object proposes is that, one way or another, regulatee behaviour speaks to the quality issue at stake—regulatee behaviour on hygiene is related to the safety of the food regulatees prepare. Regulators need to be able to render regulatee behaviour 'inspectable' and depend on regulatory instruments to do so. Regulatory instruments operationalise the regulatory object so that it might be inspected. When it comes to hygiene, inspectors can visit street food vendors and verify the temperature of the food served or the cleanliness of the utensils used. What this calls for is a series of translations—from food safety, to hygiene, to food temperature. Regulatory instruments advance particular interpretations on what 'quality' in a given situation means (clean utensils), where it might be found and how it might best be monitored. While the notion of quality, in and of itself, is "fragmented, contested, value-laden, and situation-dependent" (Dahler-Larsen, 2019, p. 11), regulatory instru-

ments can contribute to the stabilisation of particular interpretation of quality. Whether or not and how a given interpretation of quality stabilises depends on the agents that work with, invest in and (re)negotiate regulatory instruments (Dahler-Larsen, 2019).

Regulatory instruments, in advancing an interpretation of quality, recruit particular quality agents who are expected to enact the notion of quality the regulatory instrument centres on (Dahler-Larsen, 2019; Lascoumes and Le Gales, 2007). As such, regulatory instruments are political; in aiming to assess quality, they demarcate what quality supposedly means and who can engage with quality (and who cannot). In healthcare, quality standards have a history of emphasising clinical performance and in such standards patients are not envisioned as quality agents (Vincent, 2002). With the notion of performativity, I have described how instruments that set out to measure a reality can shape and transform that reality (Butler, 2010; Law, 2009; Mackenzie, 2006). Earlier I invoked the example of the CITO test, a test Dutch pupils take to conclude their primary schooling. The CITO test does more than measure students' performance; it impacts school curricula that increasingly prepare students for the test and students' results are more than indicative of their performance as it informs their chances of transferring to a particular level of secondary education. More than describing a reality, an instrument can come to 'constitute' realities (Dahler-Larsen, 2014). The activity of regulation, I argued, constitutes an institutionalised call to quality that mobilises and enacts a dynamic network. I set out to understand how, in regulating quality and safety of care, the Dutch Health and Youth Care Inspectorate (Inspectorate, hereafter) constructs regulatory objects, how regulatory instruments render regulatory objects inspectable, how regulatory instruments imply and allow for the participation of particular quality agents and how regulatory instruments can become performative.

The main research question that I set out to answer in this thesis is:

> How does the Inspectorate construct quality and safety of care as inspectable and to what effects?

The sub-questions that complement that question are:

1) How does the Inspectorate construct regulatory objects?
2) How does the Inspectorate use regulatory instruments to render regulatory objects inspectable?
3) How do quality agents enact and (re)negotiate regulatory objects?
4) What are the (constitutive) effects of the regulatory instruments thus constructed?

In the final chapter of this thesis, I set out to do (broadly) three things. First, I look to answer the research questions I formulated. I will describe how the Inspectorate constructs regulatory objects. I then go on to show how quality instruments render regulatory objects inspectable. Next, I address how quality agents are implied by the Inspectorate's regulatory instruments and how these quality agents, in turn, enact and (re)negotiate the regulatory object operationalised in those instruments. And I finally describe how regulatory instruments generate (constitutive) effects. This involves revisiting findings from preceding chapters and the effort to understand them in light of the perspective on regulation I developed. Second, I describe and aim to understand a notion of regulation I encountered throughout my research; that of regulation as the *visualisation* of quality and safety of care. I am interested in how the idea that regulation is the activity of making regulatee performance visible shapes regulatory practices. Finally, I want to reflect on the practical and theoretical implications of the vocabulary on regulation I developed; how is this vocabulary helpful to regulators and how does it aid our understanding of how regulation works and how it might be studied?

## THE CONSTRUCTION OF REGULATORY OBJECTS

Looking back on the empirical cases of regulation we studied, we can basically discern two regulatory objects: hospital mergers (chapters 2 and 3) and learning from incidents (chapters 4, 5 and 6). What we take from our study into the regulation of hospital mergers is that the construction of regulatory objects might fail and understand why it might fail. Hospital mergers constitute a legally defined regulatory object that the Inspectorate is expected to engage with, granting insight in how a hospital merger might affect quality and safety of care. The Inspectorate, however, claims that providing such insight is impossible. This opens up the question of how the Inspectorate might otherwise regulate hospital mergers and construct hospital mergers as an object of regulation. We described how inspectors conceive of how merging might pose risks to quality and safety of care along two lines. First, mergers are conceived as a demanding undertaking of organisational restructuring and as such would detract from the attention necessary for attending to and ensuring quality and safety of care. Individual and organisational attention is framed as a finite resource, such that attention for quality and safety of care cannot be expected to be sustained while merging—e.g. improvement or patient involvement projects are put on hold. Second, mergers could potentially impact and destabilise daily care practices. Here, inspectors typically worry about the way in which merging hospitals begin to relocate and move about both personnel and care services as part of the merger, while the possible detrimental effects of such relocations on care practices is not thoroughly considered—e.g. professionals have to work on locations

where they are asked to operate equipment unfamiliar to them or cannot yet access IT-systems. While this suggests that inspectors can conceive of a hospital merger posing a risk to quality and safety of care, hospital mergers do not come to be constructed as regulatory objects.

Drawing on a relational theory of risk (Boholm and Corvellec, 2011; Hilgartner, 1992), we observed that risks are not entities the presence and size of which might be objectively assessed, but rather, refers to a particular claim that depends on a risk object, an object-at-risk and a (causal) relationship that looks to legitimately connect both objects. In the case of hospital mergers, all three elements that a claim of risk would comprise of, pose challenges. Inspectors envision of mergers as unique, uncertain trajectories rather than bounded objects so that its delineations as a possible risk object are difficult to pinpoint. To say that 'quality and safety of care' is at risk due to a merger (thus constituting the object-at-risk) is too big a claim to act upon and does not help in determining how, what and/or when processes might be more specifically at risk because of a merger. Finally, to construct a relationship of risk between a merger as risk object and quality and safety of care as the object-at-risk is challenging because of the difficulties involved in constructing those two to begin with and because the evidence of studies that have tried to delineate and operationalise both 'merging' and 'quality and safety of care' as variables that could impact one another is inconclusive, finding no consistent relationship. Claims of risk always envision of ways to act upon or intervene in the relationship it establishes between a given risk object and object-at-risk. For the Inspectorate, appeals to regulatee behaviour is generally the way into intervening in a posited relationship of risk, but here, the Inspectorate is unclear about what kind of regulatee behaviour it might target or potentially look to alter when we think of a hospital merger as a risk (and regulatory) object.

Given the uncertain impact a hospital merger might have on (processes) of quality and safety and the unanswered question of if and how organisational behaviour might relate to this impact, prescriptive, first-tier regulation, that assumes that 'quality', in the event of a merger, could be safeguarded if organisations abide by a set of predefined rules, is unlikely to work. While the Inspectorate acknowledges the inadequacy of first-tier regulatory operations in response to hospital mergers, it does not explore the possibility of constructing hospital mergers as a regulatory object on the other two tiers. We argued that even if the Inspectorate considers itself unable to prescribe actions to merging hospitals, the Inspectorate might require hospitals to demonstrate the risks hospitals envision a merger might pose to daily care practices, how considerations of quality and safety feature in relocation plans and how hospitals look to integrate different ways of working and identifying and sharing best practices. Such regulatory practices would look to construct a merger as a regulatory object on the second- or third-tier. Chapter 3 demonstrated how the effort to construct a regulatory object is tied up into

and affected by how the Inspectorate thinks about risks—and how constructed risks allows for regulatory action—, the operational constraints it has to contend with and the wider political arena in which regulatory objects have to be enacted as legitimate. A collective understanding of a historical intervention in a hospital merger that inspectors believe has backfired might explain the Inspectorate's hesitancy to construct a hospital merger as a formal (second- or third-tier) regulatory object. While a hospital merger is no formal regulatory object the Inspectorate directs its regulatory practices to, this is not to say that individual inspectors do not invest in efforts to monitor a merger as a meaningful event. Inspectors colloquially understand a merger as a 'life event'—an intense and potentially destabilising event for an organisation—and for some inspectors, this warrants additional inspection visits, to 'see for themselves' how hospitals are doing, while other inspectors do not alter their practices and wait for 'real' signals indicative of (declining) organisational performance.

In chapters 4, 5 and 6 the regulatory object that emerges is that of learning from incidents. While the Inspectorate struggled to conceive of behaviour it could target in relation to mergers, when it comes to the regulation of incidents, 'learning' constitutes the activity or behaviour around which it designs its regulatory practices. As a regulatory object, learning from incidents refers to a complex social and participative activity (Leistikow et al., 2017; Macrae, 2016). In an article that describes the Inspectorate's approach to regulating learning from incidents, Leistikow et al. identify 'organisational learning'—"the process of creating and applying valid knowledge to enable an organisation to improve" (2017, p. 2)—as the Inspectorate's focus. Learning is constructed as the expected and desired activity or behaviour after an incident occurred (Inspectorate, 2016a). Referring to a 'process of creating and applying knowledge', to monitor and encourage organisational learning is to regulate a dynamic process. In chapter 5, we have seen how the regulation of a dynamic process warrants a regulatory approach that is equally dynamic or adaptive. Over time, the regulatory object of learning from incidents has been reconstructed. Previously, the Inspectorate focused on what went wrong in specific incidents—zooming in the specificities of particular incidents and what might have contributed to its occurrence—while recently, the Inspectorate focuses on the processes through which organisations are able to learn from incidents (Kok et al., 2019; Leistikow et al., 2017). A key notion that underpins the Inspectorate's focus on learning from incidents is that this 'process of creating valid knowledge' happens (primarily) within and as a result of formal investigations of incidents. It is these investigations the Inspectorate monitors as it operationalises learning.

The article by Leistikow et al. (2017) is both a description of the Inspectorate's approach to regulate learning from incidents and a legitimisation of it. While the lack of scientific consensus on the effects of a hospital merger on quality of care hampered the construction of a hospital merger as a regulatory object, the regulatory object

of learning from incidents is presented and argued for through the use of a range of studies (Leistikow et al., 2017). Studies that document problems with incident reporting systems—reporting systems "are overwhelmed by the volume of reports and fall short in defining recommendations for improving healthcare safety" (Leistikow et al., 2017, p. 1)—are cited to argue for taking a different approach; one that is responsive to how organisations learn to investigate incidents and improve their local practices. This shows how regulatory objects can be constructed as (scientifically) legitimate. In chapter 4, we documented how political pressure challenged the regulatory object of learning from incidents. Or, more specifically, politicians questioned the Inspectorate's conviction that learning from incidents would be helped if organisations are allowed to investigate their own incidents—which did not sit well with several politicians who argued that this does not favour critical, impartial inquiries. The introduction of the external chair—whose role I will be more attentive to when I discuss the part played by quality agents—is a political intervention that both challenges and subscribes to the regulatory object of the Inspectorate. What this tells us is that regulatory objects are assessed as legitimate (or not) by "a wide range of legitimacy communities" (Baldwin and Black, 2016, p. 578) and are affected by such assessments. To further understand how regulatory objects work we need to attend to how such objects are operationalised through regulatory instruments.

## REGULATORY INSTRUMENTS AND THEIR QUALITY INSCRIPTIONS

In the process of regulating quality and safety of care, the Inspectorate uses a range of regulatory instruments wherein particular interpretations of the quality of a regulatory object are solidified. Regulatory instruments help standardise the process of assessing and judging organisational behaviour, enabling consistent and fair regulatory intervention, limiting (unwarranted) discretionary room of individual inspectors (Kok et al., 2019; Rutz et al., 2017), while stimulating particular types of organisational behaviour. This also means that it is apparent to regulatees what they are being assessed on. Formal regulatory instruments enable two-directional assessment, one might say; it enables the monitoring of regulatees, but it also renders transparent the regulatory practices of the regulator, and their decision-making processes, to communities that might evaluate regulatory legitimacy (Lodge, 2004).

In chapters 2 and 3, we described how the Inspectorate struggled to explicate a relationship of risk between a hospital merger and quality and safety of care and it is unclear what organisational behaviour the Inspectorate might meaningfully monitor in the case of a merger. The uncertainty that inspectors ascribe to mergers (as unpredict-

ably disruptive events that have unique characteristics) and the unsettled question of how organisations could manage such events capably, hampers the Inspectorate's ability to define and differentiate between what would constitute 'good' or 'productive' organisational behaviour in the case of a merger and 'poor' or 'unproductive' behaviour. As such, no regulatory instrument or quality inscription supports or renders visible the regulatory object of hospital mergers, since the issue of what the 'quality' of such an object would be is uncertain. The Inspectorate's inability to construct a hospital merger as a regulatory object and to inscribe the 'quality' of that object onto an instrument are related. Given the definition of a regulatory object I proposed earlier—a quality object made inspectable—the constructed object and the instruments used to regulate that object depend on one another to work. In this case, they do not. When the Inspectorate is asked if a hospital merger should be allowed or not given the potential impact of the merger on quality and safety of care, the Inspectorate claims it cannot say. How a merger might impact quality and safety of care, therefore, is not considered when it is decided if a hospital merger should be approved or not.

The regulatory instrument—and the quality inscription, or score, it produces—that solidifies the regulatory object of learning from incidents is the scoring instrument used by inspectors to evaluate incident investigation reports of healthcare organisations (as described most elaborately in chapter 5). This instrument presents inspectors with 25 yes or no questions investigation reports can be assessed on. Investigation reports receive a score between 0% and 100% to indicate the percentage of the items adequately addressed in the reports. The 25 items represent "conditions for learning" from incidents and the overall score represents the "[quantified] quality of the learning process", enabling monitoring of organisational performance ('learning') over time and in comparison to other hospitals (Leistikow et al., 2017, p. 2). Inscriptions 'render visible and transform' complex phenomena into numbers and categories. The scoring instrument used by inspectors transforms the activity of social and participative learning from incidents into the extent to which an incident investigation report describes how it meets 25 conditions believed to be conducive to learning from incidents. Now, to point this out is not to say that the regulatory object misses its mark or to criticise the Inspectorate's scoring instrument. Rather, it calls us to recognise that the activity of learning from incidents and the score awarded to a hospital's investigation report are, simply, two different things. This opens up different ways of thinking about the effects of regulation. Departing from the idea that regulation entails the practice of rendering observable 'quality' behaviour, we can attend to what it takes to accomplish this and to the effects of the inscriptions produced through these efforts. Analytically pulling apart the regulatory object and the regulatory instrument that operationalises that object allows me to focus on the effects of the instrument, since organisations and individuals subject to regulation see themselves confronted with and are asked to respond to regulatory

instruments rather than to regulatory objects as such (Dahler-Larsen, 2014). To distinguish a regulatory object from the regulatory instrument that supports it is not critical in and of itself, but it does allow for a productive evaluative avenue through which we can question the fit between the principles underpinning a constructed regulatory object and the effects generated by the instrument made to operationalise that object.

In chapter 5, we recommended to rethink the scoring instrument by shifting its focus from conditions for investigating incidents properly (that hospitals do or do not meet) to having hospitals demonstrate how investigating an incident (or incidents) enabled them to improve their daily care practices. In a way, our recommendations engender the effort to render the instrument more reflexive, preventing decoupling (Bromley and Powell, 2012; van Loon et al., 2014), but are also the proposal to transform and render visible learning from incidents *differently*—so that, as researchers, we participate in (re) negotiating regulatory objects in particular ways. The regulatory object of learning from incidents and the organisational behaviour it solicits and assesses is supported by a regulatory scoring instrument that is located primarily on Gilad's first-tier of regulation (2010). While the regulatory object itself—with its focus on learning as the valued organisational activity the Inspectorate monitors and aims to encourage—seems geared towards regulatee self-evaluating activities on the second- and third-tier, the regulatory instrument is enacted and responded to on the first-tier. To investigate a serious incident is a legal, prescriptive requirement and the scoring instrument that enables inspectors to gauge the quality of the learning process of hospitals following incidents, is experienced and responded to by hospital respondents as prescriptive (chapter 5). Hospitals write their investigation reports in line with the scoring instrument and (re)organise their (investigative) practices so that they perform well according to the Inspectorate's scoring instrument, even if not doing so does not formally constitute non-compliance or incurs penalties. What also became apparent in this chapter is how the activity the regulatory object refers to (learning) might be dynamic, while the regulatory instrument that enacts that object remains static. The effects of the instrument, as documented in chapter 5, were temporary in that sense that they encouraged particular regulatee behaviour for a time, but the effects of the instrument can wane when the enactment of said instrument and regulatee responses to it solidify.

## THE WORK OF QUALITY AGENTS

In chapters 2 and 3, we demonstrated a faltering call to quality, the unsuccessful attempt to define and constitute what 'quality' is in the case of hospital mergers and develop regulatory practices that would be able to monitor that quality. Or, in another way, we can think of what happens (or not) in the case of the regulation of hospital

mergers as a call to quality by the government that summons the Inspectorate as a quality agent—the Inspectorate can assess the expected impact a hospital merger will have on quality of care—expectations that the Inspectorate resists. This governmental call to quality is underpinned by particular (market oriented) assumptions about organisational concentrations that envisions of a merger as a particular distinct activity the impact of which on outcomes (usually market composition, but in this case, quality of care) can be modelled or predicted. The Inspectorate operates from different assumptions on what regulation is and can do and how quality of care comes about, can be at risk and might be monitored. These assumptions inform the inability of the Inspectorate to make its own call to quality in the case of hospital mergers; while it resists its implication as a quality agent able to predict or model the impact of a merger on quality of care, it does not develop its own. Given the idea that quality agents respond to the specific instruments that accompany a regulatory object (rather than to the abstract regulatory object in-itself), the absence of formal regulatory instruments in the case of hospital mergers makes no appeal to particular agents. Instruments and the quality inscriptions they might produce, as we have seen and as the work of Kok et al. also makes apparent (2019), do not just invite and shape the work of agents external to the Inspectorate; the lack of a regulatory instrument that operationalises inspectable quality in the case of mergers also means that inspectors struggle to work on mergers. We noted how the Inspectorate does not construct the regulatory object of a hospital merger, supported by regulatory instruments, on the second or third regulatory tier. We proposed how the Inspectorate might change track and think about regulation hospital mergers on those tiers—e.g. by asking hospitals to shed light on the risks they think the merger might pose and their plans to manage them, or to highlight potential quality issues in future relocation plans. Doing so would make appeals to particular quality agents (e.g. board of directors, middle managers or quality advisers, depending on the organisation of and response to the instruments developed). In making such recommendations, we as researchers enter into the quality configuration to help think about how hospital mergers might be regulated. We are the 'evaluators' that bring in our own quality perspective and recommend constructing hospital mergers as particular regulatory objects. Below I will reflect further on this position.

In chapter 4, we saw the politically informed introduction of a new quality agent, the external chair, in response to the regulatory object of learning from incidents. We can say that two quality perspectives met; the quality perspective of the Inspectorate that advances that what constitutes the quality of an incident investigation is how it leads to social and participative learning at a local level and that of politicians that advanced that a quality incident investigation is independent and is responsive to questions and doubts patients and families might have (while also generating learning). The external chair, as the required head healthcare organisations have to recruit in incident

investigations when a resident died due to the incident, is a compromise between the Inspectorate's emphasis on local learning and the government's call for external review. We proposed to think of external chairs as knowledge brokers. They participate in the creation of knowledge in the process of investigating an incident and mediate between different professional groups and organisations to facilitate knowledge sharing (Meyer, 2010; Schlierf and Meyer, 2013; Waring et al., 2019). While external chairs were expected to boost the impartiality of incident investigations—and external chairs do see themselves as more detached from the incident and less receptive to efforts of directors to somehow influence the investigation—they also translate learning in a specific way. The regulatory object of learning from incidents is local; the investigation should result in corrective recommendations that fit a particular setting (Leistikow et al., 2017). This warrants the involvement of local practitioners in the investigations. External chairs emphasise the learning processes that happen as part of conducting the investigation, rather than the specific recommendations or the report as such. The process of investigating an incident creates a platform for knowledge sharing, the value of which extends beyond the specific corrective actions drafted and beyond the organisation where the investigation is conducted (as external chairs bring back insights to their own organisation).

In chapter 5, we documented organisational investments into the regulatory instrument that accompanies the regulatory object of learning from incidents, so that hospitals are increasingly able to demonstrate their capability to do good quality incident investigations. The key quality agents recruited by the regulatory object of learning from incidents and its instrument are incident investigators. Incident investigators increasingly professionalise in response to the importance of analysing incidents properly and reporting on that analysis. It shows how organisations invest in regulatory inscriptions of quality and how social relations and professional status might alter due to those investments (Wallenburg et al., 2019b). Still, such 'investments' are not homogenous across the board and regulatory instruments do not determine investments; some hospitals take a different approach than others (Kok et al., 2018). While there are hospitals that appoint dedicated investigators to conduct incident investigations and report on those investigations—assuring a consistent quality of reports, reflecting a concern with quality that seems to subscribe to the idea that the score received is (indicative of) that quality—other hospitals elect to have different professionals participate in investigating and report on incidents, stressing the idea that learning occurs through an investigative process that solicits the participation and contribution of multiple people. Yet, as we observed before, the scoring instrument's emphasis on the investigative process might inadvertently communicate the idea that adequately investigating an incident amounts to learning from it—a confusion others have identified (Macrae, 2016; Ramanujam and Goodman, 2011)—and falls short in emphasising and monitoring what happens

after an investigation. This favours the participation and professionalization of one particular group (investigators). These investigators, in turn, can look to further solidify the organisational investments in response to the Inspectorate's scoring instrument by stressing the importance of their position. In chapter 5, we have seen how this claim can encumber the participation, contributions and critical reflections of other actors (professionals or patients and families) as investigators stress and enact their ownership of the investigative process. Supported by the Inspectorate's scoring instrument, investigators can align with and advance their own evaluation of what qualifies as a 'good' investigation—locking in organisational processes and structures required to deliver such investigations and their own role in that (Dahler-Larsen, 2019).

In chapter 6, we showed how, through the scoring instrument, patients and family members are specifically invited to contribute to the process of learning from incidents as quality agents. Inspired by wider calls to increasingly involve patients and family members in healthcare, given that they are 'experts in their own right', with their own take on what 'good' care entails (Fitzsimons and Cornwell, 2018; O'Hara et al., 2018; Vincent, 2002), this involvement is encouraged by the Inspectorate through their scoring instrument (Bouwman et al., 2018; Kok et al., 2018). The scoring instrument stresses the participation of multiple actors, so that a richer understanding of an incident might be developed. In chapter 6, we analysed this multi-actor participation in the investigative process using the concept of epistemic injustice (Fricker, 2007). We argued for understanding an incident investigation as a practice that solicits epistemic contributions from a range of agents (Anderson, 2012)—a platform of epistemic exchange—and wherein we attended to how such epistemic contribution were valued and by whom. While patients and family members are increasingly invited to contribute to incident investigations, we showed, their 'knowledge' or the value of their contributions are subject to challenge. While the scoring instrument encourages the contribution of patients and family members in incident investigations, it simultaneously calls for a particular type of epistemic contribution that investigators argue patients and family members are not in the best position to provide. Or, the way in which learning from incidents is operationalised in the scoring instrument favours the contribution and 'knowledge' of some actors over others. While the regulatory object developed argues for (increasingly more inclusive) participation of a range of actors, its inscription builds upon RCA-methodologies that meticulously, linearly and conclusively look to unravel what caused or contributed to the occurrence of an incident (Nicolini et al., 2011), favouring the accounts of emotionally detached professionals. Perhaps ironically, the 'different' perspective patients and family members are said to have—the idea from which many calls to increasingly involve them in a wide range of practices depart—is difficult to incorporate and value in the incident investigation framework developed by the Inspectorate *because* it is different. Investigators use patients' and family members' input to 'fact check' *their* analysis, rather than as

a way to wonder what a 'good' investigation means for different people. Investigators enact evaluative criteria that render particular epistemic contributions from particular quality agents valid or not.

In all, we can think of regulation as the attempt to assemble and position particular quality agents so that they might perform quality work related to regulatory objects. Regulation participates in discussions on who 'experts' are in particular quality issues and what constitutes their expertise. In chapter 4, we described how the Inspectorate looks for ways to "penetrate organizational boundaries" (Vaughan, 1990, p. 228) to gather information on regulatee performance. The Inspectorate increasingly calls on quality agents outside of the regulator-regulatee relationship in their regulatory practices. In our studies we encountered the introduction of the external chair and the mobilisation of patients and family members in incident investigations. Under the umbrella of 'client participation', the Inspectorate has experimented with ways to increasingly involve citizens in their regulatory practices (de Graaff et al., 2018). Studies have reported on the use of experts-by-experience and mystery guests in elderly care (Adams et al., 2015; de Graaff et al., 2018) and how inspectors value the perspective of adolescents in youth care (Rutz et al., 2018). Projects undertaken with the aim to increase client participation typically look to "discover a way to include citizens in order to better explicate and utilize clients' perspectives on quality of care in order to improve regulatory work, legitimate decision-making processes and enhance the public's image of, and trust in, the IGJ [Inspectorate] more generally" (de Graaff et al., 2018, p. 276). One would be hard-pressed in arguing against user involvement (in regulation), even if the added value of doing so is debated (de Graaff et al., 2018). Still, one could make the case that in positioning agents outside of the regulator-regulatee relationship in regulatory practice (external chairs, patients and families, experts-by-experience), the Inspectorate recruits 'outsiders' to help them breach organisational boundaries and assist in information gathering. It is a way through which the Inspectorate looks to 'play the game' of distance/proximity by recruiting quality agents that are closer to care practices than inspectors are (Wallenburg et al., 2019a).

## THE CONSTITUTIVE EFFECTS OF REGULATORY OBJECTS

The term constitutive effects, as described in the introduction, refers to how regulatory instruments can come to influence the reality they claim to describe—or, indeed, assess. Assumptions about how regulatees might respond to a regulatory object are 'inscribed' onto regulatory instruments. But the constitutive effects of a regulatory object come

about as quality agents respond to and enact to that object in practice. In this way, constitutive effects are always co-produced between regulators and regulatees.

As stated before, the struggle to construct a hospital merger as a regulatory object (described in chapters 2 and 3) makes it that no quality inscriptions are made. In line with the notion of regulation as a visual practice, regulatory instruments that carry quality inscriptions can 'direct the gaze' of individuals or organisations, encouraging them to attend to particular issues of quality, at the cost, most often, of attending to other matters (of quality). In the case of hospital mergers, a lack of regulatory instruments means that the Inspectorate does not direct the gaze on organisational practices of (merging) hospitals. Without such instruments, the regulatory practices of the Inspectorate fail to perform a 'call' for quality agents to act upon such a quality inscription (Dahler-Larsen, 2019). Hospital mergers are, effectively, unregulated by the Inspectorate. Inspectors fall back on traditional signals indicative of regulatee performance (e.g. scores on performance indicators, an increase or decrease in reported incidents), while keeping the merger, as a noteworthy but uninspectable event, 'in the back of their mind'. The informal notion of a hospital merger as a 'life event' is non-performative, because it does not transform and render observable 'good' organisational behaviour in the case of a merger that hospitals would be able to enact or inspectors to assess (Butler, 2010; Mackenzie, 2006).

The regulatory object of learning from incidents is made observable and codified into a scoring instrument, the process and effects of which we explored in chapters 4, 5 and 6. In these chapters we see how the quality inscription through which the object of learning from incidents functions—the scoring instrument that specifies conditions for conducting good investigations into incidents—is enacted in healthcare organisations. In the attempt to render learning from incidents observable, the Inspectorate encourages organisational attention and investments towards the investigation of incidents—so that the regulatory object might (in part) constitute or perform what it sets out to measure. Dahler-Larsen suggests constitutive effects can be observed in:

- the content of some object or practice,
- the timing of activities related to that object or practice,
- the social relations of those involved,
- the broader worldview in which the object or practice is situated. (2019, p. 117)

We have shown how the content of the practice of doing incident investigations is (re)directed towards 'doing well' on the scoring instrument used by the Inspectorate to assess said investigations. For example, proposed recommendations following an investigation are drafted by investigators so that they match the analysis of the incident. This is not to say that this is a poor way of evaluating recommendations, but it does direct attention away from other ways of evaluating recommendations—e.g. by hav-

ing healthcare professionals that have to work with these recommendations weigh in on their fit with current practices and/or their potential to improve care practices. In terms of timing, the regulatory object of learning from incidents seems to propose that learning, as the process of creating and applying valid knowledge that would enable organisations to improve, happens within formal investigations that organisations are required to conduct within an eight-week timeframe. This has several effects. In chapter 5 we documented how investigators struggled with the work involved in consistently investigating incidents one after another. While these investigations might generate potentially valuable insights, time or resources to reflect on the implications for these insights on wider safety practices or rethinking organisational structures is scarce. Also, we have seen how respondents invoke the timeframe in arguing that participating in incident investigations for patients and families is challenging; the emotional burden might be too great for patients and family members to contribute their perspective to the investigation so soon after the event. In terms of social relations, chapter 5 documented how incident investigators can become a respected professional group that asserts its professional authority in response to the increasing importance (attributed to) conducting 'good' incident investigations. Moreover, external chairs are brought in and can contribute to strengthen the independence of incident investigations in elderly and disabled care, intervening in the relationship between directors and investigators of a given organisation. In chapter 6, we saw that although patients and family members are increasingly involved in incident investigations, their epistemic contributions to the investigation run the risk of being downplayed, so that the scoring instrument does not successfully perform patients and families as 'experts' in an equal position to contribute knowledge to incident investigations as other actors. In terms of the broader worldview the practice of investigating incidents helps shape, it constitutes a particular view of learning as a process that occurs within formal investigations and that can be regulated. The scoring instrument of the Inspectorate performs an understanding of learning as an intensive 8-week investment (a bounded project, if you will), rather than as an activity that is ongoing and embedded in the practice of providing care. The quality inscription fails to inquire into how organisations invest in sustaining and translating the insights from the investigation beyond that project, so that investigations can become standalone activities.

All of this is to say that *how learning from incidents is inscribed, helps shape what it aims to measure*; healthcare organisations design their investigation processes in such a way that they are in a position to do well on the Inspectorate's scoring instrument. The scoring instrument is not (just) representative of "the quality of the learning process" (Leistikow et al., 2017, p. 2) if that instrument intervenes in and shapes the processes it aims to observe. Rather, those processes are formed in such a way that they come to resemble the instrument. The constitutive effects of any one regulatory instrument can

travel in many directions. Given the regulatory object's emphasis on social and participative learning, the increased involvement of patients and families in incident investigations appears laudable. But inclusion is not the same as participation. As investigations become stand-alone activities, as the epistemic contributions from patients, families and involved professionals are undervalued and as an emphasis on the independence of the investigation inhibits deliberation between investigators and professionals on the value of corrective actions, we have to consider that *the very attempt to observe and measure social and participative learning hampers it*. This is a criticism that extends beyond a discussion on the validity of the scoring instrument. Any instrument or model has the potential to bring about the phenomenon it looks to describe, but equally, it can fail (or misfire) (Butler, 2010). In case of a misfire an instrument might be non-performative (e.g. failing to bring about social and participative learning), but a particular type of misfire might generate 'counter-performative' effects (Mackenzie, 2006). The practice of monitoring and assessing social and participative learning produces 'inverse effects' (e.g. the restricted or thwarted participation of particular actors) through which the investigative practices it renders inspectable become *less* social and participative.

## ON REGULATION AS VISUALIZING PRACTICE

Consistent across the different studies and shaping the Inspectorate's regulatory practices both in response to hospital mergers and incidents, is the idea that regulation needs to visualize quality and safety of care. Regulation is framed predominantly as a practice of seeing and through seeing, inspectors come to know. In the case of hospital mergers, inspectors try to get a sense of how hospitals are doing by 'seeing' how they are doing and when inspectors feel these efforts falter, they risk 'losing sight of things' (chapter 2 and 3). The value of the external chair and the (increased) involvement of patients and families in incident investigations is connected to the objective of learning from incidents and constructed *visually*. External chairs are repeatedly said to bring in a 'fresh and critical perspective', aiding the investigative process (chapter 4), while patients and families are said to 'see things differently' than professionals and for that reason should be involved in incident investigations (chapter 5 and 6). The Inspectorate's 2018 annual report wherein it states their plans and ambitions for the coming year was titled: 'Seeing with different eyes' (Inspectorate, 2017). The pervasiveness of the metaphor that presents regulation as a visual activity is such that I might be pointing out the obvious. The 'visual' is embedded in many of the words we use when we talk about regulation; we talk about 'supervision', 'monitoring', 'regulatory oversight' and the concept 'to inspect' goes back to the Latin *inspectus*, meaning as much as to 'look at, observe, view'.

What makes pointing this out worthwhile is how, in the cases studied, there seems to be a logic at play that connects seeing to knowing to acting. Operating from this logic, the practice of regulating organisational behaviour starts with answering the question if and where this type of behaviour can be observed. If it cannot be observed, or it is unclear how particular organisational behaviour impacts quality and safety of care, the regulator does not know. Not knowing, a regulator cannot (proportionally and legitimately) take regulatory action. The different approaches inspectors take in response to hospital mergers—visiting more often 'to see for themselves', 'closely looking at hospital performance behind the scenes' or criticising the idea that a merger would negatively impact quality and safety of care as a 'gut feeling', invoking a different bodily sensation than seeing that regulatory action can impossibly be based upon—substantiate this notion even if they reach different answers to the question where the behaviour relevant for quality and safety of care in the case of a merger might be observed (cf. Wallenburg et al., 2019a). *The (in)ability to visualize organisational behaviour that speaks to quality and safety of care is the first step in and informs subsequent regulatory practice*. When efforts to visualise such behaviour falter, a regulatory impasse follows (chapters 2 and 3). When efforts to visualise such behaviour succeed, regulation generates constitutive effects (chapter 4, 5 and 6).

The idea that through seeing we come to know can be traced back towards the scientific revolution—a period Latour proposes entailed "the rationalization (…) of the sight" (1986, p. 7)—and the birth of scientific objectivity (Daston and Galison, 2010). As Daston and Gilison put it:

> To be objective is to aspire to knowledge that bears no trace of the knower—knowledge unmarked by prejudice or skill, fantasy or judgement, wishing or striving. Objectivity is blind sight, seeing without interference, interpretation, or intelligence. (2010, p. 17)

The aspiration to objective knowledge, or 'blind sight', depended on the development of scientific techniques that could visualize the object under study (Daston and Galison, 2010; Latour, 1986; Lynch, 1985). The properties of an object, if it is to be studied scientifically, would need to be 'observable-reportable' (Lynch, 1985, p. 44). The regulatory practices of the Inspectorate work in a similar way, as the ability to regulate a particular quality issue depends on making regulatee behaviour that relates to that quality issue 'observable-reportable'—that is, inspectable.

The Inspectorate takes a 'perspectivist' approach in its regulatory practices (Leistikow, 2018; van Diemen, 2019). Perspectivism holds, simply, that people experience and interpret the world differently. The Inspectorate seeks to account for and increasingly looks to involve different groups of people (and their ways of seeing quality and safety

of care) in its regulatory practices (Inspectorate, 2016a; Leistikow, 2018; van Diemen, 2019). Different groups of people are asked to contribute to regulation—in particular in incident investigations, as studied in this thesis—so that they might see (observe and report) different aspects of quality and safety of care. In chapter 4, we saw this logic at work. An external chair was brought in to aid the investigative process in elderly and disabled care organisations—a regulatory intervention that came about as politicians called for external review, while the Inspectorate emphasised the involvement of local practitioners to facilitate learning. The external chair was said to have a 'fresh, critical perspective' as a relative outsider (being untied to the organisation where the incident occurred), but also holds particular expertise on how to adequately investigate an incident. Having a fresh perspective, while 'knowing where to look', is how we phrased it before. Put differently, the expertise of external chairs is valued as such because their 'way of seeing' is attuned to and in line with how the regulatory instrument of the Inspectorate operationalises learning from incidents. When perspectives do not align with the notion of quality inscribed into the regulatory instrument, their expertise can be challenged or is hard to accommodate for. Patients and families, as well as healthcare professionals involved in an incident, are at times perceived as (too) emotional to be able to contribute a valid perspective. While 'being emotional' can impossibly be separated from their perspective (as one bereaved), the regulatory instrument does not 'look for' such experiences. While perspectivism is at odds with the possibility of absolute objective inquiry, that of 'blind sight', the way in which perspectives are valued seems informed by the idea that some perspectives are more helpful in uncovering 'what really happened' than others. But, also, to involve multiple perspectives supposedly enables one to get a better sense of, get closer to, 'what really happened'. What is interesting too is how the scoring instrument seems to favour the participation and contributions of those emotionally detached—a key aspect of objectivity (Daston and Galison, 2010, p. 29)—that external chairs say they are, while patients and families and involved healthcare professionals are not. Being able to see things the right way is connected to a sense of detachment or a degree of distance from the event one is observing—or that is how any perspective is valued as the regulatory instrument is engaged with. What becomes apparent, then, is a tension between the Inspectorate's ambition to involve and do justice to different perspectives with(in) their regulatory practices and the way in which the instrument it mobilises to do so can shape or restrict those perspectives (c.f. de Graaff et al., 2018).

This focus on the visual in the regulatory practices of the Inspectorate, I suggest, does (broadly) two things: 1) it helps shape what and how regulatee behaviour can be rendered inspectable and 2) it informs how inspectors and other quality agents (external chairs, patients and families) think about and evaluate 'knowledge' on quality and safety of care. First, it seems that particular regulatee behaviour is more easily (rendered)

observable, so that the Inspectorate's focus on the visual shapes what behaviour can be regulated in the first place. Taking the regulatory object of learning from incidents, the Inspectorate developed particular regulatory practices and instruments to render learning visible. The conviction that 'learning' happens in incident investigation is argued for (Leistikow et al., 2017), but is also informed by the need to observe learning. This privileges the monitoring of formal systems of learning, the performance of which organisations can (more) easily demonstrate, but complicates taking into account informal practices of learning or knowledge sharing. While informal learning also contributes to organisational learning and patient safety, it is a lot harder to render visible (Iedema et al., 2010; Waring and Bishop, 2010). Here, we can return an observation made earlier: the idea that while the regulatory object of learning from incidents seems located on the second- and third-tier (referring to a self-evaluative activity), it is monitored primarily on the first-tier due to the regulatory instrument that accompanies it. We can wonder, then, if regulatory objects tend to be operationalised on the first regulatory tier in prescriptive fashion, because rendering regulatee behaviour visible is easier on this tier than it is on others? Second, inspectors use and invest in the regulatory instruments that look to render quality and safety inspectable. Their ideas about what good regulation is and what counts as valid knowledge about quality and safety are informed by these instruments (c.f. Kok et al., 2019). Inspectors consistently aim to see how organisations perform, turning to visualization as the legitimate way to assess regulatee performance. But, in the practice of regulating, inspectors experience other sensations too. However, when inspectors describe having a 'hunch' or a 'gut feeling', what follows is the effort to somehow substantiate these feelings through the use of established regulatory instruments. A hunch might inform a decision to more closely attend to the performance of particular regulatees by using instruments that can help confirm a hunch visually (Wallenburg et al., 2019a). When visual substantiation of other sensory experiences does not happen, regulatory intervention is not thought to be legitimate.

Regulation (and the Inspectorate more specifically) has been criticised for regulating a 'reality on paper' (Spaink, 2019)—'*papieren werklijkheid*', in Dutch—suggesting there exists another, 'real' reality that regulation fails to target. To imagine that one could directly access such a reality, without translating it through processes of inscription (onto paper), would be foolish, Latour suggests (2007b). Regulation, and process-based regulation in particular (with the risks that this might pose (Gilad, 2010; Mills and Koliba, 2015)), in a way always entails and can hardly be anything but the regulation of a documented reality. When we acknowledge as much, the question becomes *how the process of documenting quality and safety of care (with regulatory instruments and inscriptions) might enable or encourage regulatee responses that are productive considering the regulatory object defined*. This warrants, in a way, to question the idea that visualization entails substantiation. The visualization of quality and safety of care—and the recourse

to (quantitative) quality inscriptions to do so—should not be considered as representative of regulatee performance as such. Rather than substantiate, quality inscriptions indicate, perform and implicate. Realising this, the efforts of the Inspectorate to render regulatee behaviour visible and assessable should be part of an open and on-going dialogue between regulator and regulatees about how calling regulatees to account for their behaviour in a particular way helps encourage them to improve (or not) (RvS 2019). Good care, for Mol et al., is:

> the persistent tinkering in a world full of complex ambivalence and shifting tensions. (…) In care, then, 'qualification' does not precede practices, but forms a part of them. The good is not something to pass judgement on, in general terms and from the outside, but, something to do, in practice, as care goes on. (2010, pp. 13–14)

Regulating quality and safety of care, the Inspectorate is not at the side-lines of this practice, but a part of it (Wallenburg et al., 2019a). We can think of regulation as the concerted effort to make sense of, engage with and evaluate questions of 'the good, the bad and the ambivalent' (Mol et al., 2010). Being increasingly faced with uncertainty (Sabel et al., 2018; Sabel and Zeitlin, 2011)—or, as regulators become increasingly comfortable with admitting as much—what constitutes the good, the bad and the ambivalent is not readily apparent, to regulators nor regulatees (Mol et al., 2010). In the on-going dialogue between regulators and regulatees we propose, both parties acknowledge their role in enacting the good, the bad and the ambivalent, as part of the practices of providing care and regulating care—rather than as evaluative labels attached to but outside of those practices. Also, the 'good' and the 'bad' might be intertwined; one regulatory instrument can generate multi-directional effects as regulatees respond to it. The instrument that enacts the regulatory object of learning from incidents is a case in point. Although incident investigators professionalise and patients and families are increasingly involved, investigations can become stand-alone activities, disconnected from wider safety practices and the value of the contributions of patients and families is undervalued. This calls for regulation that is 'recursive' (Sabel et al., 2018; Sabel and Zeitlin, 2011) and legitimately allows for regulation to entail a 'matter of attentive experimentation' (Mol et al., 2010). In his case for an 'experimentalist' state, Latour writes:

> Whatever has been planned, there are always unwanted consequences for a reason that has nothing to do with the quality of the research or with the precision of the plan, but with the very nature of action. It is never the case that you first know and then act, you first act tentatively and then begin to know a bit more before attempting again. (2007b, p. 4)

For the Inspectorate, to 'act tentatively'—as I see it—entails the attempt to render regulatable regulatee behaviour that relates to quality and safety of care as well as a sustained dialogue about the (multi-directional) constitutive effects of that attempt. The effects of regulation, as I have noted before, are relational as regulator and regulatee respond to one another. A sustained dialogue between regulator and regulatee can help both parties understand how regulatory effects come about relationally and offers an opportunity to question how those effects are valuable given the regulatory object constructed. One of the challenges regulating tentatively poses to the Inspectorate is to design regulatory instruments and quality inscriptions that quality agents can invest in and work with (so that they might travel), but that also retain a degree of flexibility so that they might be altered if regulators and regulatees 'know a bit more' about its effects. Another challenge is that of acknowledging that 'inspecting' also entails to make room for and develop other senses than seeing. "The point of departure is that we are constantly hesitating between several often contradictory indications from our senses. Most of what we call 'abstraction' is in practice the belief that a written inscription must be believed more than any contrary indications from the senses." (Latour, 1986, p. 24) Faith in an inscription (because it has been invested in, because it is a legitimated instrument for guiding regulatory decision-making or because it enables objective, emotionally detached engagement) can be challenged by understanding its constitutive effects, but also through the development of regulatory practices that can legitimately take into account other repertoires of knowing. An emphasis on formal regulatory instruments that visualise quality of care might fixate regulatory practices and render the Inspectorate insensitive to other sources of information that inspectors might collectively make sense of (Wallenburg et al., 2019a). The dialogue as mentioned earlier can help the Inspectorate reflect on and rethink what quality inscriptions measure as well as accomplish beyond 'just' measuring. In addition, it remains worth exploring how activities other than visualizing regulatee behaviour could contribute to regulatory knowing and legitimate regulatory action.

## IMPLICATIONS FOR THEORY AND PRACTICE

Here, I want to reflect on the implications of my findings and think about the theoretical and practical value of the perspective on regulation and its effects that I have developed.

My research showed how we can think about regulation as a relational act that harbours a call to quality and that, within that call, are embedded expectations on regulatee behaviour in response to such a call. This call to quality is accompanied by the construction of regulatory objects (e.g. learning from incidents); issues that are claimed to relate to or are reflective of quality when individuals or organisations respond to

such objects in particular ways. One of the key ways through which regulation works is through the act of rendering observable and assessable 'quality'. Regulatory instruments carry quality inscriptions through which regulatee behaviour that relates to or is said to be indicative of particular aspects of quality (e.g. conducting incident investigations and reporting on those investigations) is made inspectable on one or multiple tiers. The notion that regulation is a visual practice is a particularly dominant theme that runs through both the Inspectorate's official publications and interviews with inspectors. I have shown what it takes for the Inspectorate to be able to see quality and safety of care and how the idea that the assessment of quality depends on the visualisation of it could potentially privilege the regulation of practices that are more easily rendered observable (e.g. formal systems of learning vs. informal practices of knowledge sharing). To regulate quality and safety of care encompasses bringing about a dynamic network that depends on a range of elements and continued investments of actors (quality agents) to work. I have shown how a quality network, or configuration, wherein these elements are mobilised and are related, does not come about in the case of the regulation of hospital mergers. In the regulation of incidents such a network does come about, as healthcare organisations respond to the quality inscription that accompanies the regulatory object. But, here, the dynamic regulatee behaviour the regulatory object is out to promote and assess (learning from incidents) can be hampered—at least, after a time of promoting it—as organisational practices and behaviours solidify in response to the (unchanging) regulatory instrument that accompanies the regulatory object. Often, the quality inscription a regulatory instrument produces is mistaken for 'quality', so that receiving a high score for an incident investigation report amounts to having learned from an incident. This solicits individual and organisational investments in regulatory instruments and its inscriptions by both regulators and regulatees. As this happens, regulatory instruments can generate constitutive effects, the term with which I have referred to the phenomena whereby regulatory instruments do not simply measure regulatee behaviour but constitute it. The Inspectorate, as such, does not just protect and promote quality and safety of care; through the act of regulating quality and safety of care, it advances and helps solidify notions of 'good' quality and safety of care.

This perspective on regulation contributes to the literature on regulation in multiple ways.

First, in drawing from both regulation and governance and ANT literature, I have been able to develop a perspective on regulation that attends to the different elements (regulatory objects, regulatory instruments, quality inscriptions, quality agents) through which regulation works. In thinking about regulation as an institutional call to quality that mobilises these elements with the aim to monitor or alter regulatee behaviour it becomes possible to question how these elements align. Distinguishing between a regulatory object (the object of quality that is legitimately regulated) and a regulatory

instrument (that operationalises and renders inspectable that object of quality) sheds light on the process of translation that transpires in moving from a regulatory object and the instrument that supports it. It allows for evaluating the fit between any given regulatory object and the instruments that look to render that object inspectable. It also shows how regulators do not simply monitor the quality of particular services through the use of instruments, but rather partake in defining what 'quality' is, where it might be found and who is able to engage with that quality—scripted into regulatory instruments as these ideas are.

Second, the concept of quality agents allows for understanding how regulators recruit actors outside of the regulator-regulatee relationship in its regulatory practices. Not only does this accommodate for understanding the work of actors beyond the restrictive regulator-regulatee relationship in regulation, it also helps in identifying those that are granted a position from which to speak to the quality of regulated services. Regulatory instruments pave the way for the participation of some actors (and denying or limiting that of others) while also shaping what that participation looks like or should lead to. Given this, the notion of 'quality' that regulation monitors as well as enacts, is shaped by both the regulatory objects and regulatory instruments a regulator employs and how quality agents respond to them. In this perspective on regulation, the effects of regulation are thus co-produced, contingent upon the interaction between a regulatory call to quality and the responses of those implied in that call.

Third, my research contributes to the theory of process-based regulation and the question of how quality issues can be located and rendered inspectable on one or multiple tiers. As such, the perspective on regulation developed in this thesis offers a way to think about legitimate regulatory action under conditions of uncertainty. A regulatory object might be accompanied by multiple regulatory instruments and quality inscriptions that render regulatee behaviour inspectable on multiple tiers. Regulation is, then, the assessment of regulatee performance as it aligns on the different tiers and how signals of performance on one tier mediate those on another. This means that prescriptive, first-tier regulation still has its place, but what it is able to say about regulatee performance changes when regulatee behaviour on the other tiers is taken into account. Work of Wallenburg et al. (2019a) demonstrates that a signal on the first regulatory tier (e.g. an unreported incident that should have been reported) comes to mean something different for inspectors when a hospital director is aware of the issue and takes responsibility for it, than if a director is defensive and reflects responsibility. What my analysis on the constitutive effects of regulatory instruments suggest is that to think about how regulatees perform across three tiers, is also to evaluate how the distinct regulatory instruments mobilized and their enactment in practice is conducive to such performance.

My findings are also relevant for the Inspectorate and for regulation in general.

For one thing, my perspective on regulation offers opportunities for a particular form of regulatory reflexivity. While regulatory reflexivity might be of a rather instrumental nature—wondering 'do our methods work?'—the findings presented here call for a reflexivity that acknowledges that regulatory instruments and their quality inscriptions can enact realities just as they might describe them. To recognise as much can make regulators aware of how instruments might lock in regulatee behaviour in response to those instruments. This became clear as organisations responded to the scoring instrument developed by the Inspectorate to assess how organisations learn from incidents. While the regulatory object targets and looks to encourage a dynamic practice (processes of learning), the instrument accompanying it provides a rather static interpretation of that practice. Being responsive to the learning capabilities of healthcare providers warrants the development of regulatory instruments that can accommodate for the (continued) improvement of those capabilities. When regulatee behaviour in response to a regulatory instrument solidifies, it might be time to rethink and redesign the instrument so that it encourages regulatees to improve. To give an example; asking hospitals how the contribution of patients and families has enabled them to improve their daily care practices is more responsive to regulatee performance than continuing to ask hospitals if they have asked patients and families to contribute to an investigation. To distinguish between a regulatory object and a regulatory instrument can help regulators evaluate how instruments render a quality issue solid just as it might (inadvertently) solidify regulatee behaviour in response to it. While I have not put the vocabulary of decoupling centre stage in my analysis, the distinction (and fit) between a regulatory object and its instrument can stimulate attempts to 'recouple' regulatory practices with regulatee behaviour (de Bree and Stoopendaal, 2018; van de Bovenkamp et al., 2020).

Second, this perspective on regulation is an attempt to explicate how regulation works and as such provide the Inspectorate and its inspectors with a vocabulary they can use in developing and evaluating their practices. The value of my research, in terms of the perspective on regulation it advances, can be thought of as providing an account of exnovation. "Exnovation refers to the attempt to foreground what is already present – though hidden or overlooked – in specific practices, to render explicit what is implicit in them." (Mesman, 2011, p. 72) To explicate the implicit, in an account of exnovation, serves to open up new questions and aims to improve practices (Mesman, 2011). For the Inspectorate, and other regulators, the vocabulary presented here allows for rethinking its regulatory practices. What notion of 'quality' do our regulatory instruments advance? What actors are (not) recruited in our regulatory instruments? How do the (constitutive) effects of our regulatory instrument serve our regulatory objectives? What issues of quality should we translate into regulatory objects to begin with? For regulators, the perspective developed here hopefully enables them to evaluate their practices in a new way and rethink how their practices might generate effects.

# RESEARCHERS ARE QUALITY AGENTS TOO

Much of the research conducted for this thesis was done within the Dutch Academic Collaborative on Supervision (AWT). This collaborative between the Inspectorate and four research institutes aims to scientifically study the effectivity of the Inspectorate's regulatory practices. "The use of scientific knowledge enhances the reliability and effectivity of both our risk-based and incident-based regulation," the Inspectorate reports (2017, p. 69). This collaboration came about in response to wider calls to make regulation more 'evidence-based' (Gezondheidsraad, 2011; WRR, 2013), that we can understand as calls to quality that proclaim 'good' regulation is informed by scientific evidence. In such calls, researchers are recruited as key quality agents studying regulation and its effects, contributing thereby to its legitimacy. As such, I am not external to the quality configuration that I claim regulation establishes. By studying the (constitutive) effects of the Inspectorate's regulatory instruments and the regulatory objects they operationalise, I participate in (re)constructing said instruments and objects. The recommendations that typically feature in the conclusion of the studies collected here are often proposals to construct regulatory objects differently, elsewhere (on a different tier) or redesign its accompanying instruments. The recommendations proposed often look to counter particular constitutive effects generated by a regulatory object. I am aware however, that even if these recommendations are successful in doing so, the 'new' regulatory object is likely to generate new constitutive effects. The question of how regulation works is settled in action as regulators and quality agents respond to new regulatory objects (and one another). "It is never the case that you first know and then act, you first act tentatively and then begin to know a bit more before attempting again." (Latour, 2007b, p. 4) What is true for regulators, is equally true for those interested in the effects of regulation. Above, I described how the perspective of regulation I developed allows for (a particular form of) regulatory reflexivity. The AWT harboured its own, academic reflexivity, organised outside of the organisational contours of the Inspectorate, looking in. Despite the (at the time of writing) recent discontinuation of the AWT, the fundamental inability to fully anticipate the (constitutive) effects of the Inspectorate's practices warrants the recursive opportunities for reflection that academic research into regulation offers. While both the Inspectorate and research thinks about the effects of regulatory practices, they occupy different positions from which to do so and launch different projects of inquiry. How those reflective projects might be organised and reinforce one another remains important.

## FINAL REMARKS

The practice of regulating quality and safety of care can shape quality and safety of care. In the attempt to monitor, or render visible, regulatee performance, regulation can (inadvertently or not, productively or less so) impact that performance. In distinguishing the objects of quality regulators choose to focus on and the instruments they develop to render that quality inspectable, studies on regulation can evaluate the fit between the (constitutive) effects generated by regulatory instruments with the regulatory objective they supposedly serve. Regulation can be thought of as the mobilisation of a dynamic network as it engages with questions of 'the good, the bad, and the ambivalent'. Responsive and reflexive regulation engages its regulatees in discussing what constitutes the good, the bad and the ambivalent in particular situations and how regulatory practices might play a part in assessing it. This calls for regulatory practices that are (allowed to be) experimentalist, consistently curious about how its regulatory objects and instruments encourage regulatees to improve (or not).