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# On regulating regulatory objects



On 20 April 2010, a blowout caused an explosion on the oil rig Deepwater Horizon. The explosion killed 11 people and the rig sank, two days after the explosion, in the Gulf of Mexico. Before the well the Deepwater Horizon was drilling was eventually capped on 19 September 2010, about 795 million gallons of oil had spilled into the Gulf of Mexico (Berenshtein et al., 2020; Mills and Koliba, 2015). The Deepwater Horizon oil spill is considered the largest environmental disaster in US history. Inquiries into the disaster demonstrated that decision-making processes by BP (that owned the well) were driven by considerations of profit maximization rather than safe professional practices. The inquiries also paint the picture of failing regulatory oversight. The regulator tasked with overseeing the drilling practices of the Deepwater Horizon was deferential to the professional expertise of industry to a fault. The regulator, *The New York Times* writes, “lacked the personnel, training and muscle to do its job”. “Notwithstanding [the] inherent risks [of offshore oil drilling], the accident of April 20 was avoidable,” the National Commission concludes. “It resulted from clear mistakes made in the first instance by BP, Halliburton and Transocean, and by government officials who, relying too much on industry’s assertions of the safety of their operations, failed to create and apply a program of regulatory oversight that would have properly minimized the risk of deepwater drilling.” While the regulator relied on the industry to self-regulate, that industry was geared towards profit maximization rather than the safety of its practices.

The Deepwater Horizon disaster clears the way for a myriad of questions. In this thesis I am interested in that of regulation and its effects. Two observations characterise (the difficulties particular to) the contemporary regulatory project. First, regulators are increasingly called to demonstrate and account for the effects of their work; regulation needs to generate impact or value (Leistikow, 2018; Sheldon, 2019; WRR 2013). Second, regulators contend with a complex modern world; uncertainty about how to best regulate a particular issue at stake is not uncommon (Gilad, 2010; Grit et al., 2016; Sabel et al., 2018). These observations relate to one another. In a complex world, regulators increasingly monitor the adequacy of organisations’ ‘self-regulation systems’; systems organisations have in place through which they can critically evaluate and account for the quality of their services (Gilad, 2010). The risks a regulator runs in relying on industry’s willingness and capacity to self-regulate can be considerable, as the Deepwater Horizon disaster makes apparent. In the Netherlands, the regulation of the Human Environment and Transport Inspectorate (ILT) was critiqued for being an ‘exercise on paper’ and ‘minimalist’ as it depended too readily on the safety processes of industry (Parlementaire enquêtecommissie Fyra, 2015). Following a disaster or crisis—like the Deepwater Horizon disaster or the consistent problems associated with the high-speed

rail service of the Fyra—any self-respecting inquiry into such events calls for ‘better regulation’ (that is not infrequently synonymous to ‘more regulation’) so as to prevent future incidents (WRR, 2013). In response to the financial crisis of 2007-2008, the IMF opined that good regulation needs to be ‘intrusive’ (Viñals and Fiechter, 2010). Dubbed the ‘regulatory paradox’ by the WRR, regulators tend to keep their distance when all is well, but develop more intrusive and stringent regulatory strategies in response to high-level incidents (WRR, 2013). While the failure of regulatory oversight is typically associated with (or even said to contribute to) high-level incidents, the belief that other, better regulatory strategies could prevent future incidents is unwavering.

In the quest for better regulation, calls for evidence-based regulation stress the need for scientific research into the effectivity of regulation (Gezondheidsraad, 2011). This is where this thesis comes in. It is part of the movement towards more evidence-based or evidence-informed regulation, as well as a reflection on it. In this thesis I study the regulatory practices and effects thereof of the Dutch Health and Youth Care Inspectorate (Inspectorate, hereafter). The Inspectorate is the national regulator tasked with monitoring quality and safety of care in the Netherlands. The work of the Inspectorate constitutes an interesting object of study. In our society, to be safe from danger has come to constitute a key public good (Beck, 1992; Giddens, 1999). The notion of risk—referring to a possible future hazard (like a financial crisis) that need not occur if it is adequately controlled—is expressive of our (fairly novel) preoccupation with safety and served to (re)orient the responsibilities of the state. We increasingly look to states and its regulatory agencies to anticipate risks and protect us from hazards (Baldwin et al., 2012; Beck, 1992; Giddens, 1999). The implication is that when a hazard does materialise, the regulator that ought to have monitored and foreseen it, is (also) to blame. In the Netherlands, it is not uncommon for fatal incidents in healthcare to be reported in national media and when they are, the role and responsibility of the Inspectorate is increasingly questioned (Behr et al., 2015; Leistikow, 2018). The Inspectorate contends with high public and political expectations of what regulation can and should accomplish (Legemaate et al., 2013; Leistikow, 2018). Meanwhile, there is low public and political tolerance for incidents in healthcare (Beaussier et al., 2016a; Behr et al., 2015). The Inspectorate is consistently called to account for the effects or impact of their regulatory practices (Leistikow, 2018; Rutz, 2017), while facing situations wherein it is uncertain what the best regulatory approach is (Grit et al., 2016). That the work of the Inspectorate is under a ‘social microscope’ (Leistikow, 2018) or transpires within a ‘house of glass’ (Robben, 2010) seem apt metaphors indeed.

In response to calls to make (the Inspectorate’s) regulatory practices more ‘evidence-based’ (Gezondheidsraad, 2011; WRR, 2013), the Dutch Academic Collaborative on Supervision (AWT) was established. This collaborative between the Inspectorate and four research institutes aimed to scientifically study the effectivity of the Inspectorate’s regulatory practices. “The use of scientific knowledge enhances the reliability and ef-

fectivity of both our risk-based and incident-based regulation,” the Inspectorate writes (2017, p. 69). In the chapters 2-6 of this thesis I describe the efforts of the Inspectorate to regulate hospital mergers and incidents, the difficulties it faces in doing so and how alternative regulatory practices could be developed that might be more productive. I am hesitant to say that the recommendations made in those chapters make the Inspectorate’s regulatory practices ‘more effective’. That is because I think that an inquiry into the effectivity of regulation—cast in terms of whether regulation is effective—is a problematic one, both on methodological and theoretical grounds. While the calls for demonstrating the effectivity of regulation become louder, the assumptions we need to subscribe to in order to do so are increasingly recognised to be untenable (Dahler-Larsen, 2013; Jones, 2018). It assumes we can treat regulatory practice or a regulatory intervention as a bounded variable, which is imbued with intentions we can identify analytically and theoretically, so that we can later determine the impact of a regulatory practice or intervention on regulatee behaviour as effective (or not). In the ‘multi-layered governance networks’ within which regulators function today, wherein other (non-state) actors also engage in regulatory activities, such restrictive assumptions about how regulation can generate effects do not hold (van Erp et al., 2018). Indeed, they are not very helpful. To value regulation based on its effectivity, yes or no, is to provide a limited perspective on what regulation could accomplish and how (Jones, 2018). Moreover, even if we might determine the effectivity of a given regulatory intervention, it tells us little about *why* or *how* an intervention is effective, and the context(s) that supports it (Dixon-Woods et al., 2011; Jones, 2018).

That is why, in this thesis, I attempt to conduct “more broadly conceived” research (Jones, 2018, p. 5) and study how regulatory practices generate effects and the conditions that support those effects (chapters 2-6). I use the introduction and conclusion of this thesis (chapter 1 and 7) to take a step back and rethink the practice of regulation and the manner in which it might generate effects. I aim to explicate a particular perspective and vocabulary on regulatory practice and its effects that builds upon the findings of the regulatory cases studied, but that also extends beyond those cases. This step back in order to develop a new perspective on regulation is needed, I believe. Regulators are increasingly called upon to do better. We expect a lot from regulation even if a series of inquiries into incidents has held regulators co-responsible for those incidents. But what does it mean to ‘do better’ when uncertainty about how to (best) regulate a particular issue abounds? Or indeed, if it is not apparent what issues to regulate in the first place to promote the quality and safety of particular practices? Regulation increasingly “[targets] the internal management systems of regulated entities in order to secure compliance with regulatory goals” (Scott, 2004, p. 153). When regulation (re)shapes the internal systems of the entities it regulates, how can we think about the effects of regulation? The perspective on regulation I develop engages with these questions.

To rethink regulatory practices and its effects, I draw from two distinct bodies of literature that I navigated between throughout my research. On the one hand, there is a regulation and governance literature that is typically concerned with how regulation can best meet its objectives, the different regulatory styles regulators might turn to and how changes in the provision of public services affect the work of regulators. On the other hand, actor-network theory (ANT) develops a particular perspective on how 'the social' is expressly relational; ANT attends to how any one social (or natural) state is nothing but a contingent and dynamic network that remains stable for as long as agents continue to invest in and enact that network. Both literatures have their merits, blind spots and (quite dissimilar) notions about how regulation 'works'. Brought together, these literatures can help construct a perspective on regulation that both captures and contributes to our understanding of contemporary regulatory practices.

Regulation and governance literature concerns itself with the effects of regulation and consistently looks to contribute to more effective regulation. Presently, this literature documents how regulators—embedded in a complex, fast-evolving world—frequently experience uncertainty about how best to meet regulatory objectives. "Under uncertainty (...) neither the regulator nor the regulated firms know what needs to be done." (Sabel et al., 2018, p. 372) Prescriptive regulation—the traditional *modus operandi* of regulation, by which standards are set that regulatees need to comply with and regulators ensure that they do—is ill-equipped to deal with problems of uncertainty (Baldwin et al., 2012; Gilad, 2010; Rutz, 2017; Sabel et al., 2018). For that reason, regulators develop alternative regulatory arrangements. In the turn to 'process-based regulation', regulators assess the presence and quality of processes that allow organisations to meet regulatory objectives (Gilad, 2010). My research is partly situated in this literature, as I study the regulatory practices of the Inspectorate with the aim to better understand and reflect on how regulation works under conditions of uncertainty. But, the regulation and governance literature pays little attention to the question of how regulators construct the 'quality issues' they focus on and the work needed to be able to regulate these issues. This is a pressing question, especially as new, process-based regulatory approaches are developed to deal with complexity and uncertainty. What internal processes a regulator needs to monitor given a particular quality issue is not apparent. If a regulator wants to monitor good governance of secondary schools, what processes speak to 'good governance' and how might a regulator assess the quality of such processes? Also, the regulation and governance literature tends to treat the instruments regulators use as neutral devices. Tied to the understanding that instruments are effective, yes or no, "the only questions they raise relate to whether they are the best possible ones for meeting the objectives set" (Lascoumes and Le Gales, 2007, p. 2). Trying to account for how the Inspectorate constructs the 'quality issues' it regulates and how the instruments it designs to do so help shape those very issues, I turn to ANT.

From an ANT perspective, we can think of regulation as an activity that mobilises a range of entities (organisations, people, standards and instruments) in a network constructed around particular issues of quality (e.g. good governance or hand hygiene). These issues can set the stage for regulation, but an issue needs to be translated into particular instruments for regulation to work; for good governance to become inspectable, regulatory instruments need to make explicit appeals to regulatee behaviour. What ANT has challenged scholars and policymakers alike to realise is that instruments that set out to describe a reality can come to shape that reality (Law, 2009; Mackenzie, 2006). Instruments can ‘perform’ (Mackenzie, 2006) or ‘constitute’ (Dahler-Larsen, 2014) social realities. In an example close to home, academics are increasingly evaluated on the amount of papers they have published in (high-impact) journals. While we can think of the amount of publications as simply reflecting the impact a researcher has, studies have demonstrated how such evaluative instruments (re)shape the practices of universities and researchers. Researchers ‘salami’ research findings across multiple papers in the attempt to accrue more publications and they come to prioritise publishing papers over other activities that evaluation instruments overlook (e.g. teaching or societal engagement activities) (Felt, 2017; Fochler and De Rijcke, 2017; Martin, 2013). On another level, such performance indicators have altered ideas about what constitutes good academic performance (being published and oft-cited) and as university funding is allocated based on publication output, the effects of this instrument are institutionally ‘locked-in’ (Bal, 2017; Dahler-Larsen, 2012). The structure of this thesis speaks to the constitutive effects of this evaluative instrument. Rather than writing a monograph, I have invested in writing articles and getting them published. ‘Being published’ is thought to do more for my chances at an academic career (Felt, 2017) and is favoured in my department as publications help bolster its finances (Bal, 2017). Now, to refer to these effects as intended or unintended is too limited an assessment and misses the more fundamental observation that instruments can be ‘socially productive’ (Dahler-Larsen, 2012). In thinking about what regulation does and accomplishes, I attend to how regulatory instruments might perform the realities they set out to monitor.

I argue that regulation unfolds through the construction of what I call *regulatory objects*. Quality, Dahler-Larsen argues, has become a pivotal concept through which we understand and evaluate the organisation of contemporary society (2019). The notion of quality features in a range of discourses and is applied to a range of phenomena. We can discuss the quality of this thesis as comfortably as we could the quality of primary schools, public transport, a sweater or a sandwich. Why is this relevant for my argument? Because, “[addressing] an issue of quality is often a particular way of mobilizing others or regulating the behaviour of others around a matter of public relevance” (Dahler-Larsen, 2019, p. 3). To assess the quality of an issue that we value as a society has come to form the impetus for societal change—‘quality’ is the evaluative concept along the

lines of which changes to the object of which it speaks (whether it is this thesis or a sweater) become enunciated and, indeed, expected. What is more, while the quality of any object might be debated—I might like a sandwich while you do not—the task of defining quality can also “be delegated to an institutional arrangement, so that common criteria, goals, and instruments are made possible” (Dahler-Larsen, 2019, p. 3). Regulation, I argue, constitutes the institutional embodiment of defining and assessing the quality of a matter of public relevance (such as quality and safety in healthcare). But the regulatory objective of quality and safety in healthcare needs to go through a series of translations before it might mobilise or regulate the behaviour of others. This is where the notion of a regulatory object comes in. A regulatory object, I propose, defines a particular quality issue as the (legitimate) object of regulatory scrutiny. Work is needed to transform a quality issue into a regulatory object, and not any quality issue will do. First, a regulatory object posits a relationship between the quality at stake in the object and regulatee behaviour. For example, the regulatory object of good governance posits that good governance is somehow related to and indicative of the quality of education a school provides—so that the regulation of it is legitimate. Second, regulatee behaviour that the regulatory object speaks to needs to be made inspectable. One way or another, how a regulatee performs on the quality issue at hand, needs to be made tangible and demonstrable. Regulators depend on regulatory instruments to render regulatee performance tangible. A regulatory instrument that renders good governance inspectable can require schools to account for the quality of their financial administration or the transparency of their admission policies, for example. “The notion of quality,” Dahler-Larsen writes, is “fragmented, contested, value-laden, and situation-dependent. A claim to measure quality cannot be understood as referring to an already-existing reality, but as an attempt to define reality in a particular way.” (2019, p. 11) In constructing regulatory objects and designing the regulatory instruments that render regulatee performance inspectable, the Inspectorate advances particular understandings of what quality and safety of care are and how it might best be monitored. Regulatory objects, I argue, constitute an institutionalised ‘call to quality’ that the regulator expects regulatees to respond to in specific ways. “Vocabularies are needed that connects the concept of quality with practical situations and practical consequences.” (Dahler-Larsen, 2019, p. 15) I attempt to produce such a vocabulary by thinking of regulation as a call to quality that, through its instruments, mobilises and aims to regulate the behaviour of others along the lines of regulatory objects.

With the aims of the thesis thus stated, the rest of the introduction proceeds as follows. First, I describe what I understand regulation to be within this thesis and how regulatory practices, as well as what we expect of them, have changed over the years. Following that, I further flesh out the idea that regulating quality and safety of care is a practice that occurs through the construction of regulatory objects. I will then pres-



ent the research questions that guide this research. Then I elaborate on the work of the Inspectorate and the regulation of safety of care by in the Netherlands. Finally, the methods used to answer these questions are described and an outline of the rest of the thesis is provided.

## WHAT IS REGULATION (FOR)?

Before moving forward, it is useful to consider how regulation can be understood. Levi-Faur notes that regulation is a contested, political concept that is employed differently by different people for different purposes (2011). While the idea that divergent notions of what regulation means indicate a lack of shared understanding or identify a fragmented academic endeavour is a tempting one (Clegg et al., 2005; Koop and Lodge, 2017), it is recognised that aiming towards a uniform, universally accepted definition of regulation is unproductive (Black, 2001; Levi-Faur, 2011). Such a definition would mask how different groups of people interested in regulation, be they scholars or policymakers, understand and work with regulation and neglect how our thinking about regulation changed over time. This is not to say that the different understandings of regulation that circulate lack shared characteristics, or that we can do without demarcating the concept if we are to productively study it (Koop and Lodge, 2017; Levi-Faur, 2011).

An oft-cited definition of regulation is that set forth by Selznick, as “a sustained and focused control exercised by a public agency over activities that are valued by the community” (1985, p. 363). While the field of regulation has developed since Selznick defined regulation as such—‘control’ is not the only way through which regulatory agencies operate and regulation is not an activity reserved only for public actors—this is still a useful perspective on regulation. It makes evident that regulation is a ‘sustained and focused’ activity, that in many countries is institutionalised with the creation of specific regulatory agencies, whose regulatory mandate and objective(s) are anchored in law (Baldwin et al., 2012; Levi-Faur, 2011; Walshe, 2002) and that regulation targets not just any activities, but those ‘valued by the community’. In the case of the Inspectorate, good quality and safe healthcare constitute the valued service that warrants regulatory oversight. While regulation is often thought to be necessary to guard against market failure and many financial or market regulators operate under such mandates, the Inspectorate’s objective to protect and promote quality and safety of care is (also) one that advances social objectives (Baldwin et al., 2012; Prosser, 2006; Walshe, 2002).

In a definition that builds upon and expands that of Selznick, Black proposes to understand regulation as “the sustained and focused attempt to alter the behaviour of others according to defined standards and purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-

setting, information-gathering and behaviour-modification” (2002, p. 26). Black advances a decentred definition of regulation, where regulation as an activity is not reserved for the state and that identifies the regulatory project as an intentional undertaking that aims to impact and possibly alter the behaviour of others using a set of ‘mechanisms’ (2002). The differences between the definitions of Selznick and Black are reflective of how our understanding of what regulation is and how it might effectively function has changed. Both definitions of regulation shape my understanding of regulation in this thesis; as an activity that monitors activities that a community values, undertaken by state or non-state actors, targeting the behaviour of regulated actors and making use of particular mechanisms to do so. Regulation as I understand and set out to study it, is relational. The activity of regulating establishes a relation between a regulator and regulatees and the very objective of regulation is cast in that relationship; it targets and explicates expectations about the behaviour of others. We can think of regulation as an invitation to regulatees to behave in ways that contribute to the quality of the object regulated. That ‘invitation’ can be more or less forceful given the legal mandates that underpin it and the consequences of declining said invitation. What the relationality of regulation tells us, is that the effects of regulation come about as regulators and regulatees respond to one another. Effects of regulation are not located in any one instrument or intervention. Rather, they are contingent on the expressed expectations of a regulator, on how regulatees respond to the expectations enunciated by the regulator and on how both value that interaction.

## APPROACHES TO REGULATION

### Process-based regulation

Regulation is no static practice but is developed further as our understanding of how regulation can best meet its objectives changes, or as, more fundamentally, ideas about what the object of regulation or regulatees should be changes. Typically, scholars distinguish between what is referred to as traditional ‘command and control’ regulation—also dubbed first generation regulation (Gunningham, 2012)—and a range of alternative regulatory approaches that aim to overcome the limitations of command and control regulation—constituting, rather predictably, second generation regulation (Baldwin et al., 2012; Gilad, 2010; Gunningham, 2012; Levi-Faur, 2011; Rutz, 2017).

Command and control regulation departs from the idea that one actor, typically the state, can prescribe rules that others, regulated parties, need to conform to. The regulator monitors the compliance of regulatees with these rules and can legally discipline regulatees when they do not (Baldwin et al., 2012; Gunningham, 2012; Rutz, 2017). “Regulation by command and control works well when criteria and regulated services are clear and

well-defined" (Rutz, 2017, p. 11). And this is where its critics come in. Command and control regulation assumes that the criteria regulatees need to comply with are clear and uncontested, that regulators can identify and effectively target regulatees that need to comply with said criteria and that the risks when regulatees fail to meet these criteria are apparent. The assumptions underpinning command and control regulation are problematic in our complex, modern world, wherein regulators are increasingly confronted with uncertainty (Gilad, 2010; Grit et al., 2016; Sabel et al., 2018). Command and control regulation, moreover, is considered inflexible—it can poorly accommodate innovative practices or changing societal expectations on what constitutes good regulatee behaviour (Baldwin et al., 2012; Gunningham, 2012; Rutz, 2017)—and while it might effectively prohibit particular behaviour, it has a hard time encouraging (other) forms of behaviour (Baldwin et al., 2012; Gunningham, 2012). In response to the limitations of the command and control approach, the increased expectations of regulation and the heterogeneous, fast moving-world regulators are required to operate in, alternative regulatory approaches are developed (Gilad, 2010).

Increasingly, Gilad writes, "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" (2010, p. 485). While these approaches bring with them many different labels—like management-based regulation (Coglianese and Lazer, 2003), system-based regulation (Stoopendaal et al., 2016), smart regulation (Gunningham et al., 1998), responsive regulation (Ayres and Braithwaite, 1992), really responsive regulation (Baldwin and Black, 2008), reflexive regulation (Gunningham, 2012; Rutz, 2017), experimentalist governance (Sabel and Zeitlin, 2011)—overall, these regulatory approaches subscribe to strategies that aim to foster regulatee commitment to regulatory goals, enable and strengthen the capacities of regulatees to self-regulate, recruit non-state actors in the effort to further regulatory objectives and promote reflexivity and learning (Gilad, 2010). This is not to say that there are no differences between these proposed alternatives to command and control regulation, but rather to recognise their similarities. Gilad proposes to think about regulation as targeting distinct organisational tiers and argues that organisational behaviour on these different tiers is addressed more adequately using particular regulatory approaches rather than others (see table 1). The first tier concerns organisations' key operations and procedures subject to regulatory oversight (e.g. compliance with hand hygiene standards in an operating theatre), the second monitors the systems an organisation put in place to monitor its own compliance and how it uses those systems to evaluate and improve its performance (e.g. the ability of internal procedures to monitor hand hygiene compliance and quality programs to improve compliance), and the third the willingness

**Table 1: Tiers of regulation** (Gilad, 2010, p. 490)

| Tier of regulation | Focus of regulation                           | Regulatory standards   | Type of regulation                          |
|--------------------|---|--|---|
| First              | Organisations' core production and operations | Prescribed actions, output specifications, or principles that control and constitute firms' production processes   | Prescriptive or outcome-oriented regulation |
| Second             | Organisations' compliance systems             | System-oriented specifications that direct organisations' governance and control of their compliance with first-tier specifications  | Controls-based regulation                   |
| Third              | Organisations' self-evaluation                | Process-oriented specifications that guide organisations' analysis of the risks that their operations pose to regulatory objectives and their setting of first-tier and second-tier specifications | Process-oriented regulation                 |

and ability of an organisation to deal with risk (e.g. the ways an organisation learns from deviations from normal procedures).

In practice, regulators will generally monitor and attempt to alter the behaviour of regulatees developing a hybrid regulatory approach, where alternatives to prescriptive regulation co-exist with and are layered on top of already existing regulatory arrangements (Gilad, 2010; van de Bovenkamp et al., 2014). This multi-tiered perspective on organisational activities can provide regulators with different 'signals' on how an organisation is doing. In a Dutch study on the Inspectorate, Wallenburg et al. showed that when the Inspectorate finds out about a quality issue (first-tier), it assesses if the organisational compliance systems have also made the board of directors aware of said issue (second-tier) and then assesses if the organisation takes ownership of and fittingly responds to this issue (third-tier) (2019a). The question becomes, then, if regulatee performance on the different tiers is aligned and how regulatee performance on one tier is related to performance on others. What does it say about the quality of an elderly care organisation, for example, when personnel regularly checks the temperature of its refrigerators, even if there are no internal systems that formally require and monitor such checks? Or, to turn it around, when such systems are in place, but inspectors find that some refrigerators exceed the temperature deemed safe? What the Deepwater Horizon disaster and the criticism of the regulator monitoring the safety of the Fyra trains make clear, is that to solely verify and assess the systems organisations have in place to monitor the safety of their practices (second- and third-tier), without making sure that these systems actually ensure safe practices (first-tier) does not suffice. To do so poses a particular risk of regulatory capture (Mills and Koliba, 2015), exposing regulators to the critique that they have been monitoring safety 'on paper', rather than 'in reality' (Spaink, 2019).

I suggest that any regulatory object can be defined on one, two or all three regulatory tiers—supported by a set of regulatory instruments that make regulatee behaviour on those distinct tiers visible. Using the regulatory tiers identified by Gilad, I can describe the regulatory objects of the Inspectorate as targeting one or spanning multiple tiers. It allows me to question where the Inspectorate assumes that ‘the quality’ of a particular regulatory object is to be found and might be monitored.

### **Responsive regulation**

The Inspectorate is one of the many regulators worldwide that has adopted and enacts a responsive regulation framework (Ayres and Braithwaite, 1992; Baldwin and Black, 2008; Braithwaite, 2011; Parker, 2013). Hailed as a widely influential theory of regulation (Baldwin and Black, 2008; Nielsen and Parker, 2009), the premise of responsive regulation holds that organisational compliance with regulatory objectives is best achieved when regulators engage in dialogue with regulatees to persuade compliance and only resort to more forceful, punitive strategies of enforcement in response to (persistent) organisational resistance and non-compliance (Ayres and Braithwaite, 1992; Baldwin et al., 2012; Braithwaite, 2011). Regulators should—responsive regulation is a descriptive as well as prescriptive theory of regulation (Nielsen and Parker, 2009)—move up and down a responsive pyramid of enforcement strategies; starting with persuasive strategies and ‘escalating’ to more punitive strategies if organisations do not comply, as well as ‘de-escalating’ when organisations cooperate (Ayres and Braithwaite, 1992; Baldwin et al., 2012; Braithwaite, 2011). “The paradox of responsive regulation,” Braithwaite writes, “is that by having a capability to escalate to tough enforcement, most regulation can be about collaborative capacity building.” (2011, p. 475) As such, responsive regulation calls upon regulators to not just employ a punitive regulatory style, nor only a cooperative one, but rather, draw from both approaches fittingly and situationally in response to behaviour of the regulatee.

The notion of responsive regulation allows me to think about how regulatory objects and regulatory instruments are responsive (or not) to the behaviour of regulatees. Moreover, in conjunction with the work of Gilad, as regulatee behaviour can manifest itself on multiple levels, the idea of regulatory responsiveness must equally be multi-tiered. A question that is of interest here, then, is how regulatory objects and its regulatory instruments are (and might be more) responsive to multi-tiered regulatee behaviour.

## CONSTRUCTING REGULATORY OBJECTS TO INSPECT QUALITY AND SAFETY OF CARE

The idea that regulation unfolds through the construction of regulatory objects is indebted to recent work of Dahler-Larsen (2019). The notion of quality, he argues, has increasingly come to structure social realities. More and more we understand public issues as ‘quality issues’ and to address the ‘quality’ of any particular issue can come to constitute a compelling appeal to do something about it. To assess the air quality of inner-city regions untied to future actions to improve upon it is hardly imaginable. What Dahler-Larsen convincingly demonstrates is that a call to quality depends on and mobilises other elements if it is to become a compelling appeal. I alone can call on the quality of the day-care centre my kids visit, aiming to improve it, but if that call fails to mobilise others (like other parents) or is isolated from other established calls to quality concerning day-care, it is liable to falter. The regulation of quality and safety of care, I propose, entails an institutionalised call to quality that can be more compelling given the legal frameworks and power structures within which it is articulated. Earlier, I described how a regulatory object defines a particular quality issue as the (legitimate) object of regulatory scrutiny. For a regulatory object to ‘work’, it needs to connect regulatee behaviour to a notion of quality and regulatee behaviour needs to be made inspectable. I also described how regulation is relational; it constructs and transpires within a relation between a regulator and a (set of) regulatee(s). This means that the ‘quality’ at stake in any regulatory object and the question of how regulatee behaviour impacts or is reflective of that quality, is shaped by both regulator and regulatees. In this thesis, I am interested in the processes through which ‘quality’ becomes the assessable object of regulation. Therefore, I look to answer the following research question:

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

This question is a pressing one when we acknowledge that quality is no pre-defined, agreed upon phenomenon, but is perceived differently by different groups of people and that the institutionalised construction of quality issues is not beyond normative or political considerations (Baldwin and Black, 2016; Dahler-Larsen, 2019). Dahler-Larsen developed a useful, ANT-inspired ‘quality vocabulary’ that shows how any compelling appeal to the quality of a given issue depends on other elements (2019). I draw from and repurpose some of those elements from his vocabulary to understand contemporary regulatory practice. What his vocabulary makes clear is that to call on quality mobilises and enacts a dynamic network. Thinking about regulatory practice in light of his work, I envision regulation as the institutionalised call to quality that mobilises and regulates

the behaviour of regulatees along the lines of particular regulatory objects. The practice of regulation thus constitutes a network. I use the notion of a regulatory object as an analytical point of entry into studying this network; in that network regulatory objects depend on and link up with other elements. First, regulatory objects require regulatory instruments that operationalise and render documentable the ‘quality’ of any regulatory object. Second, regulatory objects and the instruments through which they function, make appeals to and recruit particular quality agents. Third, regulatory objects, the instruments through which they function and the response of agents to both, generates (constitutive) effects. Below, I will elaborate on how these elements—regulatory objects, instruments and agents—might be mobilised as the Inspectorate regulates quality and safety of care and how their mobilisation produces effects.

## REGULATORY INSTRUMENTS AND THEIR QUALITY INSCRIPTIONS

Regulatory instruments look to document and render inspectable the ‘quality’ of a particular regulatory object. Quality issues like good governance need to be translated into regulatory instruments so that whatever forms of regulatee behaviour that might constitute good governance (or not) might be assessed. As I have noted before, the regulation and governance literature is typically interested in the effectivity of regulatory instruments. Concerns about an instrument’s effectivity tends to pave the way for new, alternative instruments that might do better (Dambrin and Robson, 2011). In such a ‘functionalist orientation’ to how instruments work (Lascoumes and Le Gales, 2007), instruments are neutral devices that are supportive (or not) of regulatory objectives. The Inspectorate employs a range of instruments that typically measure to determine the level of quality of a particular regulatory object (e.g. the quality of the learning process following an incident or the percentage of patients that have an unexpectedly long length of stay). From a ‘functionalist’ perspective, these measurements can warrant and indicate the need for regulatory interventions—say, when the percentage of patients that stay longer than expected in a given hospital exceeds a certain threshold. What science and technologies studies (STS) scholars tell us is that *to measure is an intervention in and of itself*—if only by communicating what matters enough to be measured. To treat instruments as neutral devices that are reflective of a reality, from an STS perspective, means to unduly flatten and restrict how instruments impact both the objective they supposedly support and the social realities they describe. In an influential article on public policy and its instruments, Lascoumes and Le Gales refer to instruments as institutions:

Instruments really are institutions, as they partly determine the way in which actors are going to behave; they create uncertainties about the effects of the balance of power; they will eventually privilege certain actors and interests and exclude others; they constrain the actors while offering them possibilities; they drive forward a certain representation of problems. (...) Like any institution, instruments allow forms of collective action to stabilize, and make the actors' behavior more predictable and probably more visible. From this angle, instrumentation is really a political issue, as the choice of instrument—which, moreover, may form the object of political conflicts—will partly structure the process and its results. (Lascoumes and Le Gales, 2007, p. 9)

The issue of instrumentation, Lascoumes and Le Gales encourage us to recognise, is not peripheral to the activity of governing; it is through its instruments, rather, that governing plays out. Dahler-Larsen notes that quality is an elusive notion—which partly explains how it might be used to evaluate this thesis as easily as a sweater—that is only fixed in time and place, is stabilised, through the instruments that aim to measure it (Dahler-Larsen, 2019). I use these insights to be attentive to how the regulatory instruments the Inspectorate uses to inspect particular quality issues, 'drive forward' a particular interpretation of what good quality and safe healthcare is or should be. It helps me point out how a regulatory object, such as good governance, that is flexible in what that might mean, is different from the instrument that aims to measure it, providing and locking-in particular interpretations of good governance in doing so. More often than not, regulatory instruments produce 'quality inscriptions' (Dahler-Larsen, 2019; Dambrin and Robson, 2011; Latour and Woolgar, 1979).

A quality inscription codifies and documents the 'quality' of an object or form of behaviour. "Inscription devices comprise methodological, statistical, organizational, and practical tools that render visible and transform otherwise complex, ambiguous realities into figures, scales, indicators, numbers, or categories." (Dahler-Larsen, 2019, p. 107) In the Netherlands, students who transfer from primary to secondary schooling take the CITO test (Dutch: *Centrale Eindtoets Basisonderwijs*) that assesses what they have learned during their 8-year primary school education. The test also serves to inform the decision as to what level secondary education pupils might capably transfer to. The result of the test is a score between 500 and 550. What is interest to me is the observation that the CITO test transforms a complex social phenomenon (learning) into a single number through a 'chain of transformations' (Dambrin and Robson, 2011). That chain, however, is often hidden behind the inscription it constitutes so that the inscription is often thought to represent the quality of the object it transformed (Dahler-Larsen, 2019; Dambrin and Robson, 2011; Latour and Woolgar, 1979). Some 20-odd years after having taken the test, many of my friends still recall their exact CITO score. Regulatory instruments come



about through similar processes of transformation. Instruments and the inscriptions they produce, from an ANT perspective, transform that which is remote and complex into forms more stable (Dambrin and Robson, 2011). Regulation faces the challenge of evaluating activities and regulatee behaviour to which it is not directly privy (Vaughan, 1990). Regulatory instruments typically require regulatees to self-report on their performance, so that the 'quality' of their performance becomes inspectable. The stability of the interpretation of quality and safety of care that the Inspectorate's regulatory instruments (and their quality inscriptions) advance, however, depends upon their consistent enactment. With Dahler-Larsen we might say that a regulatory instrument "is not much more than an invitation to structure reality in a particular way" (2019, p. 156). But as people invest in, work with and evaluate their performance in light of a regulatory instrument, a regulatory instrument can lock-in and constitute the reality it speaks of (Dahler-Larsen, 2019). I will return to the performative potential of regulatory instruments later on. For now, I want to address how regulatory objects and regulatory instruments call on and recruit particular quality agents in the network that regulation establishes.

## THE RECRUITMENT OF QUALITY AGENTS

Lascoumes and Le Gales, whom I have cited above, note how any instrument harbours expectations about how actors might or will behave in response to it (2007). Also, regulatory instruments set the stage for the participation of particular agents, given the notion of 'quality' the instrument advances. Dahler-Larsen refers to those agents as 'quality agents'. "Actors are interpellated or 'summoned' in very particular capacities as quality agents, such as 'evaluators,' 'users,' 'experts,' and so forth." (Dahler-Larsen, 2019, p. 170) An example might be helpful. A regulator might be interested in the responsiveness of care professionals to the needs of residents in an elderly care organisation. That might be said to constitute the rather flexible regulatory object. The 'quality' of that object can be operationalised into a regulatory instrument in different ways. One way of doing so would be to require the organisation to report their staff/patient ratio, given the idea that low levels of staffing can hinder responsiveness (Bridges et al., 2019). Another would be to require organisations to consult their residents on how they experience the responsiveness of staff and whether they feel their needs are adequately met. Both instruments operationalise a notion of responsiveness but do so differently. In doing so, the instruments recruit different quality agents. While the first instrument recruits management as key quality agent, given their ability to ensure a particular staff/patient ratio, the second instrument warrants the participation of residents as quality agents. Now, to Lascoumes and Le Gales' point; the recruitment of particular quality agents implies the exclusion of others—there is no need to involve patients in the first operationalisation. A regulatory

instrument is political as it sets forth an interpretation of what 'quality' of an object in a particular situation means, as well as in how that interpretation allows for the participation of some actors (and not others) (Dahler-Larsen, 2019; Lascoumes and Le Gales, 2007).

The term 'agent' might be deserving of some clarification. ANT is well-known for its proposition that, in a dynamic network, agency and the ability to stabilise a given network is not solely reserved for humans (Dambrin and Robson, 2011; Latour, 2007a; Wallenburg et al., 2019b). Non-human entities (like regulatory instruments or computer systems) play an important part in the production of social realities and as such can act as 'agents' in a network. A survey inquiring into resident satisfaction with staff responsiveness, to take up the previous example, can be conceived as enacting and stabilising a particular idea of 'quality'. In this thesis, I am not so much interested in studying the agency of non-human entities, but rather, in seeing how the regulation of quality and safety of care mobilises and depends on a range of human and non-human entities. The term quality agent is useful to the vocabulary of regulatory practice I develop for a different reason. In a recent research project within the AWT, Grit et al. (2016) developed a framework that states that effective, compliance-oriented regulatory practice is helped when it is clear what 1) the risk is that is monitored, 2) what standards need to be complied to in order to mitigate that risk and 3) the addressee responsible for complying to those standards. What the term of quality agents affords me, over that of addressee or regulatee, is that it helps make sense of how the Inspectorate also recruits agents outside of the regulator/regulatee relationship in its regulatory practices, like patients and family members (Kok et al., 2018) or experts-by-experience (de Graaff et al., 2018). The term of quality agent allows for more analytical flexibility, even though I will mainly use it to identify how regulatory instruments recruit particular (groups of) people.

The extent to which a regulatory instrument can fix an interpretation of quality in place is dependent on the investments of quality agents in that interpretation. The quality agents that a regulatory instrument recruits have a say in the notion of quality that stabilises. Several studies have demonstrated how 'transparency technologies'—instruments that look to render organisational or professional performance visible and auditable—are taken up, translated and (re)negotiated by the agents that are monitored (Jensen, 2011; Levay and Waks, 2009; Wallenburg et al., 2019b; Waring, 2007). Agents are not at the mercy of regulatory instruments and the interpretation of quality advanced in them; the instruments' claim to quality is settled in practice, as people work with and value those instruments (May and Finch, 2009). Levay and Waks studied how healthcare professionals responded to two initiatives (an accreditation system and national quality registries) that sought to render their performance auditable (2009). While professionals were sceptical at first, they engaged with them later on and were able to reshape the evaluative criteria on the basis of which their performance would be assessed. Wallenburg et al. studied how various professional groups in hospitals respond to hospital

rankings (2019b). Rankings, the authors conclude, “induce ambivalent responses. They are embraced, engaged, and questioned at the same time” (Wallenburg et al., 2019b, p. 21). The question of how quality agents engage with the regulatory instruments through which their participation is implied, and how this affects and stabilises a particular meaning of quality, is a question I am interested in. Additionally, I am interested in how the stabilisation of regulatory instruments and the interpretation of quality they advance, might hamper regulatory objectives. Regulatory instruments are liable to generate a range of social and organisational investments, both on the part of regulatees (Power, 2010; Wallenburg et al., 2019b) and regulators (Kok et al., 2019). “Once enrolled,” Levay & Waks write, “it was difficult for the professions to back-pedal, given the commitments and investments already undertaken.” (2009, p. 522) To stabilise a regulatory instrument takes work, but so does its de-stabilisation; once properly embedded, dis-embedding it is difficult and costly (Law, 2009; May, 2013). This is interesting as regulators target increasingly complex and dynamic social processes as their regulatory objects (Gilad, 2010; Rutz, 2017). One might wonder how a regulator can be responsive to a regulatee’s dynamic performance if the instruments that render such performance visible, fix the quality of that performance in place and are difficult to alter. Having discussed regulatory instruments and the agents they recruit, I now turn to how regulatory instruments can come to constitute or perform the reality they set out to describe.

## CONSTITUTIVE EFFECTS OF REGULATORY INSTRUMENTS

Scholars working in the ANT tradition have done much to demonstrate how instruments that aim to describe or measure a reality help to construct and shape that very reality (Dahler-Larsen, 2019; Law, 2009; Mackenzie, 2006). Instruments, then, describe as well as ‘constitutive’ or ‘perform’ realities. I will use the term ‘constitutive effects’ when discussing how regulatory instruments construct the reality they look to monitor, but the notion of performativity refers to the same phenomenon. While from a regulation and governance perspective, regulatory instruments measure the quality of a given object—that it might do so to varying degrees of success—from an ANT perspective I would argue that regulatory instruments partake in constructing that very (notion of) quality, hence constituting it. Dahler-Larsen notes that constitutive effects can occur in different domains:

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

The example invoked earlier, on the performance indicator that measures publication output of scholars, might be helpful here. The indicator can interfere in and redefine the

content of a practice as it explicates what is deemed key to the practice that it monitors. It directs the focus of participants on that which matters. What matters, as defined by the publication output indicator, are international, peer-reviewed publications. This is what good scholars should strive for; non-English publications or book chapters are considered less important or impactful (Bal, 2017; Dahler-Larsen, 2014). An indicator can also impact the timing of activities, when, for example, research projects are designed and temporalized along the lines of the amount of publications expected to come out of it. “Knowledge production must now be packaged in (generally) three-year units, and publications are required during this time-span to demonstrate the worth of the investment. The contracts of those hired for projects (mostly PhD students) are also temporalized along this logic.” (Felt, 2017, p. 55) The indicator allows for my academic performance to be compared to that of others—who has published papers where?—to which I might compare favourably or unfavourably. As such, the indicator influences social relations; it continues to do so over time as well, as being able to hand over a list of high-quality publications opens the door to sought-after post-doc positions (Felt, 2017). In terms of the broader worldview in which the indicator functions, the performance indicator construes universities and their knowledge production practices as more or less verifiably impactful. In these various ways, an indicator or an instrument that is out to measure a reality, helps shape that reality. Whether the instrument ‘really’ captures the quality of research is not the point; the phenomenon of performativity serves to demonstrate, rather, that an instrument can produce realities that actors must contend with. Now, not every instrument is (equally) performative. For an instrument to constitute the reality it sets out to describe, it needs to be invested in and consistently enacted. Butler (2010) describes how ‘theories’ of reality—like financial theories that harbour expectations of how economics works, expectations that generally solidify in economic models or instruments (Mackenzie, 2006)—can produce but can also fail to produce that reality.

(...) if we want to say that the theory *tends* to produce the phenomenon, but that it can sometimes *fail* to produce what it anticipates, then it seems we have opened up the possibility of ‘misfire’ at the basis of performativity itself. In other words, it is only under certain kinds of conditions, and with no degree or predictability that theoretical models successfully bring into being the phenomenon they describe. There are occasions in which they fail, or there are ‘counter-performative’ instances when inverse effects are produced, and both the explanatory and anticipatory dimensions of theory are foiled. (Butler, 2010, p. 152)

Or, somewhat more succinctly, we can think of regulatory instruments as “statements the further fate of which are in the hands of others. They are performative acts which can fail” (Dahler-Larsen, 2019, p. 108). In this thesis I am interested in how regulatory

instruments are engaged with, enacted and questioned by the quality agents it recruits. Moreover, I study the constitutive effects this interaction (as quality agents respond to regulatory instruments) generates and I am attentive to the ‘counter-performative’ effects that might occur. Within the relational practice that regulation is, constitutive effects are the product of the interaction between regulator and regulatees; they cannot be ascribed to any one thing (an instrument or intervention) or party.

Now that I have described how regulation can be thought of as an institutionalised appeal to quality that constructs regulatory objects, depends on regulatory instruments, recruits particular quality agents and how constitutive effects might occur, I am ready to define the sub-questions of my thesis. The sub-questions complementing the main research question of this thesis are as follows:

- 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?

## STUDYING THE HEALTH AND YOUTH CARE INSPECTORATE

The Health and Youth Care Inspectorate (or Inspectorate hereafter, Dutch: *Inspectie Gezondheidszorg en Jeugd*) is the national regulatory agency tasked with overseeing and regulating all healthcare providers and professionals in the Netherlands. In monitoring the quality and safety of care provided, and encouraging healthcare providers to improve the quality of their practices, the Inspectorate makes use of either risk-based or incident-based regulation. Risk-based regulation refers to those activities through which the Inspectorate ‘proactively and periodically’ collects information in order to identify risks in particular healthcare organisations or sectors at large (Inspectorate, 2016, p. 12). Through risk-based regulation, the Inspectorate claims, risks can be proactively acted on so that they do not materialise. Also, regulation is more effective and efficient when it is informed by previously identified risks—but necessary too, given all the individuals and organisations the Inspectorate is responsible for monitoring (Robben et al., 2015, p. 384). Incident-based regulation refers to those activities the Inspectorate undertakes in response to incidents in healthcare organisations. Currently, this means that the Inspectorate receives an incident investigation report from a healthcare provider, assesses the provider’s learning process, and determines if the incident is indicative of issues that war-

rant closer attention (Inspectorate, 2016). The regulatory practices of the Inspectorate are underpinned by 'a healthy sense of trust'; or, the conviction that healthcare providers and professionals are motivated to provide the best quality care possible (Inspectorate, 2016a, Inspectorate, 2018). Departing from this idea, "[the Inspectorate] tailors its regulatory practices to the learning capabilities and the developmental stages of healthcare providers" (Inspectorate, 2016a, p. 10). While the idea of trust underpins the Inspectorate's regulatory approach, trust is not self-evident, but a 'dynamic process', embedded in a (historical) regulator-regulatee relationship and informed by a healthcare provider's commitment to regulatory objectives and performance (Inspectorate, 2016a). When healthcare providers "fall short" in providing good and safe care, the Inspectorate can intervene by using a range of regulatory interventions that are increasingly severe—in line with the responsive regulation framework (Inspectorate, 2016a, p. 10).

To understand how the Inspectorate constructs quality and safety of care as inspectable warrants zooming in on the regulatory practices of the Inspectorate. To generate an in-depth understanding of what it is that regulation does, I turned to ethnography. At its heart, ethnography encompasses a set of methods that allow for the detailed understanding of particular social practices and demand a researcher's presence in or close proximity to those practices (Green and Thorogood, 2018). I have selected and report on two case studies that allowed for the study of particular regulatory practices: the regulation of mergers (covered in chapters 2 and 3) and the regulation of incidents (covered in chapters 4, 5 and 6). These two cases are of interest to me for different reasons. In regulating hospital mergers, the Inspectorate is unsuccessful in constructing a hospital merger as a regulatory object. That allows me to wonder why that is and what is needed to construct a regulatory object. In regulating incidents, the regulatory object that is constructed (learning) is dynamic and is inscribed into a regulatory instrument that provides a particular take on what learning is. This allows me to wonder how a regulatory object is dynamic or fixed in place by the instruments that support it. This thesis continues as follows.

## OUTLINE

Chapter 2, *Disruptive life event or reflexive instrument? On the regulation of hospital mergers from a quality of care perspective*, examines how a hospital merger might impact key processes and thus affect quality and safety of care. Research that documents how a merger impacts quality and safety of care is generally quantitative. While these studies provide no definitive answer to the question if mergers impact quality and safety of care positively or negatively, they also shed no light on how mergers impact quality and safety of care. Based on interviews with healthcare inspectors and respondents from re-

cently merged hospitals, we explored how a merger can impact key hospitals processes. Confronted with the uncertain impact of a merger, we studied how the Inspectorate regulates mergers and how hospitals aim to manage a merger.

Chapter 3, *The risk-based regulation of hospital mergers: Looking in(to) the future*, follows up on the preceding chapter and describes, more in-depth, how the Inspectorate looks to construct a hospital merger as a risk object that can be regulated. In doing so, we draw on the relational theory of risk. This theory perceives of risk as a relational construct consisting of three elements: a risk object, an object at risk and a causal relationship that specifies how the risk object might threaten the object at risk. We explore the efforts of the Inspectorate to construct a relationship that explains how a hospital merger (as a risk object) can threaten quality and safety of care (the object at risk). We also wonder how the Inspectorate's risk construction practices that serve to transform a hospital merger into a regulatable risk, are affected by theoretical, operational and reputational considerations.

Chapter 4, *Shared learning from incidents: A qualitative study into the perceived value of an external chair on incident investigation committees*, focuses on serious incident investigations in elderly and disabled care organisations. After a policy change, external chairs head investigative committees in these organisations if a serious incident resulted in the death of a resident. In this chapter, we explore the perceived value of external chairs from the perspective of healthcare inspectors as well as quality advisers and directors of four healthcare organisations.

Chapter 5, *How incident reporting systems can stimulate social and participative learning: A mixed-methods study*, studies how the Dutch incident reporting system contributed to social and participative learning from incidents. We integrate quantitative and qualitative data in a mixed-methods design. Between 1 July 2013 and 31 March 2019, Dutch hospitals reported and investigated 4667 incidents. Healthcare inspectors scored all investigations to assess hospitals' learning process following incidents. We analysed if and on what aspects hospitals improved over time. Additionally, we conducted interviews with healthcare professionals, incident investigators, quality managers and healthcare inspectors to explore how the incident reporting system affected their respective practices.

Chapter 6, *Epistemic injustice in incident investigations: a qualitative study*, revisits the practice of incident investigations and does so with the question of who is able to contribute to these investigations. The Inspectorate advocates the participation of an increasing range of actors in incident investigations. Learning from incidents might be enriched when people with different perspectives are involved. Using the concept of epistemic injustice, we wonder how the structures that govern the practice of learning (the Inspectorate's scoring instrument and the incident investigation frameworks) favour the contribution some actors over others.