Through the Regulator's

Eyes

DAVID DE KAM

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On the effects of making quality and safety of care inspectable

David de Kam

The research for this thesis was conducted at the Erasmus School of Health Policy & Management (ESHPM), Erasmus University Rotterdam. ZonMw, the Dutch organization for Health Research and Development, provided financial support for two projects that this thesis reports on in chapters 2 and 3 (project number 516001010) and chapter 5 (project number 516004604). The Dutch Health and Youth Care Inspectorate provided financial support for the research described in chapter 4.

ISBN: 978-94-6361-457-3

Cover design: Erwin Timmerman, Optima Grafische Communicatie

Printed by: Optima Grafische Communicatie, https://www.ogc.nl/#

Through the Regulator's Eyes:
On the effects of making quality and safety of care inspectable

Door de ogen van de toezichthouder:
Over de effecten van het inspecteerbaar maken van kwaliteit en veiligheid van zorg

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

Prof.dr. R.C.M.E. Engels

en volgens besluit van het College voor Promoties.
De openbare verdediging zal plaatsvinden op

donderdag 15 oktober 2020 om 11:30 uur

door

David de Kam
geboren te Nieuwegein

Erasmus University Rotterdam

PROMOTIECOMMISSIE:

Promotor:	prof.dr. R.A. Bal
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> 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 responsivity 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 responsivity 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 responsivity (Bridges et al., 2019). Another would be to require organisations to consult their residents on how they experience the responsivity of staff and whether they feel their needs are adequately met. Both instruments operationalise a notion of responsivity 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 responsivity, 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 to 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.

2

Disruptive life event or reflexive instrument? On the regulation of hospital mergers from a quality of care perspective

Published as: de Kam, D., M. van Bochove and R. Bal (2020). Disruptive life event or reflexive instrument? On the regulation of hospital mergers from a quality of care perspective. Journal of Health Organization and Management, 34 (4): 489-503.

ABSTRACT

Purpose

Despite the continuation of hospital mergers in many Western countries, it is uncertain if and how hospital mergers impact quality of care. This poses challenges for the regulation of mergers. The purpose of this paper is to understand: 1) how regulators and hospitals frame the impact of merging on the quality and safety of care and 2) how hospital mergers might be regulated given their uncertain impact on quality and safety of care.

Design/methodology/approach

This paper studies the regulation of hospital mergers in the Netherlands. In a qualitative study design, it draws on 30 semi-structured interviews with inspectors from the Dutch Health and Youth Care Inspectorate (Inspectorate) and respondents from three hospitals that merged between 2013-2015. This paper draws from literature on process-based regulation to understand how regulators can monitor hospital mergers.

Findings

This paper finds that inspectors and hospital respondents frame the process of merging as potentially disruptive to daily care practices. While inspectors emphasise the dangers of merging, hospital respondents report how merging stimulated them to reflect on their care practices and how it afforded learning between hospitals. Although the Inspectorate considers mergers a risk to quality of care, their regulatory practices are hesitant.

Originality/value

Our qualitative study sheds light on how merging might affect key hospital processes and daily care practices. It offers opportunities for the regulation of hospital mergers that acknowledges rather than aims to dispel the uncertain and potentially ambiguous impact of mergers on quality and safety of care.

BACKGROUND

Like many Western countries (Angeli and Maarse, 2012; Bazzoli et al., 2004), the Netherlands has seen its share of hospital mergers the last decades, bringing back the number of hospitals from 243 in 1978 to 79 in 2016 (den Hartog et al., 2013; Dutch Ministry of Health, n.d.(1); Roos, 2018). The continued consolidation of the Dutch hospital market played out against the backdrop of sustained public and political debate on the desirability of mergers (Postma and Roos, 2016) and throughout the restructuring of the Dutch healthcare market from 2005 onwards, to make the sector more competitive (Helderman et al., 2005; Schut and Varkevisser, 2017). Mergers, we know, are challenging organisational processes that can have "multi-layered and complex" effects on the services provided by organisations (Fulop et al., 2005, p. 120). In hospitals, those effects can impact the quality and safety of care provided. But we know little about if and, in particular, how hospital mergers might impact quality and safety of care. For one, studies that report on how hospitals perform on a set of quality indicators pre- and post-merger, deliver inconsistent and inconclusive results (Gaynor and Town, 2012; Hayford, 2012; Ho and Hamilton, 2000; Mutter et al., 2011; Romano and Balan, 2011; Vogt and Town, 2006). Also, they often offer little explanation as to how the effects observed might have come about. Second, from literature that looks into the impact of merging on organisational processes and structures, we learn that mergers might have unforeseen, destabilising effects (Dunbar, 2011; Fulop et al., 2005; Gaynor et al., 2012). But, how those effects impact quality and safety of care is left unaddressed. It is uncertain, in other words, how any merger might affect quality and safety of care. While this an interesting question to consider in its own right—and we will—it is also a pressing question for regulators tasked to regulate hospital mergers and to assess how mergers might impact quality and safety of care. Mergers between hospitals, for regulators, pose a challenge of 'regulatory uncertainty'—where it is uncertain how merging might affect quality and safety of care as well as how mergers might best be regulated (Gilad, 2010; Sabel et al., 2018). In our qualitative study, we focus on three hospital mergers in the Netherlands to answer the following questions 1) *How do regulators and hospitals frame the impact of hospital mergers on the quality and safety of care*?, and 2) *How can hospital mergers be regulated given their uncertain impact on quality and safety of care*?

In the next section of this paper we describe what we know about the impact of hospital mergers and describe a process-based approach to regulation, developed by Gilad (2010), that can serve as a framework for understanding the impact of hospital mergers and how they might be regulated. Following that, we will describe the research methods used to provide an answer to the questions formulated above and present our findings, that we reflect further on in the discussion section of this paper.

ON HOSPITAL MERGERS, QUALITY OF CARE AND REGULATION

In the shadow of literature on the relationship between mergers and efficiency (Harris et al., 2000; Kjekshus and Hagen, 2007), prices and costs of services (Carey et al., 2011; Hutchings et al., 2003) and competition and market power (Haas-Wilson and Garmon, 2011; Schmid and Ulrich, 2013; Schmid and Varkevisser, 2016; Varkevisser and Schut, 2012), several studies look into the effect of mergers on quality of care (Dutch Authority for Consumers and Markets, 2016; Hayford, 2012; Ho and Hamilton, 2000; Mutter et al., 2011; Romano and Balan, 2011). These studies operationalise quality of care by comparing a set of quality indicators pre- and post-merger, testing for differences. When reviewing what the effects of hospital mergers on quality of care are, it proves difficult to say if mergers impact quality of care positively or negatively (Gaynor and Town, 2012; Vogt and Town, 2006). Although some studies find either positive or negative effects, most studies have difficulties identifying effects in either one direction, and often the different quality indicators selected to operationalise quality of care point in different directions (Gaynor et al., 2012; Ho and Hamilton, 2000; Mutter et al., 2011). The cautious consensus among such studies is that there is no evidence that mergers improve quality of care. Studying the performance of hospitals merged between 2009 and 2013 in the US, Beaulieu et al. conclude that "[their] findings challenge arguments that hospital consolidation, which is known to increase prices, also improves quality" (Beaulieu et al., 2020, p. 58).

While most studies report on the American system or that of the United Kingdom, recently, the Dutch Competition Authority (Netherlands Authority for Consumers and Markets) commissioned a study into the effects of hospital mergers on quality of care in the Netherlands (Dutch Authority for Consumers and Markets, 2016). This study's findings, studying 14 hospital mergers between 2007-2013, are in line with those found elsewhere; while some hospitals improved on some quality indicators after merging, they scored worse on others. As quality of care is impacted by much more than merging alone, a definitive conclusion could not be drawn (Dutch Authority for Consumers and Markets, 2016). The study noted that the impact of a merger on quality and safety of care is 'intermediate'; it can impact hospital processes and structures in positive and negative ways (e.g. merging can offer increased opportunities to train medical professionals, as well as distract from the primary process), but it is unclear if this eventually affects hospital outcomes (Dutch Authority for Consumers and Markets, 2016).

Few studies have empirically studied *how* mergers affect structures and processes in healthcare organisations (Dunbar, 2011; Fulop et al., 2005; Gaynor et al., 2012). Fulop et al. study mergers from an organisational change perspective and argue that "mergers are based on simplistic notions of organisational change" (2005, p. 120) that fail to account

for how a merger might impact organisations and its personnel in unintended ways. A merger, according to Fulop et al. is a complex, layered organisational restructuring process that brings about "a period of (…) intense introspection" (2005, p. 129). Mergers often fail to deliver on their promises of services improvement (Ahgren, 2008; Fulop et al., 2005; Gaynor et al., 2012; Rohde and Torvatn, 2017) while struggling to steer clear of dysfunctional effects, "including loss of focus on services, delays in improvements, loss of organisational memory and inter-organisational relationships, and difficulties in transferring good practice" (Dunbar, 2011). Fulop et al. write that their respondents reported that "loss of managerial focus on services during the merger had harmed patient care (…) and that the merger made services worse,"—but fail to elaborate on why or to what extent this was the case (2005, p. 127). A merger is not just a means to the end of reorganising existing organisational structures, but is itself a complex 'evolutionary process' that leaves its mark on organisations (Fulop et al., 2005, p. 129). Haas et al., in a paper on health care expansions in the United States, report that mergers can create risks to patient safety as they inevitably introduce changes to 1) patient populations, 2) organisational infrastructure and/or 3) clinician practice settings (Haas et al., 2018). While the literature discussed so far relates the process of merging to quality and safety of care, it fails to make specific how or under what conditions merging has effects on quality and safety of care. It is exactly this that is necessary from a regulatory perspective.

Regulation entails "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" (Black, 2002, p. 26). This definition addresses both the goal and focus of regulation (altering behaviour to produce valued outcomes) and some of the instruments regulators might use to achieve that goal (like standard-setting). In our complex and fast-changing world, various scholars argue, regulators face challenges that prescriptive regulation—regulator's traditional mode of operation—is ill-equipped to deal with (Baldwin et al., 2012; Gilad, 2010; Gunningham, 2012). Prescriptive regulation assumes that it is clear what behaviour of regulatees is expected to ensure a valued outcome (Baldwin et al., 2012). In such cases, regulators can impose standards that regulatees ought to comply with. Yet, when there is no certainty about what kind of regulatee behaviour produces the identified outcome, or when what the outcome should be is subject to debate, prescriptive regulation is of little help (Baldwin et al., 2012; Gilad, 2010; Gunningham, 2012). That is why, Gilad writes, contemporary regulators "[experiment] 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). Rather than strictly prescribing what regulatees should and should not do, regulators expect regulatees to 'self-regulate'; to design, manage, monitor and

(re)evaluate the quality of their own services (Gilad, 2010). In this 'process-oriented' approach to regulation, regulation can target one of three distinct organisational tiers (see table 1). The first-tier concerns an organisation's key production processes. The second-tier concerns an organisation's control systems through which it monitors its first-tier production processes. The third-tier concerns an organisation's self-evaluative activities and its evaluation and (re)design of its first-tier operations and second-tier controls (see table 1). For example, a regulator might monitor: if a hospital complies with the mandated use of surgical safety checklists (first-tier), what processes or systems the hospital has put in place to ensure that these checklists are used (second-tier) and on how the use of checklists is tied to and embedded in other safety practices, or how the hospital deals with situations where professionals deviate from (using) the checklist (third-tier).

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

While Gilad developed the three regulatory tiers in a review article that spans a range of regulatory (process-based) approaches, for us it provides a framework for understanding where our respondents believe the impact of a merger on quality and safety of care is located (in terms of the three tiers). We can use it to wonder how a merger might impact hospital's key processes or its capacity to self-evaluate those processes. Also, if offers a way to think about how mergers might be regulated. Gilad notes that process-based regulatory approaches do not do away with oversight on the first- or second-tier. Rather, these new regulatory approaches tend to be layered onto already existing regulatory approaches (Gilad, 2010; van de Bovenkamp et al., 2014). When it comes to hospital mergers, we can wonder how the Inspectorate can attend to how the process of merging impacts hospital performance on all three tiers.

METHODS

To answer our research questions, we adopted a qualitative research design.

Our paper is based on 30 semi-structured interviews that we conducted throughout three phases of our research as well as document analysis. First, we browsed newspapers, healthcare management websites and blogs discussing mergers. Through our reading, we got a clear image of the discussions about mergers in relation to quality of care in the Netherlands. We also in this way identified six individuals that were often asked to weigh in on these discussions, given their experience as (former) organisational change consultants or (former) hospital directors or regulators. We approached these individuals through email, asking them to participate in our study. All were willing to be interviewed. In these interviews (n=6), we tried to better understand how the process of merging might impact hospital processes that impact quality and safety of care. Second, we approached the regulatory agencies involved in assessing and approving a merger in the Netherlands (see Box 1). We conducted interviews with inspectors and other employees of these agencies to understand how hospital mergers are currently

Box 1: Hospital merger control in the Netherlands

All mergers in the Netherlands require approval by the Netherlands Authority for Consumers and Markets (Competition Authority), if, 1) both organisations together generate an annual revenue of € 150 million or more globally and, if 2) at least two of the merging organisations each has an annual revenue of € 30 million or more in the Netherlands. The Competition Authority oversees the Competition Act and is the regulatory body that either clears or prohibits mergers. The decision of the Competition Authority to clear or prohibit a merger boils down to the question of whether a merger is (expected to be) anti-competitive. Since 2014, mergers between healthcare organisations also require approval of the Dutch Healthcare Authority (Healthcare Authority). The Healthcare Authority evaluates if the merger poses a threat to access to vital hospital services (such as emergency care) in the region. The Inspectorate enters the stage within the evaluation of the Healthcare Authority, because the Healthcare Authority can consult the Inspectorate and inquire how quality of care might be impacted by the merger. The Competition Authority, weighing both the Healthcare Authority's and Inspectorate's input, clears or prohibits the merger. The Competition Authority has approved 26 of the 27 proposed hospital mergers since 2004. Aside from mergers, the Inspectorate is charged with overseeing the quality of care provided by healthcare organisations and professionals throughout the country, which has to be up to par regardless of possible organisational concerns they might face (Inspectorate, 2016a).

regulated and what issues they encounter. We were specifically interested in how the Dutch Health and Youth Care Inspectorate (further: Inspectorate), responsible for overseeing the quality and safety of care regulates hospital mergers, so that most of the interviews we conducted in this round (n=8), were conducted with employees of the Inspectorate. Third, we purposively selected and approached three recently merged hospitals, spread throughout the country and varying in size (see Table 2). Through the board members of these hospitals we gained access to all three hospitals and in each hospital interviewed (at least): 1) the executive director, 2) the chair of the medical staff, 3) the chair of the nursing committee, 4) the chair of the patient committee and 5) a quality of care manager. We conducted 16 interviews in the hospitals.

Table 2: Studied hospital mergers

Characteristics	Merger 1	Merger 2	Merger 3
Approval Competition Authority	2012	2014	2012
Administrative merger*	2013	2015	2013
Legal merger*	2015	2017	2016
Number of beds**	555/551	923/209	545/424
Distance between hospitals***	7km	25km	8km

* Dutch law differentiates between mergers based on the level of integration between merging parties. In the case of an administrative merger, both hospitals (as distinct legal organisational entities) continue to exist but are governed by a central body (often a new legal entity that governs the two merged hospitals as subsidiaries). In the case of a legal merger, the two legally distinct hospitals merge and continue as a single legal organisational entity. Often, Dutch hospitals first merge on an administrative level to later merge into a single organisation.

** As self-reported by the separate hospitals to the Dutch Ministry of Health, in the year of approval for the merger by the Competition Authority (Dutch Ministry of Health, n.d.(2)).

*** Obtained through Google Maps, walking distance, rounded off.

Interviews were conducted between September 2015-March 2016. Most interviews were conducted by the first (DdK) and second (MvB) author together, and in some the third author participated. Interviews lasted for 61 minutes on average. Topic guides, that were prepared by DdK and discussed among all authors, structured the interviews. With consent of the respondents, interviews were taped and transcribed verbatim afterwards. Transcribed interviews were stored in accordance to Research Data Management (RDM) principles of our institution and data was only shared among and accessible to the authors of this paper. Since all the authors also conducted the interviews, transcripts were not anonymized or pseudonymized during data analysis. Anonymization of cited excepts from the interviews was done during writing of the manuscript.

To analyse our data, we opted for an abductive approach (Tavory and Timmermans, 2014), meaning that we came to understand our data as we iteratively moved back and forth between our data and theory. We coded our research data openly and through an

indicative analytic approach identified emerging themes (Green and Thorogood, 2018), but we turned towards theory to better understand the themes we identified. *Atlas.ti* was used to facilitate the coding process. DdK conducted the initial coding process and generated a multitude of codes. These codes were then discussed among DdK and MvB, as we sought to identify relationships between codes. The identification and analysis of themes in light of the theory introduced was discussed between all three authors through a series of meetings.

FINDINGS

Our findings are ordered into three parts. First, we present how our respondents framed quality and safety of care as something that needs attending to. Second, we present how merging can impact key hospital processes as care practices are reorganised. Third, we present how the Inspectorate regulates mergers as well as how hospital respondents experienced the Inspectorate's regulation.

Attending to quality and safety of care in the process merging

The Inspectorate conceives of a merger as a big organisational change that may negatively affect quality of care. "In periods of organisational change, the risks of blind spots and errors in healthcare organisations is greater: organisations are less attentive to the continuity and quality of care." (Inspectorate, 2015a) Healthcare inspectors voice similar concerns. "Mergers pose a risk to quality of care in hospitals, because attention is diverted away from the primary process." (Inspector 2) "Mergers sap all energy out of quality and safety—everything else goes on hold. So much has to be invested in merging that improving quality and safety for the patient… there's no time for that." (Inspector 1) Inspectors colloquially refer to a merger as a *life event*. Life events are "very drastic", disruptive events that shake up and (temporarily) preoccupy an organisation—like merging, facing financial problems, introducing a new Electronic Patient Record, or top-level management changes are referred to by inspectors as life events. In the case of a life event, "it becomes really hard for organisations to meet required standards." (Inspector 1)

Hospital respondents acknowledge that merging is demanding. "The merger costs a lot of time and energy. Not all specialists can do their consults or surgeries, because they have to be part of discussions about how we'll work together in the new operating theatre." (Medical specialist 3) "The merger asks a lot. (…) We have to, on the one hand, continue patient care, and on the other, involve professionals in things like aligning protocols." (Quality of care manager 2). Multiple respondents granted that, during the merger, they were "turned inwards". "Really, we focus on ourselves and less on develop-

ments outside our own hospital. So, patient self-management is a thing right now—and that'll come, but it's not our main concern now." (Nursing association chairs 1) A medical specialist noted that when occupied with the merger, innovation suffers.

Quality of care, our respondents agreed, requires constant work and attention and a merger might pose a risk to quality of care because it could (temporarily) disrupt that attention. Hospital respondents, however, also challenged the idea that merging and attending to quality of care are two disparate things—where attending to one prevents you from attending to the other. Most hospital respondents argued that because they were aware of the risks a merger might pose to quality of care, quality of care received a lot of attention. "A merging organisation is incredibly self-critical. Quality of care has never gotten the attention it's getting now that we're merging. It's great." (Quality of care adviser 1) Additionally, respondents told us that hospitals consistently face issues not directly related to quality of care. "We're always reorganising hospitals. If there's a new guideline, new medication, new operating procedure—you have to reorganise processes." (Medical specialist 1) The attention of a hospital is never exclusively directed at quality of care and non-merging hospitals equally deal with organisational change, our respondents argued. Mergers, according to hospital respondents, are no different from normal change routines, but can be seen as an intensification of those routines. Whilst the inspectorate thus frames mergers as a life event that takes attention away from quality of care, hospital respondents argue that quality of care is foregrounded during the merging process, albeit acknowledging that innovation temporarily comes to a halt.

Reorganizing care practices

Typically, when hospitals in the Netherlands merge, the hospitals become separate locations of the same hospital organisation and care services are divided between them. Some services might exist on both locations while others might be exclusive to one location. The hospitals we studied asked personnel to work at both locations. All respondents reported that this way of working poses risks. Ironing out differences between locations—in terms of protocols, electronic patient records, medical equipment, etc.—is the main priority in a merger when personnel works at both locations, respondents argued. Doing so is "a huge amount of work," that is challenging both in the effort it takes and because these differences are ingrained in the nuts and bolts of organisational processes. A consultant told of two hospitals, "that both had four-bed rooms. In one hospital they counted those beds clockwise, in the other, counterclockwise… That's dangerous with medications." (Consultant 1) Hospitals try to identify such differences by setting up 'transitional teams' or 'protocol committees' tasked with aligning these differences, often on a departmental level. But even with a committee in place it can be difficult to foresee risks.

> If you don't program an infusion pump correctly, a patient receives a wrong dose. And here they use different pumps than on the other location, but nurses work on both locations. We had not identified this as risk prior to relocating services and personnel… It's something you run into. (Quality of care adviser 1)

> Really, if you're quality-minded, you'll have to put on the brakes at times. You'll identify a safety issue, meaning you can't just merge two departments or disciplines, because different protocols need to be aligned first. (Medical specialist 2)

As personnel and care practices are relocated as part of the merging process, a merger intervenes in and potentially disrupts many interwoven processes. "Everything's connected! The moment you relocate care practices, so much changes—going back to the beds you use, the infusion pumps, administering medication..." (Quality of care manager 2) A merger challenges the historically rooted, everyday logic of 'the way we do things here', that can go back to the smallest of details. How those details might come to matter in everyday care practices and the outcomes of those practices, is hard to foresee.

Because of the work it takes to address and align these differences in how hospitals work and the risks that occur when it is not done properly, the Inspectorate considers a merger a considerable risk to quality of care.

> Protocols, ordering medication, it's all different. [Merging] is building an entirely new organisation – on top of an already busy, regular workload… All kinds of risks to patient care emerge. (Inspector 4)

Whilst hospital respondents do not deny these risks, they also point out how having to align protocols and rethinking why you do things a certain way offers learning opportunities. A director experienced the merger as a "leap forward", as it forced them to "critically question each other: 'Why do you this in this way? Can't you also do it like this?'" (Executive director 2). Respondents present a merger as a reflexive instrument that, in its potential to disrupt the historically rooted 'way we do things', offers a valuable opportunity to revaluate current care practices and improve upon them. In merging, respondents claim, they can learn from the other hospital. "On one location, when elderly are brought in through emergency care, a geriatrician assesses if someone is demented or suffers a delirium. That's a practice we'll implement here too." (Quality of care adviser 1) While the idea that in comparing care practices, hospitals can evaluate and implement best practices was voiced by multiple respondents, this is no given and the question of what a best practice is, is not beyond organisational concerns or power relationships. In the merger between a large and a small hospital this was clearly apparent:

> Chances are, our way of working will be dominant, just because we're bigger. It's way more work to implement a best practice of theirs over here, than the other way around, just because they're a much smaller hospital. I wonder if their best practices are really seen as such, if they are implemented here. (…) I don't think it likely. (Quality of care manager 3)

Both inspectors and hospitals respondents identify risks associated with how, in merging, care practices are relocated and healthcare professionals are asked to work on both hospital locations. What becomes apparent is that the process of merging, for both inspectors and hospital respondents, can (temporarily) destabilise routines. Inspectors tend to emphasise the dangers of this destabilisation of practices and routines—as healthcare professionals can be confronted with different protocols or IT-systems they are unable to access on the spot. Hospital respondents acknowledge the risks associated with redesigning practices and altering routines, as well as the time this takes, but also frame this temporary destabilisation as a productive opportunity to critically reflect on and improve one's care practices. These findings shed some light on how key processes—e.g. medication administration procedures—might be impacted as hospital merge, but rather than identifying specific processes as such, what we learn is that a merger can challenge and possibly destabilise a rooted familiarity healthcare professionals have with care processes and practices. Given this, we wonder how the Inspectorate regulates hospital mergers and how hospital respondents experience that regulation.

Regulating hospital mergers

In the regulation of mergers, the Inspectorate is involved in two stages. The first is merger control and the question if a merger should be approved, at which stage the Inspectorate can give their take on how a merger is expected to impact quality of care (Box 1). The second entails the regulation of hospitals once the merger is approved. We discuss both.

Assessing the impact of a hospital merger on quality of care

In assessing whether a merger should be approved, the Inspectorate is asked to weigh in on how the merger might impact quality of care. Inspectors perceive this as an impossible task. "The expectation is that we can predict [the impact of a merger on quality of care], (…) but we can't." (Inspector 2) A policy adviser told us, "we have an image of hospital A and of hospital B, but that doesn't become [image] C, when you merge those. That becomes a new image," underscoring the unpredictable impact of a merger. Faced with what the Inspectorate considers the impossible task of 'predicting' the impact a merger will have on quality of care, the Inspectorate refrains from giving their take on a merger and is de facto not involved in merger control. The Inspectorate's self-proclaimed

inability to predict the impact of future mergers stems from the conviction that the impact of a hospital merger on quality of care is uncertain and that as each merger is thought to have its own unique dynamic, past mergers do not provide the Inspectorate with knowledge about how a future merger might play out. The Inspectorate opts out of being meaningfully involved during hospital merger assessment, so that the risks a merger might pose to quality of care—detracting attention or destabilising familiarity with care processes and practices—do not feature in the decision to approve or prohibit a merger.

Regulating hospital mergers after approval

Although inspectors conceive of mergers as risk to quality of care—in the attention it requires, detracting from the attention (needed) for quality of care and as hospitals relocate care practices and personnel—inspectors explained that as hospitals merge, this, in itself, is no reason to alter or intensify regulation. Having said that, various inspectors monitor merging hospitals more closely "behind the scenes, so that we can intervene before performance deteriorates." (Inspector 3) The Inspectorate possesses no formal regulatory tool based on which they monitor merging hospitals differently than other hospitals. Consequently, inspectors take different approaches. While some inspectors wait for "really hard signals – more reported incidents, more complaints—that indicate quality of care is under pressure," (Inspector 2) other inspectors take a different approach.

> I visited both hospital locations, unannounced, to see how both were doing on a specific theme. I found that while they'd already relocated care practices, they had not yet aligned protocols and personnel was insufficiently trained at the new location. I said, 'You can't continue like this; you have to train personnel and align protocols and systems before you allow personnel to work at the other location!' (Inspector 4)

Despite the way inspectors previously expressed hospital mergers to be disruptive, discontinuous life events, the Inspectorate's regulatory practices do not (formally) change in response to an announced or approved merger—only to the extent that individual inspectors might opt to 'follow' hospitals more closely.

How hospital respondents experienced the Inspectorate's regulation

Multiple respondents from hospitals noted that the Inspectorate was "absent" as they prepared the merger. They expressed the expectation that the Inspectorate would be more present after plans for merging with another hospital were announced. In fact, many respondents thought it was a shame that the Inspectorate left the hospitals to their own devices and proposed ways in which the Inspectorate could be meaningfully

involved in merger assessment—without the Inspectorate feeling the pressure to predict the impact of a merger.

> The Inspectorate should look closely at the relocation of professionals and care practices—that's when things really change. Look at key processes: patient-identification, medication processes, operating theatre procedures, handovers. (Quality of care manager 2)

> The Inspectorate could say 'In merging, we see such and such risks' and: 'What care practices will you relocate?' A prospective risk analysis (…) forces you to structurally assess what might go wrong. (Executive director 1)

Before a merger is approved, respondents from hospitals envision two roles for the Inspectorate. For one, the Inspectorate could critically question hospitals about how they intend to relocate care practices and professionals safely, what risks might be involved in this relocation and how they mean to address these risks. Secondly, the Inspectorate—having seen many mergers—could share its knowledge with hospitals that are preparing a merger so they might benefit.

The Inspectorate, in turn, is hesitant to take on this second role, claiming that hospitals are well-equipped to share such knowledge amongst themselves. "That is not our role. I understand why hospitals might want us to do this, but that is not our part to play; we are not advisers, we are inspectors." (Inspectors 3) The notion that to regulate is something quite distinct from providing the parties it regulates with advice, is a notion that was (often quite strongly) expressed by multiple inspectors.

> Interviewer: So, you don't have an advisory role?

> Inspector 2: Oh no, definitely not! We stay far away from that. Whenever the expectation that we would be able to advise hospitals [on the merging process], we back away and reiterate: 'We do not advise hospitals in merger processes, nor do we judge the [merits of a] merger; that is a process between two hospitals, wherein the regulator plays no part, should play no part—unless we find that the merger negatively impacts quality of care, unless we receive signals that things go awry.'

In line with how different inspectors might take different approaches to regulating hospitals after the approval of a merger, hospital respondents experienced the Inspectorate's regulatory presence differently once the merger was approved. Whereas directors from two hospitals were visited more often at the time of the merger, another director was

unaware of any increased attention from the Inspectorate. "We're treated like any other hospital. I've talked with the Inspectorate about relocating care practices and showed them what we're doing. We've demonstrated what risks might emerge because of this and how we'll manage them." (Executive director 1) Other respondents from hospitals, quality managers and medical specialists, would value (additional) thematic regulatory visits from the Inspectorate specifically targeting risky aspects of the merger—such as the relocation of care services, or how the hospitals ensure continued access to IT-systems as personnel works at both locations. Here, too, the Inspectorate is reluctant to do so, since this, inspectors argue, would entail prioritising regulatory practices to the needs of hospitals that decided to merge, rather than to the regulatory agenda of the Inspectorate.

The Inspectorate's increased attention for merging hospitals is not formalised. That a hospital is merging is something inspectors 'keep in mind' and monitor 'behind the scenes', but the decision to act on that is up to individual inspectors and depends on additional criteria (more reported incidents or 'other signals' that a hospital is struggling).

DISCUSSION

We wanted to understand how the process of merging impacts quality and safety of care through key hospital processes and what this implies for how mergers might be regulated. Hospital respondents and inspectors acknowledge that merging is an arduous organisational process. The Inspectorate primarily conceives of a merger as a risk to quality of care, as it detracts from attention and time necessary for attending to quality of care and it disrupts safety routines. Hospital respondents point out that attending to the merger and attending to quality of care are not necessarily different things. Risks to quality of care are said to occur especially as personnel and care practices are relocated. Hospitals organise their care practices differently and use different equipment and IT-systems to support those practices. When personnel works at both locations these differences pose risks to quality and safety when they are not properly identified (e.g. 'miscounting' beds) or not yet aligned (having to operate an unfamiliar infusion pump). Ironing out these differences is a priority and a challenge, because differences can be difficult to identify and because of the work it takes.

We were also interested in how the Inspectorate regulates hospitals mergers. While the Inspectorate states a merger might detract from attending to quality and safety of care and it might destabilise care practices, its regulatory practices are hesitant. Prior to the approval of a merger, the Inspectorate can weigh in on how a merger might impact quality of care but refrains from doing so because it considers 'predicting' the impact of a merger impossible. After a merger has been given the go-ahead, the Inspectorate does

not monitor these hospitals differently than it does others, although some inspectors follow merging hospitals more intensively 'behind the scenes'. The uncertainty that surrounds the question of how a merger will play out hampers the Inspectorate in taking a more proactive regulatory stand. In terms of the regulatory framework of Gilad (2010), the Inspectorate conceives of the impact of a merger as possibly affecting a hospital's first-tier operations—like its medication processes. But a merger's unpredictable character and the idea that each merger is its own unique process, hampers the development of a prescriptive regulatory approach. What is interesting is that the Inspectorate, in ruling out the possibility of first-tier prescriptive regulation in response to mergers, does not explore the possibility for regulating hospital mergers on the second- or third-tier—that would allow for regulating the quality of the systems and self-evaluative activities of merging hospitals. Hospital respondents, meanwhile, welcome regulatory activities that requires them to account for such activities, by, for example, demonstrating how they ensure the safety of key processes as they relocate care practices.

In line with previous studies, we found that mergers initiate a period when hospitals are 'turned inwards' and staying up to date with latest developments becomes challenging. Also, while implementing best practices between hospitals was cited as a reason for why mergers help improve care practices, what these 'best' practices are is not evident, nor is implementing a practice elsewhere straightforward. We address a gap in the current literature, as outcome-oriented studies do not demonstrate how mergers impact quality of care, while the process-oriented studies insufficiently trace the impact of a merger on organisational processes to quality of care. We contribute to both literatures by demonstrating that a merger is a complex process that can intervene in interwoven care practices and uproot established, tacit ways of working. While some of its impact might be anticipated and organised for—e.g. by aligning protocols prior to relocating personnel and care practices—all the ways in which a merger might impact care practices is difficult to foresee. Allen, studying the work of nurses, notes that "[nurses] displayed a detailed understanding of the relevant activity systems in the local ecologies in which they worked, including role formats, routines, bed economy, material and psychological artefacts and temporal structures" (2015, p. 137). The manner in which nurses were able to weave together clinical and organisational knowledge depended on a (long-standing) familiarity with one's organisational surroundings (Allen, 2015). Mergers can uproot vested practices and destabilise healthcare professionals' familiarity with a hospital's 'local ecology'. This destabilisation is predominantly framed as a threat by the Inspectorate, while hospitals claim it is productive too. This period of temporary destabilisation is conceived of by hospitals as a chance to critically reflect and improve upon their care practices. The need to reassess one's routines and practices, hospital respondents claim, also allows for pin-pointing best practices—even if the evaluation and implementation of a best practice is not straightforward (cf. Fulop et al., 2005). The

impact of a merger on quality of care is said to be ambiguous (offering learning opportunities as well as posing dangers), potentially disruptive in unforeseen ways and emergent as many potential risks become visible only when stumbled upon. The multi-tiered regulatory approach we suggest below aims to be attentive to these characteristics of a merger, while also providing regulators with an approach to monitor and potentially act on how hospitals manage a merger.

Many of the studies that report on the relationship between a merger and quality and safety of care do so through quantitative research designs. While these studies might indicate if merging impacts quality and safety of care, they have some disadvantages. First, these studies must assume 'a merger' as a clearly bounded variable, to which potential differences in quality indicator scores pre- and post- merger might be ascribed. This, others recognise as well, is problematic (Dutch Authority for Consumers and Markets, 2016; Fulop et al., 2005). "A 'merger' is a unit of analysis with 'ambiguous boundaries' (…); when the process 'begins' and 'ends' is not obvious. Previous research treated 'merger' as having clear boundaries and therefore underestimated its complexity." (Fulop et al., 2005, p. 120) Second, in selecting a set of quality indicators to assess the impact of a merger, these studies predetermine what 'quality and safety of care' supposedly is. In our qualitative study, we developed a different perspective. We approached a merger as a complex organisational process with 'ambiguous boundaries' that can impact a hospital's care practices. A merger, viewed as such, is a process a range of people invest in to normalise new organisational structures and routines (May and Finch, 2009). Through our semi-structured interviews, we gained an understanding of what such investments entail and how merging, as a process, can impact key hospital processes. In our design, moreover, we did not assume to know wat quality and safety of care is, or resides, but rather, have our respondents give their take on how they perceive a merger impacting quality and safety of care. We involved both the perspectives of merging hospitals as well as healthcare inspectors since regulation is a relational practice (Gilad 2010). To regulate is to establish a relationship between a regulator and a regulatee that is directed towards a particular goal (typically a form of regulatee behaviour). To address the question of how mergers might be regulated, we therefore considered both the perspectives of regulator and regulatees. While our study design proved informative given the questions we looked to address, it also has some limitations. For one, our sample of respondents (n=30) was relatively small and true anonymization of hospitals proved difficult. This might have affected the extent to which our respondents provided socially desirable accounts of the merger process. Yet, our findings on the opportunities a merger holds and the challenges it poses (for quality and safety of care) are not dissimilar to those reported in studies that, given their data set, were better able to assure anonymity of hospitals and its employees (Fulop et al., 2005; Haas et al., 2018). Also, while we understand a merger as a complex process that people invest in over an

extended period, our interviews were conducted at one moment during that period, rather than following the merger process and our respondents over time. Having said that, the strength of our study is in how it documents the impact of a merger on quality and safety of care from multiple perspectives (hospital respondents and healthcare inspectors) and how understanding those perspectives allows for thinking about an alternative way to regulate hospital mergers.

Recommendations for the future regulation of mergers

In the introduction, we wrote about the uncertain impact a merger might have on quality and safety of care. While we shed some light about how a merger might impact quality and safety of care—destabilising healthcare professional's familiarity with care processes and practices—it remains anything but predictable. The question is, then, how the Inspectorate might develop a regulatory approach to mergers *given* their uncertain impact? Before a merger is approved, we suggest the Inspectorate requires hospitals to conduct prospective risk analyses that they report to the regulator—addressing how their plans to merge and possibly relocate care practices and personnel might impact key processes—that serves to design and possibly reorient reorganization practices. More than exhaustively identifying all the risks a merger poses, a prospective risk analyses can serve as a heuristic exercise that challenges both hospitals and regulator to reflect on the possible impact of a merger on quality of care and to acknowledge a merger as complex, disruptive reorganizational process, without giving in to the idea that all dysfunctional effects can be mitigated. This is a prescriptive regulatory intervention on the second- and third-tier, as it calls hospitals to monitor the safety and quality of their practices and the risks merging might pose to those practices, that does not require certainty about a merger's impact on care practices. It ensures hospitals focus on and think about the quality and safety of their practices in the process of merging and to install procedures that ensure that reflecting on the disruption of care and safety routines is actually done. Moreover, it can accommodate for the unique character of a merger. Hospitals have their strengths and weaknesses and the Inspectorate—that generally knows about the vulnerabilities of a given hospital—can ensure that hospitals focus on how merging impacts *their* key processes. Hospitals, in other words, are expected to tailor this regulatory instrument to their own situation (Gilad, 2010). This process-based regulatory intervention does not do away with first-tier regulation—such as monitoring a hospital's performance on those 'hard signals', like quality indicators, one inspector mentioned—but it can mediate what those signals mean. Documented poor performance in combination with a prospective risk analysis that does not convince the Inspectorate that a hospital is aware of the risk a merger might pose might be handled differently than if a risk analysis is indicative of a hospital's willingness and capacity to

critically self-evaluate its practices. Such a regulatory approach acknowledges, rather than aims to dispel, a merger's uncertain impact on quality and safety of care.

CONCLUSION

Mergers are complex reorganizational processes that can disrupt daily care practices in hospitals. In a merger, different ways of working that hospitals developed over the years meet and are challenged. While the Inspectorate emphasises how a merger poses risks to quality of care, hospitals draw attention to the productive side of having to critically reassess current care practices. We call for regulatory practices that acknowledge the uncertain impact of a merger. Adopting a process-based regulatory approach, that requires hospitals to report on the risks merging poses to the quality and safety of their care practices, can help doing so.

3

The risk-based regulation of hospital mergers: Looking in(to) the future

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Under review in: Health, Risk & Society

4

Shared learning from incidents: A qualitative study into the perceived value of an external chair on incident investigation committees

Published as: de Kam, D., K. Grit and R. Bal (2019). Shared learning from incidents: A qualitative study into the perceived value of an external chair on incident investigation committees. *Safety Science*, *120*, 57–66.

ABSTRACT

Despite continued calls to learn from patient safety incidents and a tradition of incident investigations in healthcare, there is discussion about if and how learning from incidents occurs. In this article, we study a policy change in the Netherlands that aims to encourage organisations to learn more from incidents. Dutch healthcare organisations investigate their own incidents. Recently, the Dutch government decided that when an incident leads to the death of a client in elderly or disabled care, an external chair should head the investigation committee. Thinking of learning as social, participative practice, we asked how and under what conditions an external chair might help organisations learn from incidents. We adopted a qualitative research design. We asked healthcare inspectors to assess 20 incident investigation reports by committees with (10) and without an external chair (10), using what we learned in follow-up interviews and a focus group. We interviewed investigation committee chairs, professionals involved in incidents, quality advisers and directors of four healthcare organisations (n=15) to study how they investigated incidents with external chairs. We also interviewed external chairs, healthcare inspectors and other stakeholders (n=15). Our respondents valued external chairs' methodological expertise and experience in investigating incidents. The external chair's outsider's position enables critical, impartial inquiry. Besides helping organisations identify root causes of an incident, both external chairs and organisations learn from investigating an incident. Our article contributes to literature on (shared) learning from incidents by envisioning of the external chair as fostering a social and participative form of shared learning.

INTRODUCTION

Although learning from patient safety incidents and designing reporting systems that facilitate learning have been a top priority in healthcare since *To Err is Human* (Howell et al., 2017; Kohn et al., 1999; Macrae, 2016), it remains unclear whether the widespread adoption of incident reporting has truly made healthcare safer (Howell et al., 2017; Mitchell et al., 2016; Shojania and Thomas, 2013; Stavropoulou et al., 2015). Healthcare organisations face a wide range of increasingly well-documented challenges in the attempt to learn from incidents (Anderson and Kodate, 2015; Hibbert et al., 2018; Howell et al., 2017; Macrae, 2016; Mitchell et al., 2016; Peerally et al., 2016). These challenges range from using findings of the analysis of singular incidents as driver for learning at deeper levels or failing to provide feedback to staff after incident investigations (Macrae, 2016; Peerally et al., 2016). Despite such challenges, the belief that reporting and investigating incidents offers important learning opportunities to improve the safety of care practices is not abandoned (Le Coze, 2013). Rather, there is a call for "more sophisticated infrastructures for investigation, learning and sharing, to ensure that safety incidents are routinely transformed into systemwide improvements" (Macrae, 2016, p. 74).

In the Netherlands, the discussion on the need to learn from incidents and the question of how to do so, is equally dominant (De Bruijn, 2007; Inspectorate, 2016a; Leistikow et al., 2017). The national regulator that monitors quality and safety of care, the Dutch Health and Youth Care Inspectorate (Inspectorate), features prominently in this discussion. The Inspectorate maintains that healthcare organisations should learn from incidents (Inspectorate, 2016a; Leistikow et al., 2017). To that end, healthcare organisations are required to report all serious incidents to the Inspectorate, investigate incidents and report back on their findings. The Inspectorate reviews how healthcare organisations investigated serious incidents with a scoring instrument that aims to "[quantify the] quality of the learning process" (Leistikow et al., 2017, p. 2). Key to the Inspectorate's pedagogy is the conviction that healthcare organisations learn more from investigating their own incidents than if the Inspectorate, or any other external body, conducts the investigation (Inspectorate, 2016a; Kok et al., 2019; Leistikow et al., 2017). This notion is in line with literature that proposes "learning should be as close as possible to the shop floor and the actual workers to be involved" (Lukic et al., 2010, p. 430).

Recently, this conviction was challenged. When national media reported on healthcare organisations trying to conceal incidents (Kuiken, 2015; Van Es, 2013), politicians called for more independent investigations. They questioned both the trust the Inspectorate puts in healthcare organisations to investigate their incidents openly and properly as well as the idea that organisations would learn less if their incidents were investigated by an external party (Dutch House of Representatives, 2015). Following discussions with the Inspectorate, the Dutch Ministry of Health decided that an external

chair should head the investigation committee if a serious incident led to the death of a client in elderly and disabled care organisations (Dutch Ministry of Health, 2015). Appointing an external chair strikes a balance between having an investigation conducted by a team comprised of employees or by a fully independent, external team or agency. It is a compromise between the Inspectorate's emphasis on 'internal' investigations and the government's call for 'external' review. Allowing healthcare organisations to conduct their own investigations, the Inspectorate stimulates organisations to take 'active responsibility'; organisations can acknowledge responsibility for an incident and commit to work at preventing the occurrence of future incidents, rather than being passively held responsible for an incident (Braithwaite and Roche, 2000). Although an external chair brings an independent perspective on an organisation, organisations are still themselves responsible and accountable for the incident investigation.

The idea of appointing an external chair is inspired by the practice of Dutch prisons, where it is customary for investigations into the death of an inmate to be headed by a director of a different prison, ensuring an independent investigation (Dutch Ministry of Health, 2015). Elderly and disabled care were targeted specifically because whereas hospitals have improved in investigating and learning from incidents (Leistikow et al., 2017), it was claimed elderly and disabled care organisations have not (Dutch Ministry of Health, 2015). It was believed elderly and disabled care would stand to learn most from external chairs (Dutch Ministry of Health, 2015). External chairs were thought to be most needed in cases of serious incidents leading to the death of a client, although the Ministry stated no reason for this (Dutch Ministry of Health, 2015). An external chair should have no ties to the healthcare organisation that enlists the help of that chair, but no other criteria of eligibility are prescribed by the Inspectorate. In a letter addressed to the professional association of the Dutch disabled care sector, wherein the Inspectorate describes what it expects of organisations in this new way of working, the Inspectorate writes: "Appointing an external chair is the responsibility of the healthcare organisation. The healthcare organisation has to consider what skills [the external chair] should possess and how these skills fit the specific incident and the expertise of the investigation committee." (Inspectorate, 2015b) It is up to the organisation, in other words, to decide what a capable external chair is. In Dutch healthcare policy, it is common that healthcare organisations are provided room to adapt policies, while also making them responsible for doing so in a fitting way (van de Bovenkamp et al., 2014). Equally, the Inspectorate did not specify the role or responsibilities of an external chair (Inspectorate, 2015b). The Ministry claimed that appointing an external chair to head the investigation would bolster impartiality and "strengthen the capacity to learn [from incidents] and limit chances of recurrence" (Dutch Ministry of Health, 2015, p. 3). The Inspectorate also "expects organisations to learn more from mistakes by appointing an external chair" (Inspectorate, 2015c, p. Online press statement). It is unclear, however, what constitutes

an external chair's impartiality, how it might contribute to an investigation and why or how an external chair might help organisations learn from incidents.

Our aim

In this article, we study what the obligation to appoint an external chair accomplished. Our article is no 'classic' programme theory evaluation, intent on testing whether the policy's stated objectives—improved learning from incidents so that future incidents might be prevented—are realised in practice. Rather, we recognise that policy is "characteristically ambiguous" and that a policy's effects, intended or unintended, stated or unstated, are shaped by and valued within complex, local practices (Jones, 2018, p. 264). Our article, in that sense, is an attempt at "more broadly conceived [research]", advancing "a more general orientation to what is being accomplished, whether organization is moving in a fruitful direction and the conditions that support this" (Jones, 2018, p. 266). Having said that, our focus is not without demarcations as we attend, broadly, to the relationship between enlisting the help of an external chair in investigating incidents and learning from incidents. We think of learning as "a complex social and participative process that involves people actively reflecting on and reorganising shared knowledge, technologies and practices" (Macrae, 2016, p. 74). In doing so, we adopt a constructivist perspective on learning (Le Coze, 2013) and propose that learning is a social, participative activity, accomplished in and through practice (Drupsteen and Guldenmund, 2014; Le Coze, 2013; Lukic et al., 2010; Macrae, 2016). In this article, we are interested in *how* external chairs might help organisations learn from incidents and under what conditions, since this can help us define mechanisms for stimulating learning from incidents. We hope to contribute to literature that envisions learning from incidents as a social, participatory practice by reflecting on how enlisting external chairs, as organisational outsiders, might enable shared learning from incidents. For our article's key findings, see box 1.

Serious incidents in the Netherlands

A serious incident (*calamiteit* in Dutch) is defined in Dutch law as an unintended and unexpected event, related to the quality of care and having caused death or serious harm to the patient. Organisations are legally required to report serious incidents to the Inspectorate (Inspectorate, 2016b). After having reported a serious incident to the Inspectorate, healthcare organisations are granted eight weeks within which they are expected to investigate the incident and report their findings to the Inspectorate.

While what constitutes serious incidents in elderly and disabled care varies—as are the ways in which organisations report on their investigations of serious incidents—it might be helpful to share examples of serious incidents we encountered in our research and how organisations report on these incidents. We describe two 'typical incidents'

Box 1: Key findings

- While the possibility of learning from incidents is questioned in the literature, our research found that the figure of the external chair helps organisations better identify root causes.
- External chairs are valued for their 'fresh perspective'; external chairs are both familiar with the care practices of the organisations they investigate incidents in, yet unfamiliar with and untied to these organisations. This puts external chairs in a position to develop a critical perspective on the organisation and its practices.
- Using an external chair in investigating incidents is situated between internal investigations and external review. While internal investigations typically emphasise the need to locally embed the learning process and external reviews argue for the need for critical, impartial inquiries, our research suggests that appointing an external chair can do both. Members of the organisation are still involved and invested in investigating and learning from a local incident, while the external chair strengthens an impartial, critical inquiry.
- Using an external chair can prompt a form of participative shared learning, wherein the organisation learns from investigating an incident with the help of an external chair, but wherein the external chair learns too.

in elderly and disabled care, given the challenges that providing care to elderly and disabled people presents.

In elderly care, fall-related serious incidents comprises a particular type of incident that is well-known, can severely impact clients and are challenging to fully prevent (Nurmi and Lüthje, 2002). In one incident, a nurse had just dressed a 90-year old woman, who sat on the side of her bed (that was lowered given the earlier identified risk of falling as assessed by staff) and just as the nurse turned to transfer the woman to her wheelchair using a lift, the woman fell forward, out of bed, hitting her head on the floor. Two days after falling out of bed, the woman passed away.

People with intellectual disabilities are prone to suffer from dysphagia (swallowing disorders) and dysphagia-related serious incidents, where people choke while eating, are not uncommon in disabled care (Hemsley et al., 2015). In one incident, a 68-year old man with an intellectual disability, a diagnosed mental disorder and compulsive behaviour, who was known to want to eat a lot and too fast, choked while eating bread. Despite the efforts of staff, who were quick to perform the Heimlich manoeuvre and resuscitation efforts by emergency personnel, the man died.

The incident investigation typically follows a particular order—that corresponds to the root cause analysis methodology abbreviated as PRISMA (*Prevention and Recovery Information System for Monitoring and Analysis*), that the Inspectorate supports and that

is often adopted by organisations. A description of the incident itself is preceded by a description of the client and the care the client received at the organisation. Following that, events preceding the incident (e.g. previous falls of a patient or actions taken by the organisation to prevent falls, like lowering the bed), the incident itself and events after the incident (e.g. aftercare provided to family) are reconstructed. The level of detail of such reconstructions varies; some reports reconstruct events as they unfolded hourly or daily—with reconstructions of events running for multiple pages—while others are quite concise. Following the PRISMA methodology, investigations target organisational (e.g. does the organisation have a policy on re-assessing clients with an intellectual disability on choking risks, if a client has been assessed some years before?), technical (e.g. did technology or equipment, like computer systems or lifts, contribute to the incident?) and human factors (e.g. did staff notice the choking client and did they take appropriate actions?) that might have contributed to the incident. In the elderly care incident, the report concluded that while the incident could not have been prevented, the anticoagulants the woman had been administered—the usage of which was not periodically reassessed due to organisational changes—might have exacerbated the effect of the fall. In the disabled care incident, the report equally found that the organisation and staff had done much to prevent such incidents (the food was cut into small enough pieces, in line with the speech-language pathologist's recommendations), but also noted that staff struggled to open the emergency briefcase of the doctor when asked to, because they were unaware which of the multiple keys attached to the case would open it. The right key was labelled afterwards. In line with the identified contributing factors, recommendations are formulated according to SMART-criteria (e.g. developing and implementing a policy to re-assess risks of choking for clients with an intellectual disability annually).

The investigation committee typically consists of 3-5 people that, in line with the scoring instrument used by the Inspectorate (see box 2, item 1), is multidisciplinary, featuring physicians or medical specialists, nurses, managers and quality advisers. The committee determines who it needs to speak to in order to be able to reconstruct the incident, such as professionals directly involved in the care for the client and those present at the time of the incident. The committee might also speak to external experts (e.g. a speech-language pathologist in case of dysphagia-related incidents). The 20 reviewed incident reports range from 5 to 29 pages, averaging 15 pages in length. Prior to the need to appoint external chairs, it is good to note, quality advisers or medical directors typically acted as internal chairs of investigation committees. Organisations made sure that internal chairs did not work at, or were overtly familiar with the departments where the incident occurred. Staff that took up the role of internal chair were trained in incident investigation methodologies.

Box 2: Scoring instrument to assess the quality of incident investigations

Process

1 Is the investigating committee multidisciplinary?
2 Were any members of investigating committee involved in the incident?
3 Is the method for analysis specified? (e.g., root cause analysis (RCA))
4 Was input sought from all personnel directly involved?
5 Was input sought from other staff with knowledge about the care process?
6 Was input sought from the patient/relatives?

Reconstruction

7 Does the description of the event give a complete picture of the relevant 'scenes'?

Analysis

8 Has the question 'why' been asked extensively enough to analyse the underlying cause and effect?
9 Have the investigators searched relevant scientific literature?
10 Does the report state whether applicable guidelines/protocols were followed?
11 Was external expertise consulted?
12 Does the report state whether the medical indication for the provided care was correct?

Conclusions

13 Does the report identify root causes?
14 Do the root causes fit the reconstruction and analysis?
15 Are contributing factors considered and/or identified?
16 Are contributing factors, not under the control of the healthcare organisation, considered and/or identified?

Recommendations

17 Does the report document recommendations for improving processes and systems?
18 Do these corrective actions address the identified root causes?
19 Have the corrective actions been formalised? (e.g., Specific, Measurable, Attainable, Realistic and Time-Sensitive (SMART))
20 Does the healthcare organisation have an evaluation plan to determine if the recommendations are implemented?
21 Does the healthcare organisation have an evaluation plan to determine the effect of the recommendations?

Aftercare

22 Is the aftercare for the patient/relatives described?
23 Is the aftercare for the professionals involved described?
24 Has the report been shared with the patient/relatives?

Reaction of the board of the healthcare organisation

25 Is the reaction of the board adequate?

METHODS

Data collection

In order to understand what the obligation to appoint an external chair might accomplish, we opted for a qualitative research approach. To gain an initial understanding of how external chairs might help organisations learn from incidents, we asked five healthcare inspectors from the Inspectorate ('inspectors' hereafter) to individually score a random selection of incident investigation reports predating (n=10) and following the policy change (n=10). Both batches contained five elderly care and five disabled care reports from various healthcare organisations. The inspectors scored the reports with the instrument the Inspectorate uses to assess the quality of incident investigations (Leistikow et al., 2017). This instrument contains 25 'yes or no' items (see box 2). If all items are 'yes', the report scores 100%. We took the average of the scores awarded by all inspectors. Our aim of asking inspectors to assess the included incident investigation reports was to explore and understand, with inspectors, how reports predating and postdating the policy change might differ. We did not statistically test for differences between the reports predating and postdating the policy change and draw no causal inferences about the relationship between the presence of an external chair and the quality of the incident investigation (report). Rather, the inspectors' assessment of these reports served as starting point for inquiring what involving an external chair in incident investigations might mean in terms of learning from incidents. Therefore, following the scoring phase, we held a 2.5-hour focus group with three inspectors and conducted individual interviews with the remaining two inspectors, whose busy schedules prevented them from joining a focus group. In both focus group and interviews, we discussed why the inspectors scored reports the way they did.

In consultation with the Inspectorate, we selected four healthcare organisations (two elderly care and two disabled care organisations, spread throughout the country and varying in size) that had recently reported fatal incidents. In the Netherlands, the disabled care sector encapsulates organisations that cater to people with intellectual or learning as well as physical challenges. The two disabled care organisations we studied serviced people with intellectual challenges (see table 1). In one elderly and one disabled care organisation, the serious incident occurred just before the policy change, so that external chair involvement was not required, whereas the other incidents did involve external chairs.

The Inspectorate introduced us to all four organisations. We emailed their CEOs, detailing the objective of our study and requesting their participation. All approached organisations agreed to participate. Within these four organisations we interviewed (external or internal) chairs of the investigation committees, healthcare professionals involved in the incident, quality advisers and members of the board of directors (total

Table 1: Characteristics of studied organisations

Organisation	Number of clients	Number of staff	Investigation headed by
Elderly care organisation A	<1000	<1000	Internal chair
Elderly care organisation B	7500 – 10.000	5000 – 7500	External chair
Disabled care organisation C	2500 – 5000	2500 – 5000	External chair
Disabled care organisation D	1000 - 2500	2500 – 5000	Internal chair

All organisations operate regionally and cater to people on various locations throughout the region, that range in size from larger, multi-storied facilities that house more than 60 clients, residential homes that house a handful of clients, to clients that live in their own home and receive care there. Publicly available annual reports were consulted to provide the organizational characteristics provided here. However, to ensure the anonymity of the studied organisations, links to these documents will not be provided and the number of clients and staff reported were rounded off.

n=15). Prior to the interviews, the Inspectorate provided us with the incident reports of the four organisations and in the interviews, the incidents served as a case that allowed us to discuss incident investigation practices. These interviews allowed us to study how incidents were investigated and how the involvement of the external chair was organised and valued. While the incidents we discussed in organisations A and D were investigated with internal chairs, respondents also talked about incident investigations that they had since conducted with the help of external chairs. The four incident reports from the organisations were not part of the 20 reports scored by inspectors. To understand the (un)intended and perceived effects of the policy, as well as how the policy came about, we interviewed representatives of professional associations in elderly and disabled care (n=4), healthcare inspectors (n=7), politicians (n=2), an experienced external chair (n=1) and a director of a prison (n=1). Interviews were structured through interview guides that were prepared by the first (DdK) and second author (KG). The interview guides were tailored to respondent's positions and experience and adjusted given what we had learned from previous interviews.

Data analysis

In all, we conducted 30 interviews that lasted 61 minutes on average. With the respondents' consent, both the focus group and interviews were recorded and transcribed verbatim. The transcripts were analysed and inductively coded with the aim to identify themes (Green and Thorogood, 2018). DdK first coded the transcribed material, generating a wide range of codes. Following that, all authors discussed the codes that were then clustered and identified as emerging themes. We identified five (interrelated) main themes: the selection of external chairs, the role of external chairs, the value of external chairs, difficulties in involving external chairs and learning from investigating incidents with external chairs. The presentation of our findings will be structured in line with these themes.

FINDINGS

In the first year after the policy change, elderly and disabled care organisations reported 289 serious incidents that caused the death of a client. Most incidents (256) were reported in elderly care (Inspectorate, 2016c).

Scoring the incident investigation reports

Table 2 lists the average scores for the 20 incident investigation reports we asked inspectors to score, as well as the standard deviation (SD) per group of clustered reports.

Keeping in mind that we did not statistically test for differences, we want to make three tentative observations on how the inspectors assessed the investigations reports. We explored these further in the follow-up interviews and focus group. First, the ten reports before the policy change averaged 59.7, while the ten reports after the policy change averaged 77.0. Second, inspectors scored elderly care reports lower (52.6) on average than disabled care reports (66.8) before the policy change. After it, the difference between elderly care (75.9) and disabled care (78.1) is almost negligible. Finally, it is striking that after the policy change, no report is scored as low as any of the reports predating the policy change (29.3 and 33.0 in elderly and 38.0 in disabled care). The standard deviation of the scored reports before and after the policy change decreased (from 20.6 overall to 8.1).

Table 2: Scored investigation reports

Elderly care reports before policy change		Disabled care reports before policy change	
Report 1	69.0	Report 6	73.3
Report 2	52.3	Report 7	64.0
Report 3	79.3	Report 8	68.7
Report 4	29.3	Report 9	90.0
Report 5	33.0	Report 10	38.0
Average reports before change	52.6 (SD 21.8)	Average reports before change	66.8 (SD 18.9)
Average elderly and disabled care reports predating the policy change			59.7 (SD 20.6)

Elderly care reports after policy change		Disabled care reports after policy change	
Report 11	84.0	Report 16	81.0
Report 12	70.3	Report 17	68.7
Report 13	69.3	Report 18	67.3
Report 14	82.7	Report 19	83.0
Report 15	73.3	Report 20	90.3
Average reports after change	75.9 (SD 7.0)	Average reports after change	78.1 (SD 9.8)
Average elderly and disabled care reports after the policy change			77.0 (SD 8.1)

The inspectors' take on the incident investigation reports

In the follow-up interviews and focus group, we asked inspectors how they scored the reports and what they thought accounts for their scores.

Inspectors noted that post-policy change reports adequately addressed the process and analysis items of the investigation (see box 2). Understanding what happened is key, they argued, as the rest of the report builds upon that.

> What happened has to be clear (…) so I can tell if the root causes are properly identified. This is where it starts; it determines the next steps and whether or not these steps make sense. (Inspector, disabled care 6)

When asked why inspectors scored post-policy change reports higher than the predating reports, most inspectors argued that this is at least partly due to external chairs. One inspector noted that involving an external chair ensures a certain level of quality in investigating and reporting on incidents, snuffing out the 'really bad' reports (Focus group inspectors), which is in line with the scores in Table 2. Another inspector stated that, with external chairs, more investigations identify root causes.

> We see better reports in elderly care [when an external chair is involved]. Most investigations can identify root causes better. Before, we saw organisations stopping [analysis] too early and we'd say: 'If only you'd asked more questions'. So, the medication got swapped. [The organisation said,] 'The professional didn't follow protocol', period. 'So what do we do? We will better implement protocols'. But we don't know why she didn't follow protocol. Was it a busy nightshift? Did she have problems at home? Did she not feel well? [Such] root causes (…) weren't addressed [well] enough in earlier investigations. (Inspector, elderly care 2)

Inspectors were hesitant to attribute the improvement in reports solely to the external chair though. Inspectors noted that organisations might have become better in investigating incidents over time and recounted that in the past the Inspectorate had stressed the need to properly investigate incidents. Since 2014, the Inspectorate provides organisations that report an incident with a guideline that specifies what the Inspectorate expects of the investigation. This guideline overlaps considerably with the scoring instrument the Inspectorate uses to assess investigation reports (Inspectorate, 2016d). In outlining conditions known to contribute to thorough incident investigations, the Inspectorate hoped healthcare organisations would invest and improve upon their investigative practices (Kok et al., 2019; Leistikow et al., 2017). The external chair is part of wider efforts aimed at stimulating learning from incidents.

Below, we go on to discuss how the four healthcare organisations we studied organise and value the involvement of external chairs. The five themes we identified—the selection of external chairs, the role of external chairs, the value of external chairs, difficulties in involving external chairs and learning from investigating incidents with external chairs—order our findings.

Selecting an external chair

The obligation to appoint an external chair to head the investigation committee required organisations to arrange a way of recruiting them. All four organisations contacted other organisations to set up pools of people that can act as external chairs.

> When the policy came into effect, we agreed with other directors in the region that we would provide each other with external chairs. (Executive director, elderly care B)

> We looked for an organisation with a certain vision on transparency, trust, quality and safety (...) and agreed to exchange external chairs. (Executive director, disabled care D)

Organisations can hire external chairs from firms that offer experienced investigators, but the cost involved can rise to € 25,000, so that exchanging external chairs is also seen as cost-savings measure. When it comes to what an external chair should bring to the table, directors agreed that chairs should be competent, experienced investigators.

> We specified certain criteria, related to their knowledge and experience. We don't want an external chair to be someone conducting their first incident investigation. (Executive director, elderly care B)

Asked what a director expects of an external chair, he said:

> To get to the bottom of [the incident]. To be a thorn in our side. To not settle for it if our team says 'We couldn't have avoided it'. To look past that and analyse [what happened] critically. (Executive director, disabled care D)

The external chairs we interviewed are trained, considerably experienced investigators of incidents in healthcare settings. One external chair, not in a pool set up by the organisations we studied, used to be a family physician, worked for the Ministry of Health and the Inspectorate. In the past two years he conducted 25–30 investigations as chair.

Another external chair has investigated incidents since 2010 as an expert in disability care and as external chair since 2015.

In addition to expertise, external chairs should be familiar with the context and type of care the organisations deliver, directors told us. Directors look for external chairs that 'know our world'. While one director told us she hired a former judge, other organisations use external chairs with healthcare backgrounds. Related to this is the question if an external chair should have specific incident-related expertise. One organisation reported having positive experience with a psychiatrist investigating an incident related to psychopharmaceuticals and the onset of dementia in an intellectually disabled patient, but the external chair was not selected *because* he was a psychiatrist. It seems that organisations do not select external chairs on their case-specific expertise; the fit between an incident and the external chair's background is coincidental. Respondents explained they can and do recruit external members if they lack case-specific expertise.

The role of an external chair

The role of an external chair is not predefined in policy and is negotiated in light of the question what an external chair might contribute to an investigation. The organisation and the external chair have to agree on the external chair's responsibilities with each investigation.

> If you asked me, "What should an external chair do or pay attention to?", I'm not sure I could tell you. I'd say I'm responsible for conducting the investigation in a good way, within the time limits we face. This is important, because especially when a patient dies, these investigations can drag on for ages and it's so hard on family members when it does. (…) But especially, [an external chair] has to be impartial, that's key. And know the methodology. (External chair 3)

Without being able to fall back on a prescribed role or pre-structured responsibilities, external chairs and organisations have to think about what it means to be impartial.

> I was just asked to head an investigation in an organisation I had earlier worked as external chair. I couldn't do it, because I was on holiday, but it really made me wonder if I wanted to do it. Because although it was not at the same location, I have conducted an investigation [in that organisation] before. How impartial am I then? We have to assess that among ourselves (…) but it helps, in these cases, to know if I [as external chair] am there to see things are not swept under the rug, to bolster the quality of the investigation or to ensure the independence of the investigation. (External chair 3)

Whether external chairs should participate in the interviews conducted for the investigation was a recurring question for many of our respondents and for external chairs and directors in particular. A medical director remarked that as external chair, he is adamant about participating in interviews because doing so "[lets] me get a better picture of the incident" (Medical director, disabled care D). Another external chair addressed the tendency to curtail the external chair's role because of the time it takes to arrange thorough involvement from the start.

> The external chair would jumpstart the investigation and determine who to interview but would then back off [and] other people would do the interviews. [But] I've always done interviews; that's how I like being involved. (External chair 1)

According to a board member, an external chair should interview at least some "key people" (Executive director, elderly care B). Directors as well as external chairs agreed that the external chair's responsibility ends when it comes to designing and implementing improvements.

> When the report is done, I'm done too. Responsibility for improvement lies with the organisation, not me. (External chair 1)

We will revisit this proposed link between reporting on and investigating an incident and improving.

The perceived value of an external chair

Quality advisers, directors and healthcare professionals valued the 'fresh perspective' an external chair brings. With the critical perspective of an outsider, external chairs can question things people in the organisation take for granted. However, an external chairs' fresh perspective is equally rooted in a familiarity with elderly and disabled care, so that external chairs also know where to look.

> By appointing an external chair, (…) you open the door to people from other organisations with different backgrounds, to see if the way you see things makes sense [to an outsider]. It always leads to questions you wouldn't ask yourself. (External chair 3)

> I'm no better than anyone else, but I look at things from a detached, less emotional perspective. [After an investigation] we discussed the report with the organisation and they asked me if I'd like to come to the meeting with the parent [to share

> the report's findings]. So I did. The parent objected to our conclusions, which I thought was valid [and] I noticed that people from the organisation were like "Yeah, but…" We concluded that the anaesthesiologist had "acted professionally" during a cardiopulmonary resuscitation, [but] the parent disagreed. Listening to her, I thought "You're right". The anaesthesiologist had acted professionally in her medical expertise but she had not communicated professionally with the patient's representative. So I get why our assessment of "acting professionally" upset [that parent]. I said, "You're right, ma'am." (…) I noticed that as an outsider, I wasn't uncomfortable to admit [the parent was right]. (External chair 1)

Taking the parent's perspective seriously is hard for people in the organisation because it questions if the anaesthesiologist's actions were up to professional standards. The parent's objections prompted a defensive response ("Yeah but…"). Acknowledging the parent's objections was easier for the external chair, who was able to critically challenge and reframe what acting professionally meant. Respondents valued the external chair's impartiality, both in terms of the image the appointment conveys—external chairs are said to help counter suspicions of conflict of interest—and in how that impartiality can impact an investigation.

> The external chair addressed issues that we felt were important too, but were hard for us to address about our own organisation. Because the external chair felt they were important, it strengthened our conviction that these issues had to be in the report. (Quality advisers, elderly care A)

One external chair noted that it was easier for him to defend the committee's findings to a board of directors, "because I'm not in a hierarchical relationship with these people" (External chair 1). The independent position and impartiality of the external chair permits a critical perspective that is challenging for people within the organisation to adopt.

In line with the expected competencies, directors valued the expertise and experience external chairs have with investigating incidents.

> [External chairs conduct] methodically thorough [investigations], with an open mind and fresh perspective (…) and interview people in a professional, neutral manner. (Executive director, disabled care C).

Another respondent claimed 'the why question'—that seeks to uncover factors that help explain why an incident occurred—is pivotal and that the external chair is in a unique position (as well-trained, external investigator) to ask that question.

> When it came to the root causes of the incident, [the external chair asked us]: 'Why is that the root cause? What are your reasons for assuming that?' [He helped] us critically assess and sharpen our methodology. (Medical director, disabled care D)

Difficulties in involving an external chair

Time constraints are a difficulty for organisations. After reporting a serious incident, organisations have eight weeks to investigate the incident and report to the Inspectorate. Because they felt pressed for time, two quality advisers started their investigation without an external chair.

> We'd already done a lot. We'd done the interviews and written them up. But the external chair wanted to talk to some people again, (…) because he was uncomfortable with relying solely on our accounts. (Quality advisers, elderly care A)

Given the time frame for conducting an investigation, some professional groups are overrepresented in the organisations' pools of external chairs (quality advisers), while others are underrepresented (professionals and managers).

> The pool consists mostly of policymakers and quality advisers. We have only one physician. Sometimes you think, a GP would be a good fit, but they just don't have the time. (Quality adviser, disabled care C)

The same goes for managers, who never seem to be available (External chair 3). A lack of available external chairs from diverse backgrounds might limit organisations attempting to find the right person for the job.

Learning from investigating incidents with external chairs

When asked directly if they learn *more* from incident investigations with an external chair, directors and quality advisers hesitated. They reported that earlier investigations, conducted by internal teams, were already of high quality and generated valuable opportunities to improve. At the same time, respondents acknowledged that external chairs aided the investigation process—in helping investigation teams critically reflect on root causes or by neutrally interviewing personnel. We found various ways in which organisations can learn from external chairs, given how learning is conceptualised in multiple ways and happens at different moments in time.

First of all, external chairs, directors and quality advisers alike emphasised that learning from incidents means following up and implementing recommendations from the investigation report. As such, learning happens beyond the confines of the investigation.

> Really, learning and improved quality of care reside in following up recommendations from the incident report. (…) Possibly, [external chairs] formulate better recommendations, given [their] impartiality and fresh perspective. (Executive director, disabled care C)

While external chairs might contribute to a good investigation that comes to inform an organisation's learning process, learning starts, or continues, after the external chair leaves the organisation. In this sense, as we saw in an earlier quote, the responsibility for improvement is impressed upon the organisation and not attributable to the external chair.

Secondly, learning can also occur during the investigation, as one external chair pointed out, when we think of learning as the ability to reflect on and improve care practices.

> People were already reflecting [on their practices] in the interviews [and] made improvements during the investigation. I feel I contribute to learning in that way. (External chair 3)

Here learning is an activity not separated from but part of the process of investigating an incident.

Thirdly, already hinted at by the executive director cited earlier, external chairs frequently reported that organisations can benefit and learn from their ability to conduct incident investigations capably. The reports the Inspectorate received following the obligation to appoint an external chair, which inspectors scored more favourably, seem to corroborate this. Given that a thorough investigation can clear a path for appropriate recommendations and improved care practices in the future, learning how to conduct such investigations better helps learning both during and after incident investigations.

Finally, respondents think of learning as possessing a two-way directionality. The policy documents of the Ministry of Health present a one-directional perspective on learning, claiming that organisations can learn from external chairs. But external chairs and healthcare professionals reported that learning from incident investigations is reciprocal.

> For me, the value of being an external chair is being able to learn from cases elsewhere. (…) I've seen quite a few cases where I went back [to my own organisation] thinking, "This could've happened here too. We need to do something about this." So, it really has value, we share knowledge in an interesting way, even if it was not intended as such. (External chair 3)

> I think both organisations can learn from [investigating incidents with external chairs]. Although the incident did not occur at [name organisation], they can also come to realise that there are opportunities for improvement. For both sides, investigating an incident together is useful, I think. (Nurse, disabled care C)

One quality adviser talked of "cross-fertilisation", where external chairs go back to their own organisation with an increased awareness of potential risks (Quality adviser, disabled care C). Other quality advisers were happy that setting up pools of external chairs helped create a platform—that they felt they lacked before—where advisers from various organisations now talk about trying to deliver safe care and can learn from one another (Quality advisers, elderly care B). Learning in that sense becomes collaborative across organisational boundaries.

DISCUSSION

Inspectors scored incident reports more favourably after the policy change. In follow-up interviews, inspectors claimed that external chairs help organisations come to a better understanding of why an incident occurred, leading to better scores. The value of an external chair, we found in subsequent interviews, stems (in part) from their outsider's position. Our respondents valued the fresh perspective an external chair brings to an incident and the organisation where the incident occurred. External chairs are said to pose different questions and enlisting the help of an external chair is a way for an organisation to subject itself and its care practices to the scrutiny of an outsider unfamiliar with the specific organisation. Yet, chairs also have to be familiar with providing everyday care to elderly or intellectually challenged people to be of added value. External chairs strike a balance between distance (the external chair has to be 'foreign' enough) and proximity (the external chair has to be familiar with care practices in elderly and disabled care, knowing where to look). From this position, having expertise in conducting incident investigations and in being familiar with but untied to the organisation an external chair works in, external chairs are in a good position to 1) identify blind spots and ask questions that people familiar with the organisation would not think or dare of asking, 2) develop a critical perspective on the organisation, and 3) pose questions neutrally to healthcare professionals about incidents. This position, our respondents seem to suggest, comprises of and weaves together particular conditions (being able to function outside of the organisational hierarchy) as well as individual skills (being able to interview healthcare professionals and critically analyse incidents).

Revisiting the idea of learning as "a complex social and participative process that involves people actively reflecting on and reorganising shared knowledge, technologies

and practices" (Macrae, 2016, p. 74), external chairs stimulate various forms of learning. External chairs can help organisations identify root causes and capably conduct incident investigations, allowing fitting recommendations for improvement to be implemented. Also, external chairs can foster learning during the investigation, as healthcare professionals start reflecting on their practices during an interview or when professionals are asked to rethink what it means to act professionally. Being a relative outsider—knowledgeable about care practices in the sector, from outside the organisation—the external chair is not external to this learning process, but participates in it. The process of investigating an incident, more so than the report the investigation culminates in, is valuable for both the organisation and the external chair. The external chair and the organisation's insiders on the investigation team co-create knowledge about the incident. This knowledge travels bi-directionally; learning is reciprocal as external chairs take valuable insights back to their own organisation and future investigations elsewhere, while it seeps into the organisation where the incident occurred. We can conceptually think of external chairs as 'knowledge brokers': "persons or organizations that facilitate the creation, sharing, and use of knowledge" (Meyer, 2010, p. 119) that are typically envisioned as moving knowledge from one world or field to another (Meyer, 2010; Schlierf and Meyer, 2013). But knowledge brokers do not just move knowledge from one domain to the next, as if knowledge were a pre-packed, bounded entity. Knowledge brokers are mediators who, as they move knowledge, translate it and create new forms of knowledge. For Meyer, knowledge brokers possess a 'double peripherality', as they are "partially connected to the two worlds they bridge" (Meyer, 2010, p. 122). External chairs can be said to occupy such a position, where an external chair's double peripherality stems from the familiarity of the external chair with the type of care provided (knowing where to look) and being unfamiliar with the organisation wherein the incident occurred (allowing for a fresh, critical perspective).

We can think of the need for elderly and disabled care organisations to appoint an external chair to investigate serious incidents as a politically informed regulatory intervention and, as noted earlier, a compromise between the Inspectorate's emphasis on internal investigations and the government's call for external review. The Inspectorate, nor the Ministry of Health, formalised or specified what a capable external chair is and where an external chairs' responsibilities lie (and end), but instead, advanced that an external chair might help organisations investigate and learn from incidents, leaving it up to organisations and external chairs to work out how this might happen in practice. In line with a 'soft regulatory' approach, the Inspectorate provided room for organisations and external chairs to adapt this intervention to their needs (Levay and Waks, 2009). While the Inspectorate, explicitly and openly, expects healthcare providers to be intrinsically motivated to do the right things, putting trust at the heart of the Inspectorate's regulatory relationships with healthcare organisations (Inspectorate, 2016a;

Kok et al., 2019), the obligation to appoint an external chair came about as politicians called into question the trust awarded healthcare organisations, stressing the need for external review. In light of the well-established responsive regulation framework (Ayres and Braithwaite, 1992), that proposes "that enforcement strategies should be arranged in a hierarchy or 'regulatory pyramid,' with more cooperative strategies deployed at the base of the pyramid and progressively more punitive approaches used only if and when cooperative strategies fail" (Nielsen and Parker, 2009, p. 378), external chairs offer the Inspectorate an enforcement strategy situated between asking organisations to conduct their own investigations and calling for an external investigation or conducting one themselves.

Vaughan notes that in thinking about regulators and regulatees, and regulatory effectiveness, the notions of autonomy and interdependence can prove insightful (Vaughan, 1990). She characterises organisations as autonomous entities that are, to some extent, distinct and insulated from other organisations and not easy to access. Regulators, to perform their regulatory tasks, however, depend upon access to be able to gather and interpret information on an organisation to be able to adequately monitor it. To that end, "regulators attempt to penetrate organizational boundaries by periodic site visits and/or by requiring the regulated organization to furnish information to them" (Vaughan, 1990, p. 228). But still, the regulators' perspective is partial. As a result, Vaughan notes, regulators become dependent on the regulated organisations to provide them with information, rendering organisational compliance pivotal, possibly leading to regulatory capture (Bardach and Kagan, 1982). We might say that in the relationship between care organisations and the regulator, the external chair occupies an intermediary position. External chairs penetrate organisational boundaries and partake in information gathering practices that aid the monitoring practices of the Inspectorate. The external chair grants the Inspectorate the perspective of a potentially critical outsider, while not having to intervene or visit themselves. For organisations, opening its doors and having their care practices subjected to scrutiny from an outsider might be more acceptable when this outsider is familiar with the care practices and self-selected by the organisation. Having said that, just as regulatory capture poses a risk for regulators, the same may hold for external chairs—as suggested by the external chair who wondered if doing multiple investigations in the same organisations might compromise her impartiality. Given this question of impartiality or some of the concerns respondents voiced about the ability to recruit capable external chairs given the time frame for investigating incidents, the Inspectorate would do well to continue to monitor how these practices develop and potentially curbing some (e.g. organisations recruiting the same external chair repeatedly) while stimulating other practices.

Although we studied a Dutch case, we believe our findings are relevant internationally. The mechanisms explaining why involving an external chair in incident investi-

gations leads to learning have a more general value. The external chair might foster participative shared learning between organisations on a local or regional level and can complement instruments that promote learning across and between organisations nationally, like patient safety alerts (Lankshear et al., 2008; Rhodes et al., 2008) or public inquiries (Black and Mays, 2013; Francis, 2013; Walshe and Offen, 2001). Using trained external chairs is one way to professionalise incident investigations (Anderson and Kodate, 2015; Peerally et al., 2016) while keeping the learning process close to the organisation where the incident occurred. Ramanujan and Goodman propose that learning from incidents depends on a range of temporally ordered activities (of which investigating an incident is just one) that need to foster a shared understanding of what contributed to an incident (2011). Investigating an incident with the help of an external chair still locally embeds the learning process within an organisation and can contribute to creating this shared understanding. "Simply identifying a solution is part of event analysis, but does not entail learning," Ramanujan and Goodman warn (2011, p. 85). Other studies report that when it comes to shared learning from incidents, too often this takes the form of the one-way distribution of 'lessons learned' that are disconnected from the practices wherein this learning is constructed and used (Drupsteen and Guldenmund, 2014; Macrae, 2016). The value of an external chair on incident investigation committees suggests that shared learning from incidents can also take a different, social and participative form. We hypothesise that the value of an external chair over external investigations like public inquiries resides in the balance it strikes between bringing in a critical, external perspective and locally embedding the learning process. Future research into the role and value of the external chair in incident investigations might look into how external chairs participate in and contribute to "social processes of inquiry, investigation and improvement that unfold around incidents" (Macrae, 2016, p. 74), allowing for situated, shared and participative learning. Additionally, further research might study if investigations into incidents with external chairs lead to more effective and sustainable recommendations (Hibbert et al., 2018; Kellogg et al., 2016) and their implementation into practice.

Like the policy itself, how the policy encourages particular practices of incident investigation is dynamic and contingent. While the effects of the policy spill over its intended, stated objectives (allowing for reciprocal, shared learning, rather than one-directional learning), these are also mediated by other organisational and institutional structures. Healthcare organisations are required to investigate and report on an incident within eight weeks and thus need to ensure to involvement of a capable external chair within that time frame. Such structures shape the practices of selecting an external chair; capable external chairs need to be available too. Practices of investigating patient safety incidents with the help of external chairs are consistently developed further. To our knowledge, this is the first explorative study into the perceived value of such practices to

date and further research is called for. Our study has some limitations. For one, the data we collected at four healthcare organisations centres on the occurrence and investigations of singular incidents. Also, we did not follow organisations over a longer period, so we cannot comment on how the perceived value of repeatedly involving external chairs in incident investigations changes over time. Equally, we were unable to research incident investigation practices for the same organisations prior to and after the policy change; while the policy of needing to enlist external chairs in the investigation of serious incidents was adopted in October 2015, our research, that set out to evaluate what happened as organisations conducted investigations into incidents with help of external chairs, started in 2016, which meant we were not able to analyse incident investigations before the start of the policy. The number of incident reports scored by the inspectors do not permit us to assert with certainty that organisations learn more from incidents when conducting investigations with an external chair. Nonetheless, the scored reports, combined with the conducted interviews do convey a compelling account of how external chairs might contribute to shared learning from incident investigations.

CONCLUSIONS

Our findings suggest that trained external chairs can help healthcare organisations better identify root causes of serious incidents. External chairs who strike a balance between distance from the organisation and proximity to the specific care processes can facilitate learning processes during and after incident investigations in healthcare organisations. Moreover, they facilitate learning across organisational boundaries as they travel between healthcare organisations. An investigation committee that consists of an external chair as well as people from within the organisation is a promising combination that facilitates a shared learning process through which not just the people from the organisation concerned can improve, but others elsewhere can as well.

5

How incident reporting systems can stimulate social and participative learning: A mixed-methods study

Published as: de Kam, D., J. Kok, K. Grit, I. Leistikow, M. Vlemminx and R. Bal (2020). How incident reporting systems can stimulate social and participative learning: A mixed-methods study. Health Policy, 124 (8): 834-841.

ABSTRACT

Incident reporting systems (IRSs) have been widely adopted in healthcare, calling for the investigation of serious incidents to understand what causes patient harm. In this article, we study how the Dutch IRS 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 draw from semi-structured interviews with incident investigators, quality managers, healthcare inspectors and healthcare professionals. Healthcare inspectors score incident investigation reports better over time, suggesting that hospitals conduct better investigations or have become adept at writing reports in line with inspectors' expectations. Our qualitative data suggests the IRS contributed to practices that support social and participative learning—the professionalisation of incident investigation teams, the increased involvement of patients and families in investigations—and practices that do not—not linking learning from the investigation teams to that of professionals, not consistently monitoring the recommendations that investigations identify. The IRS both hits and misses the mark. We learned that IRSs need to be responsive to the (developing) capabilities of healthcare providers to investigate and learn from incidents, if the IRS is to stimulate social and participative learning from incidents.

INTRODUCTION

The idea that incident reporting holds an important key to improving safety of healthcare is well-established (Kohn et al., 1999; Vincent, 2010). Adapted from high-risk industries, the premise of incident reporting is that by reporting and investigating incidents, we might understand what causes or contributes to patient harm, so that preventive strategies can be devised and healthcare made safer (Barach, 2000; Hudson, 2003). In many countries, incident reporting systems (IRSs) have been set up with the aim to learn from incidents (Howell et al., 2017; Mitchell et al., 2016). Research has shown, however, that IRSs struggle to foster learning (Macrae, 2016; Mitchell et al., 2016; Peerally et al., 2016; Stavropoulou et al., 2015). In these studies, learning from incidents is understood as being able to prevent future incidents, so that learning is believed to have occurred when fewer incidents are reported. When the effectivity of IRSs is evaluated in terms of the number of incidents reported, IRSs frustrate or disappoint (Shojania, 2008; Shojania and Marang-van de Mheen, 2015). IRSs fail to demonstrate progress, suggesting that learning has not occurred (Baines et al., 2013; Shojania and Thomas, 2013). We argue that such evaluations are problematic as they work with impoverished conceptualisations of what learning is—generally confusing learning with performance (Ramanujam and Goodman, 2011)—, neglect how definitions of what constitutes incidents shift (Leistikow et al., 2017; Vincent and Amalberti, 2015) and are inattentive to how more reported incidents might be reflective of a safety minded organisational culture rather than poor performance (Inspectorate, 2016a; Waring, 2005).

In the Netherlands, the Dutch Health and Youth Care Inspectorate (further: Inspectorate), the national regulator tasked with monitoring quality and safety of care, has designed and maintains a national IRS for hospitals. The Dutch IRS focuses on hospitals' learning processes following sentinel events (further: SEs) and was designed with the idea that it should "lead to social and participative learning at the local level" (Leistikow et al., 2017, p. 2). See box 1 for the type of incidents reported in the Netherlands and the role of the Inspectorate. Rather than assessing *what* hospitals learn from SEs, the Inspectorate monitors *how* hospitals learn from SEs, inquiring if hospitals *learn to learn* from SEs (Leistikow et al., 2017). Specifically, the Inspectorate monitors hospitals' ability to investigate incidents and identify fitting corrective actions. In order to monitor "the quality of the learning process" of hospitals, (Leistikow et al., 2017, p. 2) the Inspectorate developed a scoring instrument that sets forth key conditions to properly investigate and learn from SEs (Box 2). In line with this instrument, the Inspectorate published a guideline, informing hospitals on what the Inspectorate expects from an investigation (Inspectorate, 2016d). Since July 2013, every SE reported and investigated by hospitals is scored by the Inspectorate (Leistikow et al., 2017).

Box 1: Sentinel events and the Dutch Health and Youth Care Inspectorate

In the Netherlands, three types of 'unwanted events' related to the provision of care are distinguished: complications, incidents and sentinel events (Inspectorate, 2016b). In the case of incidents and sentinel events (SEs), the Inspectorate notes, 'something was not done right'—in contrast to complications, that are categorised as unwanted events following care delivery that occurred despite the fact that 'everything was done right'. While the Inspectorate expects hospitals to learn from incidents and SEs alike, hospitals only have to report their SEs to the Inspectorate—for reporting and investigating incidents, hospitals should have organisational reporting procedures in place. Incidents and SEs, then, are distinguished based on severity in terms of patient outcome. An SE is defined in Dutch law as an unintended and unexpected event, related to the quality of care and having caused the death of or serious harm to the patient. When hospitals report an SE to the Inspectorate, as they are legally required to do, hospitals conduct their own investigation into the SE and have to report the findings of that investigation to the Inspectorate within eight weeks.

The Inspectorate (Dutch: *Inspectie Gezondheidszorg en Jeugd*) is the national regulatory agency tasked with overseeing and regulating all healthcare providers and professionals in the Netherlands. As part of its regulatory activities, the Inspectorate designed and continues to monitor the national IRS. Hospitals investigate their own SEs because the Inspectorate believes that when hospitals are involved in the process of investigating incidents, they learn more. The Inspectorate monitors if hospitals capably conduct these investigations. If hospitals do not, the Inspectorate can initiate fitting regulatory interventions (Inspectorate, 2016a) These interventions, true to the responsive regulation framework (Ayres and Braithwaite, 1992), range from providing critical feedback to organisations, to require organisations to re-do the investigation or for the Inspectorate to conduct their own inquiry with specialised inspectors (Inspectorate, 2017).

In this chapter, we study the effects of the Dutch IRS on the local learning process of hospitals. In line with the aims of the IRS, we approach learning from incidents as a social and participative practice, drawing on work of Macrae (2016) and Ramanujan and Goodman (2011). Learning from incidents, for Macrae, "involves people actively reflecting on and reorganising shared knowledge, technologies and practices. It is these processes of action and reorganisation that constitute learning and must be supported through investigation and improvement." (Macrae, 2016, p. 74) For Ramanujan and Goodman, "learning represents a shared understanding among group members of a new course of action to minimize or prevent the recurrence of negative events. (…) If learning does take place from the event analysis, this new repertoire would be shared, stored, and enacted at the appropriate time." (Ramanujam and Goodman, 2011, p. 85) Our study

is guided by the question: How does the Dutch IRS stimulate social and participative learning from incidents?

Box 2: Scoring instrument to assess the quality of the SE analysis report

	Item	Judgement of inspectors
Process		
1	Is the method for analysis specified? (e.g., root cause analysis (RCA))	Yes No ? Not applicable
2	Is the investigating committee multidisciplinary?	Yes No ?
3	Are members of the investigating committee independent?	Yes No ?
4	Did all personnel directly involved contribute?	Yes No ?
5	Did other staff with knowledge about the care process contribute?	Yes No ? Not applicable
6	Was input sought from the patient/relatives?	Yes No ? Not applicable
Reconstruction		
7	Does the description of the event give a complete picture of the relevant 'scenes'?	Yes No ?
Analysis		
8	Have the investigators searched relevant scientific literature?	Yes No ? Not applicable
9	Does the report state whether applicable guidelines/ protocols were followed?	Yes No ? Not applicable
10	Was external expertise consulted?	Yes No ?
11	Does the report state whether the medical indication for the provided care was correct?	Yes No ? Not applicable
12	Has the question 'why' been asked extensively enough to analyse the underlying cause and effect?	Yes No ?
Conclusions		
13	Does the report identify root causes?	Yes No ? Not applicable
14	Do the root causes fit the reconstruction and analysis?	Yes No ? Not applicable
15	Are contributing factors considered and/or identified?	Yes No ? Not applicable
Recommendations		
16	Does the report document recommendations?	Yes No ? Not applicable
17	Do these corrective actions address the identified root causes?	Yes No ? Not applicable
18	Are these corrective actions formulated SMART? (Specific, Measurable, Attainable, Realistic and Time-Sensitive)	Yes No ? Not applicable
Aftercare		
19	Is the aftercare for the patient/relatives described?	Yes No ? Not applicable

Box 2: Scoring instrument to assess the quality of the SE analysis report (*continued*)

	Item	Judgement of inspectors
20	Is the aftercare for the professionals involved described?	Yes No ? Not applicable
21	Has the report been shared with the patient/relatives?	Yes No ? Not applicable
Reaction of the hospital board		
23	Does the board of directors provide their perspective on the analysis, conclusions and recommendations in the report?	Yes No ? Not applicable
24	Does the board of directions engage with the analysis and conclusions of the report?	Yes No ? Not applicable
25	Is it stated how the board of directors ensures the implementation of the recommendations of the report?	Yes No ? Not applicable

METHODS

To answer our research question, we adopted a sequential mixed-methods study design. Drawing on quantitative and qualitative data, we aim to generate a more comprehensive understanding of the effects of the Dutch IRS (Greene et al., 2001; Johnson et al., 2007). We present and integrate quantitative data on scored SE investigation reports and qualitative data on how SE investigators perceive the effects of the IRS on their investigation practices and learning processes.

Data collection

Database of SE investigation reports

As researchers, we were granted access to an Excel-export that listed 4667 scored SE reports, from all 96 hospitals in the Netherlands, between 1 July 2013 and 31 March 2019. We received an anonymised version and could not link hospitals to individual SE reports. The database shows how inspectors scored each of the 25 items for each SE investigation report. If an item is adequately addressed, it receives a 'yes' and is scored as '1'. If a report does not adequately address an item, it receives a 'no' and is scored as '0'. When it is unclear to inspectors whether something was or was not done, inspectors score a '?' and is scored as '0'. If an item is deemed inapplicable, it is removed from the set of questions that come to make up the total score the report receives. Based on the items scored, each report receives an overall score, expressed as a percentage from 0% to 100%. Multiple inspectors score individual reports which are discussed in weekly multidisciplinary meetings, as a result of which scores may be amended (Kok et al., 2019). Given our interest in how an IRS might stimulate social and participative learning,

the database with scored SE investigation reports potentially provides an indication if and on what items hospitals improved their capability to investigate SEs. We draw on qualitative research to understand what happens behind the numbers.

Qualitative research on the effects of the Dutch IRS

Since 2015, all authors except MV have been involved in various research projects that studied the effects of the Dutch IRS (de Kam et al., 2019; Grit et al., 2018; Kok et al., 2019, 2018). All of these projects included qualitative, ethnographic research. In all, we conducted 73 semi-structured interviews and 36 hours of ethnographic observations. In this article, we present data collected within two projects specifically (Table 1). In the first project, the objective was to explore how hospitals organise their SE investigation

Table 1: Research projects characteristics

Research project	Authors involved in fieldwork	Data collected
Project 1 Apr 2015 – Sept 2016	JK	15 semi-structured interviews in 13 Dutch hospitals with respondents involved in or responsible for conducting investigations into SEs: healthcare professionals, incident investigators, quality managers and chairs of investigation committees. Interviews lasted between 51 - 91 minutes (total 18 respondents). Respondents were approached via email and informed about the objective of the research in this email. In the email, the voluntary nature of participation was stressed, as was the fact that data would be fully anonymised. All approached respondents agreed to participate. During interviews internal incident investigation protocols and related documentation (meeting minutes, agenda's, report formats etc.) were reviewed and when possible/appropriate hard copies were collected for further analysis. We have discussed methods used to conduct this study more in-depth elsewhere (Kok et al., 2018).
Project 2 Jan 2017 – May 2018	DdK and KG	8 semi-structured interviews with (former) healthcare inspectors involved in designing and/or monitoring the IRS. Respondents included inspectors involved in scoring SE investigation reports of hospitals, as well as inspectors regulating other healthcare sectors (e.g. mental health care). Interviews lasted 57 - 103 minutes (total 10 respondents). Respondents were approached via email and informed about the objective of the research in this email. In the email, the voluntary nature of participation was stressed, as was the fact that data would be fully anonymised. All approached respondents agreed to participate. Focus groups with 1) healthcare inspectors (3 hours), 2) healthcare managers and professionals (3 hours), 3) the Dutch Ministry of Health (1.5 hours) and 4) citizens (5 hours). Field notes were made during the focus groups. Policy documents of the Inspectorate on the Dutch IRS were analysed in order to understand the historical development of the IRS. We have discussed methods used to conduct this study more in-depth elsewhere (Grit et al., 2018).

practices, how managers and SE investigators perceive the effects of investigating SEs on their learning processes and what challenges they encounter. In the second project, following the first and other research projects into the Dutch IRS, the objective was to review and synthesise findings from studies conducted in the collaborative on the effects of IRS on learning and, with stakeholders, think about how the Dutch IRS could be developed further.

In both projects, sampling was purposive and while depth was strived for in the first project—aiming to reach data saturation—breadth was strived for in the second project—soliciting insights from inspectors supervising a variety of care sectors and other stakeholders. All semi-structured interviews were structured using interview guides. Interview guides listed themes of interest and were amended in light of findings from preceding interviews. Interviews were digitally recorded following respondents' consent and transcribed verbatim.

Data analysis

Database of SE investigation reports

Descriptive statistics were applied analysing the 4667 scored SE reports. To study changes over time, we obtained how SE reports scored on each of the 25 items scored by the Inspectorate per quarter, as the percentage of reports adequately addressing each item. We also determined the average final score awarded to SE reports over time. Following two meetings with inspectors and a statistician of the Inspectorate, who were intimately familiar with the data and with how the scoring instrument was developed and used over time, we revisited the data and constructed groups of hospitals. To construct the groups, the initial year (01-07-2013/01-07-2014) was used to calculate the average score of the SE reports by each of the 96 hospitals. Hospitals that reported less than three SEs during the initial year, were not assigned to groups (n=16 hospitals). The 80 remaining hospitals were assigned to one of four quartiles, based on average scores (Table 2). We merged the two groups in between the 'low' (n=20) and 'high' (n=20) scoring hospitals, referring to that group as the 'middle' (n=40). Our reasons for doing so are informed by the Inspectorate's ideas about how hospitals should learn from SEs (Leistikow et al., 2017). For one, the Inspectorate "tailors its regulatory practices to the

Table 2: Information on hospital groups, reported and scored SEs (01-07-2013/01-07-2014)

Groups	Cut-off points of the groups (average SE report scores)	Reported SEs	Average of SE report score	StdDev of SE report score
Low (n=20)	24.0, 64.9	188	57,2	18,5
Middle (n=40)	64.9, 76.5	355	71,5	15,5
High (n=20)	76.5, 89.8	188	80,8	10,7

learning capabilities and the developmental stages of healthcare providers." (Inspectorate, 2016a, p. 10) Second, conducting good SE investigations is thought to be a skill that hospitals develop over time (Leistikow et al., 2017). So, while hospital performance—in terms of SE scores—might be benchmarked against other hospitals that are in similar developmental stages, the Inspectorate is particularly interested if hospitals improve over time (Leistikow et al., 2017). To plot the development of average SE scores for all hospitals over time masks differences between hospitals. Therefore, we constructed 4 groups of 20 hospitals that remain stable over time—the two groups between the low and high scoring hospital groups we merged into one middle group. We can expect that group construction based on received SE scores during the first year serves as an approximation of hospital's learning capabilities and the developmental stages they are in.

Semi-structured interviews

The transcribed interviews were analysed with the aim to identify themes, performing thematic analysis (Green and Thorogood, 2018). The concept of learning as social and participative practice functioned as a sensitizing concept that guided but did not restrict our analysis. DdK and JK individually analysed two interviews each, identifying themes. Following that, DdK and JK reviewed the coded material and developed a coding scheme that was reached through iterative discussions and multiple meetings between both authors. DdK and JK coded the remaining interviews with the coding scheme in Microsoft Word, at times refining or adding codes to the coding scheme. The coding scheme and the themes identified were discussed among all authors. Consensus was reached over the course of two meetings with all authors.

FINDINGS

We identified five core themes that we formulate as practices the IRS can contribute to. Respondents linked the IRS to: 1) changed staff attitudes and increased reporting, 2) improved SE investigations, 3) participative learning, 4) local learning, and 5) recommendations that improve quality and safety of care. These themes order our results and we present quantitative and qualitative data per theme.

Changed staff attitudes and increased reporting

Several hospital respondents report that the IRS contributed to changed attitudes towards patient safety, helping to generate, as they call it, 'safety thinking'.

> You learn so much by investigating SEs; you'll look at your own work differently. (…) It is really beneficial and those reports are one thing, but what I am interested in is safety thinking that needs to permeate the organisation. For that to happen, it helps to investigate SEs, because you'll force yourself to dig deep. (Investigation committee chair, 10-08-2015)

SE investigations are envisioned as a tool that can help foster safety thinking, that goes beyond learning to prevent incidents and refers, rather, to a way in which professionals approach their work, cognizant of risks their work holds.

Also, respondents credit the IRS with stressing the need for reporting SEs.

> R1 When I compare where we were five, six years ago with today, we've really developed. Also just in terms of the SEs we report. We never had SEs...
> R2 (laughs)
> R1 You had nothing to worry about when you visited our hospital; things did not go wrong… Now we report 12 SEs each year. (Investigation committee chair and incident investigator, 20-9-2016)

Many hospital respondents state that they report and investigate more SEs now than in the past. This is supported by data of the Inspectorate that shows how, since 2009, reported SEs have steadily increased (Figure 1). The quote also shows that what (the number of reported) SEs tell us has changed. "Before," an inspector told us "no SEs meant you were the best organisation. Now, when an organisation reports no SEs, something's not right" (Inspector, 30-05-2017). Thought of as reflective of an organisational safety culture, the amount of reported SEs becomes a quality metric in its own right, but one that says little about how organisations are able to learn from them (Macrae, 2016; Vincent, 2002).

Improved SE investigations

A key aim of the Dutch IRS was to have hospitals improve their capability to investigate SEs as an important step towards learning from SEs (Leistikow et al., 2017). For how SE reports are scored by inspectors since 2013, see figure 2-7.

We might conclude that the high scoring group of hospitals already did fairly well, having many of the conditions for conducting SE analysis in place and that, particularly, the low scoring group of hospitals developed. From Q4 2015 onwards, some two years after SE reports were scored in accordance to the new scoring instrument, the development of the average SE scores of low and high scoring hospitals intertwine. The IRS offers the opportunity to zoom in further, on specific items scored. This is potentially insightful given that not all items are equally easy to perform well on. Doing well on some

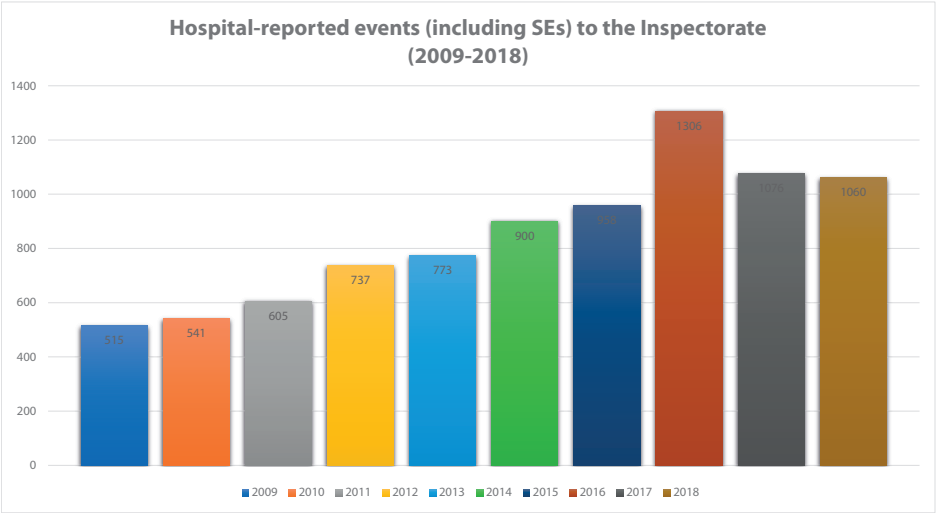

Figure 1: In addition to SEs, hospitals are also required to report 1) violence or sex in professional-patient relationships or in patient-patient relationships when violence has severe consequences and 2) when hospitals dismiss professionals because of poor professional performance. These two events were added to the requirement to report SEs on 1 January 2016. The Inspectorate reported that of the 1306 events reported in 2016, 1272 were reported as SEs. Of the 1076 events reported in 2017, 1035 were reported as SEs. Of the 1060 events reported in 2018, 1030 were reported as SEs (Inspectorate, 2019, Inspectorate, 2016e, Inspectorate, 2016f). An inspector told us the peak in reported SEs in 2016 can be attributed to considerable and sustained national media attention at the end of 2015 on (unreported) SEs and a wanting safety culture in the UMC Utrecht, one of the nation's academic hospitals (NRC, 2015). Many of the SEs hospitals reported in 2016, the inspector noted, the Inspectorate judged not to qualify as SEs.

items (e.g. 'Do the corrective actions address the identified root causes?') requires more expertise and work from investigation committees than others (e.g. 'Is the method for analysis specified?'). Moreover, while for the final score of a report each item is granted equal weight, inspectors deem some items more important than others (de Kam et al., 2019; Grit et al., 2018). We selected three specific items scored by the IRS that, according to inspectors, adequately reflect the capability to conduct SE investigations. As to the weight attributed to these items by inspectors, one inspector notes:

> What happened [leading up to and during the SE] has to be clear (…) so I can tell if the root causes are properly identified. This is where it starts; it determines the next steps and whether or not these steps make sense. (Inspector, 1-11-2016)

The items that inspectors emphasise are sequential in the sense that one item builds upon the next. The quality of an investigation, multiple inspectors report, starts with adequately addressing the 'why' question (figure 3)—so that the root causes might be identified (figure 4) and corrective actions devised that address those root causes (figure 5).

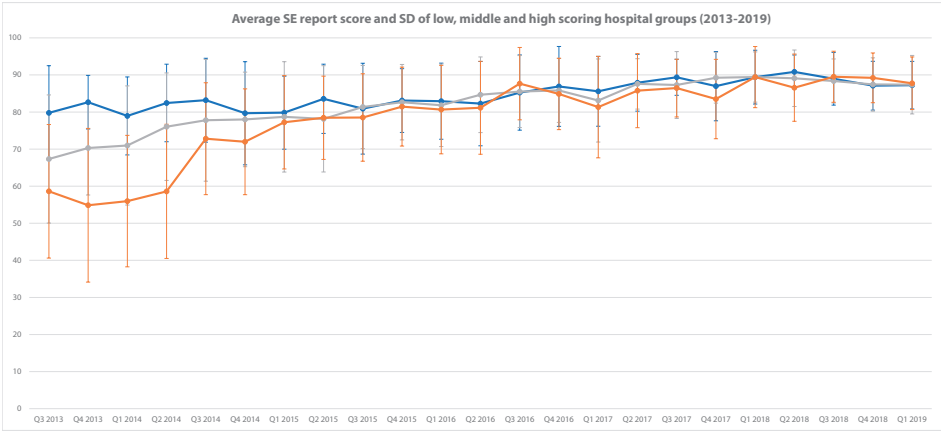

Figure 2: Presented here are the average score and standard deviation of those average scores of the low, middle and high scoring group of hospitals between 1 July 2013 to 31 March 2019 (n=4406). There is no big difference in the extent to which the high, middle and low scoring groups account for the number of reported SEs; low scoring hospitals reported 1118 SEs over the period, the middle scoring groups of hospitals 2227 (the middle group consists of 40 hospitals, rather than the 20 in the low and high scoring groups) and high scoring hospitals 1061. The high scoring group of hospitals on average received 79.8% score at the introduction of the IRS and receive a 90.0% score in Q1 2019. The low scoring group of hospitals on average received 58.6% score at the introduction of the IRS and receive an 88.8% score in Q1 2019. The middle scoring group of hospitals on average received 67.3% score at the introduction of the IRS and receive an 87.4% score in Q1 2019. Standard deviation values decrease over time. In the low scoring hospital groups, the average SD across reports in the first year (Q3 2013 to Q3 2014) was 18.6. In the final year (Q2 2018 to Q2 2019) the average SD across reports was 7.4. In the middle scoring hospital groups, the average SD across reports in the first year (Q3 2013 to Q3 2014) was 15.1. In the final year (Q2 2018 to Q2 2019) the average SD across reports was 7.2. In the high scoring hospital groups, the average SD across reports in the first year (Q3 2013 to Q3 2014) was 10.2. In the final year (Q2 2018 to Q2 2019) the average SD across reports was 6.2.

While the data clearly shows progress of hospital scores over time, we cannot determine based on this data whether hospitals have become better at investigating SEs or if hospitals have become more adept at writing SE reports in line with the scoring instrument of the Inspectorate. From our interviews, we know respondents are well aware of what needs to be in the SE report. Also, the score awarded to SE reports is interpreted by hospital respondents as a 'grade' and the investigation becomes a practice respondents want to score well on.

> If the Inspectorate wants us to note down how many hours we have spent doing something, or whatever criteria they have thought of, well then we add it to our checklist of things to add in the report. We want to score 100%. (Committee chair, 20-09-2016)

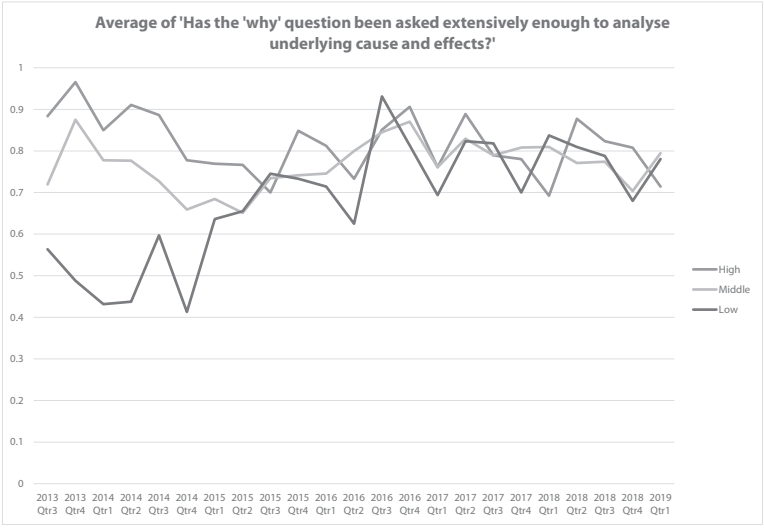

Figure 3: Across all items scored, this item is both pivotal according to inspectors (de Kam et al., 2019)—as their assessment of the SE report builds upon the investigation's ability to address the why-question thoroughly—and challenging for hospitals to do well on. The overall development mirrors that of the average SE scores, where the low group of hospitals matches the scores of high groups of hospitals after about two years since the IRS's introduction, after which point they intertwine.

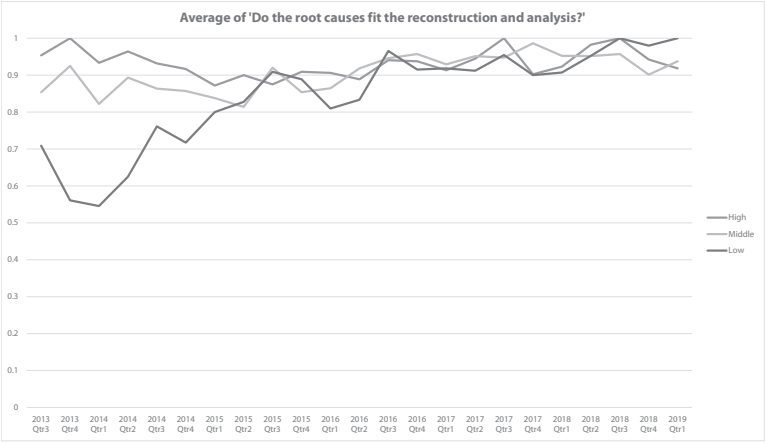

Figure 4: This item, that scores the consistency of/link between the causes identified and the preceding analysis of the SE, demonstrates a similar development to item C and the average scores of SE reports. Interestingly, hospitals groups average 100% on this item at some points in time—e.g. in Q3 2017 all 38 SE investigation reports by high groups of hospitals addressed this item adequately.

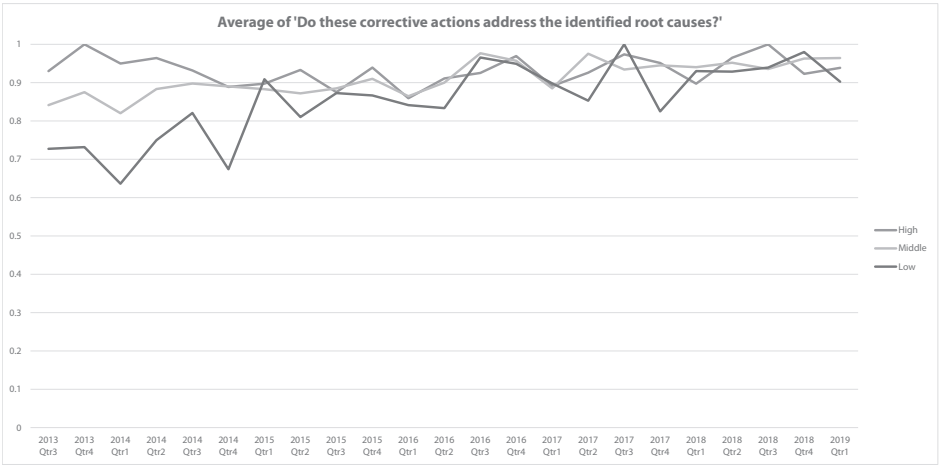

Figure 5: This item assesses whether or not the corrective actions formulated address the earlier identified root causes.

Hospitals have invested in the professionalisation of investigation teams—emphasised and argued for in multiple studies (NHS England and NHS Improvement, 2019; Peerally et al., 2016)—by training them in methods on how to conduct SE investigations and by keeping teams consistent, allowing investigators to develop expertise. But, dedicated teams are also needed due to the increased numbers of SEs that are reported and need to be investigated.

> These investigations take so much time. Medical specialists do them on the side, while a dedicated [investigation] team develops experience [with SE investigations] so that the quality of investigations is consistent. And yeah, it takes an incredible amount of time… and you want the investigations to be of good quality. (…) These reports go to the Inspectorate. (Medical doctor, 18-08-2016)

As hospitals increasingly set up dedicated teams in response to increasing numbers of SEs that need to be investigated, coupled to the desire to 'score' well, conducting SE investigations becomes a particular organisational activity and responsibility, targeted at creating reports that fit the requirements of the Inspectorate. Input from concerned professionals, especially in the recommendation phase, is often not taken seriously.

> I What if professionals don't agree with the root causes you've identified and the recommendations you propose… Does that happen?

R Yeah, sure, that happens (laughs). Um, so, with the investigators we'll look at the response [of the professionals]. What do we think? Are they correct? And are we going to change that? If we believe that it does not fit the investigation we conducted, we do not change it in the report. (Committee chair, 28-06-2016)

Another hospital respondent told us that when professionals disagree with the recommendations of the investigation team, the team is willing to consider the professionals' perspective when it identifies 'errors' in the report, but that when "[professionals] think our recommendations are radical or something else, well…, it's *our* recommendation" (Medical doctor, 18-08-2016). Investigators develop recommendations in light of how the Inspectorate scores them—as fitting the analysis—rather than if they contribute to the quality and safety of care practices.

Participative learning

The importance of involving patients and families in incident investigations is increasingly recognised and is spurred by the idea that healthcare can learn from the patients' and families' perspectives (Fitzsimons and Cornwell, 2018; Iedema and Allen, 2012a; O'Hara et al., 2018). In the Dutch IRS, hospitals are expected to involve patients and families in SE investigations and as such, it encouraged hospitals to widen the circle of people able to participate in and contribute to SE investigations.

Yeah, [involving patients and families in SE investigations] it's something we've wanted for some time, thinking 'we need to do this, this is important'. But to actually start doing it, is quite a big step. (…) So, on the one hand, we were motivated to involve patients and families, having heard how important it is and on the other hand, the pressure from the Inspectorate to start doing this…, it helped. (Medical doctor, 28-06-2016)

The quantitative data suggest that, in 2013, involving patients and families in SE investigations was no customary practice (figure 6). Similarly, the IRS assessed and contributed to the degree to which SE investigations reports are shared with patients and families afterwards (figure 7). The IRS contributed to the normalisation of a practice—the increased involvement of patients and families—that is widely argued for.

But involving patients and families in SE investigations is not the same as learning from them. The IRS operationalises the need "to engage the patient or a patient representative in SE analysis" (Leistikow et al., 2017, p. 3) by inquiring if 'input was sought from patient/relatives?' The IRS does not specify what constitutes such 'input' or the extent to which hospitals need to involve patients and families. Hospitals, in response to the

IRS's encouragement to involve patients and families, have developed different ways of organising said involvement. Typically, however—and we report on practices of patient and family involvement in SE investigations more extensively in our other work (see Kok et al., 2018 and chapter 6)—incident investigators predetermine the scope and the questions the investigation needs to provide answers to.

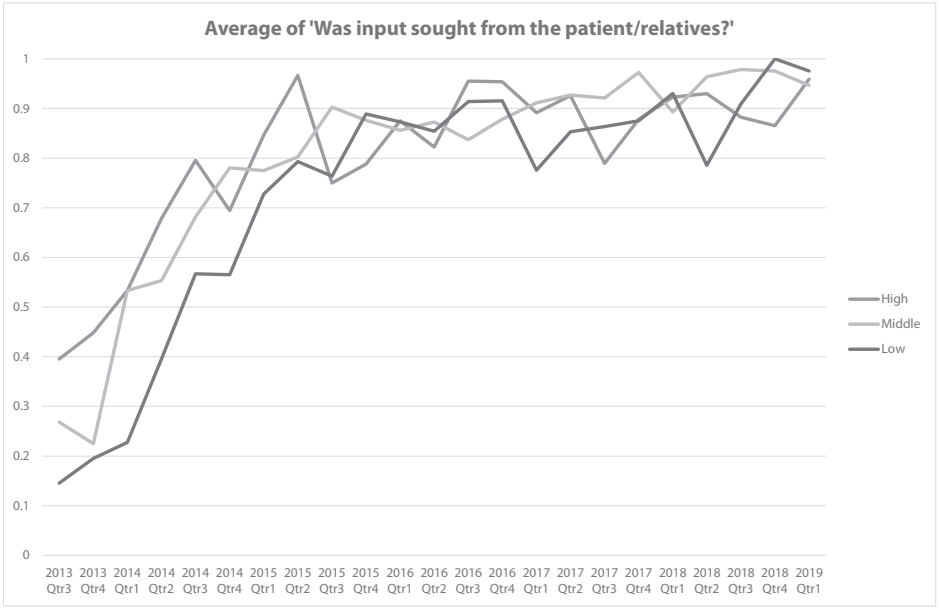

Figure 6: In contrast to the other items presented (figures 3-5), asking patients and families for input in an SE investigation was not a customary practice for either of the two hospitals groups. Currently, Dutch hospitals routinely ask patients and families for input in SE investigations.

> [In case of an SE] we [the investigative team] look at: what is the focus of the investigation and based on that, what do we want to know? We draft the research questions. And then we decide, given all that, who we want to speak to. We schedule appointments with those people and then, basically, we have all the information we need. (Committee chair, 28-06-2016)

Patient and family input and the perceived value thereof is restricted to the ability of patients and families to contribute to the analysis of SE as set forth by the IRS. Sometimes, patients and families are 'eyewitnesses' who provide 'new facts' (Incident investigator, 20-09-2016), but this is not always the case.

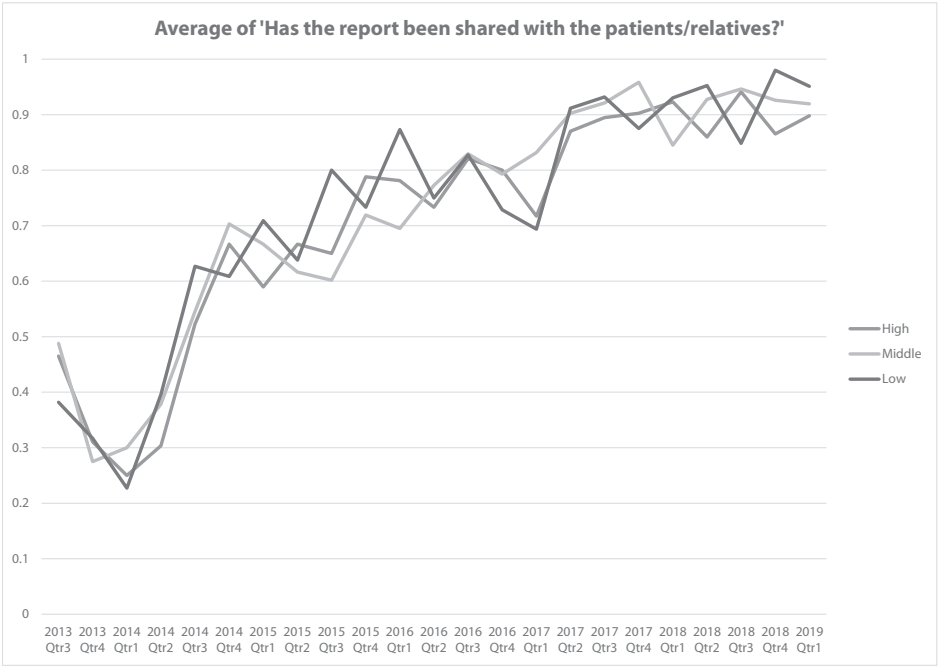

Figure 7: Much like figure 6, when the IRS started asking hospitals to report if they shared the SE report with patients or relatives, hospitals of either of the two groups did not often do this. Now hospitals of both groups report they routinely share the SE report with patients or relatives. We were unable to explain the development of the scores awarded to this item from Q3 2013-Q3 2014, a one-year period in which the average score quickly decreased and increased.

> Sometimes, I really wonder 'what could the family possibly add to this [analysis]?' And then, we still have to involve them, for the Inspectorate, really. (Incident investigator, 12-07-2016)

> Look, if families are really distanced… or have nothing to do [with the SE], I don't think you should involve them just because the protocol says you should. It takes a lot of time; involvement has to be of value. But, if a family member was physically present [at the time of the SE] or really played a part in the process that led to the SE, well yeah, then it makes sense to involve them. (Medical doctor and investigation committee chair, 16-08-2016)

Moreover, although hospitals are committed to involving patients and families in SE investigations, when the perspective of patients and families does not align with that of professionals, investigators tend to grant the professional perspective more weight. Hospitals also have different ways of sharing SE investigation reports; while some share reports in full, others provide summaries to patients and families or arrange a face-to-

face meeting wherein the investigation's findings are presented to patients and families. While some hospitals explore possibilities for more comprehensive patient and family involvement—e.g. by asking patients and families what kind of questions they would like to see the investigation address—this involvement in SE investigations generally happens on the hospital's terms. Clearly then, the IRS—in inquiring if hospitals solicit input from patients and families—does not attend to or discern between the different ways in which hospitals look to involve patients and families in SE investigations.

Local learning

While investigating SEs is expected to generate learning, the need to investigate SEs is not prompted by the potential learning opportunities an SE holds but because it is severe in terms of patient outcome (see box 1). This, respondents point out, means that organisational resources and time are committed to investigating SEs at the cost of attending to less severe incidents that might hold valuable learning opportunities.

> I just came back from a holiday and wanted to get back to my plan on how to take these [SE investigations] to a higher level and then I saw three more SEs in my inbox. (…) It's frustrating; we want to do it the right way… It's like… running; you can train for endurance or for speed. When you do both at the same time, you'll get injured. So, we always have to investigate more and, at the same time, the investigations have to be better, because every time we receive feedback [from the Inspectorate] 'you're not doing this well enough'. And it's making me anxious. We get the idea [of the Inspectorate], but we struggle keeping up. (Committee chair, 10-08-2015)

The incessant stream of reported SEs that need to be investigated by hospitals comes at the cost of reflecting on what singular SEs tell a hospital about its quality and safety of care and how findings from particular investigations might generate aggregated learning at a deeper level. Inspectors report similar experiences. As hospitals continue to investigate and report on SEs, inspectors have to keep scoring them. "What do all these SEs tell us? How might other organisations learn from this? (…) We want to get to those questions, but we don't have the time. We are so caught up in getting these SEs wrapped up… it's overwhelming" (Inspector, 25-09-2017).

Recommendations that improve quality and safety of care

One of the aims of the Dutch IRS was to have hospitals learn to devise corrective actions that fit their context. While figure 5 seems to suggest hospitals are increasingly capable of doing so, recommendations are scored in light of whether or not they fit the analysis, rather than if they contribute to safe care practices. Also, hospital respondents acknowl-

edge that it is a challenge to keep track of all the recommendations SE investigations identify.

> Sometimes I find out a particular recommendation has just vanished. Then there is a new manager and nobody is able to recall that recommendation. (Incident investigator, 12-07-2016)

> Um, we have all these recommendations in an Excel-sheet and we try to follow up on these every three months, asking people how they're faring. At times, our annual meeting with the Inspectorate serves as a trigger to think 'oh, right, we still have to do this'. (Incident investigator, 18-05-2016)

Our interviews suggest that hospitals struggle to keep track of and evaluate the effects of the identified recommendations. Respondents suggest that while organisational investment into investigating SE is considerable, following up on recommendations after the investigation does not receive the same (structured) attention.

DISCUSSION

In drawing on and integrating quantitative and qualitative data on the Dutch IRS, our study suggests that the IRS contributed to a range of practices in hospitals. In terms of its contribution to social and participative learning from SEs, the IRS both hits and misses the mark. Going back to Ramanujan and Goodman's definition of social and participative learning, " learning represents a shared understanding among group members of a new course of action to minimize or prevent the recurrence of negative events." (Ramanujam and Goodman, 2011, p. 85) Our study finds that while hospitals invest in the training of incident investigators and while hospital SE investigation reports are scored higher by inspectors over time, the learning process of the investigation teams is not or poorly connected to that of the involved healthcare professionals. While patients and family members are increasingly involved, their input is not always valued by investigators. The input and perceived value of both patients and professionals is linked to the extent to which it helps investigators conduct the investigation as outlined by the IRS. The 'shared understanding of a new course of action' that Ramanujan and Goodman speak of, is mostly shared among incident investigators, who—on account of their expertise and the need for an independent investigation—claim ownership over the investigation which can hamper the participation of others and shared learning. Paradoxically, in the attempt to encourage and measure social and participative learning, the IRS engendered practices of learning that restrict who can truly participate. Investigators can act as gate-

keepers of the investigative process; investigations are organisationally cordoned off and participation is valued in light of the standard the Inspectorate holds investigations to. Moments of reflection and opportunities for aggregated learning, meanwhile, are scarce given the consistent pressure to report and investigate (for hospitals) as well as score (for the Inspectorate) more SEs. This is a trend we can expect to continue as reporting behaviour has become a quality metric in its own right, that is said to be indicative of a hospitals' safety-mindedness and transparency (Macrae, 2016). While corrective actions are adequately identified, they are not consistently monitored or evaluated by hospitals. Also, corrective actions are assessed in terms of coherence with the SE analysis rather than if or how they are of value for the practice of healthcare professionals. "If learning does take place from the event analysis," Ramanujan and Goodman further write, "this new repertoire would be shared, stored, and enacted at the appropriate time." (2011, p. 85) The data collected through the IRS sheds no light on if and how hospitals share, store or appropriately enact this new repertoire that the investigation ideally results in.

Given that we know that organisations invest in practices that are externally monitored (Dahler-Larsen, 2014; Wallenburg et al., 2019b), it is hardly surprising that hospitals consistently deliver higher scoring SE reports. Still, our findings resist the interpretation that the Dutch IRS is a tick box exercise hospitals have become increasingly adept at. Asking hospitals whether they asked the patient and family for input generated discussions about the value of patient and family involvement and hospitals organise for and value such involvement differently (Kok et al., 2018). Here we want to point out that the involvement of both patients and professionals in SE investigations is instrumental to the objective of learning from an SE and that the emotional impact of SEs, on both patients, families and professionals, is not accommodated for in these investigations (Nicolini et al., 2011). As Nicolini et al. already pointed out, failing to engage with and make room for the emotional impact of an SE in favour of the quest for facts and evidence can actually hamper learning (Nicolini et al., 2011). In chapter 6, we explore how 'being emotional' renders patients and professionals prone to being disqualified as contributing valuable input in an SE investigation. Now, the IRS does inquire into aftercare practices of hospitals following an SE, for both patients and professionals, that might make room for said impact—even if the IRS does not follow up on how those aftercare practices are organised and valued by those who make use of them. The professionalisation of SE investigators and the reports they deliver is a valuable achievement, even if that also allows a hospital to score well. Our respondents note that knowledge about patient safety has increased as a result of investigations. But although it is acknowledged that investigating incidents "is just one step in the path to improvement" (Leistikow et al., 2017, p. 4), the IRS risks singling out the investigation as the most important one. Scoring SE reports as reflective of hospitals' learning process perpetuates, or at least does little to dispel the mistaken notion that investigating incidents is the same as learning from incidents (Anderson

et al., 2013; Macrae, 2016; Ramanujam and Goodman, 2011). With the aim to encourage and contribute to social and participative learning from incidents, the Dutch IRS monitors a dynamic practice, rather than an outcome. However, we conclude that the IRS does not adequately reflect the dynamic practice it monitors. Now that the conditions for hospitals to properly investigate their SEs seem in place, the IRS should redirect its focus to encourage reflection, monitor how shared understanding develops after an SE and stress the linkage between investigating and learning. We propose two ways in which an IRS might further encourage shared and participative learning from SEs.

First, there is a need to rethink the emphasis on investigating singular SEs. Investigations are prone to become stand-alone activities, disconnected from wider organisational safety practices and learning opportunities (Hibbert et al., 2018; Peerally et al., 2016; Stavropoulou et al., 2015). In the Netherlands, as in other countries, "the perimeter[s] of patient safety" (Vincent and Amalberti, 2015, p. 539) keep expanding as more events qualify as SEs (Leistikow et al., 2017). As both hospital respondents and inspectors struggle with the amount of SEs that have to be investigated and assessed, a continued focus on singular SEs might become untenable. Especially for hospitals that consistently demonstrate the ability to adequately investigate singular SEs, the IRS would do well to accommodate an aggregated level of analysis, encouraging hospitals to reflect on and learn from SEs in connection to their wider safety policies and practices (Hibbert et al., 2018; Peerally et al., 2016; Stavropoulou et al., 2015). Second, there is a need to move beyond the investigation practices and monitor how hospitals use SEs to improve daily care practices. Following Ramanujan and Goodman, the IRS can monitor how hospitals work to link the analysis of an SE with learning by posing questions that address how learning is shared, stored and enacted. For example: How did patients and families contribute to your understanding of the SE? How do you link the learning process of the investigation team to the professionals working with their solutions? How do you institutionalise and normalise the solutions identified so that they are used in practice? (Ramanujam and Goodman, 2011) Such open questions encourage hospitals to reflect on how investigation practices (of singular SEs when this is warranted or at an aggregated level) are meaningful to their safety practices and enable hospitals to demonstrate ownership of these practices.

Our study has some limitations. The Dutch IRS's focus on social and participative learning of hospitals following SEs is unique and developed in response to problems identified in other IRSs, so that our findings are specific to the Dutch IRS. Still, how the Dutch IRS, as a monitoring instrument, encourages and generates particular organisational practices and investments can be valuable for the design and continued development of IRSs that have a different focus. Our findings could have been strengthened by the perspectives of SE involved healthcare professionals as well as patients. In our focus on how the IRS encourages practices of social and participative learning, we fore-

grounded the accounts of incident investigators and committee chairs; the professional groups that, in hospitals, organise the investigative practices that aim to support such learning. By conceptualising learning as a social and participative practice, we were able to demonstrate how IRSs can encourage hospitals to develop valuable practices. Drawing from both quantitative and qualitative data, we were able to generate an insightful understanding of the effects of the Dutch IRS.

CONCLUSION

IRSs can encourage hospitals to develop and invest in practices that contribute to social and participative learning from incidents. IRSs need to be dynamic to accommodate for the improved learning capabilities of healthcare providers and encourage continued improvement. When providers succeed in meeting the demands an IRS set, these demands should be adjusted towards a next level. Continuously raising the bar or adding new elements prevents a plateau effect that would diminish the effectiveness of measures over time and stagnate further learning. Assessing and stimulating hospitals' learning process with the aid of IRSs is a promising strategy, but its success depends on the consistent evaluation of its effects and its further development.

6

Epistemic injustice in incident investigations: a qualitative study

Co-authors: J. Kok, K. Grit, I. Leistikow and R. Bal

Under review in: Health Care Analysis

CONCLUSION

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 stand-alone 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).

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SUMMARY

Regulation is an important way through which states exert control over and monitor activities valuable to communities. Regulation typically refers to the focused attempt to supervise and possibly alter the behaviour of others (be they financial institutions, public schools or hospitals) to produce desirable outcomes (like public schools providing good education). Society's expectations about what regulation can and should accomplish are high. We look to states and their regulatory agencies to anticipate and mitigate risks that would jeopardise our safety, as well as promote the quality of a range of services. Hand in hand with those high expectations goes an increased scrutiny of regulatory activities. The effectivity, impact or added value of regulation is repeatedly questioned. Especially after high-level incidents covered in the media, there is often the call for better regulation, so that such future incidents need not happen.

In the quest for better regulation, calls for evidence-based regulation stress the need for scientific research into the effectivity of regulation. This thesis is both part of this movement towards more evidence-based regulation and a reflection on it, based on a study of the regulatory practices and effects thereof of the Dutch Health and Youth Care Inspectorate (Inspectorate, hereafter). The Inspectorate monitors the quality and safety of healthcare in the Netherlands. The aim of this thesis is to study the effects of the Inspectorate's regulatory practices, to reflect on how regulation might generate effects and to rethink the practice of regulation itself.

A key notion underpinning this thesis is that 'quality and safety of care' needs to go through a series of translations before inspectors might assess it. Quality and safety of care, if it is to be regulated, needs to be rendered 'inspectable'; it needs to be translated into activities or behaviours that the Inspectorate can supervise and assess. The main question that this thesis looks to answer is: *How does the Inspectorate construct quality and safety of care as inspectable and to what effects?* In this thesis ethnographic research methods are used to generate an in-depth understanding of the regulatory practices of the Inspectorate. In particular, it reports on two case studies: the Inspectorate's regulation of hospital mergers (in chapters 2 and 3) and the Inspectorate's regulation of serious incidents (in chapters 4, 5 and 6). Both cases allow for studying how the Inspectorate constructs the 'quality' at stake in mergers and incidents as inspectable.

Chapter 2 describes how both the Inspectorate and hospitals frame the impact merging has on the quality and safety of care. It also describes how the Inspectorate regulates mergers. Despite the continuation of hospital mergers in the Netherlands, we know little about how merging might impact quality and safety of care. This chapter, that primarily draws from semi-structured interviews with both hospital respondents and healthcare inspectors, reveals that the process of merging is understood as potentially disruptive to daily care practices. Hospitals organise their care practices differently and use different equipment and IT systems to support those practices. These practices develop over time and professionals become familiar with those practices. When hospi-

tals merge, these different ways of working meet and professionals' sense of familiarity is disturbed. This poses risks, respondents agreed, especially as healthcare personnel is asked to work on both hospital locations. Moreover, merging as a process takes time and attention away from both managers and professionals. While the Inspectorate emphasises the dangers of merging, hospitals framed merging as an opportunity to reflect on their care practices, allowing for learning between hospitals.

Despite the risk that merging holds for quality and safety of care, for the Inspectorate, its regulatory practices are hesitant. While inspectors might monitor merging hospitals closely 'behind the scenes', the unpredictable way in which merging might affect daily care practices hampers the Inspectorate in developing a more proactive regulatory approach. The chapter concludes in suggesting the Inspectorate adopt a process-based regulatory approach that acknowledges the uncertain impact of a merger, monitoring how quality and safety considerations feature in hospital merger plans and the procedures hospitals put in place to guard against a merger's potentially disruptive impact.

Chapter 3 describes the efforts of the Inspectorate to construct a hospital merger into a 'regulatable object'. While the preceding chapter explored how a merger might pose a risk to quality and safety of care, this chapter explores how and under what conditions a risk becomes an inspectable risk for the Inspectorate. It zooms in on the role of the Inspectorate prior to the approval of a hospital merger, when the Inspectorate can give their take on the possible impact of the merger on quality and safety of care. Combining literature on the relational theory of risk and risk-based regulation, the aim of this chapter is to understand how the Inspectorate's risk construction practices are affected by theoretical, operational and reputational considerations and how constructed risks allow for regulation. This chapter shows that the uncertain impact a merger might have on quality and safety of care hampers the construction of a merger as a formal, regulatable risk object. For the Inspectorate, an actionable risk is one that is, in one way or another, rendered documentable so that it can be regulated. Inspectors conceive of a merger as a unique, unpredictable and dynamic process, that resists being transformed into a bounded object that predictably relates to quality and safety of care. The question of how and under what conditions a risk object becomes regulatable is also settled by how a regulator interprets its regulatory capabilities, mandate and identity. The Inspectorate is critical of a risk-based regulatory strategy that assumes the consequences of a hospital merger for quality and safety of care can be predicted. The chapter concludes with suggesting how alternative regulatory strategies can help transform a hospital merger into a regulatable risk object in a way that is attuned to the Inspectorate's perspective on risk-based regulation and the mandate with which it operates.

Chapter 4 is the first of three chapters that examines how healthcare organisations investigate serious incidents and how the Inspectorate monitors that investigative process. This chapter reports on a policy change that dictated that following a serious

incident involving the death of a resident in an elderly or disabled care organisation, an external chair should head the investigation into that incident. The policy change was informed by the idea that elderly and disabled care organisations had a lot to learn when it came to the investigation of serious incidents. While the Inspectorate called for internal investigations of such incidents, emphasising how the organisation's participation in understanding what caused the incident would help the learning process, the government called for external review, emphasising the need for objectivity and disclosure on the other hand. The introduction of the external chair, from outside the healthcare organisation but heading an investigative team with professionals from that organisation, became the compromise settled on. The chapter describes how healthcare inspectors, quality advisers and directors of elderly and disabled care organisations perceive the value of the external chair in the investigation of serious incidents and the learning process. External chairs were credited with bringing a 'fresh perspective' to the incident and the organisation where the incident occurred. External chairs help the investigation into a serious incident forward by asking questions that people familiar with the organisation would not readily think of. External chairs strike a balance between distance (the external chair must be 'foreign' enough to the organisation to bring a fresh, objective perspective) and proximity (the external chair must be familiar with care practices in elderly and disabled care, knowing where to look). The chapter concludes by describing how external chairs can act as knowledge brokers, enabling a form of shared learning from (investigating) incidents that moves between professionals and organisations because the external chair moves.

Chapter 5 analyses to what extent the Dutch Incident Reporting System (IRS) stimulates social and participative learning from serious incidents. All healthcare organisations in the Netherlands are required to investigate and report on serious incidents that are related to the quality of care and caused death or serious harm to the patient. The Inspectorate designed a 25-item scoring instrument that looks to assess and quantifies the quality of the investigation. Every investigation, from the introduction of the instrument in 2013, is awarded a score between 0-100% to indicate the percentage of (yes or no) items the investigation report adequately addressed. This chapter adopts a mixed-methods design and integrates both quantitative and qualitative findings. It reports on 4667 serious incidents that Dutch hospitals reported and investigated between 1 July 2013 and 31 March 2019. All investigations were scored by healthcare inspectors (using the 25-item scoring instrument) and the chapter provides an analysis on if and on what aspects hospitals improved over time. Interviews with healthcare professionals, incident investigators, quality managers and healthcare inspectors shed light on how the IRS affected their respective practices. The chapter reveals that healthcare inspectors score incident investigation reports better over time. The qualitative data suggests that while the IRS stimulated practices that support social and participative learning—incident in-

vestigation teams are often well-trained, patients and families are more frequently heard and involved in investigations—it also contributed to practices that do not—learning from the investigative teams are not always or poorly connected to that of professionals, recommendations that investigations identify are not always put into practice or evaluated if they are. The IRS both hits and misses the mark. If an IRS is to stimulate social and participative learning from incidents, the chapter shows, it needs to accommodate the (developing) capabilities of healthcare providers to investigate and learn from incidents—resetting the bar of what constitutes a 'good' incident investigation if the previous bar is consistently met.

Chapter 6 builds on insights from the two preceding chapters and explores how the IRS and the investigative structures along which learning from incidents is expected to occur, favours the participation in the incident investigation of some actors over others. The Inspectorate has consistently advocated the participation of an increasing range of actors in incident investigations (such as patients, families, different groups of healthcare professionals). Underpinning those efforts is the conviction that different people see things differently and that incident investigations stand to learn from a variety of perspectives. At the same time, however, studies report how patients' and families' stories may go unheard and accounts of particular professional groups tend to be overruled by others. By using the notion of 'epistemic injustice'—referring to how someone might be unduly disqualified or discredited in their capacity as knower—this chapter studies the structural organisation of incident investigations and aims to understand why learning from multiple perspectives is difficult in incident investigations. Structures that guide the investigative process after a serious incident set the stage for the credible participation of some, while hindering that of others. In trying to provide a detailed, chronological reconstruction of a serious incident, investigators are encouraged to identify verifiable facts or 'hard' evidence. Dissent or a difference in how an event was experienced has little place in the linear narrative investigators look for. Testimonies of actors that are beyond the scope of this timeline or are unverifiable, are at risk of being valued less credible. Patients, families and involved professionals are at times labelled as 'too emotional' to contribute to the incident investigation. While the Inspectorate has successfully encouraged multi-voiced engagement in incident investigations (to involve patients and families in investigations is routine now, where it was not before), particular structures surrounding or supporting the investigation pose barriers to do justice to and learn from all testimonies equally.

Chapter 7, the conclusion of this thesis, provides an answer to the main research question and offers some reflections on how regulation and the effects it generates can be conceptualised, as well as how they might be studied.

First, the Inspectorate constructs 'regulatory objects'; a regulatory object transforms a particular quality issue into the (legitimate) object of regulation. Any regulatory object

proposes a relationship between regulatee behaviour and the given quality issue that is at stake. In chapters 4, 5 and 6, 'learning from incidents' figured as the primary regulatory object. This regulatory object was translated into the activity of 'properly conducting investigations into incidents', that the Inspectorate was then able to assess. Chapters 2 and 3 however show that constructing a regulatory object does not always succeed as the Inspectorate proved unable to construct mergers as such.

Second, the Inspectorate depends on regulatory instruments to render regulatee behaviour (such as the manner in which healthcare organisations conduct incident investigations) inspectable. Regulatory instruments play a pivotal role in a chain of translations that transform a quality issue (like patient safety) into a documentable set of activities or behaviours that speak to that issue. Not only do regulatory instruments render something like patient safety inspectable, in doing so regulatory instruments advance particular interpretations of what 'quality' in a given situation means and how it might best be monitored. This can also fail. Given the uncertain impact of merging on quality and safety of care, there is no regulatory instrument that inspectors can use to monitor mergers; it is not apparent what (activities or behaviours) the Inspectorate should render inspectable and assess.

Third, the regulatory instruments the Inspectorate employs make an appeal to a specific group of people or agents. In setting forth a particular interpretation of quality, regulatory instruments also pave the way for who is able to engage with that quality. The scoring instrument with which the Inspectorate assesses incident investigations empowers incident investigators—who can enact ownership of the investigative process, hampering the participation of other agents (like involved professionals or patients). The external chair is an agent specifically introduced to help elderly and disabled care organisations investigate and learn from incidents. Regulation could be thought about as the attempt to assemble and position particular agents (rather than others) that take up and work on the quality issue set forth by a regulator.

Fourth, the Inspectorate's regulatory instruments that aim to describe a reality can help shape or bring about that reality. The scoring instrument inspectors use to assess incident investigations sets out to measure and benchmark hospital performance, but as people invest in the Inspectorate's expectations, the assumptions about learning it communicates—that 'learning' happens within the bounded project that an investigation is and that this learning is helped by the reconstruction of a chronological timeline of the event—can take hold. As organisations restructure their practices and devote resources to 'do well' on the Inspectorate's scoring instrument, the instrument affects the reality it set out to monitor. The potential of a regulatory instrument to bring about the reality it describes is in the hands of the agents that buy into and invest in it. It is also possible that the very attempt to observe a reality hampers it; responses to a regulatory instrument may generate inverse effects. In more way than one, the incident

investigation scoring instrument has contributed to investigative practices that are less social and participative; investigations are prone to become stand-alone activities, organisationally cordoned off from other quality and safety structures and epistemic contributions from patients, families and involved professionals are undervalued in favour of more distanced testimonies.

This thesis also sheds light on how the regulatory object the Inspectorate constructs and the regulatee behaviour it is tied to, can be operationalised on different organisational tiers. Regulators can use instruments to render regulatee behaviour inspectable on one of three tiers that range from its key operations and procedures (first-tier), an organisation's systems and abilities to monitor its own operations (second-tier) to an organisation's self-evaluative activities and its evaluation and (re)design of its first-tier operations and second-tier controls (third-tier). In such a process-based perspective on regulation, regulators face questions like: what type of regulatee behaviour on which tier speaks to a given regulatory object (on what organisational tier might learning reside?) and how could a singular regulatory object render regulatee behaviour inspectable on different tiers? Regulation could entail the construction of tier-spanning regulatory objects and the assessment of regulatee behaviour as it aligns (or not) across these different organisational tiers.

This final chapter also reflects on the regulatory tendency to visualise regulatee behaviour in order to regulate it. Underpinning this tendency is the idea that through seeing, inspectors come to know and take legitimate regulatory action. The regulatory tendency to visualise regulatee behaviour, apparent in the regulatory practices of the Inspectorate, helps shape what and how regulatee behaviour can be rendered inspectable and it informs how inspectors and other agents (external chairs, patients) think about what counts as 'knowledge' on quality and safety of care. In response to this regulatory tendency to visualise, this chapters addresses how 'inspecting' also entails making room for and developing other senses than seeing. The chapter also considers how this thesis contributed to the academic literature on regulation and reflects on possible implications for the work of the Inspectorate and other regulators.

To regulate quality and safety of care is to shape what we understand quality and safety of care to be. As regulators attempt to monitor and measure regulatee performance, regulation can (inadvertently or not, productively or less so) impact that performance. By distinguishing the objects of quality regulators 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 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).

SAMENVATTING

Het houden van toezicht is een belangrijke manier waarop overheden proberen controle uit te oefenen en zicht te houden op activiteiten die de samenleving van waarde vindt. Toezicht verwijst naar de poging om het gedrag van andere partijen (zoals financiële instellingen, scholen of ziekenhuizen) te monitoren en mogelijk te doen wijzigen om zo gewenste uitkomsten te realiseren (zoals scholen die goed onderwijs bieden). De verwachtingen die we als samenleving van het toezicht hebben zijn hooggespannen. Van overheden en haar toezichthoudende instanties verwachten we dat ze anticiperen op en ons beschermen tegen risico's, alsmede de kwaliteit van uitlopende typen dienstverlening naar een hoger plan tillen. Daarmee gepaard gaat een toenemend kritische houding ten opzichte van het functioneren van toezichthouders. De effectiviteit, impact of toegevoegde waarde van het toezicht wordt vaker bevraagd. Vooral als incidenten het nieuws halen klinkt de roep om beter toezicht, zodat soortgelijke incident in de toekomst voorkomen kunnen worden.

Wetenschappelijk onderzoek naar de effectiviteit van toezicht speelt een grote rol in de zoektocht naar toezicht dat meer 'evidence-based' is. Dit proefschrift past in de beweging naar meer 'evidence-based' toezicht, maar biedt daar ook een reflectie op. Centraal in dit proefschrift staat het toezicht van de Inspectie Gezondheidszorg en Jeugd (hierna: Inspectie). De Inspectie houdt toezicht op de kwaliteit en veiligheid van de gezondheidszorg in Nederland. Het doel van dit proefschrift is om de effecten van het toezicht van de Inspectie te bestuderen, te reflecteren op hoe toezicht effecten genereert en om een ander perspectief op de praktijk van toezicht houden te ontwikkelen.

Een vertrekpunt van dit proefschrift is het idee dat 'kwaliteit en veiligheid van zorg' eerst een aantal keer vertaald dient te worden voordat inspecteurs in staat zijn het te beoordelen. Kwaliteit en veiligheid van zorg, als er toezicht op gehouden moet kunnen worden, dient 'inspecteerbaar' gemaakt te worden; het moet kunnen worden vertaald naar activiteiten of organisationeel gedrag waar de Inspectie op toe kan zien. De onderzoeksvraag die centraal staat in dit proefschrift is: *Hoe maakt de Inspectie kwaliteit en veiligheid van zorg inspecteerbaar en welke effecten heeft dit?* Door middel van etnografisch onderzoek worden de praktijken van de Inspectie bestudeert. Er wordt ingezoomd op twee casestudies: het toezicht van de Inspectie op ziekenhuisfusies (in hoofdstukken 2 en 3) en het toezicht van de Inspectie op calamiteiten (hoofdstukken 4, 5 en 6). Beide casestudies werpen licht op hoe de Inspectie 'kwaliteit' inspecteerbaar maakt als het gaat om fuserende ziekenhuizen of (leren van) calamiteiten.

Hoofdstuk 2 beschrijft hoe zowel de Inspectie als ziekenhuizen denken over de impact die fuseren heeft op kwaliteit en veiligheid van zorg. Het beschrijft tevens hoe de Inspectie toezicht houdt op ziekenhuisfusies. Terwijl ziekenhuizen in Nederland blijven fuseren, weten we weinig over hoe een fusie mogelijk impact heeft op kwaliteit en veiligheid van zorg. Dit hoofdstuk, dat gebaseerd is op semigestructureerde interviews met respondenten uit ziekenhuizen en inspecteurs, toont aan dat een fusieproces dagelijkse

zorgpraktijken kan ontwrichten. Ziekenhuizen richten hun dagelijkse zorgpraktijken verschillend in en ze gebruiken verschillende IT-systemen om die praktijken te ondersteunen. Deze praktijken ontwikkelen zich over de tijd heen en zorgprofessionals raken daar vertrouwd mee. Wanneer ziekenhuizen fuseren komen de verschillende manieren van werken bij elkaar, moeten op elkaar worden afgestemd en het vertrouwen van zorgprofessionals in hoe zorgpraktijken in elkaar steken is niet meer vanzelfsprekend. Dit is risicovol volgens onze respondenten, vooral als het personeel gevraagd wordt om op beide ziekenhuislocaties aan de slag te gaan. Bovendien wordt het proces van fuseren voorgesteld als een intensief proces dat tijd en aandacht opslokt van zowel managers als zorgprofessionals. Hoewel de Inspectie vooral de gevaren van fuseren benadrukt, wijzen ziekenhuizen erop dat een fusie ook de mogelijkheid biedt om te reflecteren op hun zorgpraktijken en ziekenhuizen stimuleert om van elkaar te leren.

Ondanks het feit dat de Inspectie vooral wijst op de risico's van een fusie voor kwaliteit en veiligheid van zorg, is het toezicht van de Inspectie afwachtend. Inspecteurs geven aan fuserende ziekenhuizen 'achter de schermen' met extra aandacht te volgen, maar de onvoorspelbare wijze waarop een fusie mogelijk ingrijpt op de dagelijkse zorgpraktijk staat volgens de Inspectie meer proactief toezicht in de weg. Dit hoofdstuk sluit af met de aanbeveling aan de Inspectie 'proces-gericht' toezicht te ontwikkelen. Dergelijk toezicht erkent de onzekere impact van een fusie, en schetst hoe de Inspectie kan toezien op hoe ziekenhuizen overwegingen van kwaliteit en veiligheid een plek geven in hun fusieplannen en de processen die ziekenhuizen inrichten om grip te houden op de impact van een fusie.

Hoofdstuk 3 beschrijft de pogingen van de Inspectie om ziekenhuisfusies te transformeren tot 'toezichtsobject'. Daar waar het eerdere hoofdstuk ging over hoe een fusie mogelijk een risico kan vormen voor kwaliteit en veiligheid van zorg, gaat dit hoofdstuk over hoe en onder welke voorwaarden een risico inspecteerbaar wordt voor de Inspectie. Specifiek zoomt het hoofdstuk in op de rol die de Inspectie heeft in de beoordeling van een fusie, waarin de Inspectie haar zienswijze kan geven over de mogelijke impact van de voorgenomen fusie op de kwaliteit en veiligheid van zorg. Vertrekkend vanuit een relationeel perspectief op risico's, is het doel van dit hoofdstuk om te begrijpen hoe de risico-construerende praktijken van de Inspectie mede bepaald worden door theoretische, operationele en politieke overwegingen en hoe geconstrueerde risico's toezicht mogelijk maken. Dit hoofdstuk toont aan dat de onzekere impact die een fusie mogelijk heeft op kwaliteit en veiligheid van zorg, het transformeren van een fusie tot een formeel toezichtsobject in de weg staan. Een risico waar de Inspectie op kan toezien is een risico dat, op een bepaalde manier, gedocumenteerd kan worden. Inspecteurs zien een fusie als een uniek, onvoorspelbaar en dynamisch proces—in plaats van een afgebakend object dat op een voorspelbare manier effect heeft op de kwaliteit en veiligheid van zorg. De wijze waarop de Inspectie invulling geeft aan haar mandaat en identiteit als

toezichthouder bepaalt mede hoe en wanneer de Inspectie toezicht kan houden op de risico's die ze construeert. De Inspectie is kritisch op een risico-gebaseerde benadering die veronderstelt dat de gevolgen van een fusie voor kwaliteit en veiligheid van zorg voorspeld zouden kunnen worden. Dit hoofdstuk stelt alternatieve toezicht strategieën voor die toestaan een fusie te transformeren tot toezichtsobject op een manier die past bij het perspectief dat de Inspectie heeft op risico-gebaseerd toezicht en het mandaat waarbinnen ze opereert.

Hoofdstuk 4 gaat, net als de twee hoofdstukken die hierop volgen, over hoe zorgorganisaties calamiteiten onderzoeken en hoe de Inspectie vervolgens toezicht houdt op dat calamiteitenonderzoek. Dit hoofdstuk beschrijft een beleidswijziging waarmee organisaties in de ouderen- en gehandicaptenzorg verplicht werden om een externe voorzitter te betrekken bij onderzoeken naar calamiteiten als gevolg waarvan een cliënt is komen te overlijden. Deze beleidswijziging was gebaseerd op het idee dat ouderen- en gehandicaptenzorginstellingen nog wat te leren hadden op het gebied van het doen van goed onderzoek naar calamiteiten. In de discussie rondom onderzoek naar calamiteiten maakte de Inspectie zich hard voor intern onderzoek omdat de betrokkenheid van een organisatie bij onderzoek naar de oorzaken van een calamiteit het leerproces zou helpen. Vanuit de Tweede Kamer klonk echter sterk de roep om onafhankelijk onderzoek en werd juist het belang van objectiviteit en openheid benadrukt. De introductie van de externe voorzitter, die van buiten de organisatie kwam en een team van interne onderzoekers voorzat, is het compromis waar uiteindelijk voor gekozen is. Dit hoofdstuk beschrijft hoe inspecteurs, kwaliteitsmedewerkers en managers van ouderen- en gehandicaptenzorginstellingen de rol van externe voorzitter in onderzoek naar calamiteiten en het leerproces waarderen. Externe voorzitters zouden beschikken over een 'frisse blik', op zowel de organisatie als de calamiteit. Ze helpen het onderzoek verder door vragen te stellen waar mensen van binnen de organisatie niet aan denken. Externe voorzitters moeten een balans vinden tussen afstand (ze moeten voldoende onbekend zijn met de organisatie om een frisse, onafhankelijke blik mee te kunnen brengen) en nabijheid (ze dienen bekend te zijn met het type zorg in ouderen- en gehandicaptenzorginstellingen zodat ze weten waar ze die blik op moeten richten). Dit hoofdstuk sluit af door te beschrijven hoe externe voorzitters als 'knowledge brokers' opereren; externe voorzitters faciliteren een vorm van kennisuitwisseling tussen professionals en organisaties omdat de externe voorzitter tussen hen heen en weer beweegt.

Hoofdstuk 5 bestudeert in hoeverre het Nederlandse incidentenrapportage systeem (IRS) sociaal en participatief leren van calamiteiten stimuleert. In Nederland zijn alle zorgorganisaties verplicht om calamiteiten—incidenten gerelateerd aan de kwaliteit van zorg die serieuze schade hebben toegebracht aan de patiënt of als gevolg waarvan de patiënt is overleden—te rapporteren en te onderzoeken. De Inspectie heeft een score instrument ontwikkeld aan de hand waarvan inspecteurs, op basis van 25

items, de kwaliteit van calamiteitenrapportages van zorginstellingen beoordelen. Elke rapportage krijgt (sinds de introductie van het score instrument in 2013) een score tussen de 0-100%; dat percentage geeft aan hoeveel van de 25 items een calamiteitenrapportage adequaat behandelt. In dit hoofdstuk is gekozen voor mixed-methods onderzoek, waarbinnen kwalitatieve en kwantitatieve data worden gecombineerd. Er wordt data gepresenteerd van 4667 calamiteiten die Nederlandse ziekenhuizen tussen 1 juli 2013 en 31 maart 2019 hebben onderzocht. De rapportages die ziekenhuizen hebben aangeleverd zijn allen beoordeeld door inspecteurs en dit hoofdstuk bestudeert of en op welke aspecten ziekenhuizen over de tijd heen verbeterd zijn. Semigestructureerde interviews met zorgprofessionals, calamiteitenonderzoekers, kwaliteitsmedewerkers en inspecteurs laten zien hoe het IRS effect heeft gehad op het werk dat ze doen. Dit hoofdstuk toont aan dat inspecteurs calamiteitenrapportages met een hoger cijfer zijn gaan waarderen. De kwalitatieve data suggereren dat hoewel het IRS praktijken heeft gestimuleerd die sociaal en participatief leren bevorderen—teams van onderzoekers zijn vaak goed getraind, patiënten en families worden steeds vaker betrokken bij onderzoek naar calamiteiten—de IRS ook heeft bijgedragen aan praktijken die dat niet doen. Het leerproces van onderzoekers is niet altijd of matig gekoppeld aan het leerproces van professionals, verbetermaatregelen die in rapportages worden aangedragen worden niet altijd geïmplementeerd of worden later niet meer geëvalueerd. Het IRS helpt en hindert sociaal en participatief leren. Als het IRS sociaal en participatief leren wil blijven bevorderen, zo toont dit hoofdstuk aan, zal het moeten kunnen inspelen op het zich ontwikkelde vermogen van zorginstellingen om calamiteiten te onderzoeken en daarvan te leren—het dient de lat van wat 'goed' onderzoek is hoger te leggen naarmate meer calamiteitenrapportages die lat halen.

Hoofdstuk 6 bouwt voort op de inzichten uit de eerste hoofdstukken en verkent hoe het IRS en de structuren waarlangs het onderzoek naar calamiteiten is ingericht, sommige actoren makkelijker in staat stelt om mee te doen en te praten dan anderen. De Inspectie heeft zich steeds ingezet voor de betrokkenheid van meerdere groepen actoren in onderzoek naar calamiteiten, zoals patiënten, families en verschillende groepen zorgprofessionals. Het idee daarachter is dat verschillende groepen actoren anders tegen een calamiteit aankijken en dat onderzoeken naar calamiteiten baat kunnen hebben bij een veelvoud aan perspectieven. Tegelijkertijd laten verschillende studies zien dat patiënten en families zich vaak niet gehoord voelen en dat aan de verhalen van sommige groepen zorgprofessionals meer gewicht wordt toegekend door onderzoekers dan anderen. Aan de hand van het concept van 'epistemic injustice'—dat refereert aan de wijze waarop iemand onterecht gediskwalificeerd kan worden als een persoon die waardevolle kennis bezit—bestudeert dit hoofdstuk hoe het doen van calamiteitenonderzoek georganiseerd is en geeft het inzicht in waarom leren van verschillende perspectieven in calamiteitenonderzoek moeilijk is. Er zijn structuren die

de manier waarop onderzoek naar calamiteiten gebeurt sturen; die structuren kunnen voorrang geven aan de betrokkenheid van bepaalde groepen, terwijl ze die van anderen hindert. Met het belang van het chronologisch reconstrueren van een calamiteit worden onderzoekers aangemoedigd op zoek te gaan naar verifieerbaar bewijs over wat heeft bijgedragen aan het ontstaan van die calamiteit. Voor onenigheid of verschillen in hoe actoren iets beleefd hebben is, binnen het lineaire narratief waar onderzoekers op zoek naar zijn, weinig plaats. De verhalen van actoren die niet passen binnen het tijdbestek dat gereconstrueerd dient te worden of die niet te verifiëren zijn, worden sneller als onbetrouwbaar bestempeld. Patiënten, families en betrokken zorgprofessionals worden gezien als te emotioneel om (op een neutrale wijze) bij te dragen aan het onderzoek naar een calamiteit. Hoewel de Inspectie met succes de betrokkenheid van meerdere actoren bij onderzoek naar calamiteiten heeft bevorderd, staat de wijze waarop calamiteitenonderzoek gestructureerd en georganiseerd is het recht kunnen doen aan en het leren van verschillende perspectieven in de weg.

Hoofdstuk 7, de conclusie van dit proefschrift, beantwoordt de hoofdvraag van dit onderzoek en vraagt zich af hoe we toezicht en de effecten die ze produceert kunnen conceptualiseren en bestuderen. Het antwoord op de vraag hoe de Inspectie kwaliteit en veiligheid van zorg inspecteerbaar maakt kent vier componenten.

Ten eerste, de Inspectie maakt 'toezichtsobjecten'; met een toezichtsobject wordt een bepaald kwaliteitsvraagstuk getransformeerd tot een (legitiem) object waar een toezichthouder toezicht op kan houden. Elk toezichtsobject poneert een relatie tussen het gedrag van een onder toezicht staande en het kwaliteitsvraagstuk waar het om draait. In hoofdstukken 4, 5 en 6 was het 'leren van calamiteiten' het voornaamste toezichtsobject. Het adequaat onderzoeken van calamiteiten was het gedrag dat de Inspectie in relatie daartoe evalueerde. Hoofdstukken 2 en 3 tonen aan dat het niet altijd lukt om van een bepaald fenomeen een toezichtsobject te maken; bij ziekenhuisfusies slaagde dit niet.

Ten tweede heeft de Inspectie toezichtsinstrumenten nodig om het gedrag van onder toezicht staanden (zoals de wijze waarop zorgorganisaties onderzoek doen naar calamiteiten) inspecteerbaar te maken. Toezichtsinstrumenten spelen een cruciale rol in het vertalen van een kwaliteitsvraagstuk (zoals patiëntveiligheid) naar een te documenteren cluster van activiteiten of gedrag dat iets zegt over dat vraagstuk. Toezichtsinstrumenten maken niet alleen zoiets als patiëntveiligheid inspecteerbaar; door dat te doen bepalen ze mede wat 'kwaliteit' in bepaalde situaties betekent en hoe daar het beste toezicht op te houden is. Dit kan ook mislukken. Gegeven de onzekere impact van een fusie op kwaliteit en veiligheid van zorg is er geen toezichtinstrument aan de hand waarvan inspecteurs toezicht houden op fusies; het is onhelder wat voor activiteiten of gedrag de Inspectie inspecteerbaar zou moeten maken om iets te kunnen zeggen over fusies.

Ten derde blijkt dat toezichtsinstrumenten een beroep doen op bepaalde groepen actoren. Door een bepaalde interpretatie van wat 'kwaliteit' betekent voor te stellen, staan toezichtsinstrumenten ook het meedoen van bepaalde groepen actoren voor. Het score instrument waarmee de Inspectie onderzoekrapportages van calamiteiten beoordeelt bekrachtigt een groep speciaal getrainde calamiteitenonderzoekers. Deze onderzoekers kunnen het onderzoeksproces naar zich toe trekken, maar hebben ook een stem hebben in hoe en of anderen aan het onderzoek kunnen bijdragen (zoals betrokken zorgprofessionals of patiënten). De externe voorzitter is een actor die een specifieke rol kreeg in het stimuleren van goed onderzoek naar en het leren van calamiteiten binnen ouderenzorg- en gehandicaptenzorginstellingen. We zouden kunnen stellen dat toezicht houden het positioneren en legitimeren van bepaalde groepen actoren behelst; actoren die vervolgens aan de slag gaan met de 'kwaliteit' zoals dit in een toezichtsobject besloten ligt.

Ten vierde kunnen de toezichtsinstrumenten van de Inspectie de realiteit die ze beogen te beschrijven of te meten, doen ontstaan. Het score instrument dat inspecteurs gebruiken om de rapportages van calamiteitenonderzoeken te beoordelen beoogt de prestaties van ziekenhuizen te meten en tegen elkaar af te kunnen zetten, maar naarmate groepen mensen de verwachtingen van de Inspectie ter harte nemen, kunnen de veronderstellingen over leren die in dat instrument besloten zitten—dat 'leren' plaatsvindt binnen het gekaderde project van een onderzoek en dat dit leren gebaat is bij het reconstrueren van een tijdslijn—bestendigen. Naarmate organisaties hun onderzoekspraktijken reorganiseren en geld en energie investeren in het 'goed' kunnen presteren langs de lat van het score instrument van de Inspectie, beïnvloedt dat instrument de realiteit die het in kaart wil brengen. De mate waarin toezichtsinstrumenten de realiteit die ze meten ook construeren is afhankelijk van de manier waarop actoren de instrumenten (en de veronderstellingen in die instrumenten) legitimeren door ermee aan de slag te gaan. Het is bovendien mogelijk dat de poging om een bepaalde realiteit in kaart te brengen die realiteit in de weg staat; toezichtsinstrumenten kunnen tegengestelde effecten genereren. Op meerdere manieren heeft de beoordeling van calamiteitenrapportages bijgedragen aan onderzoekspraktijken die minder sociaal en participatief zijn; onderzoeken zijn als activiteit losgezongen van andere zorgpraktijken en niet aangehaakt bij andere kwaliteitsstructuren in zorgorganisaties. Bovendien wordt de kennis en bijdrage van patiënten, families en betrokken zorgprofessionals in onderzoek naar calamiteiten ondergewaardeerd en wordt er een voorkeur gegeven aan meer afstandelijke, 'objectieve' actoren.

Dit proefschrift toont ook aan dat het toezichtsobject dat de Inspectie construeert en het gedrag van onder toezicht staanden dat daaraan gekoppeld wordt, geoperationaliseerd kan worden op verschillende organisationele niveaus. Toezichthouders kunnen instrumenten inzetten die het gedrag van onder toezicht staanden op drie verschillende

niveaus inspecteerbaar maken, variërend van de primaire processen van een organisatie (eerste niveau), de systemen en het vermogen van de organisatie waarmee het haar eigen primaire proces in kaart brengt (tweede niveau) en de wijze waarop een organisatie haar eigen praktijken evalueert en, op basis daarvan, haar primaire processen en monitoringssystemen herinricht (derde niveau). In een dergelijke 'proces-gebaseerde' benadering van toezicht houden worden toezichthouders geconfronteerd met vragen als: wat voor soort gedrag van onder toezicht staanden op welk niveau zegt iets over het toezichtsobject (op welk niveau zouden we 'leren' kunnen vinden?) en hoe kan een enkel toezichtsobject gedrag van onder toezicht staanden op meerdere niveaus inspecteerbaar maken? Toezicht kan het construeren van niveau-overstijgende toezichtsobjecten behelzen en het evalueren van het gedrag van onder toezicht staanden over de verschillende niveaus heen.

Dit hoofdstuk reflecteert bovendien op de neiging van toezichthouders om het gedrag van onder toezicht staanden te visualiseren alvorens het te (kunnen) reguleren. Het idee is dat door te zien inspecteurs komen tot kennis op basis waarvan interventies legitiem worden. Maar de neiging van de Inspectie om het gedrag van onder toezicht staanden inzichtelijk te maken heeft gevolgen voor wat voor soort gedrag überhaupt inspecteerbaar gemaakt kan worden. Het heeft bovendien invloed op hoe inspecteurs en andere actoren (zoals externe voorzitters en patiënten) denken over wat telt als 'kennis' over kwaliteit en veiligheid van zorg. Door de neiging tot het visualiseren van gedrag te benoemen probeert dit hoofdstuk aan te geven dat 'inspecteren' meer is dan alleen zien en roept het op tot het ruimte maken voor en het ontwikkelen van andere toezichthoudende zintuigen. Dit hoofdstuk staat bovendien stil bij de manier waarop dit proefschrift heeft bijgedragen aan de wetenschappelijke literatuur over toezicht en reflecteert op de implicaties die dit proefschrift heeft voor het werk van de Inspectie en andere toezichthouders.

Het toezicht op kwaliteit en veiligheid van zorg bepaalt mede wat we onder kwaliteit en veiligheid van zorg verstaan. Wanneer toezichthouders proberen om de prestaties van onder toezicht staanden te meten kan toezicht (ongewenst of niet, op een productieve wijze of niet) die prestaties beïnvloeden. Door onderscheid te maken tussen de kwaliteitsvraagstukken waar toezichthouders zich op richten en de instrumenten die ze ontwikkelen om die kwaliteit inspecteerbaar te maken, kan onderzoek naar toezicht zich richten op de vraag hoe de effecten die toezichtsinstrumenten kunnen genereren zich verhouden tot het toezichtsobject waar het instrument (idealiter) ten dienste van staat. We kunnen denken over toezicht als het mobiliseren van een dynamisch netwerk waarin vragen over 'het goede, het slechte en het grijze' centraal staan. Responsief en reflexief toezicht betrekt haar onder toezicht staanden in een voortdurende discussie over wat dat goede, slechte en grijze in bepaalde situaties betekent en hoe toezicht een rol kan spelen in het evalueren hiervan. Dit vraagt om toezichtspraktijken die experimenteel

mogen zijn, en waarin een constante nieuwsgierigheid bestaat naar de vraag hoe de toezichtsobjecten die een toezichthouder construeert en de instrumenten die ze inzet, onder toezicht staanden helpt verbeteren (of niet). Onderzoek kan een bijdrage leveren om dit reflexieve proces te ondersteunen.

DANKWOORD

'There's always as much belowground as above.'

Richard Powers – The Overstory

Dit proefschrift is geworteld. Bij wortels denk ik aan houvast, groei, het gevoel ergens te horen; aan een netwerk van verbindingen en mogelijkheden die even essentieel zijn als onzichtbaar. In dit dankwoord probeer ik een aantal van die wortels zichtbaar te maken en spreek ik mijn dank uit naar de mensen die mij hebben bijgestaan in mijn promotietraject.

Roland, ik ben dankbaar dat je me de mogelijkheid hebt gegeven te kunnen promoveren, maar ik ben vooral blij dat *jij* me wilde begeleiden. Je had altijd tijd voor me, ook als je die niet had. Je scherpe en bemoedigende feedback op mijn (soms meanderende) stukken hebben me enorm geholpen. Vooral ook je steun in periodes dat ik me niet of minder op mijn promotie kon richten, heb ik erg gewaardeerd. Kor, jij was mijn enthousiaste gids in de wondere wereld van het toezicht die je zo goed kent. Je bent vrijgevig met wat je weet en net zo benieuwd naar wat ik te zeggen had. Dat is een combinatie die ik bewonder en die me in staat heeft gesteld om in mijn promotie te groeien en op mezelf te vertrouwen.

Van alle HCG-collega's die het promoveren zo leuk hebben gemaakt, bedank ik er graag een aantal in het bijzonder. Marianne, vanaf de allereerste dag hebben wij samen onderzoek gedaan en naast en door jou ben ik een betere onderzoeker geworden. Onvermoeibaar heb je me geholpen en meegedacht over de artikelen die hier nu verzameld zijn. Iris, vanaf het moment van mijn scriptieverdediging heb je me constant uitgedaagd een volgende stap in mijn denken te zetten. Hoewel het artikel waar we lang samen aan hebben gewerkt buiten de kaften van dit boekje is gevallen, is wat er wél in staat beter geworden door jouw suggesties. Ian, vooral tegen het einde van mijn proefschrift ben jij hier meer bij betrokken geraakt en daar ben ik dankbaar voor. Je bent een scherp lezer en je passie voor goed en mooi onderzoek naar toezicht is aanstekelijk. Josje, ik heb met veel plezier 'promovendus zijn' samen met je meegemaakt. Je niet aflatende optimisme en je betrokkenheid hebben me gesterkt. Ik kijk met trots terug op onze presentatie samen in Amsterdam en met plezier op al onze gesprekken over hoe je in hemelsnaam een promotie combineert met het krijgen van baby's.

Alle respondenten die mij in het kader van dit onderzoek te woord hebben willen staan en iedereen binnen de Inspectie Gezondheidszorg en Jeugd waarmee ik van gedachten heb mogen wisselen, hartelijk bedankt. Zonder jullie bereidheid om mij inzicht te geven in jullie ideeën, overwegingen en professioneel doen en laten had dit boekje er niet gelegen. De commissieleden wil ik bedanken voor hun tijd en hun kritisch lezen van dit proefschrift.

Hans en Joop, jullie staan mij vandaag in het bijzonder bij, maar eigenlijk al veel langer, net als al die andere vrienden die ik om mij heen mag koesteren. Dank jullie wel.

Frans, José, Eveline en Rui, bedankt voor jullie betrokkenheid, aanmoedigingen en, vanaf dag een, enorm warme welkom.

Pim, Tecla, Klaas en Laura, bedankt voor al jullie steun, liefde en interesse. Ik heb me altijd vrij om te ontdekken gevoeld, om 'mijn pad' uit te stippelen, waar dat ook heen zou leiden en om jullie, in die zoektocht, altijd aan mijn zijde te vinden. Dat is een groot goed en daar ben ik jullie blijvend dankbaar voor.

Stéphanie, Floor en Job – jullie zijn mijn thuis. Bij jullie ben ik wie ik wil zijn. Na lange, enerverende, moeizame of goede dagen werd dit proefschrift thuis weer wat het hoorde te zijn: gewoonweg werk en een (meestal) gesloten laptop. Ik ben blij en dankbaar dat ik promoveren samen met jullie heb kunnen beleven, het soms te vervloeken, te vergeten en nu af te sluiten en te vieren. "1, 2, 3…", roep je door de kamer, je handen maar half voor je ogen, "4, 5, 6, 7…", ik kijk om de hoek, je ziet me, grijnst, "8, 9, …10!" Je hebt me allang gezien. Blijf me vinden. Ik heb jullie nodig.

CURRICULUM VITAE

ABOUT THE AUTHOR

David de Kam (1986) studied Comparative Literature at Utrecht University, obtaining a bachelor's (2006-2009) and research master's degree (2009-2011) in the discipline (both with honours). Following a period of work in healthcare and education organisations, he obtained a master's degree in Healthcare Management (2014-2015) from Erasmus University Rotterdam (with honours). From 2015 he was a PhD researcher at the Erasmus School of Health Policy & Management (ESHPM). He has been involved in several research projects that studied the effects of the regulatory practices of the Dutch Health and Youth Care Inspectorate. David de Kam has published his research in international peer reviewed journals as well as in Dutch research reports. As a teacher he was involved in the bachelor, premaster and masters of ESHPM, teaching courses on qualitative research and quality and safety of healthcare, as well as supervising student theses. He currently works at the Ministry of Social Affairs and Employment.

PHD PORTFOLIO

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Introductory course in didactics	2016
Tutor training problem-based learning	2016
WTMC Graduate program	2016-2019
The method of 'con/text analysis' for interviews and other biographic data	2017
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Presentations at conferences, seminars and symposia

Dutch Health and Youth Care Inspectorate colloquium, Utrecht	2016
WTMC Summer School, Ravenstein (student presentation)	2017
ISQua International scientific meeting on quality and safety in health care, London	2017
BMJ International Forum on Quality and Safety in Healthcare, Amsterdam	2018

Teaching activities

Supervising and co-evaluating bachelor and master thesis	2017, 2018
Workgroup tutor Quality and Safety of Healthcare	2016, 2017, 2018
Workgroup tutor Qualitative research in healthcare	2018, 2019
Workgroup tutor Advanced research Methods	2019
Lecture on qualitative interviewing in Qualitative research in healthcare	2018, 2019

Non-peer reviewed publications and research reports

K. Grit, D. de Kam, R. Bouwman, M. Harmsen, R. Friele en R. Bal. 2018. *Kennissynthese calamiteitentoezicht*. Rotterdam: Erasmus School of Health, Policy & Management.

Kam, D. de, K. Grit en R. Bal. 2017. *Calamiteitentoezicht in de ouderenzorg en gehandicaptenzorg. Een evaluatie van een beleidswijziging in de care-sector per 1 oktober 2015*. Rotterdam: Instituut Beleid en Management Gezondheidszorg.

Kam, D. de, M. van Bochove en R. Bal. 2017. *Toezicht houden op veranderingen in governance: Ziekenhuisfusies en het medisch specialistisch bedrijf*. Rotterdam: Instituut Beleid en Management Gezondheidszorg.

Wat betekent het om toezicht te houden op kwaliteit en veiligheid van zorg? Hoe maakt een toezichthouder kwaliteit en veiligheid van zorg inspecteerbaar? Hoe kan een toezichthouder vaststellen dat het goed zit, of juist niet? Dat zijn een aantal vragen waar dit boek antwoorden op zoekt. *Through the Regulator's Eyes* bestudeert de toezichtspraktijken van de Inspectie Gezondheidszorg en Jeugd. Het probeert uiteen te zetten hoe toezicht werkt, hoe het effecten sorteert en hoe we toezicht kunnen bestuderen. Het boek is interessant voor toezichthouders, beleidsmakers, wetenschappers en eenieder die geïnteresseerd is in wat het betekent om ergens de kwaliteit van vast te stellen.