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).