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

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ABSTRACT

Risk-based regulation is widely adopted by different regulators but is not without its challenges. What risks a regulator should focus on and what regulatory strategies should be developed is not apparent. In this article, we empirically study the regulation of hospital mergers in the Netherlands by the Dutch Health and Youth Care Inspectorate (Inspectorate). We combine literature on the relational theory of risk and risk-based regulation with the aim to understand how a regulator's risk construction practices are affected by theoretical, operational and reputational considerations and how constructed risks allow for regulation. In our qualitative study, we draw on 30 in-depth interviews with healthcare inspectors, hospital directors, healthcare professionals and quality managers. Our respondents envision of a merger as an intensive and dynamic reorganizational process that can detract from attending to quality of care and might destabilise care practices. This, however, does not allow the Inspectorate to construct hospital mergers as formalised risk objects that predictably pose a risk to quality and safety of care. The Inspectorate's risk construction practices, besides, are meaningfully affected by theoretical, operational and reputational considerations. In addition to being able to construct a risk, regulators need to render that risk regulatable. The uncertain impact of a merger challenges being transformed into a regulatable risk object given the regulatory mandate of the Inspectorate. We suggest how other regulatory approaches might render a hospital merger regulatable, even if its impact is potentially multi-directional and impossible to predict.

INTRODUCTION

Risk-based regulation is fast becoming standard regulatory practice that is adopted by regulators around the world to oversee a range of different activities (Beaussier et al., 2016b; Rothstein et al., 2013). The premise of risk-based regulation is that regulators should focus their attention and resources on the risks that pose the greatest threats to meeting their regulatory objectives (Baldwin and Black, 2016). Having identified such risks, regulators can identify and prioritise future regulatory actions. Those actions can be rather immediate (e.g. informing decisions about inspecting providers) or impact a regulator's wider practices (e.g. (re)shaping regulatory agendas). Risk-based regulation is assumed to be (more) efficient and to effectively channel time and resources to the most pressing issues (Baldwin and Black, 2016; Beaussier et al., 2016b). At its heart, risk-based regulation calls upon regulators to focus on that which matters most. Despite the appeal of its call, risk-based regulation is not without its challenges (Baldwin and Black, 2016; Beaussier et al., 2016b; Lloyd-Bostock and Hutter, 2008). For one, regulators find that 'what matters most' is not self-evident or easily determined. Risks are not 'out there,' but need to be constructed and prioritised (Baldwin and Black, 2016; Maguire and Hardy, 2013; Nyberg and Wright, 2016). Also, rather than facing calculable risks, regulators (increasingly) have to cope with uncertainty (Sabel et al., 2018). And, having identified risks does not answer the question of how best to regulate them (Baldwin and Black, 2016; Sabel et al., 2018). In this article, we empirically study a specific case—the regulation of hospital mergers in the Netherlands—to understand how a regulator constructs and regulates risk.

To understand how a regulator constructs risks that it can regulate, we draw on and combine the insights of literature on risk construction practices and risk-based regulation. For one, we draw on the *relational theory of risk*. This theory, that builds on the work of Hilgartner (1992) and is expanded upon by Boholm and Corvellec (2011), unfolds a social constructivist perspective on risk, explicating how risk is an epistemic construct that orders the social world around us. To construct a risk is to make sense of and value one's surroundings and the potential hazards in it. Valuable for our research—in addition to the notion that risks are constructed rather than exist as entities external to our efforts to capture and measure them (Maguire and Hardy, 2013; Nyberg and Wright, 2016)—is the claim that a risk, in fact, consists of three connected conceptual elements: 1) a risk object, 2) an object at risk and 3) a relationship that ties the risk object to the object at risk (Boholm and Corvellec, 2011; Hilgartner, 1992). Take the statement that smoking can lead to (lung) cancer and premature death. In terms of the relational theory of risk, smoking constitutes behaviour that is established as the risk object, the object at risk here is being in good health and the research that documents that the act of smoking causes harm to being in good health establishes the causal link between the risk object and

the object at risk. While this theory allows us to study the risk construction practices of a regulator, it is not tailored to regulatory practice as such. Therefore, it does not attend to the institutionalised character of regulation nor to how practices of risk construction inform regulatory practice. For that reason, we also draw on a recent article by Baldwin and Black (2016) on risk-based regulation. In that article, Baldwin and Black note that three 'sets of drivers' shape how regulators come to construct and prioritise the risks that they do: 1) a regulator's theoretical perspectives on risk, 2) its operational constraints and 3) political, communicative or reputational factors (2016). We will get to what these drivers mean more specifically below, but what Baldwin and Black demonstrate is that for a regulator, practices of risk construction and the question of what to focus on are impacted by other considerations, specific to the objectives and context of regulation. Bringing these two strands of literature—literature on the relational theory of risk that unfolds a social constructivist perspective on risk and literature on (the challenges of) risk-based regulation—together, allows us to study the risk construction practices of a regulator while understanding how those practices are affected by the context in which they transpire.

In this article, we study the risk-based regulation of upcoming hospital mergers in the Netherlands by the Dutch Health and Youth Care Inspectorate (Inspectorate). The Inspectorate is the national regulator that monitors quality and safety of healthcare. In the case of a future merger between hospitals, the Inspectorate is tasked, by law, to "[provide] insight in the consequences the merger will have (…) for quality of care" (Health competition act, 2006). The question posed to the Inspectorate, here, is if (and to what extent) mergers pose a risk to quality of care. A relationship of risk between a merger (as a potential risk object) and quality of care (as a potential object at risk) is implied and we wonder how the Inspectorate constructs and regulates upcoming hospital mergers as risk. Hospital mergers provide an interesting case study in looking to understand a regulator's risk construction practices. While mergers continue to take place in the Dutch hospital sector (Postma and Roos, 2016), their impact on quality of care is uncertain (Vogt and Town, 2006). Studies that address if mergers impact quality of care generally compare quality indicator outcomes pre- and post-merger (Hayford, 2012; Mutter et al., 2011; Romano and Balan, 2011). Some studies find improved quality, others reduced quality and still others find no effect at all. Moreover, different quality indicators tell different stories, so that assessing the impact of a merger on quality of care becomes difficult indeed. These studies shed no light on how a merger impacts quality of care. Faced with such uncertainty, it is interesting to study how the Inspectorate constructs and regulates hospital mergers as a potential risk to quality and safety of care. The research questions that inform our study are: 1) *How does the Inspectorate construct hospital mergers as a risk to quality and safety of care?* and 2) *How does this construction allow for regulating mergers?*

ON THE CONSTRUCTION AND REGULATION OF RISK

In a society ever more obsessed with safety (Furedi, 2009; Giddens, 1999), one of the key responsibilities attributed to today's states and its regulatory agencies is to anticipate and protect its citizens from risks (Baldwin et al., 2012). Risk-based regulation is a temporal practice embedded in a *logic of anticipatory action* with regard to safety—prescribing the need to act today in response to future dangers—that states and its agencies are increasingly compelled to adopt (Adams et al., 2009; Amoore, 2013; de Goede et al., 2014). Risk-based regulation equally holds "that regulators cannot, and indeed should not even try, to prevent all possible harms", focusing instead on those that pose the "greatest potential threats" (Beaussier et al., 2016b, p. 206). What those threats are, however, is not a given and the question of what possible harms should be subject to regulatory scrutiny is a normative one (Baldwin and Black, 2016). That is why we would do well in understanding why and how regulators come to identify and prioritise the risks that they do.

The relational theory of risk helps unpack what any given 'risk' consists of. It understands risk as a 'social phenomenon' that depends on three elements: "an *object* deemed to 'pose' the risk, a putative *harm*, and a *linkage* alleging some form of causation between the object and the harm" (Hilgartner, 1992, p. 40). In this social constructivist perspective on risk, objects do not possess innate characteristics that define them as either risk objects or object-at-risks; they are constructed as such as they enter a *relationship of risk* with other objects. We should note that these objects are also not objects in the strict sense of the word; they can refer to behaviour (such as smoking), natural phenomena (like a tsunami) or products (like alcohol). What the relational theory of risk proposes, however, is that these different things are then transformed into objects. To construct something as a risk is a 'creative act' that accomplishes or assumes a couple of things that are of interest to us here (Boholm and Corvellec, 2011). First, to delineate something, a potential hazard, as a risk is productive. "Designating something as of one kind rather than another is a constitutive act that outlines the object's contours." (Boholm and Corvellec, 2011, p. 179) It is an act of categorisation that is reflective of what we deem important. Second, to designate something as an object at risk (such as one's good health or safety of healthcare) is to ascribe value to that object. "The object at risk is understood as something that ought to be allowed to last, and therefore deserves attention and care." (Boholm and Corvellec, 2011, p. 180) And third, relationships of risk both explicate how and why the hazardous risk object threatens the valued object at risk *and* imagines possibilities to act on or intervene in this relationship. Constructing anything as risk serves the possibility of acting upon it, so as to keep the hazard that threatens that which we value at bay (Boholm and Corvellec, 2011). With the relational

theory of risk, we can study what it takes for the Inspectorate to construct a hospital merger as a risk and how doing so can allow for regulatory action.

Baldwin and Black (2016) propose that three factors influence regulators in their attempts to identify and prioritise risks. First, they identify the importance of a regulator's *theoretical or ideological perspective*. "What constitutes a risk," Baldwin and Black note, "can be contested, and perceptions and evaluations can vary considerably" (2016, p. 566). Different (groups of) people can perceive and construct risks differently. How regulators understand risk impacts how they construct, identify and prioritise them. We are interested to see from what kind of perspective the Inspectorate constructs hospital mergers as potential risk and how that allows for regulatory action. Second, regulators are influenced by *operational constraints*. This can refer to a regulator's resources, the legal framework a regulator is embedded in and its mandate, and the extent to which a regulator depends on other organisations or co-regulators to achieve its objectives (Baldwin and Black, 2016). Regulators do not lack agency in these legal or institutional frameworks; regulators interpret and enact their mandate, strategically employ their resources and negotiate their relationships with other organisations and co-regulators (van Erp, Wallenburg, and Bal 2018). But, to acknowledge a regulator's operational constraints is to realise that regulators are locally, legally and institutionally positioned and that their risk construction practices cannot be separated from such positions. Third, regulators must take *political and reputational factors* into account when constructing risks. Regulators must (increasingly) account for the effectivity and legitimacy of their work in a range of public and political arenas (Baldwin and Black, 2016). Differentiating between societal and institutional risks, Rothstein holds that as regulators attempt to manage societal risks (e.g. risks to quality of care), they face institutional risks in failing to do so and therefore need to frame their regulatory practices as legitimate and effective (Rothstein, 2006). What is of interest to us in addition to seeing how the three drivers impact the risk construction practices of the Inspectorate, is to see how these different drivers interact, potentially "[pulling] in similar or opposite directions" (Baldwin and Black, 2016, p. 566).

Combining the relational theory of risk with the drivers that shape a regulator's risk construction practices offers a valuable perspective through which we can understand the Inspectorate's regulation of future hospital mergers. It allows us to study how the risk-based regulation of mergers depends on the mobilisation of different elements that make up a constructed risk and wonder how the context and the possibility for regulatory action to which its risk construction practices are tied shape those practices.

METHODS

In this article we report on a research project studying how the Inspectorate regulates upcoming hospital mergers and how it might do so more productively in the future. This article, more specifically, focuses on and theorises how a regulator's risk-construction practices allow for regulatory action (or not). To answer our research questions, we adopted a qualitative research design. We draw from a total of 30 semi-structured, in-depth interviews. While this article focuses on the risk construction practices and regulation of the Inspectorate specifically, we did not exclusively interview respondents from the Inspectorate.

We conducted interviews in three phases. First, we interviewed individuals whom we had identified as experts on hospital mergers and quality of care. These people, predominantly (former) CEOs of hospitals and consultants on hospital governance and quality of care (n=6), were identified through news reports concerning hospital mergers, wherein they often featured as authorities on hospital mergers and quality of care. Second, we interviewed healthcare inspectors (n=5) and a policy adviser (n=1) from the Inspectorate, as well as inspectors from other regulatory agencies involved in the assessment of mergers between healthcare providers (n=2). We discussed the risks involved in mergers for quality of care and the regulatory practices they developed to target these risks. Finally, we conducted three case studies of recently merged hospitals spread throughout the Netherlands. In these hospitals, we interviewed executive directors, chairs of medical specialist associations, chairs of nursing associations, chairs of patient associations and quality managers (n=16). In these interviews, we discussed how hospitals sought to address quality of care during the merger and how they experienced the regulation of the Inspectorate. We elected to interview a wider set of actors involved in the regulation of hospital mergers. We did so to understand the wider context in which the regulation of hospital mergers unfolds and to account for how the Inspectorate's regulatory practices are valued by those it regulates. Today, regulators operate within 'multi-layered governance networks' and their regulatory (risk construction) practices are shaped by and implicate other agents (e.g. co-regulators, regulatees, professional associations, etc.) (van de Bovenkamp et al., 2014; van Erp et al., 2018). While transforming an object into a risk is a creative act, "it is not an act that exists in a social vacuum" (Boholm and Corvellec, 2011, p. 179). So, for us, we can expect the risk construction practices of the Inspectorate to be shaped by and relate to how others (hospitals respondents and co-regulators) construct mergers as a possible risk to quality and safety of care. In box 1, we provide context to the history and practices of the Inspectorate and the regulation of (hospital) mergers in the Netherlands.

Box 1: On the Inspectorate and the regulation of hospital mergers in the Netherlands

On the Dutch Health and Youth Care Inspectorate

The Inspectorate envisions itself as a "future-oriented regulator" and aims to "safeguard and advance" quality and safety of care (Inspectorate, 2016a, p. 15). The Inspectorate makes use of risk-based and incident-based regulation. With risk-based regulation the Inspectorate "proactively and periodically" collects information in order to identify risks in particular healthcare organisations or sectors at large (Inspectorate, 2016a, p. 12). Risk-based regulation is said to allow the Inspectorate to proactively act on risks before harm occurs and is effective and efficient (Inspectorate, 2016a), but it is also necessary given the number of individuals and organisations the Inspectorate is responsible for monitoring (Robben et al., 2015, p. 384). Through incident-based regulation the Inspectorate receives and assesses adverse event reports from healthcare organisations, determining if these events indicate structural problems that might lead to unsafe care (Inspectorate, 2016a). The Inspectorate has increasingly invested in ensuring that incident-based regulation informs risk-based regulation and vice versa (Inspectorate, 2017). Key to the Inspectorate's regulatory philosophy are: 1) the trust the Inspectorate puts in healthcare providers to ensure the best possible care, assuming that providers are intrinsically motivated to do so and 2) how the Inspectorate tries to engage both the parties it monitors and its co-regulators in constructive dialogues about proportionate and effective regulatory interventions (Inspectorate, 2016a). Both reflect a governance perspective on quality and safety of care, where quality and safety of care comes about through the work of many, co-dependent actors. The Inspectorate is not the sole regulatory agency involved in monitoring (quality of) care, but plays its part in wider 'regulatory arrangements' (Inspectorate, 2016a, p. 17). In regulating hospital mergers, we see such a regulatory arrangement at work.

On the regulation of mergers

All mergers in the Netherlands are subject to approval by the Dutch Authority for Consumers and Markets (Competition Authority), if the annual revenue of one of the merging organisations surpasses a particular threshold. The decision of the Competition Authority to clear or prohibit a merger boils down to the question if a merger is likely to be anti-competitive. Mergers between *healthcare* organisations also require approval of the Dutch Healthcare Authority (Healthcare Authority). The Healthcare Authority assesses how the merger impacts the continued accessibility of critical hospital services (like emergency care) in a region. In granting or withholding their approval, the Healthcare Authority can ask the Inspectorate "to provide insight in the consequences the merger will have (…) for quality of care" (*Health competition act*, 2006). Weighing the input of both the Healthcare Authority and the Inspectorate, the Competition Authority makes the final call.

The first (DdK) and second author (MvB) conducted most of the 30 interviews. The third author (RB) participated in three interviews. Interviews were conducted between September 2015 and March 2016. Pre-structured topic lists, that were typically prepared and revised by DdK and agreed on by DdK and MvB, helped in structuring the interviews. All interviews were audiotaped after having obtained consent for doing so from our respondents. The interviews were transcribed verbatim by DdK afterwards. On average, the interviews lasted for 61 minutes. Characteristic of an abductive approach to data analysis, we went back and forth between our research data and the theory we used to better understand that data (Tavory and Timmermans, 2014). While we inductively coded our interview transcripts and selected policy documents with the aim to identify themes (Green and Thorogood, 2018), we compared and came to understand those themes in light of the theoretical notions introduced before. To support the coding process, *Atlas.ti* was used. All three authors consented on the main themes and how we might theorise those in a series of meetings. To improve the validity of our findings, we provided every respondent the opportunity to review their quoted material, we presented preliminary findings of our research to the Inspectorate and, throughout our research, we met with an advisory committee (consisting of three (senior) inspectors of the Inspectorate) that provided feedback on all stages of our research.

FINDINGS

Our findings are ordered into three sections. First, we focus on how the Inspectorate constructs hospital mergers as risk to quality and safety of care. Second, we attend to how the Inspectorate's efforts to construct hospital mergers as risk to quality and safety of care are affected by theoretical, operational and reputational considerations. Third, we describe how the risk construction practices of the Inspectorate allows for particular regulatory actions.

Constructing hospital mergers as risk to quality and safety of care

The Inspectorate constructs hospital mergers as a risk to quality of care in the sense that mergers initiate a demanding period of organisational restructuring. "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) Mergers require a lot of attention from a range of people in hospitals and as such, a merger might detract from the attention awarded to and necessary for quality of care.

> 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)

Other inspectors voiced similar concerns. In this sense, a merger as a project of organisational restructuring and quality and safety of care constitute two broad categories that both, in attending to them, demand time and attention. From this perspective, quality and safety of care is not the outcome of particular activities, but rather, embedded in daily care activities—so that any other activity (such as restructuring a hospital organisation) that would detract from it, could threaten it. The relationship that seemingly ties a hospital merger (as a risk object) to quality and safety of care (as object at risk) is cast in terms of 'attentiveness'; merging is an activity competing for the limited attention of healthcare personnel and other actors, attention that might otherwise be directed towards (improving or ensuring the continuity of) quality and safety of care. In this construction of attentiveness, merging features as an activity other than that of attending to quality and safety of care. But inspectors also construct merger-specific risks to quality of care. In the Netherlands, as hospitals merge, they generally become locations of the same organisation. Between these two locations, care services are divided; some services may exist on just one location, others on both. Care professionals are often asked to take shifts on both locations and patients too, depending on their care trajectories, travel between locations. This way of (re)organising care services poses risks, inspectors agreed.

> Hospitals have different systems, protocols, procedures… When patients and professionals move between locations, professionals find the other location uses different protocols or that they can't access the IT-system because they lack required credentials. (Inspector 5)

As hospitals developed their practices over the course of years, differences between hospitals are multiple and well-entrenched in (tacit) ways of doing things—going back to a hospital's materiality (e.g. beds, infusion pumps) and 'softer' elements (e.g. incident reporting attitudes, interdisciplinary communication). Because of the risks associated with such differences as professionals and patients travel between locations, inspectors argued that ironing out these differences is top priority in a merger. But doing so is difficult and time-consuming. "It takes hours and hours of work to bring it all together," one inspector noted. Here, a hospital merger is constructed as a more specific risk to quality and safety of care, tying common organisational restructuring practices a merger calls for (e.g. making sure the same protocols are used on both locations) to the ability to provide good quality and safe care. Quality and safety of care, here, depends on a

familiarity with care practices and the ability to trust that other care professionals are (equally) familiar with those same practices. It is this familiarity that a hospital merger can threaten. So, a hospital merger, for the Inspectorate, can pose a risk to quality of care through how it detracts attention from quality and safety of care and for how it might destabilise familiarity with care practices. The question that presents itself here is if these are *regulatable* risk constructions—do they allow the Inspectorate to provide insight in the impact a merger might have on quality and safety of care? Before addressing that question, let us see how the Inspectorate's risk construction practices are shaped by theoretical, operational and reputational factors.

The Inspectorate's theoretical perspective on risk

From our interviews we discern four theoretical propositions on risks, mergers and regulation that shape the Inspectorate's risk construction practices.

1. *Risks have no predictive value*. While inspectors have an understanding of how a merger might pose a risk to quality of care, as described above, this does not allow for statements as to the consequences a merger will have for quality and safety of care. Inspectors interpret the task of providing insight into these consequences as a predictive endeavour that cannot be substantiated by the presence of risk. "We can't say in advance: 'The board of directors and professionals cannot guarantee the quality and safety of care because they'll merge and there are so many risks.'" (Inspector 1)
2. *Mergers are discontinuous events.* For inspectors, a merger constitutes a discontinuity in the history of a hospital and the information the Inspectorate has on that hospital. Whereas the Inspectorate has data on both separate hospitals, in merging these hospitals become a new organisational (and legal) entity that is to be regulated. "Sure, we have an image of hospital A and of hospital B, but that does not become [image] C, when you merge those. That becomes a new image." (Senior policy adviser Inspectorate) Inspectors also suggest that each merger has 'its own story'. While the phrase 'hospital merger' suggests an unequivocal phenomenon, one inspector warned, this is far from true; histories of hospitals, characteristics of the region where hospitals are located, care services offered, the population they cater to, its culture, it is all different with each new merger (Inspector 4). Mergers are constructed by inspectors as singular events that tell the Inspectorate little about the consequences of other hospitals mergers on quality and safety of care.
3. *Risks can and need to be seen.* A dominant understanding of risk inspectors advanced states that risks can and needed to be seen; inspectors consistently discussed their efforts to gauge how a hospital was doing in terms of *seeing* how it was doing. "Often one hospital becomes elective [meaning the they operate with planned procedures], while the other one becomes acute and we see healthcare practices shift—we see that. When a merger is further along, we might see a serious incident because a patient

was considered to be elective but required embolization and needed to be at the other location. So, those kinds of things we do see. But 'hard evidence' [that mergers negatively impact quality of care] in terms of outcome measures? No, because we haven't looked at it like that." (Inspector 4) In discussing risks as things inspectors do or do not see—depending on how or where they look—risk-based regulation is framed as a visual practice. Moreover, it suggests that the Inspectorate not only sees, but that, through seeing they (come to) know.

4. *Risk-based regulation requires input from other regulatory practices.* For the Inspectorate, risk-based regulation is no stand-alone activity but is connected to other regulatory practices. In the attempt to construct risks, the Inspectorate collects and assesses information from multiple sources. Previously reported incidents and how hospitals have dealt with those incidents provides one such source, as incident-based regulation informs risk-based regulation. For one inspector, risk-based regulation depends on "really hard signals—an increase in reported incidents, more complaints, news reports in the media—or otherwise signals that indicate quality of care is under pressure" (Inspector 2) to function. Such (visualised) signals are needed to substantiate risks and render them regulatable.

These four propositions underpin the Inspectorate's theoretical perspective on hospital mergers as regulatable risk objects. The propositions speak both to the perceived nature of a merger as a complex reorganizational process as well as to the conditions and workings of risk-based regulation. The propositions and how they seem to reinforce one another—e.g. past information on (separate) hospital performance cannot be relied on to speak to the unique and discontinuous character of a future merger between those hospitals—allow for thinking about fitting regulatory practices in response to mergers, practices that are further mediated by operational and reputational considerations.

The Inspectorate's operational constraints

Regulatory practices are both constrained and enabled through the legal framework a regulator is embedded in. A key constraint that influences the risk construction practices of the Inspectorate in regulating upcoming mergers, is the legal role carved out for the Inspectorate as being able to provide insight in the consequences of a merger for quality of care. Inspectors either interpret this as needing to predict the future impact of a merger or as involving saying yes or no to the proposed merger. Both, the Inspectorate claims, it cannot do. "We cannot deliver on that expectation" (inspector 2) as one inspector put it, while another said, "those shoes don't fit" (Inspector 1). Also, to predict what happens when hospitals merge or to argue in favour of or against a merger, are practices ill-befitting the regulatory philosophy of the Inspectorate.

> I truly feel that, from our position, we cannot tell the Competition Authority: 'Prohibit [or approve] this merger'. We would have to take that up with the board of directors of the hospitals and their supervisory boards. (Inspector 4)

To make such "hard statements" (Policy adviser Inspectorate) about future hospital mergers is impossible both for the theoretical reasons we presented earlier and because doing so is incompatible with the Inspectorate's wider regulatory philosophy and practices. To predict how a merger will play out, inspectors noted, side-lines hospitals and fails to consider their abilities to manage the merger process capably. Now, the Inspectorate is one of three regulatory agencies involved in assessing mergers between healthcare organisations and its regulatory practices are shaped and constrained by how these affect the other regulators.

> I know that the Inspectorate is uncomfortable with predicting the future and it's tricky, but the Competition Authority is supposed to do just that; they have to predict what will happen. (Policy adviser Healthcare Authority)

> As I understand it, a merger is a risk for the Inspectorate, but they're very hesitant to make statements about that. (…) The Inspectorate maintains that based on the information they have; they can tell us little… That's tough at times, but it's all we get. (…) I get it's very difficult to say: 'This will happen to quality of care.' We're a different regulator; we focus on competition and assume that competition ensures affordability, quality and access of care. (Team manager Healthcare, Competition Authority)

The differences between the Competition Authority and the Inspectorate—going back to how both conceptualise quality of care, the theoretical perspectives on risk they employ, its regulatory philosophies, the legal framework they are embedded in and the roles they have in the assessment of mergers—makes that the Competition Authority does regulate based on how they 'expect things to develop', whereas the Inspectorate does not. For the Competition Authority, the impact of a merger—modelled as the extent to which it would grant the merged hospital market power and, as such, might be anti-competitive—is rendered calculable with the aim of making prospective statements. Given that the final responsibility for approving or prohibiting a merger resides with the Competition Authority, to whose decision the Inspectorate can potentially contribute by giving their "point of view" (Policy adviser Inspectorate), the Inspectorate can afford to be hesitant. The mandate of the Inspectorate in the regulation of mergers—being able to provide their 'point of view' on the expected consequences of a hospital merger

for quality and safety of care—is not just limited; it also runs counter to the theoretical propositions we identified earlier.

Political and reputational factors affecting the Inspectorate

In 2008, two hospitals in the southeast of the Netherlands announced their plans to merge. At the time, both hospitals struggled finding qualified personnel and patients often had to visit other hospitals to receive care. The hospitals argued a merger was necessary to ensure the continuity of care within the region (Competition Authority, 2009). The hospital market composition in that part of the Netherlands made the Competition Authority conclude that the merger would grant the hospitals a "near-monopoly" (Competition Authority 2009, p. 29). This calls for the prohibition of the merger on anti-competitive grounds, but, to considerable effect, the Inspectorate spoke out and sided with the hospitals.

> We said: 'This merger is necessary (…) to ensure continuity of care'. That merger would not have been approved if we had not said it was necessary, because the Competition Authority and Healthcare Authority both said 'No, this results in market power' and both wanted to prohibit the merger. We argued the hospitals could not survive individually and that quality of care was at risk if they did not merge. The positions of the Competition Authority and Healthcare Authority were based on market power. We argued from a quality of care perspective and then you win. (Former inspector)

Looking back on that decision, this former inspector said the Inspectorate "really put its neck on the line". An employee from the Competition Authority, tasked with merger assessment of healthcare organisations, recalled that decision.

> When the Inspectorate tells us 'if you prohibit this merger, a lot [of bad things] will happen,' this is very important to us (…), so we allowed the merger. (Healthcare merger assessor, Competition Authority)

This is the only time the Inspectorate argued in favour of or against a proposed merger. Whether or not the Inspectorate did well in advocating the merger is contested. Throughout our interviews, inspectors revisited this case to explain why the Inspectorate currently refrains from weighing in on upcoming mergers. One inspector stated the decision to support the merger "back-fired" (Inspector 1) and according to a policy adviser the Inspectorate came to "regret [that decision] because you cannot make hard statements [about how a merger will impact quality of care] in advance". The former inspector, who assessed the merger, looks back on it as "a triumph". The merger,

meanwhile, was no smooth sailing. Some years after the merger was approved, the hospital was put under increased surveillance because of concerns the Inspectorate had about the quality of care provided (Inspectorate, 2014). The Competition Authority was openly criticised for its decision to allow the merger (Reerink, 2009). Inspectors today conceive of that decision as case in point that the impact of a merger can impossibly be predicted, so that the regulation of hospital mergers is only viable after a merger. The Inspectorate's perspective on a merger can influence the decision to approve or prohibit a merger and providing such a perspective, thus, can hold political and reputational risk. The uncertain impact that inspectors envision a merger might have on quality and safety of care and a past decision to argue in favour of a merger that is now viewed as problematic, make that the Inspectorate is unwilling to run those risks.

Regulating hospital mergers

The risk construction practices of a regulator ultimately service its ability to regulate that given risk. For the Inspectorate, the expectation is that they are in a position "to provide insight in the consequences the merger will have (…) for quality of care" (Health competition act, 2006). When we asked our respondents from the Inspectorate how they provide insight into these consequences, they were adamant they could impossibly do so. It became clear that this role of 'providing insight in' for inspectors either meant 'to predict' the consequences of a merger or speak out in favour of or against the proposed merger.

> Really…it has to be an exceptional situation if we would, based on quality of care arguments, advise against a merger. (Inspector 4).

> The expectation is we're able to predict [the consequences of a merger for the quality of care] and that we can somehow see what is going on in these hospitals, but we can't. (Inspector 2).

Given the perceived impossibility of providing insight in the consequences of a merger, the Inspectorate gives out nondescript statements when hospitals merge:

> The Inspectorate sees no reason to assume that the safety of patient care is currently at risk in both hospitals. (…) The Inspectorate stresses the retrospective character of her regulatory findings: these are based on information on quality or regulatory visits from the past. A prospective statement by the Inspectorate concerning the quality of care is impossible according to the Inspectorate. (Competition Authority 2013, p. 3)

The way in which the Inspectorate constructs hospital mergers as a risk to quality and safety of care—as detracting from attention for quality and safety of care or destabilising healthcare personnel's familiarity with care practices—do not constitute formalised risk objects and objects at risk that help the Inspectorate in shedding light on the impact of future hospital mergers on the quality and safety of care. Cast in terms of the relational theory of risk, a hospital merger is not transformed into a bounded object, but is, rather, an activity with its own dynamic, unpredictable and discontinuous. While a merger might threaten quality and safety of care, no causal relationship between both is established and the relationships that are advanced (that of attentiveness and destabilisation of familiarity) do not lend themselves for prediction. Now, as a result, the Inspectorate enacts no formal risk-based regulatory instruments in the regulation of upcoming hospital mergers and the expected consequences a merger might have on quality and safety of care are not taken into account when it is decided if a merger should be allowed or not.

Having said that, regulation is more than its formal instruments and, in our interviews, inspectors discussed ways of monitoring merging hospitals despite the absence of these instruments. One inspector told us,

> 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)

Other inspectors note that they monitor merging hospitals more attentively 'behind the scenes'. This non-formalised, additional investment on the part of inspectors is informed by their own risk construction practices. That a merger might destabilise a familiarity with care practices or detract attention from quality of care does not allow for predictive statements on the impact of future mergers, but it does sensitise inspectors to how they might get a sense of how merging hospitals are doing. Rather than a formalised risk object as such, inspectors think of a merger as a 'life event' in a hospital's history; an intense event that could negatively impact a hospital's performance, as it demands attention and can destabilise day-to-day practices.

DISCUSSION

In this article, we studied the Inspectorate's attempts to construct upcoming hospital mergers as risk objects and wondered how those constructions allowed for regulatory action. Drawing from the relational theory of risk, we described how inspectors constructed mergers as a risk object to quality of care (as the object at risk) as a demanding activity of hospital reorganisation that can detract from the attention available to quality and safety of care and as it might destabilise care personnel's familiarity with care services. These constructions, however, do not enable the Inspectorate to provide insight into the consequences of a future merger on quality and safety of care. What we have learned is that the risk construction practices of a regulator ultimately serve the construction of *regulatable*—also, visible—risk. We also looked to identify how theoretical, operational and reputational considerations impacted the Inspectorate's risk construction practices.

The four theoretical propositions on risk and mergers we identified—the idea that risks are not predictive heuristics, that mergers are discontinuous events, that risks should be seen and that risk-based regulation should be informed by other regulatory practices—reinforce one another. The discontinuity of a merger means it is difficult for other regulatory practices to inform the Inspectorate's risk-based regulation of upcoming mergers. Data on the two separate hospitals (e.g. previously reported incidents) fail to speak to how care practices will change and develop in the merged hospital. The Inspectorate's interpretation of its role in merger assessment as predicting the future impact of a hospital merger on quality of care collides with its theoretical perspectives on risk and hospital mergers that stress the impossibility of doing so. A past decision to argue in favour of a hospital merger in 2009 became a pivotal event in the Inspectorate's regulatory history of mergers, lending (political and reputational) credence to and informing the theoretically constructed inability to predict the impact of mergers on quality of care. The Inspectorate's conviction that it is impossible to predict the impact of a merger on quality of care is embedded in and afforded by the regulatory arrangement in which it plays its part of 'just' providing a viewpoint on a merger. Knowing that the Competition Authority makes the final call, the Inspectorate *can* be hesitant.

In drawing from literature on the relational theory of risk and risk-based regulation to understand the regulation of hospital mergers, we learned several things. First, we recognise that, for a regulator, a constructed risk needs to be regulatable—which means, visible or in some ways documentable. This is a requirement that exists in addition to the three conceptual elements that characterise the relational theory of risk (the risk object, object at risk and a causal relationship tying the former to the latter) and calls for the transformation of any hazard into a (somehow) observable risk object. Second, risk-based regulation is a practice enacted within a particular institutional context. Not only

do theoretical propositions, operational constraints and institutional risks have their own institutional histories and entrenchments, what they come to mean and how they are able (or unable) to inform regulatory practice is settled within a regulator's wider (legal and regulatory) positioning, philosophy and history. The effects of how risk-based regulatory practices are made to fit into existing regulatory practices and a regulator's institutional context spill over the boundaries between a regulator's theoretical perspectives, operational constraints and political factors. The collective valuation of 'the 2009 decision' as regrettable and the Inspectorate's regulatory philosophy feed into how inspectors think about risk, the regulatory (im)possibilities risk-based regulation is thought to afford and how a regulator envisions of and contends with political factors. The comparison with the Competition Authority demonstrates that other regulators, unfolding different theoretical perspectives that are equally informed by its institutional identity and regulatory history and mandate, envision different (im)possibilities for risk-based regulation. Third, the lack of a formalised regulatory approach to hospital mergers and the challenges inspectors face in constructing a causal relationship of risk between mergers and quality of care, does not mean that inspectors cannot or do not monitor hospital mergers. Despite the proclaimed impossibility of providing insight in the future impact of hospital mergers on quality and safety of care, other regulatory strategies are worth pursuing.

The Inspectorate does not seem to consider the possibility of *anticipating* what might happen when hospitals merge. Rethinking the role of the Inspectorate as anticipating rather than predicting the impact of a merger—the difference being that prediction implies one future, while anticipation "acts on multiple potential futures that are rendered actionable (…) in the present" (de Goede et al., 2014, p. 413)—allows us to think about a risk-based regulatory practice more in line with the Inspectorate's theoretical perspectives and its wider regulatory practices and history. We suggest the Inspectorate can engage merging hospitals in dialogues about the possible impact of mergers on quality of care early on, acknowledging and departing from the uncertainty of this impact. In these dialogues, hospitals and the Inspectorate can engage in a process of joint risk construction, or 'risk conversations' (Baldwin and Black, 2016, p. 594), by envisioning how mergers might pose risks to quality of care in these specific hospitals. These dialogues approach risk in a different way. Rather than aiming to identify the presence of (documentable) risk, such dialogues can allow the Inspectorate to assess a hospital's attitude towards those risk, to assess a hospital's plans for putting quality and safety of healthcare first while merging. This means gravitating towards a process-based regulatory approach—one that some inspectors informally adopt—that is not just attentive to potential risks as such, but to how a hospital evaluates and engages with said risks (Gilad, 2010).

CONCLUSION

In this article, we studied the risk construction practices of a regulator through the case of hospital mergers. We learned that an actionable risk, for a regulator, constitutes a regulatable risk; a risk that is, in some way, rendered documentable. A merger, for the Inspectorate, cannot be transformed into a bounded object that predictably relates to quality and safety of care. It is an intensive, dynamic process of restructuring, rather, that might detract from the attention for quality and safety of care and destabilise established care practices. A regulator's risk construction practices are affected by theoretical, operational and reputational considerations. The Inspectorate's notions about risk or mergers are ill-befitting a predictive, risk-based regulatory strategy that assumes the consequences of a hospital merger for quality and safety of care can be predicted. We suggest how alternative regulatory strategies can transform a merger into a regulatable risk object given the Inspectorate's perspective on risk-based regulation and the mandate with which it operates.