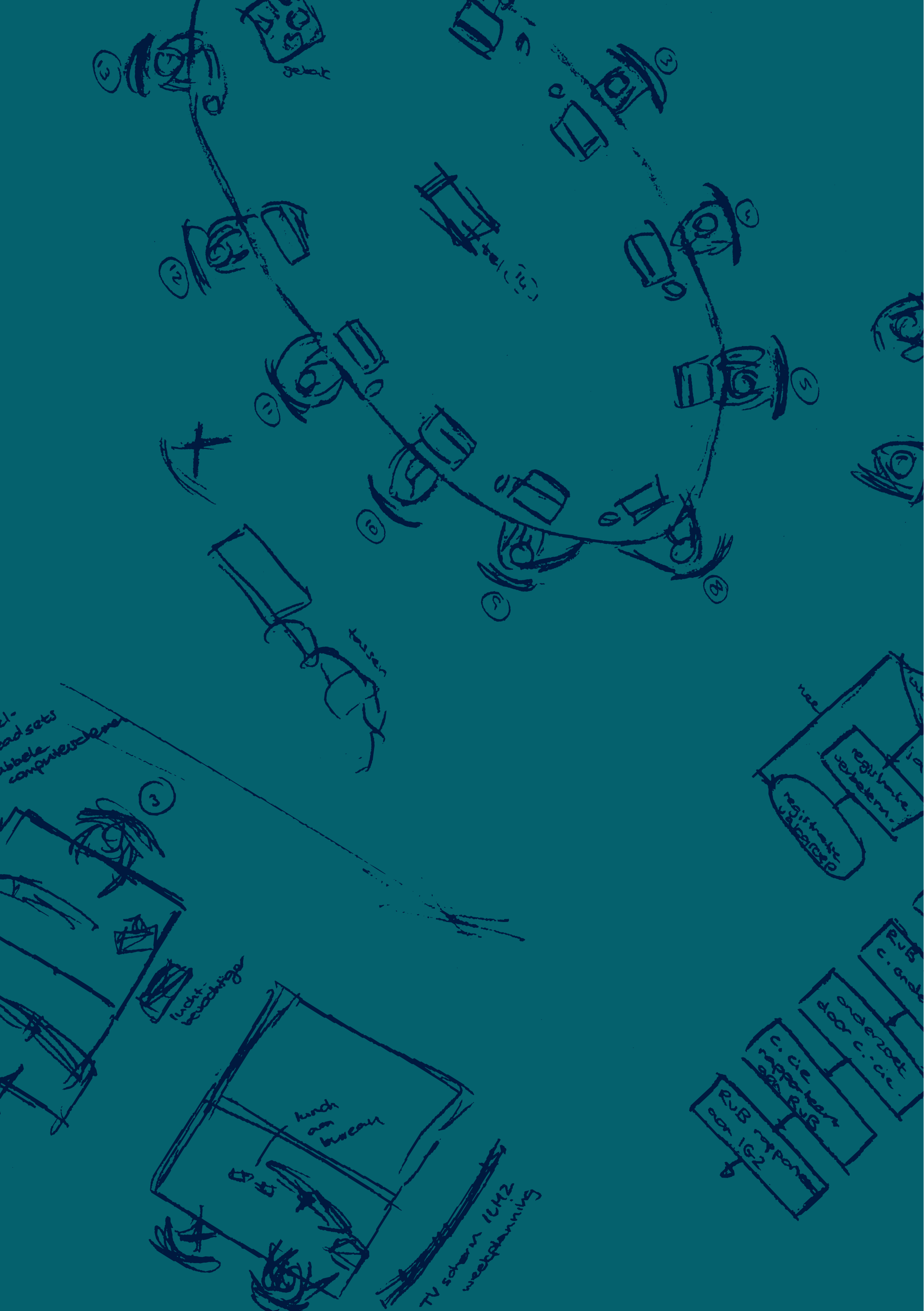
A STANDARD STORY

On the use and consequences of standards in healthcare regulation

JOSJE KOK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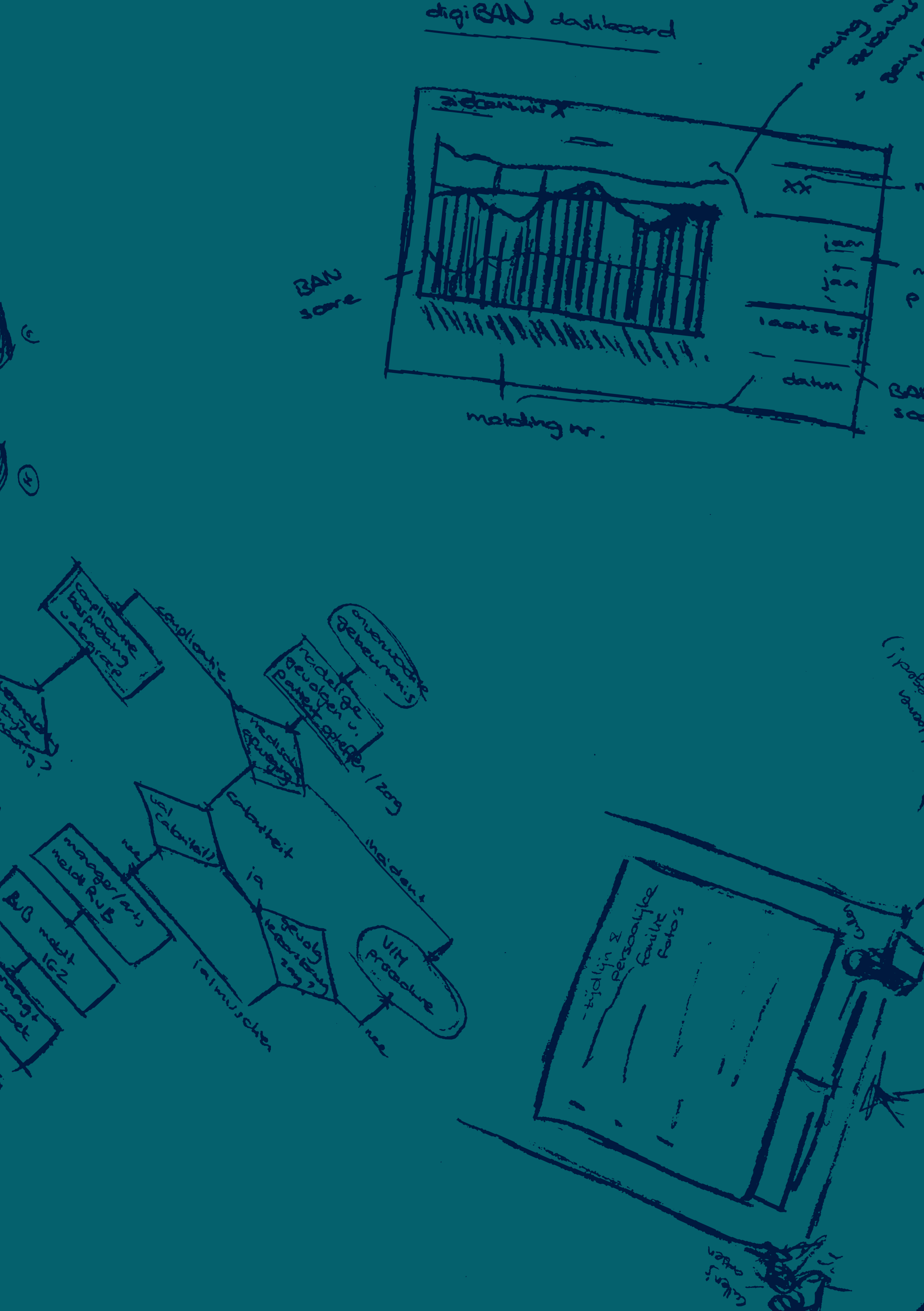
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A STANDARD
STORY
On the use and consequences of standards
in healthcare regulation

EEN STANDAARD
VERHAAL
Over het gebruik en de consequenties van standaarden
in gezondheidszorg toezicht

Thesis

to obtain the degree of Doctor from the
Erasmus University Rotterdam
by command of the
rector magnificus

Prof.dr. F.A. van der Duijn Schouten

and in accordance with the decision of the Doctorate Board.
The public defence shall be held on

Friday 18 June 2021 at 13:00 hrs

by

Josje Harmke Kok
born in Rotterdam

Erasmus University Rotterdam

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For Siem and Lou,
my non-standard children
in a world full of standards

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1

GENERAL INTRODUCTION: STANDARDS IN REGULATION

Narrator:	Today, Peppa and her friends are going on a train ride.
Teacher:	Here are your activity sheets.
Children:	(happily) Oeewww.
Narrator:	The children have to spot everything that is on the activity sheet.
Peppa Pig:	(looking at the activity sheet) A boat.
Suzy Sheep:	A signal box.
Danny Dog:	And, a tunnel.
Peppa Pig:	(looking out the window) I can see trees.
Rebecca Rabbit:	Are trees on the list?
Peppa Pig:	Eh, no.
Candy Cat:	I can see clouds.
Danny Dog:	Are clouds on the list?
Suzy Sheep:	No.
Peppa Pig:	I can see Granddad Dog (sailing past on a boat).
Granddad Dog:	Ahoy there!
Children:	Hello Granddad Dog!
Peppa Pig:	Is Granddad Dog on the list?
Danny Dog:	Silly Peppa, my granddad won't be on the list.
Rebecca Rabbit:	But he is sailing a boat.
Zoe Zebra:	And a boat is on the list.
Children:	Hurray!
Narrator:	The children tick the boat on their activity sheets.[1]

1. *Screenshot and screenplay text taken from YouTube, Peppa Pig, Episode "The Train Ride". Peppa Pig, Astley Baker Davies Ltd / Entertainment One UK Limited 2019.*

INTRODUCTION

The ubiquity of standards

We live in a world of standards (Bowker & Star, 1999; Brunsson & Jacobsson, 2000; Lampland & Star, 2009; Timmermans & Epstein, 2010). We are confronted with them in formal and informal settings, at the most minute level and at the most macro level, in very subtle and not-so-subtle ways (Lampland & Star, 2009). Take Peppa Pig and her friends. As they are riding the train, they are surrounded by standards and standardized practices. The train runs according to a predefined timetable and leaves each station after the conductor has performed a routinized procedure; a procedure dictated by the train company's safety guidelines. The children are sitting on benches that have been manufactured and installed according to international standards for product quality and passenger safety. Madame Gazelle, Peppa's teacher, will have obtained a teaching license from an accredited institution, that provides an educational program in line with internationally recognized standards. The activity sheets too are likely to, at least in some way, reflect the content of a standardized school curriculum that dictates what the children should know, should learn, and will be tested on – and what counts as 'true' or 'good' (i.e. the sailing boat).

What are the consequences of the standards that surround us? How do they influence behavior and work processes? Stefano Ponte and colleagues (2011) explain that standards define constrains or boundaries but also enable interaction by providing common language and means of communication. In other words, standards 'do' a lot – or hold the potential of doing a lot – but how this actually works in practice and to what effects has rarely been the direct topic of study (Timmermans & Epstein, 2010). What's more, the existing literature that does engage with the topic of standards, draws a conflicting picture on the workings and consequences of standards. For – as I will show in this Introduction – on the one hand standards are said to be normative

boundary objects, that constitute daily life and directly dictate or constrain behavior. On the other hand, there is literature that shows that standards are gamed and ignored, and as such do not determine behavior.

This paradox, I propose, calls for more research to be done into the performance and performative nature of standards. Not only because of their ubiquitous nature, but also because there are many contexts in which standards are explicitly introduced and used to steer and monitor behavior. One of these contexts is (governmental) regulation, where all sorts of standards – in the form of indicators, checklists, protocols, guidelines, and the like – are used to translate a public interest purpose into something that can be steered and monitored (Black, 2002; Walshe & Boyd, 2007). That is, regulatory authorities need some form of standard – inscribed with norms of conduct or aspired principles – to secure compliance with the public interests they are supposed to protect and encourage. For regulators that are increasingly pressed to account for their impact (Dute, 2015; Leistikow, 2018; Rutz, 2017; WRR, 2013), it is thus relevant to find out if and how the standards that they use produce effects (Weenink, Wallenburg, Leistikow, & Bal, 2020). We can learn about these effects by studying the daily practices in which standards are used; at a local level. Ethnographic fieldwork lends itself well for that purpose. What's more, ethnography will help us to unveil some of the many unknowns surrounding the practical execution of daily work within regulatory institutions (Sparrow, 2000; Van Rooij, 2016), including their use of standards.

This then is the core focus of my thesis: an ethnographic exploration of the consequences of standards, set in the regulatory domain of the Dutch healthcare sector. In what follows I will elaborate on the relevant theoretical concepts and analytical underpinnings of this thesis and sketch a brief contextual backdrop of the Dutch healthcare sector and its regulation. Then I will introduce the overarching research questions and research methods used and I wrap up with an outline of this book.

THEORETICAL AND ANALYTICAL UNDERPINNINGS, AND CONTEXTUAL BACKDROP

The effects of standards are (still) debated

Specifically, in this thesis 'standards' refer to the instruments that have been developed to manage risks and steer behavior, through the description of norms or principles for (good) conduct and/or by explicating measurement criteria for the quality and performance of goods, processes and practices. It is because these instruments carry norms that they implicitly or explicitly dictate what is 'good', 'true' or 'correct'. Standards are often in de background of other kinds of work (Bowker & Star, 1999; Lampland & Star, 2009), and come in all shapes and sizes: legal mandates, guidelines, protocols, checklists, uniform tests and curricula, indicators, forms or entire classification and performance measurement systems. What's more, standards are nested inside one another like a set of Russian dolls (Lampland & Star, 2009, pp. 5-6). A seemingly small and simple standard, such as the standardized *activity sheet* that is filled in by Peppa Pig and her friends, is linked to a standardized *school curriculum*, which is linked to nationally set *practice guidelines* and *certification schemes* for educational quality, required subjects and basic readings, to international *laws* dictating a child's right to education. The flexibility of these linkages is variable but changing the format of, for instance the standardized activity sheet, essentially does not disturb the nested system of standards as a whole (Lampland & Star, 2009).

Whatever form standards take and in whatever nested system they appear, standards have in common that they are introduced to generate some form of coordinated social and organizational order (Bowker & Star, 1999; Brunsson & Jacobsson, 2000; Lampland & Star, 2009; Ponte et al., 2011). It is through these coordinating and standardizing means that standards are said to have great consequences for individuals and organizations (Dahler-Larsen, 2012;

Dahler-Larsen, 2014; Lampland & Star, 2009; Slager, Gond, & Moon, 2012). Scholarship, however, is not in agreement on what the exact consequences are and how these consequences come about.

On the one hand there are sociologists who argue that standards embody or prescribe social beliefs and values and reflect political and normative choices that directly influence behavior and learning (Dahler-Larsen, 2012; Dahler-Larsen, 2014; Lampland & Star, 2009; Slager et al., 2012). For example, as Peppa and her friends use their activity sheets, they are asked to pay attention to and record specific observations (a boat, a signal box, a tunnel) and – albeit implicitly – ignore others (trees, clouds, granddads, or anything else that is not on the list). The standard – or standard maker, if you will – has thus quite subtly prescribed what is more important. In this case Granddad Dog is not significant but the boat that he is sailing, is. Should Peppa later be tested on the elements on the fieldtrip activity sheet, the importance of this boat is emphasized further, likely directing Peppa's studying priorities and subsequent learning. What's more: if the children's test scores are not only used to monitor their learning, but are also utilized to evaluate the teacher's performance and school's effectiveness – as increasingly the case for standardized testing (see Firestone, Schorr, & Monfils, 2004; Volante, 2004) – the content of the activity sheet is prone to influence Madame Gazelle's teaching behavior as well. In this sense, standards then are thought of having a linear dynamic. That is, standards are instruments that govern and regulate behavior; what the standard dictates is translated into action – and learning – that can be monitored, ranked, compared and even steered (Brunsson & Jacobsson, 2000; Ponte et al., 2011).

On the other hand, there is literature that shows that standards – even mandatory types[2] – are ignored entirely, not followed precisely and/or cause all sorts

2. *Here I mean 'mandatory' in the sense that the standard is backed up and monitored by an external body of some sort, such as a professional organization, an accreditation authority, regulatory body or the state (Ponte et al., 2011; Timmermans & Epstein, 2010), see also table 1.1 for a categorization of different types of standards one can come across in the field of regulation.*

of conflicts and resistance thereby suggesting that standards *do not* determine behavior. For example, for some time now the field of healthcare is engaged in a massive standardization movement called evidence-based medicine. A movement whereby professional organizations and regulatory bodies make the scientifically best evidence available to health professionals in the form of meta-reviews of the literature, practice guidelines, assessment tools and standardized outcome measures (Timmermans & Berg, 2003; Timmermans & Epstein, 2010, p. 80). Aside from the debate this movement spikes about what constitutes as 'evidence' (see Latour & Woolgar, 1987), research has shown that in practice these guidelines have a limited effect on actual clinical decision making (McGlynn et al., 2003; Timmermans & Epstein, 2010). In a similar vein, – also in healthcare – Hollnagel, Braithwaite, and Wears (2013) have introduced the concept 'work as imagined (WAI) versus work as done (WAD)', to illustrate that the standards that outline the way work should be done (WAI) are rarely carried out that way in daily practice (WAD). They argue that healthcare is made up of complex socio-technical systems resulting in differences between everyday clinical work and what was intended, planned and prescribed by guidelines and protocols (Hollnagel et al., 2013).

Against the backdrop of this scholarly dispute, I started my PhD fieldwork at the Dutch Health and Youth Care Inspectorate (hereafter HYCI or Inspectorate, see box 1.1 for a description of the Inspectorate's activities and institutional responsibilities), the national regulatory authority tasked with the regulation of all healthcare providers in the Netherlands. A setting – I soon discovered – filled with standards *and* questions about the practical consequences of these standards. Before continuing to detail the specifics of this research setting, it is important to define what I mean by regulation and explain the role of standards in regulation.

The definition of regulation and regulatory standards

The definition of regulation is contested (Baldwin, Cave, & Lodge, 2012; Levi-Faur, 2011; Walshe & Boyd, 2007; Windholz, 2018). As Levi-Faur observes, regulation means different things to different people, with definitions varying

according to professional discipline, political ideology and even geography (Levi-Faur, 2011, p. 4; Windholz, 2018, p. 7). In political science literature, the definitions by Philip Selznick (1985) and Julia Black (2002) are often cited. Selznick describes regulation as "structured and focused control exercised by a public agency over activities that are valued by a community" (1985, p. 363). Years later, Black build on Selznick's definition posing that regulation is "the sustained and focused attempt to alter the behavior 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 behavior-modification" (2002, p. 26). Rather than attempting to provide an exhaustive overview of the diverse definitions of regulation, for the purposes of this thesis it is arguably more helpful to point out the common thread in these definitions, and regulatory regimes in practice more generally.

Overall it can be said that regulation has four key characteristics. First, there is a public interest purpose for which behavior by individuals and organizations must be altered and (structurally) monitored (Black, 2002; Selznick, 1985; Walshe & Boyd, 2007, p. 7). Second, there is a regulatory agency. The type and nature of the organization can vary, but the key point is that this agency is given the job of exercising control on behalf of society, rather than for example passing laws that would allow individuals to exercise control for themselves (Walshe & Boyd, 2007, p. 7; Windholz, 2018). To be able to exercise this control and influence, the regulator is thus always backed up by some form of formal institutional arrangements – such as the law – explicating what authority it has (Walshe & Boyd, 2007, p. 7; Windholz, 2018). Third, there is an addressee or regulatee that is regulated. The addressee can be persons or organizations (Windholz, 2018). And fourth, there are standards reflecting the public interest purpose and regulatory objective; they set out what needs to be done and/or achieved (Black, 2002; Windholz, 2018, p. 154). To be clear, unlike Black (2002) seems to suggest in her definition, it is not always the case that a regulatory authority is the actual and sole standard setter. Standards, as noted earlier, are nested (see figure 1.1). As such, practice guidelines and protocols

that have been co-constructed with or created by other standard setting bodies such as professional organizations or manufacturers' associations, can be (and usually are) adopted and used by a regulator to steer and monitor compliance (Timmermans & Epstein, 2010).

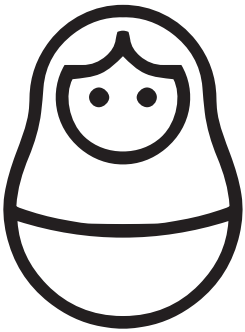
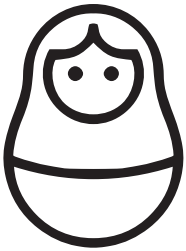
Nested regulatory standards		
		
Law	**Professional guideline**	**Regulatory framework**
set by the nation State and/ or internationally	set by professional organization	set by regulatory body
Example: Legislation depicting that patients have a right to safe and good care	Example: A directive/clinical practice guideline specifying what 'good' care entails for, e.g. preoperative care	Example: Criteria checklist used by the regulator to monitor and/or assess if the regulatee is complying to the professional guideline for preoperative care

Figure 1.1. An example of the diverse standards that a healthcare regulator and healthcare provider face and work with. These standards are nested; they interlink and fit inside one another like Russian *Matryoshka* dolls (Lampland & Star, 2009). Please note that this is a simplified example. Internationally, standard setting bodies differ greatly and there are always regulatory themes for which there exists no professional or academic consensus, let alone clearly formulated professional guidelines because the associated risks are (too) complex and ambiguous (see Rutz, 2017). What's more, in reality of course there are many more, nested layers of standards.

Table 1.1. Categorization of standards, summarized from Windholz (2018, pp. 154-160)[3]

Category	Dimensions		Specific forms / examples*	
Legal operation	Mandatory	Standards that operate with the force of law		Standards that have been developed by government and enshrined in legislation or standards developed by non-governmental bodies and incorporated into legislation by reference
	Consensual	Standards that operate by virtue of the regulatee agreeing to comply with them		Standards that operate as a contract between those promulgating them, like industry or a professional body, and the person or organization agreeing to comply with them. Examples include: professional accreditation schemes for accountants that operate as criteria for employment and enable the holder to charge higher fees and fair-trade certification schemes
Character and Application	Prescriptive	Standards that prescribe how something is to be done, usually with a high level of specificity	Direct:	Standards that operate directly upon a person or organizations, for example by only permitting conduct with the permission of the state. That permission could come in the form of a license, authorization, registration, permit accreditation or certification
			Indirect:	Standards that operate indirectly on persons or organizations by targeting products, processes, markets or transactions they engage in. For example, standards for maximum work hours or product specifications like mandatory weight or size

Character and Application	Outcome-orientated	Standards that articulate the outcome to be achieved, not how it should be achieved	Performance-based:	Standards focused on output, such as a standard that specifies how a product must perform before it can be sold or used
			Process- (or systems / management) based:	Standards focused on the systems and processes employed by organizations. For example, a standard that asks management to account for the processes and systems in place that ensure regulatory compliance, usually through detecting, assessing and addressing sources or harm and risk
			Principle-based:	Standards that express the outcome to be achieved as a principle, usually expressed at a higher level of abstraction, such as in environmental regulation where the outcome is frequently expressed in terms of 'ecologically sustainable development' or in financial regulation where there is a requirement to act 'with integrity'

**These are ideal types; in practice one may come across blended forms*

3. *Scholars of regulation may recognize the similarity of the labels 'prescriptive', 'outcome-orientated' and 'process-orientated', for these are also used to differentiate between different regulatory styles (see Gilad, 2010; May, 2007). Confusingly, in the regulatory style typology 'process-orientated' regulation is placed in a different category than 'outcome-orientated' regulation. For the typology of regulatory standards 'process-based' standards do fit the outcome-orientated category, because even regulation that targets processes, systems and management needs standards, in the form of guidelines, protocols and so forth, that communicate what is expected of the regulatee.*

There are many ways in which all these (nested) standards can be categorized (see Baldwin et al., 2012; Timmermans & Berg, 2003). Windholz (2018) provides an overview of these categorizations, summarized in table 1.1. Generally speaking, Windholz explains, standards can be divided into two categories: their legal operation (whether they are mandatory or consensual) and their character and application (whether they are prescriptive or outcome-orientated; and whether they apply to inputs, outputs, processes or principles (Windholz, 2018, p. 154). For the purpose of my exploration, the exact labels given to these ideal types are not that relevant – as I am particularly interested in what standards (can) do – but it is useful to have an appreciation for the many different types of regulatory standards that one can come across in the field.

Scholars argue that the type of regulatory standard(s) will coincide with the approach of regulation, i.e. the enforcement style used by the regulator. For example, where there is a standard, such as a guideline or checklist, prescribing the outcome to be achieved in great detail it becomes relatively easy for a regulator to monitor if a regulatee is complying to the rules (Gilad, 2010), making strict compliance or command and control regulatory styles possible. When there are performance- or principle-based standards in place, the regulator will likely opt for a more cooperative regulatory approach, with a focus on dialogue and stimulating the desired behavior (Braithwaite, 2011; Legemaate et al., 2013). In practice – driven by the increasing complexity of high-performance industries such as oil and gas, nuclear power and healthcare – research has shown, regulators have moved away from this classical divide between strict disciplinary enforcement approaches on the one hand and cooperative styles on the other. Rather, they use more responsive or process-based regulatory styles that combine these approaches (Ayres & Braithwaite, 1992; Gilad, 2010), and develop or are guided by a combination of mandatory, consensual, prescriptive and outcome-orientated standards to steer and monitor the desired behavior (Gilad, 2010; Levi-Faur, 2011; Windholz, 2018).

Clearly then, standards are a central element of regulation and regulatory activities in terms of securing compliance and steering behavior. What has received less explicit attention in regulatory scholarship, is the fact that standards are often also introduced as a 'trust device' (Halffman, 1998; Porter, 1996). That is, they are instituted to standardize a regulator's work processes, with the aim to professionalize and objectify work practices, to prevent regulatory capture, create traceable outputs and limit inter-inspector variation (see chapter 3). Importantly, both the idea that standards steer the behavior of regulatees to meet the regulatory objective, as well as standards dictating the behavior and work processes of the regulator, presume the ability of a standard to regulate behavior and work, in a more or less linear motion. But, as I have argued, it is unclear if and how such effects come about. This is problematic for regulatory authorities – usually publicly funded – that, stemming from the increased socio-political demands for accountability and control (Power, 2000), are pressed to account for their activities and produce (measurable) results (Leistikow, 2018; Robben, 2010; WRR, 2013). Accordingly, it is relevant to study the consequences of standards that are used, for regulators and regulatees alike.

There are of course many ways in which standards can be studied. In my analysis I am particularly interested in the norms, principles and expectations that are inscribed in regulatory standards and their performative effects. To further unravel these 'workings' of standards I therefore use the concept of 'script', which is discussed next.

Studying standards using a script approach

> "What can be studied is always a relationship or an infinite regress of relationships. Never a 'thing'." (Bateson, 1978, p. 249)

The script metaphor has been developed by Madeline Akrich, who – influenced by Bourdieu's work on designers as "cultural intermediaries" (Bourdieu, 1984) – argues that technical objects embody social relationships and are not neutral as they produce 'things' like expectations, norms and related actions (Akrich, 1992; Oudshoorn, Saetnan, & Lie, 2002). The approach has been applied in

the field of Science and Technology Studies on the level of single products (e.g. household appliances) mainly with respect to usability and gender questions[4] (Jelsema & Knot, 2002), but I feel the concept is also useful to enable further insight in the workings of standards. Let me explain.

Akrich theorizes that in the design and creation phase of a product, the makers anticipate the interests, skills, motives and behavior of future users. Subsequently, these representations of users become materialized into the design of the new product; which results in a script or scenario. The script attributes and delegates specific competencies, actions and responsibilities to users, and as such directs (human) action in a certain direction and constrains it in others (Akrich, 1992; Jelsema & Knot, 2002). Safety belts in cars, for example, are inscribed with the principle that driving a car must be done safely.[5] They have been designed to force car drivers to use the belt: the car will sound a difficult-to-ignore alarm if the driver has not fastened the seatbelt. The responsibility for the safety of the driver is thus delegated to the automatic system (Latour, 1992), and through the programmed incentive (the alarm), the designers encourage drivers to buckle up. In practice though, it may well be that no actors will come forward to play the roles envisaged by the makers, due to their external environment, by internalizing societal views or due to personal circumstances (Wilson, 2002). Or, like in a real filmscript, the actors may define and enact their role quite differently than the screenwriter or producer had envisioned. For instance, if a car driver cheats the system, and clicks the belt into the buckle without first crossing it along his/her chest and lap. This is called de-scripting (Akrich, 1992, p. 208; Oudshoorn et al., 2002, p. 477), and will cause a product to be used in another way than originally intended. Clearly then, the actors as well as their external surroundings have an active role in the shaping, development and application of an object (Wilson, 2002).

4. *But, see: Vennik, Adams, and Putters (2015) for an analysis of how 'active patients' are inscribed in the development of assistive online medical technologies, such as patient websites.*
5. *Who would disagree?*

Like technical objects, I propose that a standard is not a lifeless "thing" (Bateson, 1978), for it carries norms and assumptions about its addressees; it (or the standard maker) intends to direct human action into a certain direction and sets boundaries by posing inclusion and exclusion criteria (Lampland & Star, 2009; Ponte et al., 2011; Timmermans & Epstein, 2010). In healthcare for example, performance indicators specify what should be monitored (and what not), how it should be measured, and as such – albeit implicitly – how an actor should perform. The indicator holds a specific meaning or significance for a regulatory body (as performance data, for instance), but it may hold a different meaning, or be performed differently by regulatees. Using a script approach when studying standards, can help us to unravel these differences, and as such aid us to better understand how standards work and produce effects.

In sum, what we gain from the script metaphor is that it allows us to conceptualize standards as relationally enacted (regulatory) instruments, that are not unitary, static or stable but open for various interpretations that are locally enacted (Oudshoorn et al., 2002). Not only their design, but also how they are used in practice matters for what they 'do' and what their consequences are. As such, to study standards and gain an insight into their consequences, it is helpful to – empirically – study the standard makers, the users and context(s) in which the standards are used. Or, in other words: to understand the consequences of a standard, I pose, implies knowing its script, and the enactment (including the non- or altered use) of this script in a specific context.

Let me now continue by highlighting some relevant details of, and developments in, the research setting, i.e. the Dutch healthcare sector, to acquire a general feel for this context.

The Dutch healthcare sector and role of the Dutch Health and Youth Care Inspectorate

> "Quality of care is not so much the product of the requirements that have been set by the legislator, rather it is the outcome of the way in which the healthcare provider has organized its services." (Parliamentary documents House of Representatives II, 1993-1994, 23 633, 3, p.3, cited in Legemaate et al., 2013, p. 52)

Healthcare sectors, as well as the regulatory bodies that operate within these sectors, are constantly influenced by political and societal developments (Jordana & Levi-Faur, 2004; Legemaate et al., 2013; Robben, Bal, & Grol, 2012). Accordingly, it is appropriate to sketch out a brief contextual backdrop of some important recent developments.

Dutch healthcare compares well on an international level. As in any healthcare sector, there are significant challenges but overall accessibility is good, the quality in many areas is above average and the care costs – although high – are in line with those of neighboring countries (Björnberg & Phang, 2019; EU, 2019; Robben et al., 2012, p. 11). The healthcare regulator, the Inspectorate, is part of but operates independent from the Ministry of Health, Welfare and Sports. It oversees and regulates all Dutch healthcare providers and professionals, as well as all medicines, medical devices and medical technologies (see also box 1.1). It is legally mandated to use enforcement measures if regulatees do not comply, but is also tasked to provide advice and promote good and safe care (IGZ, 2016d; Leistikow, Mulder, Vesseur, & Robben, 2017). For an important part, the contours of the current healthcare sector, including the role and responsibilities of the Inspectorate, stem from several significant socio-political developments and care quality policy reforms that have taken place over the last two decades[6] (Dute, 2015; Legemaate et al., 2013; Robben et al., 2012).

6. *For a comprehensive overview of historical developments and reforms of the Dutch healthcare sector see Schäfer et al. (2010) and Boot (2013).*

In the nineties of the last century, the Dutch legislator passed three[7] healthcare related laws that reflected a changed way of thinking with regards to who is legally responsible for organizing and maintaining the quality of healthcare (Legemaate et al., 2013). Where previously the government set and monitored basic quality norms, now (the directors of) healthcare organizations as well as healthcare professionals were made responsible for the quality of care provided (Dute, 2015, see also opening quote). Important to note here, is that these new laws were effectuated as a result of widespread frustration about the 'old situation' (Legemaate et al., 2013, p. 53). That is, the development and monitoring of quality norms became increasingly difficult and time consuming, for the required expertise – particularly considering the ever increasing complexity of care – essentially lies within the healthcare sector (Dute, 2015, p. 79). Moreover, these laws also exposed the gradual advent of New Public Management (NPM) reforms, that apply business-like models and market logics to public service provisions, effectively putting (central) government at a distance (Legemaate et al., 2013; Simonet, 2008; Van de Bovenkamp, De Mul, Quartz, Weggelaar-Jansen, & Bal, 2014). As an effect, regulation becomes more important to compensate or bridge this distance (Power, 2000). And, indeed the Inspectorate's disciplinary armory, i.e. its legal enforcement instruments, were expanded to be able to act more forcefully if regulatees did not take up their (new) responsibilities (Legemaate et al., 2013).

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7. Namely: (1) Medical Treatment Agreement Act (Wet Op de Geneeskundige Behandelingsovereenkomst, WGBO), which regulates the right to information, consent for medical treatment and access to medical files; (2) Individual Health Care Professions Act (Wet op de Beroepen in de Individuele Gezondheidszorg, Wet-BIG), which sets out rules and norms to protect patients against unprofessional and careless care by health professionals and articulates disciplinary rules when misconduct has occurred. It included the establishment of the publicly accessible BIG-registry where all healthcare professionals must be registered; (3) Quality of Health Services Act (Kwaliteitswet Zorginstellingen, KWZ), which regulates the quality policy of organizations providing healthcare (Kroneman et al., 2016). Successor of the KWZ, the Healthcare Quality, Complaints and Disputes Act introduced in 2015 (Wet Kwaliteit, Klachten en Geschillen Zorg, WKKGZ) still echo's the idea that healthcare professionals are responsible for good quality of care.

In a continuation of the NPM-spirit, in 2006, a major reform of the Dutch healthcare sector – which was almost twenty years in the making – came into effect. The Health Insurance Act (*Zorgverzekeringswet, Zvw*) was introduced, instigating compulsory health insurance for all Dutch citizens and managed competition for healthcare providers and health insurers. The philosophy was to introduce more market mechanisms in order to create incentives for a more efficient organization of the healthcare sector and to curb the increasing healthcare expenditures (Schäfer et al., 2010, p. 171-172). As an effect the role of the government changed further: from direct control of volumes, prices and productive capacity, to merely setting the 'rules of the game' and supervising whether markets are working as intended (Schäfer et al., 2010). Health insurers, healthcare providers and citizens became the market players with central government safeguarding overall accessibility, efficiency and quality of care from a distance; at a system level (Kroneman et al., 2016; Van de Bovenkamp et al., 2014). In theory the role of the Inspectorate would not change, for the healthcare field still remained responsible for providing healthcare quality (Legemaate et al., 2013). In practice however, the Inspectorate – as well as other regulatory bodies – were increasingly pressed to provide measurable results and account for their work, fueling the need to standardize work, be consistent and transparent (Robben, 2010; Robben et al., 2012). The fact that the Dutch governmental regulation of healthcare quality is entirely funded by public resources, or, put differently: the state forces all citizens to pay for regulation by imposing taxes (Leistikow, 2018), arguably intensifies the Inspectorate's necessity to demonstrate its effectiveness and efficiency.

The last, and most recent development that has greatly influenced the healthcare sector and subsequent regulation, is the patient safety movement and increased focus on safety, as an integral element of quality of care (Dute, 2015; Grit et al., 2018; Legemaate et al., 2013). The roots of this movement and thinking stem from the publication of the influential report "To Err is Human" (Kohn, Corrigan, & Donaldson, 1999). The report revealed that in American hospitals at least 44,000, and possibly even 98,000 patients, die on a yearly basis as a result of preventable error. Aside from the shockwave and increased media

attention for adverse events in healthcare (Dute, 2015; Legemaate et al., 2013; Millenson, 2002; Palmer & Murcott, 2011), the report triggered a new way of thinking about risks, the definition of, and pre-conditions for quality and safety in healthcare (Rowley & Waring, 2011). Central to this new way of thinking is the so called 'systems approach', that argues to look at the organizational factors that underpin unsafe healthcare and/or mistakes, rather than blaming and prosecuting individuals that have made a mistake within the (bad or dysfunctional) system (Kohn et al., 1999; Leape & Berwick, 2005).

The patient safety movement[8] and system-based thinking gradually spread around the world, including the Netherlands, and have influenced regulatory practice in two fundamental ways. First, the increased (media) attention for adverse events and risks in healthcare (see also chapter 2) has put the spotlight on the Inspectorate and its functioning; fueling calls for more and stricter regulation of healthcare providers (Dute, 2015; Legemaate et al., 2013). Second, it changed the focus of the Inspectorate's regulation and regulatory approach; what has caused the safety incident or problem is deemed more relevant and useful to examine than who[9] has caused the incident. Today, the Inspectorate has strongly embraced the idea that safety incidents and human errors made within the complex realm of healthcare are inevitable, and should be embraced as learning opportunities to continuously improve the quality and safety of healthcare (IGZ, 2016d). This idea is reflected in the standards that have been developed by the Inspectorate to stimulate and monitor organizational learning in the wake of an adverse event. It is these standards then, that lie at the heart of my research, as I wonder how they have influenced work processes for both the regulator and regulatees, as well as the organizational learning of regulatees.

8. *Interesting detail: until 2003 there was no Dutch word for 'patient safety' (patiëntveiligheid) (Leistikow, 2019) and the word was thus also not used in legislation.*
9. *Naturally, 'who' is still relevant in the case of grave and/or deliberate misconduct.*

The Dutch Health and Youth Care Inspectorate's introduction of standards for learning

In reaction to the afore sketched developments, in 2013 the Inspectorate[10] introduced a regulatory framework to stimulate and monitor learning from safety incidents. For the Inspectorate's regulation of adverse events (see box 1.1 for a description and definition of 'adverse events'), an intricate scoring instrument and monitoring system was developed that assesses how healthcare organizations learn from adverse events (Leistikow et al., 2017). A supplementary guideline and protocol to inform healthcare organizations what they should do in the wake of an adverse event (i.e. in what way the adverse event should be investigated and who should be involved) was also introduced (IGZ, 2013a; 2014, and see chapter 3 for a detailed description of all these standards and chapter 5, box 5.2 for an illustration of the checklist). Importantly, the introduction of these standards not only intended to steer and monitor the behavior of regulatees. For, following long lasting media coverage of several high-profile incidents (see chapter 3), the new regulatory framework was also introduced to discipline the Inspectorate's own work by professionalizing the work of individual inspector's, to limit their discretion, prevent regulatory capture and to create traceable outputs and speed up work processes. The dual role of these standards makes the Inspectorate's regulation program for adverse events a good setting to empirically explore the consequences of standards on behavior and organizational learning.

10. *As Walsh and Boyd noted, the terms regulation and inspection are often used interchangeably, and are defined and applied differently in different countries and sectors. Many organizations that fit the definition of a regulatory authority – as worked out above – are called 'Inspectorates'. This may give the incorrect impression that 'inspection' is all the regulatory authority does. Inspection or inspecting is a process that usually – but not always – forms part of the armory of a regulatory authority, conducted alongside many other types of activities like providing advice or taking disciplinary measures (2007, p. 8).*

Box 1.1. The Dutch Health and Youth Care Inspectorate

The Dutch Health and Youth Care Inspectorate (HYCI)

The Dutch Health and Youth Care Inspectorate (Dutch: *Inspectie Gezondheidzorg en Jeugd* or *IGJ*, in this thesis 'HYCI' or 'Inspectorate') is the national regulatory authority tasked with overseeing and regulating all health and youth care providers as well as healthcare professionals in the Netherlands. The Inspectorate was formally formed in 2018 with the merger of two regulatory authorities: the Dutch Healthcare Inspectorate (Dutch: *Inspectie voor de Gezondheidzorg* or *IGZ*) and the Dutch Inspectorate for Youth Care (Dutch: *Inspectie Jeugdzorg* or *IJZ*). In 2019 the Inspectorate employed a workforce of 754 persons (fulltime-equivalent) and was publicly funded with a year budget of 89 million euros (IGJ, 2018c).

Like most regulators, the Inspectorate regulates based on the premise that the compliance to laws, rules and norms is a prerequisite to minimizing risks, and by monitoring regulatee compliance the quality and safety of healthcare is promoted and maintained (Leistikow & Robben, 2016; Robben, Grit, & Bal, 2015). As such, the Inspectorate depends on the existence of laws, rules and norms to be able to do its job; securing compliance is only possible when there are standards – that embody these rules and norms – to comply to. Where there are no clear rules or norms the Inspectorate stimulates the field to develop these and materialize these in the form of practice guidelines, etc., so it can develop a regulatory framework (i.e. criteria checklists) to assess if the field norms are adhered to, and sanction in the case of non-compliance (Leistikow & Robben, 2016).

Due to the vastness and complexity of the healthcare sector, as well as its limited resources, the Inspectorate concentrates its regulatory focus on the greatest risks for patients and/or clients. To assess which risks are most prominent and warrant attention the Inspectorate has two regulatory programs in place: risk-based regulation (*risicotoezicht*) and adverse event regulation (*incidententoezicht* or *calamiteitentoezicht*, as it is referred to more recently). Both programs collect information that inform the Inspectorate's risk assessments and subsequent actions, but this information is retrieved in different ways.

Determining risks: risk-based and adverse event regulation

Risk-based regulation refers to those activities through which the Inspectorate periodically collects information to assess risks, present in individual organizations as well as the healthcare sector as a whole (IGZ, 2016d). For the regulation of hospitals, most of the information is collected through a set of outcome indicators, defined by professional organizations and other field organizations (Wallenburg, Mol, Harmsen, & De Bruijne, 2018). Risk-based regulation is seen as 'proactive' in nature, as through the monitoring of indicator scores, the Inspectorate attempts to minimize risks, before harm has taken place (Leistikow & Robben, 2016). Adverse event regulation refers to the Inspectorate's (reactive) activities in relation to adverse events. This program is described next.

Definition and regulation of adverse events

In 2018 it was estimated that adverse event based regulation takes up about half of the capacity of the Inspectorate (Bal, Leistikow, & Stoopendaal, 2017; Grit et al., 2018). Dutch law defines an adverse event as an unintended and/or unexpected event related to the quality of care, having caused the death of, or serious harm to the patient (Buijsen, 2014). Healthcare providers are legally mandated to report an adverse event to the Inspectorate, investigate what happened along the lines of the Inspectorate's set guidelines, and formulate improvement measures. The Inspectorate assesses the investigation report to determine if the healthcare organization has learned from the event. Moreover, it uses the reports to identify structural risks to patient safety, at the level of individual healthcare organizations and the healthcare sector more broadly (IGJ, 2018c). In case of grave misconduct, a very serious or high-profile event or initial unsatisfactory investigation, the Inspectorate may conduct or follow-up with its own inquiry.

The ideals of being open about safety incidents ("for if it is not visible, you cannot improve it" (Leistikow & Robben, 2016)) and learning from safety incidents, to further quality and safety and maintain public trust in the healthcare sector, lie at the heart of this regulation program. Importantly, though, it also shelters two more underlying goals. Namely, to correct and prosecute in the case of misconduct and to provide accountability and transparency to the patient, their loved ones and society at large (Grit et al., 2018).

RESEARCH AIMS AND QUESTIONS

This book aims to add to our understanding of the consequences of standards on behavior and organizational work practices. By applying the earlier described script approach, the empirical exploration can (1) help further the academic debate on the workings of standards, and; (2) help the practice of regulation by uncovering how the standards that regulators use produce effects.

To this end, my exploration was guided by the following overarching research questions:

1. What script has been inscribed in the regulatory standards that are used in the regulation of adverse events?
2. How is this script enacted by the regulator (the Inspectorate) and regulatees?

3. What are the consequences of this script and the way that it is enacted, for the actors involved and for organizational learning in hospitals?

With regards to organizational learning, I am specifically interested how the script in use influences: what learning is; who must learn and who is involved in that process; and what is seen as valid input for the learning process. In the next section I outline how I have conducted my research.

RESEARCH TRAJECTORY AND METHODS

> "It takes some digging to unearth the dramas inherent in system design creating, to restore narrative to what appears to be dead lists." (Star, 1999, p. 377)

In this thesis each chapter details the specifics of the empirical work and subsequent data analysis approach. There are however also some general points that can be made about the multi-year (2015-2019) research – or "digging" (Star, 1999) – process and methods employed.

The data presented in the empirical chapters was collected alongside as well as part of research projects embedded within the Academic Collaborative Center for Research on Regulation (*Academische Werkplaats Toezicht, AWT*). The AWT was a collaborative where academics from four Dutch research organizations cooperated with (researchers from) the Inspectorate to address and tackle regulation-related queries and evaluate ongoing regulatory programs.[11]

Fitting the earlier addressed script approach – as well as my anthropological roots – I used a flexible research design (Green & Thorogood, 2006; Haverland & Yanow, 2012; Schwartz-Shea & Yanow, 2012), in which not all research steps to be taken were known or established beforehand. This was an intentional and necessary strategy to allow me to be responsive to developments

11. Practice-based research is still conducted at the Inspectorate in collaboration with academic research partners but as of 2020 this no longer takes place under the AWT umbrella.

at the Inspectorate and the healthcare sector more broadly (Schwartz-Shea & Yanow, 2012). What's more, it allowed the fieldwork to support regulation in practice as well as contribute to academic theoretical debates (Bouwman, 2016). As such, I – quite literally – followed this 'standard story' where it took me. With the 'story', then, I do not mean a fixed account that was already there; objectively observable and steady; a story that only needed writing down. Rather, what I mean by 'story' is an unfolding narrative, actively constructed by the questions I asked; shaped through the interactions with my respondents and broader socio-political developments in the field; shaped by my continuous reflections and moments of joint sense-making (Weick, Sutcliffe, & Obstfeld, 2005) with colleagues and supervisors. What you will read then, is the product of an interpretive and iterative research trajectory, whereby both data-collection and analysis preceded in tandem; continuously going back and forth building on insights along the way (Bryman, 2016; Haverland & Yanow, 2012). To strengthen the academic rigor of my work I triangulated different qualitative methods including ethnographic observations, in-depth and informal interviews as well as document analyses (Green & Thorogood, 2006; Schwartz-Shea, 2015).

My digging and the story started with my ethnographic work at the Inspectorate, where I specifically zoomed-in (Nicolini, 2009) on the work done by a team of inspectors and support staff, mandated with the task of monitoring the quality and quantity of inquiry reports sent to the Inspectorate by hospitals. I was guided by the broad aim to document the work processes as done and experienced by these inspectors, in an attempt to understand how the regulation of adverse events 'worked' in practice and what (side) effects occurred. At all times I upheld an overt researcher role (Green & Thorogood, 2006): openly watching, listening, collecting documents, asking questions as the team went about their work, or more casually over lunch and coffee and in the car, when I joined inspectors on inspection visits to hospitals and other types of work-related voyages.

It was here, at the start of my fieldwork within the walls of the Inspectorate, that the relationship with one of my PhD supervisors, an active – and, arguably also well-respected – member of this inspection team, proved invaluable. At times it felt as if I was conducting an at-home ethnography (Alvesson, 2009), for he provided quick insider-knowledge and updates of relevant developments, allowed easy access to (internal) data sources and helped build rapport. Contrastingly, once leaving this 'nest' – as I trailed the story to other research settings – our association became trickier, at times even proved unhelpful. I quickly learned that I would not be welcome – or not welcome enough – in other settings, such as hospitals, if I was associated with the Inspectorate. What's more, to maximize openness and build trust it was important to assure respondents full anonymity; that their organizational names and identities were not shared with the Inspectorate and my supervisor. This situation thus fueled a research-association characterized by a continuous balancing-act between closeness and distance as well as the sharing of in-depth details and anonymized accounts. Monthly meetings with both supervisors to zoom-out (Nicolini, 2009), reflect on our roles, the research developments and unfolding story, helped to make-sense of this 'puzzle' (Haverland & Yanow, 2012).

Using the insights obtained at the Inspectorate, I drafted topic lists for in-depth interviews in diverse Dutch hospitals, about their adverse event investigation routines and their relationship with the Inspectorate. I spoke with quality and safety managers, incident investigators, medical professionals and Board members. Whilst conducting these interviews, there was growing political and societal turmoil as diverse national (news) media platforms publicized an array of dramatic 'bad-news' stories about hospital "death cover-ups" (Wester, 2016), failing patient safety cultures (Zembla, 2015) and silencing-clauses in adverse event settlement agreements with patients (Van Yperen, 2016, and see chapters 2 and 4). The external turmoil and the subsequent unease it was creating inside healthcare organizations, permeated into my interviews and became an important theme. It was clear that the socio-political debate was hitting a nerve inside healthcare organizations. This underscored the sensitivity of the topic at hand; it clearly remained difficult to talk about safety incidents in

an open, safe and non-judgmental setting (Legemaate, 2015). Consequently, I continued to – also – trail this part of the story. With the help of thesis-students I drafted up a media timeline to map the societal debate and I diversified my respondent-sample by interviewing hospital spokespersons, communication officers, news journalists and editors. The reflections of these findings have been drawn up in chapter 2.

For my work on the 'soft signals' AWT research project (chapter 4) – a project that was initiated due to the earlier described media context – I found my way back to the Inspectorate. I conducted follow-up interviews; I interviewed HYCI employees with different roles and from different positions within the organization; and I collected more internal documents on specific soft signals related case studies. This project gave me the unique opportunity to position my earlier findings, on the use and consequences of standards in the regulation of adverse events in hospitals, in a broader framework of regulatory work performed by the Inspectorate. As part of this project I also approached key actors from other national and international regulatory authorities for interviews, to mirror findings and interpretations.

My wish to conduct a 'tracer project', in which I would trail adverse event investigations within a hospital, to the Inspectorate and back, to map and reconstruct all the different stages of the adverse event investigation process, failed to take flight. This ethnographic approach[12] would have suited the endeavor to observe 'work as done' by all the actors involved (Hollnagel et al., 2013). Despite thorough preparations and careful dialogue, a hospital Board 'pulled the plug' on a tracer I was about to start with. In other hospitals the door for such ethnographic research remained closed entirely. The consequences of this for the quality of my analysis will be reflected on the final discussion of this book, chapter 8.

12. *See Ziewitz (2017) for an engaging example of a tracer-type research approach, as he 'followed' or 'traced' online patient postings and reconstructs the journey of accounts of care through different stages of the process.*

Lastly, for two chapters (5 and 7), I teamed up with colleagues, who conducted regulation-related fieldwork within the AWT, in a different part of the Dutch healthcare sector. By sharing our data and insights we were able to further our understanding about the Inspectorate's regulatory work, their use of standards and subsequent consequences.

OUTLINE OF THIS THESIS

It is appropriate to note that the empirical chapters (2-7) have been submitted or published as individual academic articles. Front-to-back readers will find some overlap in the detailing of the methods, and descriptions of the research setting, the Inspectorate's work routine and regulatory framework. At the same time, the chapters build on each other to draw a picture of a complex regulatory field; each chapter zooming-in on different aspects of the use and workings of regulatory standards. This book will continue as follows:

Chapter 2 Patient safety, healthcare and the news media: escaping the standoff, sets the scene (to stay in the script metaphor). The chapter was written as a short essay, that does not specifically discuss the standards or standardized practices we come across in the Dutch healthcare sector but reports on the socio-political climate in which the Inspectorate's regulation of adverse events is enacted. An appreciation for this climate is relevant because we know that regulatory programs, like that for adverse events, are not performed in a social-vacuum (Burgess et al., 2019; Jordana & Levi-Faur, 2004). Scholars have pointed to the influence of the institutional constellation – including the media – on regulatory practice (Jordana & Levi-Faur, 2004). Based on insights obtained throughout the multi-year research project, the chapter unveils the strained relationship between healthcare organizations and the (news) media. It explains how this relationship hampers transparency and open dialogue about the safety incidents that occur in healthcare; precisely the argued for preconditions for reporting, investigating and learning from adverse events (IGZ, 2016b).

Chapter 3 The pedagogy of regulation: strategies and instruments to supervise learning from adverse events, describes, in detail, the introduction of the standards and coupled performance management system in the Inspectorate's regulation program for adverse events. Based on ethnographic observations and interviews with inspectors, this chapter illustrates what theory of learning is inscribed inside the standards that are used, i.e. what it is the Inspectorate wants hospitals to learn in the wake of an adverse event. Moreover, it illustrates how the standards are enacted inside the Inspectorate and sheds light on the consequences of these standards for the Inspectorate's own work practices.

Chapter 4 The doctor was rude, the toilets are dirty: utilizing soft signals in healthcare regulation, outlines the (social)processes and activities that take place inside the Inspectorate alongside its use of formal standards and standardized practices. It shows that 'soft signals' are vital for inspectors to perform their everyday work, as they provide context to the 'hard' data and findings collected in their performance management system, adverse event investigation reports, etc. What's more, it shows that making sense of and assessing risks is not a neutral practice, as it is driven by normative and political choices.

Chapter 5 How incident reporting systems can stimulate social and participative learning: a mixed methods study, discusses how the current incident reporting system, i.e. the institutionalized process of reporting and investigating adverse events as directed by the Inspectorate's regulatory framework, has contributed to social and participative learning in Dutch hospitals. Using quantitative data from the Inspectorate's performance management system, we examined if and on what aspects of the Inspectorate's scoring instrument hospitals improved over time. Following, we conducted semi-structured interviews to reflect with stakeholders (incident investigators, quality managers, etc.) on the actual organizational practices and developed routines behind these figures.

Chapter 6 Patient and family engagement in incident investigations: exploring hospital manager and incident investigators' experiences and challenges, zooms in closer on one of the elements of the Inspectorate's adverse event investigation framework, namely the directive to involve patients and/or their families in adverse event investigations. The chapter explores how hospitals organize patient and family engagement in these investigations and maps out their challenges with involvement. The chapter reveals that even though hospitals do involve patients/their families more, their epistemic contributions are not always seen as valid input for learning from an adverse event.

Chapter 7 Epistemic injustice in incident investigations: a qualitative study, again discusses the practice of multi-voiced involvement in adverse event investigations. Using the concept of 'epistemic injustice' (Fricker, 2009), the chapter reflects on how the standards that have been developed by the Inspectorate (their scoring instrument and incident investigation framework) may favor the contribution of some actors over others, ultimately influencing what is and can be learned from adverse events.

Chapter 8 Discussion: standards and their consequences, reflects on the empirical findings, answers the research questions and discusses the implications of the findings for the theoretical debate on standards and regulatory practice. The chapter shows that standards have the power to regulate behavior and work practices but are not by definition instruments of control. It argues that making a standard 'do' something requires continuous (interpretative and maintenance) work as well as social organization to embed the standard in. Every standard, I conclude, has a unique story.

2

PATIENT SAFETY, HEALTHCARE AND THE NEWS MEDIA: ESCAPING THE STANDOFF

SUBMITTED

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ABSTRACT

In this short essay we address and reflect on the strained relationship between the (news) media and medical professionals with the aim to help healthcare organizations and professionals shape more productive ways of interacting with journalists and prevent some of the harmful ways in which patient safety matters hit the news. Previous studies have illustrated that when it comes to patient safety stories covered by the media, all news tends to be bad news. Fatal adverse events and other serious patient safety incidents frequently garner huge media attention, but success stories rarely do. Many healthcare professionals will recognize that news coverage plays an important role in shaping the political and societal debate on patient safety and healthcare risks. But, in our work we have noticed that many healthcare professionals are unaware about the underlying mechanisms and logic that make the media behave the way they do. This is a problem, especially now healthcare organizations and medical professionals are increasingly expected to be transparent about quality and open about mistakes. Based on our experiences in the Dutch healthcare sector it is clear that healthcare organizations and professionals often feel victimized by the negative media attention and internationally there have been calls for journalists to be 'fairer' and more 'nuanced', but these calls have no effect on the media. Based on insights from our own research and social scientific scholarship, we argue that the field of healthcare must seek to understand media for what it is, rather than what it should be. Misunderstanding the core values of the media has put healthcare organizations and media in a deadlock that is not only harmful for quality improvement but also denies the public a realistic view of healthcare. This essay unravels the logic of the media and we offer recommendations how healthcare organizations can shape more productive ways of interacting with the media. We discuss some best practices to illustrate our claims.

"Being open and transparent ... and building trust has become all the more difficult in light of recent media reporting."

(Hospital Risk Manager quoted in 'Evaluation of the National Open Disclosure Pilot' in Pillinger, 2016)

INTRODUCTION

On April 13th 2018, the first Annual Adrienne Cullen Lecture was held at the University Medical Center Utrecht (UMCU) in the Netherlands. A seminar on open disclosure practices after serious harm. Organized in honor of Cullen, a woman who became terminally ill as a result of mistakes made at the UMCU and – until her recent death – campaigned for transparency and open dialogue surrounding medical error (see Cullen, 2019). Cullen and her doctors addressed the auditorium in turn. They recounted mistakes made in the clinical care and support for Cullen and her family; they shared shortcomings in the support for the involved 'second victims';[13] they spoke of a hospital administration struggling to attend to everyone's needs and interests.

Contrasting the openness of these narratives, the afternoon commenced with an UMCU representative warning the audience not to make audio recordings, take notes or share details of the lecture on social media. There were security guards at each one the main doors, requesting credentials upon arrival. Reporters with cameras were asked to leave 15 minutes into the lecture. And, outside of the auditorium, attendees witnessed a journalist – well-known for his earlier series

13. *The term 'second victims' refers to the healthcare professional(s) that have been involved in an adverse event. They are referred to as 'victims' for they, like the patient, can also be traumatized by the unanticipated event (Wu, 2000).*

on patient safety issues at the UMCU[14] (Zembla, 2015) – in a verbal brawl with the hospital's press officer. The latter threatened to remove the journalist from the vicinity. Their exchange – "No, I won't let you in, because I don't trust you!", "But I am just doing my job!" – was widely publicized that evening. An event that was meant as a showcase of openness instead radiated the strained relationship between healthcare and the media.

Recognizing that media coverage plays an important role in molding the political and societal debate on patient safety (Kasperson, Renn, Slovic, & Bown, 1988; Millenson, 2002; Wiig, Aase, Bourrier, & Roise, 2018), we propose that addressing this troubled relationship is essential. In what follows, we shed light on this relationship, the underlying expectations and work logics, in an attempt to help healthcare organizations and professionals shape more productive ways of interacting with journalists *and* prevent some of the harmful ways in which patient safety matters hit the news. To support our argument, we draw from social scientific literature and insights obtained through our research in the Dutch healthcare sector.

THE STANDOFF

As we live in an age of transparency (Hood & Dixon, 2015), healthcare systems around the world are called upon to be open about medical error and other types of patient safety incidents (CPSI, 2015). Research has shown that being open about mistakes remains difficult (Iedema & Allen, 2012; Pillinger, 2016; Wiig et al., 2018). The media is mentioned as a significant barrier on the road to disclosure (Pillinger, 2016), sometimes even an obstacle to furthering patient safety more broadly (Woodier, 2015). Concerns about (negative) publicity, naming and shaming, hamper transparency and open dialogue (Pillinger, 2016; Schwitzer et al., 2005; Woodier, 2015). Where does the distrust towards the media come from?

14. See also chapter 4; this case served as a starting point for the 'soft signals' research project.

This question requires a layered answer. First, traditional news media, such as newspapers, TV and radio, are generally argued to have a powerful position in society. Not only as sources of entertainment and platforms for distributing information, but also in their position of setting the (political) agenda and shaping public opinion (Hjarvard, 2008; Klijn, Van Twist, Van der Steen, & Jeffares, 2014). With the emergence of social media, this powerful role has amplified, posing all sorts of risks – as well as opportunities – for healthcare users, organizations and professionals (Harcup & O'Neill, 2017; Hjarvard, 2008; Klijn et al., 2014). Studies have shown that patient safety stories frequently garner huge media attention, especially when things have gone wrong (Palmer & Murcott, 2011; Stebbing & Kaushal, 2006).

Second, reflecting on the influence of media on healthcare, it has been noted that media coverage of patient safety issues has played an important role in prompting professional and governmental responses to patient safety failures (chapter 4; Millenson, 2002; Palmer & Murcott, 2011; Wallenburg, Kok, & Bal, 2019; Wiig et al., 2018). At the same time, the field of healthcare has voiced frustration about the media's tendency to focus on a small number of high-profile scandals and incidents, as well as the style and manner in which they report (Jackson & Harper, 2001; Nelkin, 1996; Woodier, 2015). All of which – some have argued – can ruin reputations, erode public confidence, amplify risk perceptions and cause distress among healthcare users and staff alike (Kasperson et al., 1988; Schwitzer et al., 2005; Woodier, 2015). UK headlines referring to Hadiza Bawa-Garba as a "killer doctor"[15] (Fricker, 2015), or a Dutch newspaper accusing a hospital of an attempted "death

15. *Junior doctor Hadiza Bawa-Garba treated a 6 year-old-patient, who was admitted to an NHS Trust early 2011. The patient died later that day, in part because of failings in his treatment. Bawa-Garba was found guilty of manslaughter on the grounds of gross negligence. The case was fuel for debate about a doctor's culpability versus a context of system failures (that day notably the work pressure and understaffing at the NHS Trust) (Pasha-Robinson, 2018).*

cover-up"[16] (Wester, 2016) after the unexpected death of a 21-year old male, arguably make this frustration conceivable. For, even if these stories provide context, such headlines point fingers, shame and blame. They overlook the complexity of healthcare systems and underscore the widespread myth that doctors – and their leaders – should be infallible (Jackson & Harper, 2001).

Third, the distrust towards the media quite possibly also stems from some of the strategies journalists employ to construct their stories and approach their sources. In healthcare literature these strategies have rarely been publicized, but in our qualitative research on the regulation of patient safety in the Dutch healthcare system frustration about, and the impact of, media reporting and journalists' behavior were recurring themes. Our interview respondents (hospital communication officers, quality and safety managers, medical professionals) disclosed their correspondence with journalists, unveiling the intimidating behavior and demands that they are confronted with. Interestingly, the journalists and news editors that we interviewed were very candid about the – at times manipulative and aggressive – tactics they sometimes use behind the scenes. See the interview excerpt in box 2.1 as an illustration (quote used with permission). Journalists too, as box 2.1 reveals, feel frustrated about their relationship with healthcare organizations. They argue that the sector's lack of transparency, defensive and elitist culture block public scrutiny and hampers the production of contextual (news) stories that further public understanding. Mutual distrust and frustration then have positioned both parties into a standoff; the guns are raised hindering open communication.

16. *In 2014 a 21 year-old-patient died unexpectedly after being admitted to the Tergooi-hospital in Blaricum. Whether his death was an adverse event that should have been reported to the HYCI was broadly discussed in the media. Initially the hospital had not reported the event to the Inspectorate and was publicly accused of covering up patient safety incidents (Meurs, Danner, Legemaate, & De Lint, 2016; Wester, 2016).*

Box 2.1. Journalistic tactics from behind the scenes

The interview excerpt below illustrates the manipulative journalistic tactics that a Dutch healthcare organization was confronted with; an organization that was not the main subject of inquiry. In this specific case, journalists were working on an extended item on safety culture in healthcare. A respected physician – well-known for his work on this matter – was enthusiastic and agreed to an interview. He requested the journalists to arrange the interview via the hospital's Communication Office, which they did:

> Suddenly our source no longer wanted to contribute to the item we were making. The hospital's Communications Team let us know he had camera phobia. So, I was like, 'Okay, then I guess we'll do it without him; we'll look for someone else to help us with our story.'
>
> But then, we found out, via other informants, that there was a quarrel at this hospital. More specifically: a dispute at the department where this source worked. We thought: 'Aha! So that's what's going on!', 'Now we're going to go after you, Communications Team!'
>
> So, I sent them [Communication Office] an email. I wrote: "We [journalist and his colleague] really want to work on constructive stories in which we provide context. To be able to do that we need informants. Please disclose your medical and academic knowledge. But your hospital is not doing that." And then – and this is what I call the media politics – I add to the email: "We know about the dispute; we want an explanation before noon tomorrow. What's going on? You better let us know! We have already informed other parties; we have inquired after this matter at the Health Care Inspectorate [regulator] and we have shared our intelligence with another news platform." Indeed, we do inform other news stations, so everyone will know that if this hospital comes with an official press release, it was because we were asking questions.
>
> Now, I'm sharing this with you to illustrate how strained our relationship is with the medical world. They [healthcare organizations] are scared. So scared when we call. ... I do think, in part, we have ourselves to blame for that. I guess the media do sometimes have a tendency to overdramatize.

(Anonymized excerpt interview with journalist 15-06-2016, audio-recorded and used with permission)

DIFFERENT LOGICS AND SOCIETAL ROLES

The healthcare-media standoff reflects underlying expectations about each other's roles and responsibilities. As 'watchdogs' many journalists feel transparency is fundamentally important from a democratic perspective (Wiig et al., 2018); the public simply has a right to be fully informed and make informed decisions (Susskind & Field, 1996). Echoing the ideals of today's 'transparency society' (Han, 2015), they thus demand performance accountability from (semi) public organizations, particularly when things have gone wrong. Healthcare practitioners – in line with the hospital staff we interviewed – feel the media have the responsibility to educate the public about the complexities of healthcare but call on the media to be more representative and nuanced, and weigh the possible effects of (negative) patient safety stories on individuals as well as the public at large (Jackson & Harper, 2001; Schwitzer et al., 2005; Woodier, 2015). These calls reflect a normative assumption that it is indeed a journalist's (first) obligation to educate and inform in a manner and tone that is attuned to healthcare standards (Nelkin, 1996; Palmer & Murcott, 2011).

Just like healthcare professionals, journalists have a job to do; a job that is performed within a specific reality, along the lines of cultural and organizational principles and standards (Susskind & Field, 1996). However, media follow a different logic than healthcare organizations do. Practices in healthcare tend to be methodological, slow, highly complex and are preferably 'evidence-based' (Schwitzer et al., 2005). Moreover, healthcare professionals often have a responsibility to follow-up on the information that has been provided and are responsible for – or at a minimum feel concerned about – the outcome of the message they have shared, for this can have a direct influence on someone's (future) health. These principles are not necessarily the same for the news media (Entwistle, 1995; Nelkin, 1996).

Whilst journalists come in all shapes and sizes, and media platforms differ, the news media functions along a common logic that drives the way news stories are constructed and told (Klijn et al., 2014). Journalists face constraints and

(commercial) pressures: short deadlines, fierce competition and they must write stories that fit short TV slots or limited newspaper space (Entwistle, 1995; Klijn et al., 2014; Millenson, 2002; Schwitzer et al., 2005). A journalist's key objective is to be read or heard and shared in other media (Entwistle, 1995; Nelkin, 1996; Palmer & Murcott, 2011) and they are therefore pressed to engage the audience using a set of 'news-values' (Harcup & O'Neill, 2017). News-values refer to the characteristics of a story that make it particularly newsworthy (Galtung & Ruge, 1973). These include stories that contain – amongst others – elements of personal drama, bad news, conflict, surprise, hold relevance and familiarity for the audience and/or feature the power-elite. Moreover, the story is preferably 'sharable' and easily 'liked' online (Harcup & O'Neill, 2017).

When reflecting on these values, it is evident why stories about patient safety failures receive considerable coverage (Palmer & Murcott, 2011). From a media perspective, patient safety incidents hold in them clear drama, they are by definition bad news and there is a surprising conflict and element of surprise because the system in which the audience has placed their faith as a source of healing and care instead turned out to be a source of grave personal risk (Palmer & Murcott, 2011, p. 22). Also, patient safety incidents frequently star the 'the power elite'; individuals and organizations that the public depends on. In practice we also know that healthcare stories sell (Schwitzer et al., 2005), they are easily dramatized and personalized with photographs and witty headlines, and as such also highly sharable online. What's more, patient safety incidents hold relevance to the public at large because everyone comes into contact with healthcare at some point in their lives.

Based on this logic it is evident that depersonalized, highly contextualized and complex stories will not sell, or not sell as well. Acknowledging 'the rules' of a journalist's 'game', and working with these rules, instead of against them, will likely produce more productive means of interaction.

A WAY FORWARD

Fortunately, as we wish to move forward and break the standoff, there are good examples out there that illustrate how healthcare organizations can 'work' with the media to inform and educate the public about the complex reality that is healthcare. In box 2.2 we have summarized two 'best-practice' cases from our experience in the Dutch healthcare system. Case 1 discusses the pro-active and open communication by a hospital in the face of an anesthesia crisis. Seven patients fell seriously ill and there was enough fuel there for largescale public distrust and reputational damage but instead the hospital was praised for its transparency. Case 2 illustrates an effective approach employed by an elderly care facility in the face of national negative publicity when its name was published on the health regulator's poor performance 'blacklist'. Instead of defending themselves, leaders and staff worked with journalists and invited them 'in' to allow journalists to document and televise the structural challenges facing elderly care. The series prompted a more nuanced public debate about 'good' and 'bad' service performance.

Based on these best-practice examples, literature and the insights obtained through our interviews, we have formulated four recommendations for healthcare organizations and professionals (summarized in box 2.3). These recommendations will not prevent all harmful patient safety stories from hitting the news, but they can help to mitigate some of the structural mechanisms that fuel the current healthcare-media standoff.

First, be proactive in sharing good and bad news. Only actively seeking out to the press when wishing to publicize good news or advances in patient safety, creates an unreal and suspicious aura of infallibility, that can come crashing down hard when there is a crisis (Susskind & Field, 1996). Being proactive can help to build public trust and credibility, breaking down the stereotypical view that healthcare organizations house and nurture elitist, closed cultures.

Box 2.2. Best-practice examples

Case 1: Proactive communication during 'Propofol crisis' at a general hospital

In 2008 seven patients fell seriously ill after undergoing routine surgeries at the Havenziekenhuis in Rotterdam (Buikema, 2011). It took the hospital's crisis team and external investigators almost a week to uncover what had made these patients sick; a medical error had been made. The sedation agent, Propofol, administered for general anesthesia was contaminated with bacteria after it had been stored improperly. Shortly after the first mysterious illness case was reported, the hospital informed the press proactively and as the investigation was ongoing, daily press conferences were held to keep the public updated on developments. Rather than being blamed and shamed, the public praised the hospital for their openness and none of the involved patients issued a formal complaint or took legal action.

Case 2: Furthering public understanding about the complexities of elderly care delivery while in the spotlight

In 2016 the Dutch minister of Health ordered the national healthcare regulator, HYCI, to publish a 'blacklist' of underperforming elderly care facilities. The list caused controversy: the public was concerned about the quality of care (are my parents safe?), the named organizations felt betrayed and their staff felt victimized. The Executive chairman of Humanitas, one of the organizations on the blacklist, invited journalists over to one of the care facilities. On camera the chairman acknowledged that Humanitas' services needed to improve and that he and all the staff were working hard to so (EenVandaag, 2016a). He requested the public to follow them on their path to improvement. This invitation translated into a 4-part televised series. Humanitas' employees were filmed during their daily work routines, and the public gained an insight into the struggles and dilemmas surrounding quality of care and patient safety. At the end of the series, the audience witnessed Humanitas' Executive Board and staff, clients and their families as well as the journalists raise champagne glasses to celebrate their blacklist-removal.

Second, be clear and open about things that have gone wrong or could have gone better (CPSI, 2015; Palmer & Murcott, 2011). And, in the spirit of full transparency also be forthcoming about things you do not know (yet), for reassurances or unsupported claims of certainty are often rated as worse than a "I don't know" (Susskind & Field, 1996). Not being open or honest and not providing the necessary context, can trigger – as we have shown – journalists to look for conflict or failure and vigorous journalists are likely to discover anything you have not been transparent about and report about it out of context (Susskind & Field, 1996). This risks you to take up a defensive tone, wasting time and resources on damage control.

Third, treating the media like enemies will create a self-fulfilling prophecy (Palmer & Murcott, 2011; Susskind & Field, 1996), so invest in building honest relationships with journalists to minimize distrust across the board. Respecting and understanding their interests, independence, work routines, possibilities and impossibilities, can help to communicate and work together in a less toxic atmosphere. Also, knowing who to confide in when dealing with delicate matters simply makes life easier.

Fourth, invite journalists in to familiarize and educate them – and through them the public – about the complexities of your organization, work processes and healthcare delivery more generally. This can help to tone down unrealistic expectations and raise public understanding of the complexities of care. Allowing journalists to come up close, provides them an insight into the hard work by dedicated staff, who face personal and professional challenges and make mistakes, like any other human being.

Box 2.3. Key messages

To shape more productive ways of interacting with journalists *and* prevent some of the harmful ways in which patient safety matters hit the news, healthcare organizations and staff should attempt to:

- **Be proactive** in sharing good *and* bad news;
- **Be open** about things that have gone wrong and be forthcoming about things you do not know (yet);
- **Invest in building honest relationships** with journalists to minimize distrust across the board;
- **Invite journalists in** to familiarize and educate them – and through them the public – about the complexities of healthcare.

3

THE PEDAGOGY OF REGULATION: STRATEGIES AND INSTRUMENTS TO SUPERVISE LEARNING FROM ADVERSE EVENTS

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ABSTRACT

Diverse scholars have argued that standards and performance measurements are instruments of control that have a profound influence on the day-to-day lives of individuals and organizations, causing constitutive effects. Regulatory bodies increasingly use standards to oversee and monitor the regulated. This chapter discusses the Dutch Health and Youth Care Inspectorate's use of standards and a coupled performance measurement system introduced to monitor how Dutch hospitals investigate and learn from adverse events. Rather than focusing on how standards affect regulated practices and organizations, our study examines how the use of these instruments affects the standard maker, that is, the Inspectorate. We explore how the Inspectorate's work practices, standards, and coupled performance measurement system influence its regulatory pedagogy, reviewing practices, and decision making. We conclude that standards and performance measurement systems are not by definition instruments of control as their constitutive effects are (under)determined by the relationships in which they are enacted.

"Making mistakes is inevitable, not learning from them is unacceptable."

(Long-term policy plan, Dutch Health Care Inspectorate 2016–2019, citing Sir Liam Donaldson, England's Chief Medical Officer, 2004, cited in IGZ (2016d)

INTRODUCTION

A growing number of social scientists argue that both standards and performance measurements are highly relational (Lampland & Star, 2009; Porter, 1996), shaped in a process of collective sense-making (Garfinkel, 1967; Weick, 2001). Although widely used as instruments of objectification, standards and performance measurements are in themselves interpretations that set their own political and normative effects in motion and demarcate the way in which the world is defined (Bowker & Star, 1999; Dahler-Larsen, 2014). As a consequence, the use of standards and performance measurements has constitutive effects in that they constitute the very practices that they measure.

Originally introduced by Dahler-Larsen (2012; 2014), the concept of constitutive effects refers to the many subtle and not-so-subtle ways in which evaluation machines steer certain values, orientations, interpretations, and practices in the direction of a particular construction of social reality (Dahler-Larsen, 2012). These constitutive effects result from the profound influence of standards on the day-to-day lives of individuals and organizations (Bowker & Star, 1999; Lampland & Star, 2009). Performance measurements and standards are therefore increasingly recognized as "instruments of control," holding the power to regulate behavior (Brunsson & Jacobsson, 2000; Lascoumes & Le Gales, 2007). But as Slager et al. (2012) have illustrated, little is known about the ways in which the regulatory power of standards is created and maintained over time. Also, most studies interested in the power and effects of standards have focused on the receiving end of the line: the outcome of standards on

the actors who are the objects of regulation. What is missing is an analysis of how standards discipline and control the standard makers and have constitutive effects on the regulators themselves. To understand these effects, just looking at the standard or performance measurement system and examining its content is insufficient. Rather, we must look at the way in which they are shaped and used in practice.

In this chapter we explore the ways in which standards and performance measurements are "instruments of control" (Brunsson & Jacobsson, 2000), and how internal constitutive effects in regulatory agencies are enacted in a real-life empirical setting. We do so by focusing on the daily work practices of the Dutch Health and Youth Care Inspectorate; a regulatory body responsible for – among numerous other tasks – overseeing that Dutch healthcare organizations learn from serious adverse events. To be precise, we use the term adverse event to denote "an unintended and/or unexpected event related to the quality of care, having caused the death of or serious harm to the patient or client" (Buijsen, 2014, p. 388).

The Dutch Health and Youth Care Inspectorate (hereafter "Inspectorate") has only recently attempted to benchmark "learning" via self-developed standards and a coupled performance measurement system (Leistikow et al., 2017). As well as regulating and monitoring healthcare organizations, forcing organizations to manage risks and be accountable for mistakes "from the inside" (Power, 2007), these instruments were also introduced after a public crisis at the Inspectorate (see "Contextual backdrop" section) to objectify the Inspectorate's internal work practices, limit individual inspector's "street-level discretion" (Lipsky, 2010), and improve efficiency and traceability; an intervention in the relationship between Inspectorate and regulatees. This dual role of the introduced standards and performance management system makes the Dutch setting particularly interesting to examine.

In the Netherlands, as in other Western countries, a national adverse event reporting system is in place;[17] in the Netherlands this system is overseen by the Inspectorate. Dutch law mandates healthcare organizations to report adverse events to the Inspectorate and investigate the cause(s). The required investigations usually consist of a root-cause, or similar form of analysis, complemented with proposed improvement measures to minimize the risk of reoccurrence. The Inspectorate evaluates these inquiry reports[18], provides feedback, and uses the data to monitor risk trends – both nationally and at the level of individual healthcare organizations.

However, how and what healthcare organizations can learn from adverse events is debated, as we shall explain in our theoretical framework (Anderson, Kodate, Walters, & Dodds, 2013; Mitchell, Schuster, Smith, Pronovost, & Wu, 2015; Tamuz, Franchois, & Thomas, 2011; Tucker & Edmondson, 2003). Thus it is relevant to explore exactly what the Inspectorate wants healthcare organizations to learn – what, in other words, is its pedagogy? We hypothesize that this "theory of learning" (Kenklies, 2012) is embedded in the above-mentioned infrastructure of the Inspectorate's standards and work routines. That is, by studying this infrastructure in practice, we expect to find the pedagogy in use by the Inspectorate. The following research questions guide our exploration: How do the Inspectorate's standards and performance measurement system manage to control the Inspectorate's work routine, and which pedagogy can be distilled from this work routine?

To answer these questions, we foreground the backstage elements of work practices (Lampland & Star, 2009) at the Inspectorate. Hereby we not only build on the theoretical notion of standards and performance measurement systems but also shed light on some of the many unknowns surrounding the

17. *Later in this book (chapter 5) we refer to this system as the 'national incident reporting system' or IRS.*
18. *In other parts of this book "inquiry reports" are also called "incident investigation reports" or "adverse event investigation reports".*

practical execution of daily work within regulatory institutions (Sparrow, 2000), globally faced with an ever more critical public and political arena demanding the management of risks and uncertainty (Power, 2007).

This chapter consists of six sections. Recognizing the influence of the institutional constellation on regulatory processes (Jordana & Levi-Faur, 2004), we start by presenting a brief historical and political overview and discuss the subsequent influence on the Inspectorate's current work routine, to serve as a contextual backdrop. We then introduce the theoretical framework, discussing the concepts of learning and pedagogy, as well as the notion of standards and performance measurement systems as instruments of control. The framework is followed by a description of the research methods used. In the fourth and fifth sections, we present the research findings and discuss our results. In the concluding section, we reflect on the implications of our analysis.

Contextual backdrop: a new "sharpened" work routine

The Inspectorate has a long history of overseeing the quality of Dutch healthcare services (Boot, 2013; Robben et al., 2015). It does so by inspecting, advising, and stimulating organizations and sanctions in the case of non-compliance; an approach based on Ayres and Braithwaite's (1992) responsive regulation model. The Inspectorate's current approach to monitoring adverse events is relatively new; a regulatory framework that has been shaped by a complex configuration of external and internal drivers, including societal, political, legal, and institutional changes (Baldwin & Black, 2016; Jordana & Levi-Faur, 2004).

In line with the increasing global political and societal demands for public institutions and private organizations to control and manage risks (Power, 2000, 2007), the current routine was set in motion in 2012 in the wake of wide media coverage of several high-profile incidents that had impaired the Inspectorate's reputation. In the aftermath of these incidents, the public complained that the Inspectorate's method of dealing with adverse events was careless, inadequate, and favored the medical professionals under regulation (Dute, 2015; Ombudsman, 2011, 2012). Moreover, the organization was

accused of passivity, lacking vision and transparency (Dute, 2015). Alongside the public turmoil and political accusations of regulatory capture (Bardach & Kagan, 1982), internally the Inspectorate was struggling to cope with an ever-increasing administrative workload (Legemaate et al., 2013; Schippers, 2013; Sorgdrager, 2012), as well as continual reorganizations (De Vries, 2011). To come to terms with the public's mistrust, deal with the increasing workload, and put the political unease to rest, Edith Schippers, then Minister of Health, Welfare & Sports, geared the Inspectorate toward a new way of working, formulated as a "sharpened work method" (Schippers, 2013; VWS, 2012). The sharpened routine introduced the work practices, standards, and performance management system this chapter explores (see figure 3.1 for a concise overview).

First, the formerly contested regional focus that held individual inspectors responsible for assessing inquiry reports sent in by local healthcare organizations was reorganized into national incident reporting consultation teams, called LMO teams (short for *Landelijk Meldingen Overleg*) or National Incident Reporting Consultation teams (IGZ, 2013b; Legemaate et al., 2013). These comprised a mix of 'general' inspectors, including former nurses, lab technicians, and biomedical scientists, and 'specialized' inspectors, predominately non-practicing medical specialists. Each LMO team was made responsible for a different part of the healthcare sector, for example, hospitals, long-term elderly care, and general practitioners. Henceforth, assessments were a group effort performed at the national level, limiting individual inspector's regulatory discretion.

Following this shift, the guideline for reporting adverse events to the Inspectorate (IGZ, 2013a) was updated, specifying how adverse events should be reported to the Inspectorate and what procedure the Inspectorate follows once a report has been made (De Vries, 2011; Legemaate et al., 2013). In addition, a uniform protocol for inquiry reports (IGZ, 2014) replaced all earlier guidelines, specifically instructing healthcare organizations as to what their inquiry reports need to contain.

Last, and perhaps most significant, the Inspectorate's problem definition changed: not learning from mistakes was deemed a greater risk than making mistakes. The regulatory focus therefore switched from the medical content of an adverse events (what went wrong?) to primarily an assessment of the quality of the learning process reflected in the inquiry report (how has the organization learned from the event?) (Legemaate et al., 2013; Leistikow et al., 2017). To track and document these learning processes, the LMO team responsible for watching over hospitals created a standardized scoring instrument, coupled to a performance management database, called "digiBAN". Both were introduced to the LMO work routine in the first quarter of 2013. Here it is noteworthy that the BAN system in use by the Inspectorate is founded on the assumption that hospitals awarded a high BAN score for their inquiry report have effectively learned from the adverse event at hand.

In short, the historical contextual setting outlined above reveals the influence of external drivers and factors on regulatory processes, whereby the changing social and political climate played a key role to switch gears (Jordana & Levi-Faur, 2004). Other factors, such as those defined by Baldwin and Black (2016), including a regulator's risk and problem definition, operational constraints, and reputational factors, also played a role. The new work routine, standards, and performance measurement system were introduced to regulate the field of healthcare organizations and make it easier to monitor their performance. But the "sharpened" routine was also introduced as a trust device (Halffman, 1998; Porter, 1996); the standardizations needed to discipline the Inspectorate's work by: objectifying the evaluation practices, limiting inspectors' regulatory discretion, preventing regulatory capture, creating traceable outputs, and speeding up work processes. It is this objective of the sharpened work routine that we analyze in this chapter. The next section lays out the theoretical perspective applied in our analysis.

	**LMO team**, Department of Medical Specialist Care A team of 12 to 14 inspectors holding medical and non-medical backgrounds. **Core responsibility**: monitor quality and quantity of inquiry reports sent in by hospitals.

KEY ACTIVITIES:

	Individual team members evaluate and score inquiry reports using the national guideline 'Uniform Guideline Inquiry Reports' and a self-developed **scoring system** named '**BAN**'. The BAN standard is based on the World Health Organizations' (WHO) 'Concise Incident Analysis' protocol.
	The evaluations and scores are recorded in a specially designed **performance measurement database** named '**digiBAN**'. The digiBAN system allows the team to monitor safety related trends and overtime performances as hospitals are ranked according to their scores.
	In weekly **LMO meetings**, the evaluated inquiry reports are discussed within the team, and BAN scores may be amended / finalized.
	Based on the evaluation / finalized BAN scores, the team sends hospitals **feedback letters**.
	If the team feels hospitals fail to adequately improve their inquiry reports / are not learning from AEs, the team may visit hospitals in so called '**LMO interventions**'.

Figure 3.1. The LMO team's responsibilities and activities

THEORETICAL FRAMEWORK

Learning from mistakes and the "theory of learning"

The concept of learning is widely used in relation to patient safety and quality improvement initiatives (Rowley & Waring, 2011). Since the turn of the century there has been a general consensus within the safety movement that safety incidents and human errors made within the complex realm of healthcare – or any other high-risk industry for that matter – are inevitable (Kohn et al., 1999; Mitchell et al., 2015; Rowley & Waring, 2011). Scientists, healthcare professionals, and policymakers alike have campaigned for the importance of using such incidents as a catalyst for learning, advocating that inquiries into adverse events should stimulate the continuous improvement of patient safety (Iedema et al., 2006; Kohn et al., 1999; Tucker & Edmondson, 2003). The Inspectorate shares this notion, declaring that drawing lessons in the wake of an adverse event is an imperative (IGZ, 2016d).

However, what must be learned, who must learn and how one – or an organization – can learn to improve the safety of patients are debated (see also chapter 5). With regard to what and who must learn, Jensen (2008) illustrated that healthcare is often viewed as a system (see for example the 1999 well-known and celebrated Institute of Medicine report "To Err is Human"), but in the wake of an adverse event it is often the medical professional who receives the blame: to err is human, not system-based. This, Jensen argued, is a contradictory state of affairs, as he explained that dysfunction(s) in a system can be attributed to a wide range of actors and processes included in that system: individual end-users (i.e. doctors and nurses), but also the engineers or designers of products and procedures used in the system. The focus and/or where the line of inquiry is drawn ultimately dictates what and who can or needs to learn from the incident at hand. Illustrative of this is a study by Behr et al. (2015) revealing that the manner in which a medical error or incident is framed by the actors involved, shapes the way an inquiry is carried out and presented in a report. This ultimately influences what is – or can be – learned from the event and by whom (Behr et al., 2015).

How organizations or individuals in an organization can learn is also much debated. Tucker and Edmondson (2003), for example, show the difficulties hospital employees face using problems and mistakes as opportunities for improvement because of existing system and cultural barriers. Anderson et al. (2013) also highlight the complexities of trying to learn from inquiry reports, as the reports do not provide unambiguous data on how to improve safety. Some scholars (Hollnagel et al., 2013; Rowley & Waring, 2011) have even argued that aside from the practical difficulties of learning from mistakes it is more effective to learn from the things that go right rather than concentrating on the things that go wrong, thereby questioning the whole idea of learning from error.

In light of these debates it is clear that learning is a controversial matter and therefore it is interesting to explore how the standards made and used by the Inspectorate constitute learning and dictate what the process of learning from mistakes must entail.[19] To explore this "theory of learning" we use the concept of pedagogy as originally introduced by Johann Herbart (Kenklies, 2012). Herbart suggested that the concept refers to the assumptions of an educator who acts upon these assumptions using a specific set of skills, with a deliberate end goal in mind (Kenklies, 2012). An educator can be anyone or any organization who intends to teach, either implicitly or explicitly, by explaining, demonstrating, correcting and the like, and in so doing to be a felt presence, as well as having a reverberating influence on the knowledge or behavior of another party (Hansen & Laverty, 2010). Thus, for our analysis we identify the Inspectorate as an educator of healthcare organizations, stimulating those organizations to learn from (the analysis of) adverse events.

Denoting a regulator as an educator is not entirely new. Moving away from the traditional dichotomy of rule orientated/legalistic versus cooperative/

19. *Here we must stress that although the questions "how, what and who learns in the wake of an adverse event" are relevant, deserving thorough scientific research, they lie beyond the scope of this specific chapter. We argue that in order to answer such questions it is first necessary to gain insight into the Inspectorate's attempts to steer this learning process. Thus, our focus is on the Inspectorate's "theory of learning," or pedagogy.*

conciliatory enforcement approaches (Scholtz, 1984) – regulatory scholars increasingly describe enforcement approaches as holding a variety of different interactional styles (Ayres & Braithwaite, 1992; Lo, Fryxell, & Van Rooij, 2009; May & Winter, 2000), an educational approach being one of these possible dimensions. But although the educative approach of a regulator has been recognized, to the best of our knowledge, empirically little is known about what such a role entails in practice.

Standards and performance measurement systems as "instruments of control"

As learning is envisioned as an important way to stimulate and improve patient safety, the Inspectorate has made the concept into something that needs to be governed and monitored. To do so, the Inspectorate devised standards in the form of guidelines dictating what healthcare organizations need to do and investigate in the wake of an adverse event. The BAN scoring system was developed to aid inspectors in the process of evaluating and ranking the inquiry reports sent in (Leistikow et al., 2017).

Numerous social scientists have pointed to the way in which the creation and use of standards shapes new realities and impacts relationships and subsequent behavior (Bowker & Star, 1999; Dahler-Larsen, 2012; Dahler-Larsen, 2014; Lampland & Star, 2009). As Bowker and Star (1999) explain, each standard valorizes some point of view and silences another. In other words, standards are not only helpful to control or govern a messy reality (Lampland & Star, 2009) but also define this reality as well, revealing what is deemed to be important and what is not. Moreover, as Porter (1996) explains, standards are often introduced to replace human judgment but are simultaneously created and used by humans who carry with them ideas and interpretations of what those standards mean and represent. Thus, as we try to underpin the Inspectorate's pedagogy, it will be fruitful for us to closely examine their (use of) standards.

The standards formulated by the Inspectorate feed into a performance measurement system ranking healthcare organizations' learning abilities. We

know that rankings commensurate practices. That is, rankings transform qualities into quantities so as to reduce and simplify information into easily comparable figures (Espeland & Stevens, 1998). However, we have very little understanding of how these help organizations govern activities (Wallenburg, Quartz, & Bal, 2019). Thus, the way rankings in the Inspectorate's performance measurement system are performed in a social process also deserves our attention.

This 'performance' or practical use of rankings and standards by the actors involved is another matter of interest as we wish to examine the regulatory power (Slager et al., 2012) of these instruments. Standardization and ranking practices are increasingly recognized and acknowledged as a form of regulation (Slager et al., 2012) and standards are regarded as "instruments of control" that carry the capacity to generate order and facilitate coordination and cooperation, thereby creating similarity and homogeneity (Brunsson & Jacobsson, 2000). As Slager et al. (2012) state, standards facilitate coordination by defining the appropriate attributes of the standardized subject – in our case what hospitals need to do and investigate in the wake of an adverse event – rendering these aspects visible to external inspection and opening up the possibility of sanctioning non-compliance. This gives the standard makers power: external regulatory power. But standard makers should then also be regulated by those same standards, given that standards limit discretion and influence the relationship between regulators and the regulated.

To examine the regulatory power exerted internally, Dahler-Larsen's (2012; 2014) concept of "constitutive effects" may help us. The concept acknowledges the profound influence standardizing and evaluating activities may have on what learning is and/or should entail (Hulst & Segerholm, 2012). The concept can help us understand how the infrastructure in use by the Inspectorate has formative effects on the standard makers themselves – in this case the Inspectorate.

In sum, in our data analysis we set out to explore if and how standards affect decision making by the Inspectorate and how the Inspectorate's pedagogy is constituted through its work routine and instruments.

METHODS

Fitting our interest to examine the effects of standards and a performance measurement system in use, we employed an ethnographic fieldwork approach. The merit of this approach is that it allows for insight into the internal processes of a group and organization and to recover the distinct meaning given to these processes by the actors involved (Emerson, Fretz, & Shaw, 2015; Rhodes, 2015). Moreover, "being there," closely observing and listening to the inspectors at work allowed us to get below the surface of official accounts by providing texture, depth, and nuance (Rhodes, 2015).

Over the course of seven months (February–August 2015), the first author (JK) studied the work performed by the Inspectorate's LMO team, which was mandated the task of monitoring the quality and quantity of inquiry reports sent in by hospitals (see figure 3.1 for a brief LMO team description). To gather comprehensive insight into the team's daily work practices and increase the validity of our data, we triangulated diverse methods: a quantitative analysis of the data in the database, observations, informal interviews, document analysis, and a focus group discussion (see table 3.1 for a schematic overview).

During the observations we upheld an overt researcher role (Green & Thorogood, 2006), openly jotting field notes (Emerson et al., 2015) and, when appropriate, asking questions. To respect the confidential nature of the discussions observed, no audio or video recordings were made. Instead, the field notes were quickly drawn up into observation reports to safeguard as many details as possible (Emerson et al., 2015; Green & Thorogood, 2006) and generate detailed "thick" descriptions (Geertz, 1973). To enrich the quality of the observation reports, internal documents, such as meeting agendas and PowerPoint presentations, were also obtained.

For our quantitative analysis, we asked the team of inspectors to send us details on the LMO interventions they had executed in 2014. These records were matched with data from the digiBAN database, allowing us to document which

Table 3.1. Overview of fieldwork activities conducted at the Inspectorate, February–August 2015

Fieldwork activity	Description	Raw data collected	Output for analysis
Qualitative data analysis	Analysis BAN scores in digiBAN database and interventions performed	BAN figures and intervention	Graphs and tables
Document analysis	Collecting internal documents	Diverse protocols, guidelines and internal digital communication	N/A
Observations including informal interviews* (* see Green & Thorogood, 2006, p. 80)	LMO meetings (9 meetings)	20.75 hours of field notes / meeting minutes & agenda	Observation reports
	LMO interventions (2 interventions)	2.5 hours of field notes / PPT presentation and meeting minutes & agenda	Observation reports
	Inspectors at work preparing meetings / scoring inquiry reports (5 different Inspectors)	10 hours of field notes	Observation reports
Focus group discussion	Inspectors LMO meetings	1.5 hours of audio recording / field notes	Interview transcript

hospitals were visited, what their average BAN scores were (the quality of the inquiry reports as assessed by the Inspectorate), and how many adverse events were reported.

Lastly, a focus group discussion was organized to interview the team about their daily work. Rather than using a tightly structured topic guide (Green & Thorogood, 2006), the first author presented observation excerpts and quantitative data from our database analysis, asking the team to reflect on these findings. Realizing that this approach could possibly influence the inspectors' daily work thereafter, it was deemed necessary to capture the inspectors' reactions to reveal their underlying assumptions, which were of interest to us for this chapter. Besides being a data collection tool, we thus also embraced the focus group as a "member check" or reflexive instrument (Alvesson, 2003) to validate our interpretations and collectively reflect on them. With permission, the group interview was audio recorded and transcribed verbatim.

In all documents, the names of hospitals and inspectors were anonymized to protect their privacy. Also, all (confidential) internal documents were obtained with the permission of the LMO team members. The documents were systematically labeled; labels we will refer to when citing these nonpublic data sources. The observation reports, transcript, and collected internal documents were inductively coded in the form of a thematic content analysis (Green & Thorogood, 2006). The thematic exploration – a joint effort by the first (JK) and third (RB) authors – was followed up by a deductive analysis, recoding and assembling the data using the concepts from our theoretical framework.

It is appropriate to note that during the fieldwork study, the second author (IL) was a member of the LMO team. The second author allowed the first author easy access to data sources and provided helpful insider-knowledge of processes and procedures (Rutz, Mathew, Robben, & De Bont, 2017). This 'easy access,' as well as the close proximity of the first author to the studied setting – often the case in ethnographic studies – increased the risk of being unable to liberate

oneself from some taken-for-granted ideas (Alvesson, 2009). To minimize this risk, regular meetings were held with all three authors to reflect on the research findings.

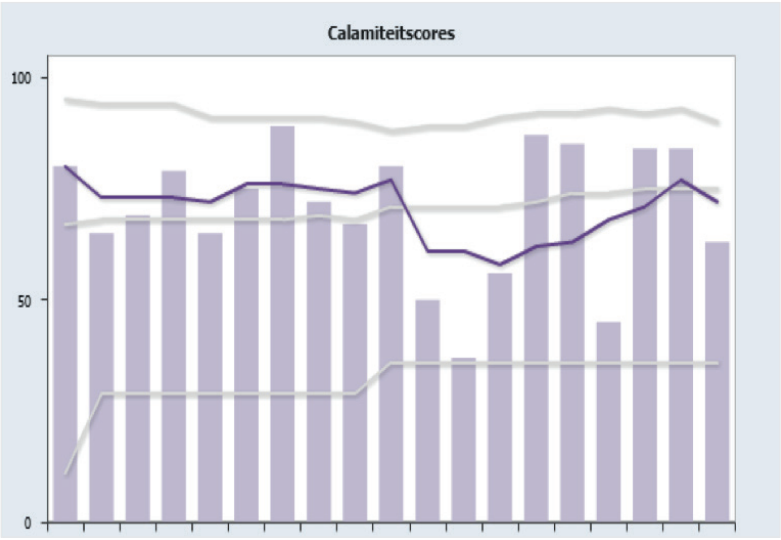
FINDINGS

In the following passages we discuss our findings on the three interlinked activities that we examined at the Inspectorate. First, the scoring and evaluation of reports using the BAN standard; second, the LMO meetings; and third, the process of providing hospitals with feedback and executing interventions.

Scoring and evaluating reports: standards creating meaning

The evaluation of an inquiry report is an intensive, time-consuming process. It is repetitive – "essentially it's production work, done for hours on end" – but the very nature of the reports makes the evaluation process "far from easy or routine." (Observation, field notes, Inspector 7, 11 August 2015)

> While reading the inquiry report the inspector mumbles, her hand covering her mouth: "Jeez." I don't react. We continue to read. She sighs, frowning: "Huh? Oh, no." She shifts on her seat, wiggling her legs restlessly, still reading. Hissing at her computer screen, she shrugs her shoulders: "Ow, people, this is such terrible care. This is truly unbelievable!" (...) After 15 minutes we reach the last page of the report. She turns to me, smiling. I am confused. As if the inspector could read my mind, she explains: "Well, I do think they [the hospital] have investigated the incident well. Let's have a look how my BAN score will turn out." And she opens the digiBAN database to start scoring. (Observation, field notes, Inspector 8 scoring, 20 July 2015)



The above chart is an overview of the quality and quantity of the inquiry reports sent to the Inspectorate by hospital X, during 2014. The digiBAN has a scoring table for each Dutch hospital.

On the x-axis, the bars in the chart represent the individual inquiry reports. The y-axis reveals the quality of the inquiry reports (BAN score of 0 – 100).

The dark purple line denotes the moving-average of hospital X (BAN score of the last 5 reports), revealing its overtime progress. The three gray lines indicate the mean moving-average score of all other hospitals at that point in time: lowest ranking hospitals, average and highest scoring. This overview allows the Inspectorate to compare hospital X to all other Dutch hospitals.

Due to the limited scope of quantitative data, we were not able to perform a significant statistical analysis to determine if the LMO team's interventions produced a significant effect on the quality of the BAN scores. The figure does demonstrate that the quality of hospital X's inquiry reports yo-yo's greatly. The moving-average of all Dutch hospitals appears to be relatively steady over the year 2014.

Figure 3.2. Screenshot from the digiBAN database, 27 March 2015: BAN scores for hospital X

As this observation illustrates, each inquiry report is evaluated by a 'general' inspector who scores the document and drafts a letter to the hospital commenting on the inquiry process, that is, what the hospital has done right and what can – or should still – be improved. However awful an adverse event may be in terms of content, inspectors are searching for the potential lessons that are drawn from the event and can thus be pleased if the event has been examined thoroughly. If the quality of the inquiry report is deemed adequate (a BAN score of 80 or more on a scale of 100, see figure 3.2) and/or the reported adverse events is not overly complex in nature, the case is closed and a letter is sent to the hospital. All other reports make the LMO meeting agenda, requiring the initial assessment to be followed up by other team members – usually two or three 'specialized' inspectors – who read the report and proposed return letter and provide feedback on the text. The inquiry report and the team's feedback are discussed during the LMO meeting. The outcome of this discussion determines how the Inspectorate ultimately judges and responds to the inquiry report.

Determining the complexity of an adverse event and its accompanying inquiry report is only partly formally defined. Certainly, internal guidelines dictate when inspectors need to collectively discuss a specific report, for example, if the inquiry reveals that the adverse event was caused by the culpable behavior of a medical professional. There are, however, informal dynamics at play. For instance, if an inquiry report is difficult to understand because it has been "poorly written," (field notes, 16 July 2015) is "very technical in nature," (field notes 21 August 2015, 16 July 2015, 24 February 2015) or if the incident is "outrageously shocking!" (field notes, 24 February 2015). We also observed instances where reports were set on the LMO agenda because the evaluating inspector had a "hunch" about a safety trend specific to the hospital or the healthcare field in general.

Although informal dynamics are at play, when it comes to determining the quality of an inquiry report, the BAN standard plays a key role. As presented in figure 3.1, the BAN scoring system is based on the World Health Organization's (WHO) "Concise Incident Analysis Protocol" dictating that an

incident inquiry must be timely (start as soon as possible); interdisciplinary and impartial; involve the actors familiar with the event; continuously dig deeper by asking "why, why, and why" at each level of cause and effect; and, finally, identify the changes that should be made to prevent reoccurrence (IGZ, internal document #2013C1). To be thorough, the inquiry must include a description of the incident, the underlying causes and effects must be analyzed, all contributing factors must be identified, and the findings and recommendations must be documented and formalized. Furthermore, to be credible, an inquiry should include the participation of leadership (managers and/or board of directors) and those closely involved; it should address conclusions with recommendations for reducing risk, include consideration of relevant literature and other sources of information, and include an evaluation plan to determine if recommendations are implemented (IGZ, internal document #2013C1). In addition to the WHO inspired criteria, the Inspectorate added extra criteria to their BAN standard – principles they "find particularly important." (Inspector 7 and 14, field notes) These criteria include involving the patient or their next of kin in the reconstruction of the event, as well as a description of the aftercare process for both patients and involved professionals (i.e. "second victims") (IGZ, internal document #2013B1).

All of these criteria coincide with the uniform guideline for inquiry reports (IGZ, 2014), which is sent to a hospital once it has reported an adverse event and starts an inquiry. In theory, hospitals thus know what is expected of them – and how the Inspectorate judges their inquiries. In practice, the quality of the inquiry reports – as determined by the Inspectorate – varies greatly, not only across but also within hospitals (see figure 3.2). Likewise, we observed that not all hospitals cover and/or interpret the criteria of the guideline in the same way. Some hospitals, for instance, refuse to involve patients in their inquiry report, which is one of the Inspectorate's requirements. Or, in another example, when the LMO team concludes that a hospital has not identified all of the causes and effects in its analysis, frustrating a team eager for their 'pupils' to do better and pick up on pointers provided in earlier feedback letters:

> Chairperson: "This is a bad analysis! We helped them last time but they still haven't improved!" (Observation, field notes, LMO meeting, 7 April 2015)

For the Inspectorate, a good inquiry into an adverse event ticks all of the boxes of the BAN scoring form; the more ticked boxes, the higher the BAN score. The BAN thus molds how an inquiry process is (to be) executed: it constitutes norms to which hospitals must adhere and (to a certain extent) regulates behavior (Lampland & Star, 2009), thereby exerting regulatory power on the hospitals (Brunsson & Jacobsson, 2000), especially because hospitals that consistently score poorly on specific criteria of the BAN can be reprimanded.

The BAN standard and subsequent scoring system has practical advantages for the Inspectorate. The standard helps to organize a sometimes messy reality (Lampland & Star, 2009) and aids inspectors to read through the inquiry reports – sometimes exceeding 30 pages in length – in a systematized manner; while reading sometimes physically checking-off the various criteria before they give the inquiry report a formal score:

> As we read, Inspector 4 scribbles in her notebook, mumbling to herself: "Date is correct." She writes down the date.
> "Reaction board of directors? Yes. Ok." Check.
> "Aftercare patient? Yes." Check.
> "Do I understand what has happened here?" Scrolls back and forth through the pages, rereading, and concludes
> "Um yes. I understand." Check. (Observation, field notes, Inspector 4 scoring, 21 August 2015)

The standard ultimately defines and communicates to the hospitals what the Inspectorate believes is important. This is a good example of assisted sense-making whereby a constructed mechanism for creating meaning organizes a complex reality (Dahler-Larsen, 2012). This is practical but it has consequences and potential downfalls. One pitfall concerns the procedural focus of the BAN, neglecting content-related details. By concentrating on ticking off the BAN criteria boxes, the Inspectorate risks losing sight of other elements

that may have been important. This became clear when a dismissed inquiry report was reopened and put on the LMO meeting agenda. The quality of the inquiry report had been sufficient; the hospital had met all the criteria of the BAN standard and thus the case was closed. Later, however, the Inspectorate received news that the hospital had failed to mention essential medical details. If the evaluating inspector had focused on these medical specifics in the inquiry report, the inconsistency in the reconstruction of the event may have come to the fore earlier. Inspector 9 explains:

> This is the pitfall of this type of regulation. The problem is caused by the way we judge the inquiry reports. Sometimes you miss things by not looking at the medical details. (Observation, field notes, LMO meeting, 7 October 2015)

This example also illustrates the relationship of dependence between the Inspectorate and hospitals; it is a continuous balancing act between regulator and regulated (Hawkins, 1983). The LMO team needs to trust the reporting hospitals to convey all relevant details and produce a truthful representation of what went wrong. Equally, the team needs to trust hospitals to follow through on their proposed improvements, as the Inspectorate does not monitor them.[20] This recurring state of tension fuels arguments at the weekly LMO meetings, which we will discuss next.

LMO meetings: Negotiations and collective sense-making

The weekly LMO meetings serve as a platform to jointly discuss inquiry reports, reflect on, and (re-)negotiate the awarded BAN scores and subsequent feedback letters:

> I sit in the corner of the room, notebook on my lap, watching the inspectors settle down at the oval-shaped conference table. Coffee cups in hands, friendly

20. *At the time of the fieldwork project the Inspectorate had no programs in place to monitor these suggested improvements. We have since learned, however, that the Inspectorate plans to start monitoring this in the (near) future.*

chatter, laughter here and there. A homemade pie is cut into generous pieces and passed around on paper plates; someone's birthday treat. I find the ambiance amicable; these colleagues seem to know each other well.

At 10:40, slightly delayed, the meeting starts. Thirteen inspectors, women in the majority, gaze at a case file projected on a flat television screen at the far end of the room. "We have a busy schedule today!" the chairperson notes. I glance at the agenda; 22 inquiry reports need to be discussed in the coming two and a half hours [...]

At 11:06 the third inquiry report is presented; a young patient unexpectedly died shortly after she was hospitalized. In its report, the hospital concludes that the patient was misdiagnosed: a fatal mistake. Inspector 7, who has evaluated the inquiry report, suggests the case can be closed. "Although the quality of their [the hospital's] investigation can be improved, I think they have devised appropriate measures to minimize the risk of reoccurrence." I observe head[s] nodding quietly around the table but then Inspector 6 sits up and raises her arms: "I don't agree [with closing the case]. It [the adverse event] is so serious! You all just assume that the hospitals are going to carry out the measures they suggest in their reports. Let them report back to us, to prove that they have followed up on their promises!" Inspector 14 is quick with his response: "Everything we discuss here is serious. The point of our LMO meetings is to jointly establish that hospitals demonstrate that they are learning from their mistakes. We [the Inspectorate] need to trust hospitals to execute the improvements they formulate in their reports. Legally they have a responsibility to do so. So all adverse events reported to us, no matter how serious, are good. If we [inspectors] ask this hospital to re-do their inquiry or report back to us again, we may discourage them from reporting their mistakes in future. I mean, look at the BAN score, this inquiry report is better than the last one" [...]

As the discussion wraps up, in line with Inspector 7's suggestion the case is closed (...). The meeting continues, the inspectors press on; 19 reports to go. (Observation, field notes, LMO meeting, 10 February 2015)

For the team members it is tiresome and at times emotionally straining work. The subject matter of the meetings emotionally affects inspectors, powerfully exemplified in this excerpt:

> These meetings and the preparation [assessing reports and drafting feedback letters] cost so much time. The work pressure is tremendous. It's a never-ending flood of misery. [...] You know their [the hospital's] intentions are good but sometimes you lose sight of that when you read and discuss inquiry reports all day. Quite frankly I feel disappointed in my former colleagues [practicing physicians]. I feel like: Jesus man, please stop doing this! Stop making these mistakes! (Inspector 16, Observation, field notes, LMO meeting, Inspector 6, 10 August 2015)

During the meetings there is room for inspectors to vent their frustration and concern – exclamations such as "Oh, this poor patient!" are commonplace – but most of the discussions concentrate on the quality of the inquiry reports. The team openly deliberates on whether the hospital has learned from the event under examination. Sometimes the inspectors see eye-to-eye, sometimes they don't. This in itself is interesting because the BAN standard was introduced to assess the quality of the reports uniformly and to objectify the inspectors' evaluation. Certainly, individual discretion is limited but the emotions of the inspectors are never far away.

When closely examining the discussions, it becomes clear that it is difficult for the team to purely use a set standard, the BAN, to evaluate the reports. The occasionally shocking details of an event sometimes cloud one's judgment or cause conflicting positions. Emotions regularly overflow the boundaries of the standard. For example:

> Inspector 16: "The doctor made the wrong decision!"
> Inspector 2: "Yes, but the reconstruction of the event is correct [according to the BAN standard], so I am going to give them a point for that." (Observation, field notes, LMO meeting, 17 February 2015)

When confronted with this and other similar observations in the focus group discussion, Inspector 3 explained:

> At one point we decided that we would focus on the process instead of judging the care, [w]hen we formed the LMO. But you can see how hard it is to do.

The team considers the quality of the inquiry report and the medical care to be two values that are indeed different but closely interlinked. Inspector 6 explains:

> You can have a situation where a doctor has made an error of judgment. One of many things that can go wrong in the care process. If they [the hospital performing the inquiry] don't take that aspect into consideration in their inquiry, they may have performed a fair analysis, according to our BAN criteria. But still, their assessment will not be complete because I feel like they have left something out. Because they forgot to ask one 'why' question. Why has the doctor made a judgmental error? So, they are two different values [process versus care content] but they are linked to each other. (Observation, field notes, 16 July 2015)

Throughout the meetings these different, yet intertwined, viewpoints are negotiated. The team uses each other's expertise – some have a surgical background, others have experience in the field of nursing etc. – to muddle through these queries and form a joint assessment. For every unique case they literally make sense of the situation, sometimes having to 'read between the lines' of the BAN standard, determining what is important and what should be learned to improve the quality of care. These findings suggest that the BAN standard cannot just be applied and/or does not just work. Rather, the inspectors interpret the inquiry, use their individual discretion to make choices about the key learning lessons, and eventually confer on these choices in meetings with the rest of the team. While the standard surely influences the discussions, the internal regulatory power of the standard is influenced – in this case limited – by the context in which it is used. To be precise, in this setting the context is shaped by the relationship of dependence between Inspectorate and

hospitals, the (informal) knowledge individual inspectors carry about hospital practices (see also chapter 4), and inspectors' affective response to the adverse event at hand.

Providing feedback: pedagogic reasoning

Once the BAN score is agreed, the content of the proposed feedback letter is discussed, settled, and sent to the hospital. This return letter is a preformatted document that is amended and personalized to suit the feedback the LMO team decides to communicate. In general there are three options: (i) a case can be closed, in which event the Inspectorate merely provides recommendations for possible improvements to future inquiries; (ii) the Inspectorate may request the hospital to "dig deeper" by asking the hospital to answer imminent questions or re-do the inquiry entirely; or (iii) when there are serious care-related quality concerns and the inquiry report is not up to the Inspectorate's standards, the LMO team will send the hospital a letter announcing that the Inspectorate will start its own inquiry, performed by a specialized team of inspectors.

Whichever course is decided on, the common point is that the communicated message is carefully constructed: content as well as tone matter. The team's goal is to stimulate hospitals to learn from adverse events; the inspectors feel it is best – in most cases – not to be too "harsh," even if the inquiry has not been performed according to the Inspectorate's standards. The team is aware that hospitals invest a lot of time in investigating adverse events and do not want to discourage them, even if there is room for improvement:

> We shouldn't send back too many points [of improvements] and remarks because we may overwhelm them [the hospital] with a flood of information. (Observation, field notes, LMO meeting, Inspector 4, 10 February 2015)

Or,

> You shouldn't give an unsatisfactory score. That will only scare them off. It's risky because they might stop reporting their adverse events. (Observation, field notes, LMO meeting, Inspector 8, 17 February 2015)

Like teachers, the inspectors carefully deliberate on what to address and how their feedback should be constructed. The team recognizes that their feedback letters to the hospitals have a disciplinary effect. Aside from illustrating the pedagogic reasoning behind the Inspectorate's feedback to hospitals, these quotes once more stress the relationship of dependence between the Inspectorate and the hospitals. The Inspectorate reasons that hospitals must report and investigate adverse events, otherwise they miss learning opportunities (IGZ, 2016d) and therefore the LMO team is challenged to uphold a delicate balance between evaluating, stimulating, and/or reprimanding the hospitals. The need to uphold a continuing relationship of trust shapes the team's compliance strategy (Hawkins, 1983).

We observed that the LMO team is eagerly trying to find (new) ways of maintaining this balance. For instance, inspectors recently started to telephone hospitals as well as sending return letters. When asked about this development, Inspector 3 explains:

> Yes, we do that more often. (...) [We call] to ask them a question but also to announce that a return letter is coming. It's like decorating our unpopular message with a small red ribbon. By calling we give them [the hospital] some context, so they understand where we [the Inspectorate] are coming from when we ask them to re-do the inquiry. We explain why we think it will help them.

Inspector 4, adds:

> [I]f you send a critical letter then on paper it comes across different than if you do it verbally. Over the phone you can be more refined. So when you call in advance [before the feedback letter is sent] and clarify your critical message, it comes across better. (Quotes, focus group discussion, 2 June 2015)

The BAN standard and coupled digiBAN database are also a source for the team to fine tune their pedagogic approach, as the scores allow inspectors to track overtime progress for individual hospitals but also for the field as a whole. Knowing which elements a hospital is struggling with and/or what the overall quality of inquiries are provides inspectors with the opportunity to formulate

their feedback accordingly. When asked what role the BAN plays in monitoring and steering the hospitals, inspectors explained that the standard and database do indeed "provide context" (Inspector 4) and are therefore "looked at systematically" (Inspector 14). Moreover:

> When we evaluate the inquiry reports, we often look at the BAN score in relation to earlier inquiries. Then you determine: have they [the hospital] improved? Have they worsened? And this codetermines what you [the inspector] write in your letter. (Focus group discussion, Inspector 11, 2 June 2015)

Our data, however, do not convincingly support these claims. While observing inspectors (n = 5) score reports and draft return letters, earlier BAN scores were consulted in only two of the 12 cases. Likewise, at LMO meetings we did occasionally hear inspectors refer to BAN scores; for example "Look at the BAN, they're doing better now than last time" or "They have an average score of 80!," but this was not a consistent occurrence. With regard to using the BAN score as a ranking tool to become "sharper" in monitoring learning development and acting accordingly – that is, deciding when and where an intervention is necessary (IGZ internal document #2013C1) – we were surprised to discover that the LMO team apparently does not use the data systematically in that way (see figure 3.2, illustrating what the scoring tables look like).

In our fieldwork we discovered that the LMO team performed 11 interventions in 2014 that addressed the quality of inquiry reports. Unexpectedly, these interventions were not targeted at the poorest scoring hospitals. Informed of our findings, the team was surprised:

> "Why did we go there?" (Inspector 14)

> "I didn't expect [name hospital] to score so high." (Inspector 11)

> "One case I find interesting is [name hospital]. They have a low ranking. But I feel like they have the capacity to learn and we could help them. But we haven't gone there." (Inspector 8) (Quotes, focus group discussion, 2 June 2015)

These statements once more illustrate that the inspectors use informal knowledge and/or personal conviction to assess the (learning) needs of a hospital, ultimately shaping their course of action. The next excerpt confirms this:

> Inspector 11: My first thought when I read [name poorly scoring hospital], well, you know. Sometimes it's just not worth flogging a dead horse. (...)
> Interviewer: What do you mean by that?
> Inspector 11: Well, it is a hospital that I, personally, feel is not strong at learning. Let me leave it at that.
> Interviewer: Ok. So is that a reason not to go there?
> Inspector 11: Well, it wouldn't be my first pick.
> Inspector 3: But we are worried about them [the hospital].
> Inspector 11: Yes, we are worried. (...) But if you go around [performing interventions to support hospitals in their quest to learn from mistakes] I can imagine you would first visit the hospitals where you have a good hope that your visit will have an effect.
> Inspector 8: But this is not something we formally decide or discuss.
> Inspectors 11 & 3, simultaneously: No.
> Inspector 8: So, it's something that just happens.
> Interviewer: There is no protocol?
> Inspector 3: Nope. (Excerpt, focus group discussion, 2 June 2015)

The "willingness" and "ability" of a hospital to learn thus plays a large role in what regulatory action, if any, is taken by the Inspectorate. However, there is no formal standard to measure "willingness" and when the team is asked what the "learning ability" of a hospital entails exactly, there is no concrete answer.

We found that the informal knowledge used to determine a hospital's "willingness" and "ability" to learn or to generally establish a pedagogic approach comes in various forms. We can provide countless examples of when inspectors not only used the BAN standard to formulate their feedback or decide on their course of action, but also relied on their own experiences, personal networks, professional expertise, and/or awareness of other ongoing regulatory programs:

> Who's going to call? It's [name responsible board member], she hates us! (Observation, field notes, LMO meeting, Inspector 16, 3 March 2015)

> With their [the hospital's] ongoing development project and renovations, they are really in over their heads. This is really one of our high-alert merger hospitals.

> Ok. Then we'll make our [feedback] letter stricter and we'll send it to the accountholder[21] to alert her as well. (Observation, field notes, LMO meeting, dialogue Inspector 3 and chairperson, 3 March 2015)

Such statements reveal the informal dynamics at play at the LMO conference table, coloring the debates, stipulating enforcement tactics, and influencing the ultimate regulatory actions taken (see also chapter 4). On occasion, personal sentiments and experiences even dominate the discussions and the team members need to remind each other to uphold their own standards and protocols. For example, after a heated discussion, the chairperson pleaded:

> Come on guys, please. Next time I will remove the [hospital's] name from the report and then we'll see how you judge it [the inquiry report]. (Observation field notes, LMO meeting, 17 February 2015)

As a concluding note it is interesting to mention that during the focus group discussion we confronted the LMO team with our observations on how they use informal knowledge and (sometimes) struggle to adhere to their own BAN standard. During the observed LMO internal governance meetings, which the first author attended after the focus group, the team again discussed these struggles and the inspectors expressed their willingness to use the BAN standard and digiBAN database the way they were (originally) intended to be used. However, their work routines have not changed (yet), as became apparent in follow-up interviews.

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21. *For its supervision of hospitals, the Inspectorate has assigned an "accountholder" at each hospital. These (senior) inspectors are generally not on an LMO team, but may be consulted on specific decisions.*

DISCUSSION

In this chapter we explored how standards and coupled performance management system influence decision making by the Dutch Health and Youth Care Inspectorate and how the Inspectorate's pedagogy is constituted through its work routine. Theoretically, these findings are relevant because they draw attention to the understudied effects of standards and performance measurement systems on standard makers themselves, furthering our understanding of the workings of regulatory power (Slager et al., 2012). Also, empirically, our findings are interesting because they shed light on the multifaceted nature of an educative regulatory style.

The Inspectorate's BAN standard and subsequent guidelines aim to constitute the learning processes of hospitals. The standard dictates what hospitals must do in the wake of an adverse event, how they must investigate it, who to involve etc. The standard ultimately requests hospitals to identify specific root causes and use these to formulate suitable measures. If a hospital does not comply with the standard it risks receiving a reprimand and/or regulatory sanctions. In this way the BAN standard may have considerable external regulatory power as it molds hospital behavior; it is in the hospitals' interest to comply with the Inspectorate's checklists. From a pedagogic notion, one may say that the Inspectorate's BAN standard, just like an educator's classroom rules, has a reverberating influence on the behavior of another party (Hansen & Laverty, 2010).

Internally for the Inspectorate, the introduction of the BAN standard and digiBAN database has had a profound influence on the way in which the LMO team executes its work in practical terms. For instance, the standard dictates the way inspectors read through the inquiry reports and has standardized work practices; reports are judged using the BAN scoring instrument, feedback letters are drafted, LMO meetings take place to discuss the BAN scores etc. The introduced standard thus manages to standardize daily work practices,

possibly even improving efficiency and traceability; which were important goals of the newly introduced "sharpened" work routine. But there are limits to the standards' internal regulatory power.

Stemming from a changed definition of risk, the BAN standard reflects the Inspectorate's intention to evaluate inquiry reports based on process instead of content; learning from what went wrong is deemed more important than what actually went wrong. In practice, however, our findings show that splitting these two values is difficult and sometimes even problematic, fueling negotiations at the LMO conference table. This leads us to conclude that in terms of content, the standards used by the Inspectorate have limited internal regulatory power as the assessment of inquiry reports and the subsequent feedback provided to hospitals is colored by the content of the incident as well as other forms of informal knowledge about hospital practice (see also chapter 4). That is, the standard in itself does not have the power to fully discipline inspector's behavior and objectify their assessments; additional 'work' needs to be performed to make the standard an "instrument of control" (Brunsson & Jacobsson, 2000), as exemplified by the many discussions in the LMO team. Expert judgment, ideas and interpretations are needed (Porter, 1996). Continuously, informal knowledge, emotions, and the medical expertise of the inspectors slips through the Inspectorate's actions – precisely those elements that the standard seeks to keep out in light of the public debate about the Inspectorates' presumed capture by the hospital sector and the discretionary space of individual inspectors. One may argue that the "sharpened" work routine has indeed limited the discretion of individual inspectors, but our study demonstrates that regulatory discretion has not been eliminated. Rather, regulatory discretion has acquired a collective nature (Rutz et al., 2017) as it has become embedded within the LMO team during their meetings, as well as through the build-up of common routines. This collective discretion becomes apparent in the overflow of substantive and affective reasoning in relation to the otherwise processual standard, and is equally visible in the pedagogic reasoning underlying decision making.

Because of the focus on learning, the existing relationship of dependence between the regulator and the regulated (Hawkins, 1983; Legemaate et al., 2013) is cultivated further, thereby not necessarily limiting the politically criticized capture-style relationships. In order to live up to its regulatory promise, the Inspectorate depends on hospitals to report adverse events, provide truthful inquiry reports and follow through on proposed improvement measures. As an internal constitutive effect, this dependency forces the Inspectorate into a teacher or mentor role and may explain the cautious behavior and substantial pedagogic reasoning we observed throughout the LMO team's regulatory activities. It appears that balancing this relationship at times weighs heavier than upholding the logic of the BAN standard; feeding the pedagogic approach wherein the LMO team wraps its reprimanding feedback with "red ribbons" to soften or tone down their critical feedback letters. Pupils must remain motivated to keep learning, thus enforcement tactics are carefully weighed in order to preserve, even nurture, the continuing relationship (Hawkins, 1983). An educative regulatory style is therefore multifaceted, holding both deterrence and cooperative style elements and is influenced by the historical and institutional setting, both of the regulator and the regulated. In part, it entails a communicative strategy to educate the regulated of responsible behavior (Lo et al., 2009), in our case stimulating healthcare organizations to learn from adverse events. Based on the underlying theory of learning and depending on the relationship between regulator and regulated, as well as the emotions at play, deterrent or more cooperative strategies can be played out to attain results.

The BAN standard used by the Inspectorate has allowed for the creation and subsequent utilization of a performance measurement system. Based on our findings we can identify three types of rankings in this system. First, an absolute ranking, whereby a BAN score allows the quality of an individual report, with all of its different elements, to be compared to an absolute maximum score. Second, a longitudinal ranking revealing the progress of scores over time for an individual hospital. Third, a ranking to compare the performance of an individual hospital to all other hospitals, in general or on specific elements. In

theory, all of these rankings provide the Inspectorate with a situational context on which to base its (pedagogic) feedback and/or other regulatory activities. But surprisingly, the rankings are not systematically used that way. Instead, other sources of information, such as informal knowledge about a hospital, previous experiences, professional knowhow, and emotions play a mediating role in the assessment of inquiry reports. Thus, both the BAN standard and performance measurement database – although introduced to benchmark learning and support learning processes over time – shape the process as a whole but do not manage to standardize it. Instead, there are many overflows that influence the ways in which the standard is put to use.

Clearly our findings demonstrate that standards and performance measurement systems are not by definition instruments of control (Brunsson & Jacobsson, 2000). They do in part constitute the practices that they measure but these constitutive effects are (under)determined by the relationships and affects in which they are enacted. Although the standard has changed the relationship between the regulators and the regulated, the Inspectorate remains dependent on hospitals as they need hospitals to report adverse events and be honest about what they report. The LMO team also negotiates and is influenced by personal contextual knowledge about hospitals – both in terms of their knowledge about hospital practices in general and by specific hospital organizations. That is, information from other sources, personal emotions, earlier experiences, and subjective ideas about the willingness of a hospital to work on improving quality and safety and learn from their mistakes play a role alongside the standard and rankings. For policymakers and researchers this is a relevant point to take away from this study, as the functioning of standards is often taken for granted. Our study illustrates that one should be mindful of not only the script in use (what is the purpose of the standard) but also the context in which the script unfolds, closely examining how it is used in regulatory practices, how users make sense of the standard, and which relationships influence this use and sense-making. In this case, the constitutive effects of the standards and rankings in the performance measurement system seem to hinge on the working practices of the regulator who propagates these very standards and rankings. Standards and rankings do

not just have the power to control, objectify, limit regulatory discretion, capture relationships, or regulate. We stress that when one determines that they do carry constitutive effects, one needs to closely examine what the exact source of the effect is.

This conclusion is underlined by the limited impact of our focus group discussion, wherein the LMO team was confronted with their unintentional use of their own standards and performance measurement system. The inspectors were surprised by the findings, yet despite the expressed intention, their daily work routines have not changed. We might hypothesize that this is not because the inspectors are unwilling but because the nature of the dependent relationship between the LMO team and hospitals is stronger than the BAN standard and digiBAN system. Thus the tendency to focus on "good students" and ignore "bad apples" (Bardach & Kagan, 1982) is not just a functional hiccup. Rather, it may be a direct product of the chosen regulatory approach. That is, the focus on learning from an adverse event rather than the specifics and associated risks of an adverse event, executed inside a web of dependency relationships.

With regard to the Inspectorate's "theory of learning," we conclude that their assumptions about what hospitals should learn in the wake of an adverse event, are not just formally embedded in the standards and performance measurement system used. Formally, the individual elements of the BAN standard and coupled system carry with them an underlying assumption that they reflect effective learning. In practice, the definition of effective learning does not end there, as our study shows that the Inspectorate's pedagogy is collectively negotiated. Using a pool of informal knowledge, the LMO team decides where they need – or want – to turn a watchful eye. This is clearly demonstrated by the decision to visit hospitals that do not necessarily score the lowest (the "bad apples") but do hold the greatest potential to benefit from an intervention. These grounds for "learning potential" are not formally embedded in the LMO team's protocols and are not standardized; they are informally enacted. In this case revealing the assumptions of an educator who feels that "sometimes it's just not worth flogging a dead horse."

CONCLUSION

This chapter sought to cast light on the function of standards and performance measurement systems in regulatory contexts. For scholars, policymakers and regulators, our findings are interesting as they lend weight to the notion that evaluation, monitoring, and ranking practices – increasingly introduced and used in a regulatory context confronted with a complex mix of political, societal, and reputational demands, as well as limited resources – do not operate neutrally and affect both sides of the regulatory equation: regulators and regulatees. Although we show that standards and performance measurement systems indeed carry the power to constitute the very practices that they measure, we stress that they are not by definition instruments of control. Their constitutive effects are (under)determined by the relationships in which they are enacted. As an implication we thus recommend that policymakers and regulators actively monitor and critically reflect on their own work practices and use of standards to educate themselves about the limitations and implications of these evaluation mechanisms. Scholars of regulation evaluating the effects of standards and performance measurements would do well to examine not only how these affect the regulated, but also how the consequences of such regulatory instruments are mediated by the practices in which they are put to use. As Power (2000) argued for auditing practices, the consequences of each standard, monitoring, or ranking system should be appraised on its own merits.

To conclude, we are hopeful that our ethnographic study contributes to the gap in knowledge surrounding the practical execution of regulatory work by providing a glimpse into the everyday practices and struggles of a particular regulatory body, as well as the multifaceted nature of an educational enforcement approach, holding both rule-orientated and cooperative style elements. Now that we know how the Inspectorate uses standards and have determined how standards influence the internal regulatory context, we can extend our exploration inside healthcare organizations. Is the Inspectorate's pedagogic approach a fruitful way to support learning from adverse events and patient safety more generally? Does the chosen regulatory methodology

actually make healthcare safer? For future research, the insights provided in this study allow us to better understand the effect of regulation practices and standards on the ways in which hospitals organize their internal inquiry processes and learn from mistakes, as well as how regulatory activities have an impact on patient safety in general.

4

THE DOCTOR WAS RUDE, THE TOILETS ARE DIRTY: UTILIZING SOFT SIGNALS IN THE REGULATION OF PATIENT SAFETY

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ABSTRACT

Modern healthcare systems are highly data and evidence driven. The use of indicators and other performance management devices, introduced by healthcare leaders and regulators to monitor performance and address patient safety matters, are just two examples. Research has shown that the wish to manage and address risks via measuring practices does not always do justice to the complexities of healthcare organization and delivery, for (patient) safety and quality are not only about measurable things. So, while recognized as valuable, there are calls that hard metrics must be supplemented with soft signals – generally known as qualitative or informal data – to gain a better representation of actual performance and tackle safety issues. With the aim to contribute to the theoretical notion that a dialogical approach to knowledge and information-management is a fruitful way to manage and address risks and problems in healthcare, this chapter addresses the research question 'What role do soft signals play in the assessment of patient safety risks and how are these signals employed in everyday regulatory practices?' We draw from qualitative interviews, observations and document analyses in a multi-year (2015-2019) research project to show that soft signals are vital to everyday regulatory practices, as they provide context to 'hard' signals and help to make sense of and weigh risks. Based on these findings we encourage policy makers and regulatory bodies to start an active dialogue on their use of soft signals and develop work models and working routines for discussing them as well as their implications.

INTRODUCTION

The governance of safety risks has become increasingly data driven. High-complex industries, such as oil and gas, nuclear power and aviation, have invested heavily in measuring and monitoring systems in the past decades (Macrae, 2014a; Power, 2007). Fueled by the public's diminishing acceptance of (patient safety) risks as well as the general acknowledgement that healthcare delivery has become increasingly complex, modern healthcare systems too have rapidly become more data and evidence driven. The widespread use of performance management and accreditation systems, the use of indicators, standardized protocols and rankings of best performing hospitals, are just some examples (Dixon-Woods, Leslie, Bion, & Tarrant, 2012; Wallenburg et al., 2019; Waring & Currie, 2009). Many of these practices have been introduced to improve performance and provide accountability; to both the internal organization as well as external stakeholders (Power, 2007). Moreover, there exists a general consensus that data generated through these technologies and practices of accountability play a valuable role in assessing practices of care and monitoring safety problems.

At the same time, an expanding group of practitioners, policy makers and scholars argue that the data produced and shared in these systems tell only part of the story. Data collection, and its ensuing taxation of risk, only focuses on what can be measured using specific calculating models and may therefore not yield full insight into the range of fallibilities in healthcare organizations (Martin, McKee, & Dixon-Woods, 2015). Scholars have shown that standardization and commensuration practices can generate unintended blind spots as they render some aspects of care and its governance invisible or irrelevant (Espeland & Stevens, 1998; Lampland & Star, 2009). Official incident reports, indicator scores or other 'formal' metrics may thus generate an incomplete picture of actual practice (Liberati et al., 2019). A striking example is the public inquiry

of the Mid Staffordshire Trust scandal in the UK.[22] Whilst the Trust performed well on formal performance indicators, healthcare delivery was found to be poor, at times even "devastating" (Francis, 2013). The public inquiry revealed that there were numerous slumbering 'softer' warning signs pointing to problems with the safety of care. These included patient complaints about poor hygiene, whistleblowing complaints from staff, observed inappropriate staff behavior, and auditor concerns about an inadequate learning culture (Francis, 2013). The involved regulators did not manage to filter out these signals, contributing to overdue regulatory action. A more recent case in the Netherlands (2016) suggests that even if a soft signal is distilled from the mass, marked as legitimate and investigated, a regulator may still come up dry. This case concerned anonymous complaints reported to the Dutch Health and Youth Care Inspectorate (hereafter HYCI or Inspectorate), by staff members from the University Medical Center Utrecht (UMCU) regarding an unsafe working climate at the Ear, Nose and Throat department. HYCI's efforts to concretize and seize these concerns led inspectors to a dead end. Inspectors could not find any 'hard' evidence to substantiate the complaints and the signal was put aside as "non-actionable" (IGZ, 2017a). Mere months later, HYCI's decision backfired when journalists managed to expose comprehensive safety issues at the medical center – causing public criticism and reputational damage for both the hospital and the Inspectorate (IGZ, 2017a). These examples reveal the importance – and difficultly, for that matter – of the use of 'soft information' in dealing with uncertainty and detecting safety risks (Goddard, Mannion, & Smith, 1999; Macrae, 2014a; Martin et al., 2018; Martin et al., 2015).

In existing literature, the label 'soft' points at those sources of knowledge and information that are not formally measured or recorded (Goddard et al., 1999; Macrae, 2014b; Martin et al., 2015). Moreover, the labels of 'soft' and 'hard'

22. *It has been estimated that between 400 and 1200 patients died as a result of poor care between January 2005 and March 2009 at Stafford hospital, a small district general hospital in Staffordshire. This 'case' is often described as the worst hospital care scandal of recent times in the UK. Diverse public inquiries concluded that chronic staff shortages were largely responsible for the poor and unsafe care delivery (Campbell, 2013).*

are framed as mutually exclusive, assigned as self-evident categories and are rarely problematized. For our research we started with a rough definition of soft signals, namely: the indication that something might be wrong within an organization with the possible consequence of inflicting harm. But, fitting with a practice-based or pragmatist approach (see below) we chose to follow the strategies through which actors themselves give practical meaning to the term as we were interested in how decisions to act come about. In so doing, it became necessary to open up the often taken for granted 'hard-soft' discourse by empirically examining how and what types of signals are used by the HYCI to determine and act on possible threats to patient safety. That is, hardness or softness, we came to understand, is not an a priori characteristic of a signal, but relates to its actionability. We will use the term 'signal' rather than 'information' or 'data' because we are specifically interested in the (pieces of) information that incite regulatory action.

In our analysis we take up a pragmatist approach (Martin et al., 2015) to study how signals are received, labeled, made sense of and used by inspectors at the HYCI in everyday regulatory practice. The study was conducted as part of a wider qualitative research program (2015-2019) examining the effects of Dutch regulatory policies on the quality and safety of care. We particularly draw on a sub-project (February – September 2018) in which we studied how signals are received, labeled and used by the HYCI. With this chapter, we aim to contribute to the theoretical notion that a dialogical approach to knowledge and information-management is a fruitful way to manage and address risks and problems in healthcare practices (Ayres & Braithwaite, 1992; Mills & Koliba, 2015; Sabel, Herrigel, & Kristensen, 2018). To that end, the central research question guiding this chapter is: What role do soft signals play in the assessment of patient safety risks and how are these signals employed in everyday regulatory practices?

This chapter continues as follows: first we present our theoretical framework in which we elaborate on the notion of measuring ambiguity in patient safety and briefly reflect on the earlier sketched 'hard-soft' dichotomy. We relate these

insights to theories on responsive regulation and the challenge of determining regulatory compliance. We then describe the methods employed for this study and present our findings. In the last two sections we discuss the implications of our findings for regulatory practices and healthcare safety management more broadly and wrap up with some general conclusions.

THEORETICAL FRAMEWORK

Measuring ambiguous matters?

Managers, organizational leaders and their regulators use all kinds of information to assess the quality of performance, identify risks and problems that warrant attention. Traditionally in regulatory and management science there is a tendency to manage and monitor performance via a 'hard systems' approach, characterized by a search for objectivity (Goddard et al., 1999). This 'measure, manage and regulate' attitude has also been dominant in the patient safety movement since the turn of the century (Rowley & Waring, 2011). Undeniably, this approach has helped to yield significant improvements but the focus on measuring, quantifying and objectifying also raises challenges.

First, the wish to manage and address risks via measuring practices does not always do justice to the complexities of healthcare organization and delivery. That is, patient safety is not only about measurable things (Rowley & Waring, 2011). 'Culture' is a good example. Public inquiries into high-profile scandals, including Mid Staffordshire, often position 'culture' as a cause of and explanation for healthcare failures. Dawn Goodwin analyzed: "A culture of fear *explains* the non-reporting of incidents, a culture of secrecy *explains* the denial of appalling standards of care, and a culture of bullying *explains* why people don't do their jobs properly" (2018, p. 109, emphasis in the original). Sociological work around patient safety has problematized the idea that culture can be known and manipulated in predictable ways (Goodwin, 2018; Hillman et al., 2013; Latour, 1984; Rowley & Waring, 2011), meaning that it is difficult to capture in formal metrics. Actors responsible for overseeing and

tackling patient safety issues are thus faced with the task of getting a grip on ambiguous, evolving, relational and non-quantifiable issues that are then also challenging to govern. This stresses the need to use and act upon a broader array of information to determine the state of quality and safety at the sharp end of care (Goddard et al., 1999). Berwick's recent call to "put measurement on a diet", because "we cannot measure ourselves better" reflects this changing sentiment (Berwick & Bisonano, 2019).

Another challenge that rises from the 'measure, manage and regulate' attitude is the tendency to see formally measured data as more valid and reliable than other forms of information (Goddard et al., 1999). In patient safety literature, quantitative data, such as performance indicator scores, are marked as 'hard', 'formal', 'objective' and 'official' (Goddard et al., 1999; Macrae, 2014b; Martin et al., 2015; Sibley, 2019). By contrast, qualitative data and knowledge is interchangeably used with the terms 'soft', 'informal', 'subjective' and 'weak' (ibid.). As a consequence, the legitimacy of personal intuition, gut-feelings and tacit-knowledge – often seen as invaluable assets to good performance (Douw et al., 2015) – are put under strain.

The labels 'soft' and 'hard' reflect the notion that numbers have become instruments to represent objectivity (Porter, 1996). But critical analysts have shown that measuring is never a neutral activity: numerical data produced through standards, indicators and other performance measurement devices reflect the (subjective) values embedded in these socially produced classification systems (Bowker & Star, 1999; Lampland & Star, 2009). Moreover, measuring practices can be manipulated and misrepresent actual performance (Dixon-Woods, 2010). Solely relying on 'hard data' would therefore be a denial of the constructed character of such data, as the Mid Staffordshire case has already shown.

In contrast to the notion that hard and soft can be distinguished a priori, we take a pragmatist perspective, arguing that 'hardness' or 'softness' of data does not so much reside in the character or origin of the data, but in how data is used in specific contexts (Martin et al., 2015). That is: whether data can be labeled

as hard or soft is an empirical question, that can be answered by analyzing the consequences of such data. In this regard, we are interested in the ways in which regulators deal with and give meaning to different types of data—and how they make these into 'signals' of safety of care.

We use the concept of "sensemaking" (Weick et al., 2005) to understand the active interpretive work required for inspectors to assess the validity, scope and importance of signals to make them intelligible, give them instrumental utility and come to enforcement decisions (Martin et al., 2015, p. 22). Sensemaking is the process through which people work to understand issues or events that are novel, ambiguous, confusing, or in some other way violate expectations (Maitlis & Christianson, 2014). It is a retrospective act, as sense is made after the issue or event has taken place (Weick et al., 2005). From within this shared understanding, inspectors can come into coordinated action and therefore it is important for us to look at how inspectors make sense of signals, and how they use them in their regulatory practices. This is especially important in the context of responsive regulation, as we explain in the following section.

Responsive regulation

As the health sector is characterized by many complexities, a plurality of actors and rapid change, it has been argued that responsive regulation is a promising strategy for improving the quality and safety of healthcare (Braithwaite, Healy, & Dwan, 2005; Healy, 2013; Healy & Braithwaite, 2006). Since the introduction of Ayres and Braithwaite's (1992) responsive regulation theory, countless regulatory authorities around the world have moved away from the classical divide between strict disciplinary enforcement styles on the one hand and more cooperative styles on the other. Responsive regulation is best known for its pyramid shape of interventions, which dictates that regulators should – irrespective of the type of problem or risk – first commence to modest interventions, i.e. education or persuasion strategies (at the base of the pyramid) and only upscale to more invasive measures such as disciplinary or corrective actions (at the top of the pyramid) when dialogue fails (Braithwaite, 2011). Regulators are not denied the use of stern disciplinary actions but ideally the

threat of the 'big stick' looming in the distance is effective enough to ensure that organizations voluntarily comply with more conciliatory approaches (Ayres & Braithwaite, 1992; Drahos, 2017; Healy, 2013). Rather than hierarchical and coercive, the regulatory process is thus envisioned as a relational and communicative one, attuned to the context in which it is applied (Mascini & Wijk, 2009; Van Erp, Wallenburg, & Bal, 2018).

Within this relational perspective, regulators are required to make careful decisions about the most appropriate enforcement style. If the seriousness of the offense, risk or problem is not leading, assessments need to be made about the capacity and willingness of an organization – and its leaders – to comply with, take responsibility for, be in control of and address the issue(s) at hand. Inspectors often struggle to decide what would be the most suitable enforcement style (Mascini & Wijk, 2009; Van de Bunt, Van Erp, & Van Wingerde, 2007), but to the best of our knowledge, little empirical research has been done to provide an insight in that decision-making process. Within responsive regulatory regimes, in line with the previous paragraph, the softness or hardness of a signal needs to be determined. Or, put otherwise, soft or hard then become the outcomes of such regimes. In the next section we will first outline the methods, after which we will turn to the findings that describe how (soft) signals are received and acted upon in everyday regulatory practice.

METHODS

As a regulator, the HYCI receives and gathers a continuous stream of signals about the safety of care in healthcare organizations obtained from patients, their families, professionals, through inspection visits, indicator and other performance scores. This makes the HYCI a valuable case study to examine in order to further our understanding of the ways in which diverse types and sources of signals on the safety of care can and are pieced together. This study was conducted as part of a multi-year (2015-2019) research program examining the effects of Dutch regulatory policies on quality of care, in which patient safety is a key concern. We build on the insights obtained in this program

(see chapters 3 and 6), and specifically draw from newly collected data in a sub-project investigating the HYCI's use of soft signals (February – September 2018); the details of which are outlined below.

Setting, sampling, data collection and analysis

For this specific study (see also Wallenburg et al., 2019), diverse qualitative methods were triangulated, including semi-structured interviews (n = 33, with 27 respondents), observations (n = 4 hours) and document analysis. The study was built up in four phases. Table 4.1 outlines the phases and summarizes the main themes on which we focused during data collection. In the first explorative phase we interviewed purposively selected participants (i.e. inspectors, legal officers, program managers, team coordinators as well as accountholders)[23] at the Inspectorate to become familiar with the meaning and practices of dealing with the variety of signals within the HYCI. In phase two, we broadened our scope by interviewing two leaders from the Dutch Education Inspectorate and the Dutch Food Inspectorate, next to three senior leaders from two international (English and Danish) healthcare regulators. Based on the first two phases, a topic list was constructed for in-depth interviews with accountholders, team coordinators and one member of the management team of the HYCI (for more details about the interviewees see table 4.1). Issues that were addressed during the interviews included questions about the interviewee's definition of, and experiences with, soft signals and the challenges of assessing, ascertaining, making sense of signals and how signals are acted upon in their work, fitting with our practice-based approach (Martin et al., 2015). Some respondents were interviewed twice, because of their different roles or because interviewees themselves requested a second interview as they felt they hadn't explored the issues enough and/or new concerns had raised after the interview – which reflects their engagement with the topic of soft signals. Furthermore, to deepen

23. *For its supervision of hospitals, the HYCI has assigned an 'accountholder' at each hospital. The accountholder is a senior inspector who monitors a hospital's performance, overlooks hospital-related inspection activities, serves as a first point of contact for the hospital and chairs the annual evaluation meeting with the hospital board.*

our understanding of how signals are received and acted upon, we conducted 4 hours of observation at the National Healthcare Report Centre (*'Landelijk Meldpunt Zorg',* LMZ), a helpdesk hosted by the HYCI that provides advice and guidance to citizens with questions and complaints about the quality of healthcare. The first two authors (JK, IW) were seated next to the helpdesk's employees and observed their work, following the method of 'interviewing by the double' (Nicolini, 2009). Field notes were transferred into observation reports. These were made part of the analysis (see below).

Finally, in phase four we selected two cases in which soft signals had played a significant role in the HCYI's regulation strategy (the analysis of both cases is summarized in table 4.2). The cases concerned intensified supervision trajectories[24] instituted by the HYCI in two Dutch hospitals. The goal of diving into these case studies was to deepen our understanding of the mechanisms at play when HYCI employees make sense of and act on signals. From inventory lists, confidential as well as public documents were selected, necessary to draw up detailed thick descriptions (Geertz, 1973). A HYCI employee assisted with the document retrieval. The thick descriptions included a chronological timeline of the key events and involved actors, an analysis of what regulatory decisions were made and how signals – hard and soft – played a role in the trajectory. The case studies were followed by four semi-structured in-depth interviews with four hospital directors (in all cases, chairs of the board of directors) to harvest their experiences with, and thoughts on, soft signals, as well as their experiences with the HYCI on this matter. One of these directors was involved in a case study. We did not get permission to interview the director of the other case as the aftermath of the intensified regulatory trajectory with the HYCI was still ongoing; also illustrating the sensitivity of the topic.

24. *An 'intensified supervision trajectory' is an undefined period wherein the HYCI intensifies its supervision activities within the healthcare facility, in the attempt to force its leadership and management to 'sort out' serious issues that have been identified.*

Participants were invited for an interview or observation via email. A description of the project accompanied the invitation. Except for two telephone-interviews, all interviews were conducted face-to-face. The interviews were recorded with permission and transcribed verbatim. Throughout the research project, data collection and analysis were executed in an iterative approach (Bryman, 2016). That is: in recurrent meetings all authors reflected on the developing insights, discussing themes that emerged from the data, and these themes then informed the consecutive research steps taken. The first two authors led the final analysis by once more individually reviewing and assigning inductive open-codes to the transcripts, observation reports and case-study descriptions. In the tradition of thematic content analysis (Green & Thorogood, 2006) and our practice-based approach (Martin et al., 2015) we upheld an inductive logic – staying close to the experiences and meanings voiced by the study participants – but the central research themes (as outlined in table 4.1) further informed the analysis. The final codes could be categorized along the lines of the overarching research themes (i.e. 'definition of soft signals', 'types of signals', 'sensemaking practices' etc.) that were discussed and agreed on in reflective meetings, attended by all authors. To further assure analytic rigor and improve the validity of our data, our findings and analytical interpretations were presented to HYCI employees for member-checks.

The research was funded by the Dutch Health and Youth Care Inspectorate (contract number 201800274.185.001). Under Dutch law this study did not require approval from national or local ethical committees. This was formally confirmed by the Medical Ethics Committee Erasmus MC (MEC-2018-054). Due to the sensitive nature of the narratives and confidential documents retrieved the interview transcripts as well as the case-studies were anonymized.

Table 4.1. Overview collected data and key themes of focus during data collection/analysis

Research phases & fieldwork activities	Fieldwork activities conducted by (author initials)	➔	Key themes of interest
Phase 1: initial exploration at HYCI 14 **semi-structured interviews** with diverse HYCI employees (n = 8), incl. inspectors, legal officers, program managers, team coordinators and accountholders	JK, IW		• What are the respondent's work practices and how are these organized: formally and informally • How and with who do HYCI employees communicate and through what means/channels? (internal & external communication) • What types of information is collected /received and used for regulatory work and how is it processed? • How do HYCI employees define soft signals? • How and where are signals (soft and hard) received, processed and collected?
Phase 2: broadening exploration / mirroring initial findings 4 **semi-structured interviews** with senior leaders (n = 5) from Dutch, English (Care Quality Commission, CQC) and Danish (Danish Patient Safety Authority, DPSA) regulatory bodies	JK, IW		• Do other regulatory bodies define soft in the same way as HYCI employees? What is their definition and how do they work with soft signals? • How are signals soft and hard received, processed and collected? • How are signals pieced together, formally and informally?

Table 4.1. Continued

Research phases & fieldwork activities	Fieldwork activities conducted by (author initials)	➔	Key themes of interest
Phase 3: Zooming-in on HYCI work practices with soft signals 11 **in-depth interviews** with HYCI accountholders, team coordinators and a senior manager (n = 8). 4 hours of **observations** at the National Healthcare Report Center (HYCI incident report center)	JK, IW JK, IW		Using the earlier conducted exploration, zooming-in further on: • Respondents' experiences with (the use) of soft signals; • Challenges with and opportunities that come with soft signals; • How are signals pieced together, formally and informally? • How do HYCI employees act on signals and how do they come to these regulatory decisions? • What types of signals are collected at the Center? • How do employees use, make sense of soft signals? • How are signals processed and acted on?
Phase 4: Zooming-in on two practical case studies **Document analysis***** of HYCI internal (incl. confidential correspondence, inspection reports) as well as publicly available documents 4 **semi-structured interviews** with leaders from 4 Dutch hospitals (n = 6) *** See table 4.2 for a summary of this analysis	JK, IW JK, IW, RB		• What risks were defined in the case studies and what regulatory decisions were made? (reconstruction of events / timeline) • Who and what signals played a role in the assessment of these risks/decisions? • How were the signals acted on and to what effect? • How do hospital leaders define soft signals? How do they work with and/or act on them? • How do hospitals communicate with the HYCI, what information is shared/ not shared and why?

Table 4.2. Concise summary of the two case studies assembled through document-analysis and interviews

Case study	Description
Hospital A	A general hospital that has been on HYCI's radar for some time. There are concerns that the hospital is not learning enough from adverse events, as the quality of the adverse event inquiry reports remains mediocre. Nonetheless, the hospital leaders have been given the 'benefit of the doubt' as HYCI inspectors decided to give them time and space to show improvements and demonstrate their commitment to tackling patient safety issues. Against this backdrop, an unannounced HYCI inspection visit reveals discrepancies between what is being observed by inspectors in practice and earlier made agreements with the hospital Board. When the HYCI accountholder decides to confront the Board with these findings, the Board Chairman uses the meeting as an opportunity to present how well things are going. This alarms the accountholder and accompanying inspectors further, feeding their distrust and doubt about the willingness and competence of the hospital leaders to attend to the lingering patient safety issues. After deliberation, the HYCI places the hospital under intensified supervision, arguing that they sense a 'lack of insight' and 'sense of reality' that may be potentially dangerous for patient safety and quality of care. During the intensified supervision period the Board is requested to produce monthly status reports to allow the HYCI to monitor the improvements made.
Hospital B	A general hospital that is in the process of merging with another regional hospital. As a result of the merger, in due time the intensive care unit from one of the locations will be closed. Upon HYCI's request the hospital leaders have presented plans how they will keep the quality of care and patient safety norms up to standards whilst the merger is ongoing. The plan is approved by the HYCI. During an unannounced inspection visit, HYCI inspectors observe that Hospital B is not following through on the plan. Several intensive care quality norms are not being met, which the HYCI considers a serious risk to patient safety. When the hospital Board is confronted with these findings, they are of the opinion that enough informal systems have been put into place to maintain good and safe practices of care. This response instills HYCI inspectors with the impression that the hospital leaders lack a sense of urgency, inhibiting their ability to comply with standards. In response the HYCI places the hospital under intensified supervision. During the intensified supervision period the Board members proactively inform the HYCI of positive and negative developments. This transparency reestablished trust, leading the HYCI to give the Board (more) room on their path to improvement.

FINDINGS

In light of our quest to understand the role of soft signals in the assessment of patient safety risks as well as their use in everyday regulatory practices, our findings will be presented in three sections. First, we present how and what types of signals are received and made sense of within the HYCI. Second, we illustrate how soft and hard signals play a role in regulatory assessments of risks and subsequent actions. Finally, we discuss some of the challenges of utilizing soft and hard signals in light of a regulator's institutional effectiveness, and how signals may also backfire in case they are missed or not adequately made sense of.

The definition of soft signals, their sources and how to make sense of them

In this section we address how our interview participants defined soft signals, what their sources are and how they are made sense of and used in every day regulatory practices.

When asked to define soft signals, our study participants provided numerous practice-based examples but shared similar definitions. Generally, soft signals are thought of as ambiguous pieces of information that are difficult to commensurate and are not easily classified within existing data management systems. Soft signals may point to risks or possible fallibilities in a healthcare organization but can also elicit positive feelings; that "all is well and up to standards" (HYCI accountholder 4). In that sense, soft signals frequently appeal to an inspector's intuition or gut feeling; triggering unease and concern or trust and confidence. Illustratively, one inspector referred to soft signals as "tin-openers" (HYCI team coordinator 1): they are the starting point in a search for and deliberation process of possible risks and problems that need a regulator's attention and elicit action. Equally then, they can also be 'tin-closers' when an inspector's gut feeling suggests things are well, justifying inaction.

At the HYCI, signals arrive and/or are picked up through various paths. The two most explicit entryways are the National Healthcare Report Center (LMZ) and the Report Center (*'Meldpunt'*), instated to process questions, complaints and formal notifications and reports from respectively the public at large (LMZ) and the healthcare sector (Meldpunt). Both platforms amass, monitor and attend to thousands of healthcare related signals each year. This number is ever increasing and both LMZ and Meldpunt participants mentioned they struggle to keep up. Many of the signals they receive are labeled as 'soft' as the signals relate to a diverse array of mundane issues that one may come across in processes of care giving and care receiving:

> As I sit next to Emma,* a LMZ employee, she selects a case file from her digital to-do list and explains: "Now, I am going to call this lady. She has used our online form to issue a complaint about her mother's caregiver, an elderly care facility." I nod and glance at a lengthy written complaint. "It's a bit of a long story; she's unhappy about all sorts of things and apparently the care provider has not responded to the complaints she has voiced internally. The food isn't tasty, her mother's clothing was dirty, something about medication. But there," Emma points to her computer screen, "this short sentence in the middle of the report caught my attention: 'Mother has fallen off the toilet because she was left alone'. A fall incident. This is something that we [the HYCI] may need to attend to, so I am calling back to retrieve further details." (Observation LMZ, *pseudonym)

This excerpt illustrates the diffuse nature of soft signals; the receiver needs to recognize its potential and concretize it. From, often lengthy, qualitative texts, HYCI employees filter out what the exact risk or problem is – are these 'just' complaints caused by, for instance, a troubled relationship between a patient and caregiver or is something more severe going on? One may note that falling off the toilet is quite a concrete, tangible event, but in this scenario, it is perceived as a soft signal because it is unclear if and how this piece of information speaks to patient safety risks or quality problems within the healthcare organization at large. Further details are needed to sort this out. What is soft or hard, the

excerpt shows, is situational and not always so clear-cut; labeling a signal as soft or hard is influenced by the institutional environment as well as the intuitive or gut feeling of the signal receiver – a point will we come back to.

Our analysis also revealed that signals are often layered: a concrete incident or problem, either reported via the earlier mentioned reporting platforms, picked up during inspections or radiating from the performance management systems, is coupled to a softer sign, namely: how is the risk perceived or problem being managed by the organization leaders?

> "If things are not in order [according to standards] then we confront them [organization leaders]. 'Ok, so you [CEO] say you are aware of the problem, how are you dealing with it? Show us how you are in control. And if you already knew that this is an issue, how come we [HYCI] didn't know about it?' ... For me this is a soft signal about transparency. Being open, being confident enough to share." (HYCI Accountholder 2)

A soft signal can weigh heavier or be louder – in the alarming sense – than the hard signal that has preceded it, diluting the clear-cut boundaries between the two labels. That is, while inspectors know that things can and do go wrong in hospitals, the ways in which the hospital (leadership) reacts to these wrongs is relevant: are the leaders 'in control', are they open about what is going on? It is signals about the latter issues that are deemed important.

Filtering out these layered signals is time-consuming work and at the starting point of the search it is not clear where the signal(s) may lead. A UK CQC inspector recognized this challenge:

> "The vast majority of the problems that we read qualitatively are usually not about the thing that's on the piece of paper... If I'm reading a complaint that's gone to a Trust that they [the Trust] should have dealt with but have failed to do so... The complaint might be about the quality of the treatment but it's told me something actually to do with the ability of that organization for managing complaints and its complaints management process. So the complaint has told me two things." (CQC inspector)

Soft signals 'in themselves' won't do the job; they are part of a broader story that needs to be pieced together. Therefore, participants explained, soft signals are carefully considered and triangulated with other sources of information – soft and hard – to make sense of the (potential) problem or risk. What is already known about an organization, informally and formally steers that process of sensemaking. Whilst information about a healthcare organization is collected in a register, this in itself does not do the trick, as one respondent explained:

> "Registration is information without interpretation. Attributing meaning is an active process. It [the register] is not a container of individual marbles, rather they are pieces of Lego, whereby you build on the work that has already been done and the choices that have been made. You make linkages between the signals and [hard] information you have. Afterwards you see it [what the risk or problem was]." (HYCI Team coordinator 1)

Soft signals are also picked up through more implicit means, by reading, listening or observing 'between the lines'. Aside from the content of a complaint, intonation, pauses and the types of words that are used over the phone may trigger a feeling that "something really isn't right here" (Report Center team coordinator). Inspectors who review adverse event inquiry reports or other formal reports and letters noted that even if a report is written exactly according to HYCI standards, they sometimes discern ancillary safety issues or problems just by the way in which the report is written. One inspector shared the anecdote about reading an inquiry report that seemed to hint at a conflict between medical specialists on a ward, even though this was not explicitly mentioned. When she called the hospital CEO, her 'hunch' was confirmed and hearing that the CEO was not only aware but also actively dealing with the conflict a reassurance, or 'tin-closer'. Inspectors thus check into the subtle soft signal they've picked up and use (triangulate it with) another (soft) signal – in this case the response by the CEO – to decide on follow-up action. Likewise, participants mentioned that they pick up all sorts of soft signals during inspection visits and annual meetings with organizational leaders. Aside from gathering 'hard' data during these visits to assess performance and compliance, soft cues are collected by observing and listening closely during face-to-face encounters

with healthcare professionals, management and leaders. How a hospital Board or doctor should behave during an inspection and/or what they should say is not formalized in any supervision instrument, but it does play a role in an inspector's assessment:

> "You're limited in the information that you have and receive. So you are guided by the hard data, the formal reports. But when you are speaking to people you notice how things are being said, and who is looking at whom. Sometimes it's also timing. Do I receive the report half an hour before the meeting or have they sent it to me a few days in advance so I can have a good read? ... These things are not hard, but they might point to something... They are signals. (Member hospital supervisory board/former HYCI inspector)

As inspectors can and do differ in their interpretations of signals, the search for potential underlying risks or problems radiating from these types of (soft) signals is done in collective deliberation processes. Our interviews and observations revealed that these processes are tacitly institutionalized in existing work structures. We observed LMZ employees listen along and help each other whilst attending to complaints over the phone, as if they had collective antennae out to see how pieces of information collected over time could be matched up. And in another example, there are diverse recurring (multidisciplinary) meetings, introduced to minimize inter-inspector variation. During these meetings HYCI employees from different departments and backgrounds come together to reflect on the hard metrics and figures, registered complaints, reports and letters, as well as their own experiences with and feelings about a specific healthcare organization. Meetings, in other words, where hard and soft information are triangulated and are made sense of, after which action strategies are wrought.

To sum up, soft signals are ambiguous in that they transcend formal criteria, but they are seen as important in regulatory work at the Inspectorate as they 'tell' something about the ways in which a healthcare organization handles risks to patient safety. The sources of soft signals are multiple, but are mainly read

'between the lines', in formal reports and complaints as well as in meetings with healthcare leaders, managers or professionals. They are seen as 'tin openers', eliciting further research, but can also be 'tin closers', providing reassurance.

Making soft signals actionable in regulatory practice

In this section we turn to how signals – soft and hard – are handled in decision-making practices at the Inspectorate. Our analysis reveals that for a regulatory body, soft signals alone do not carry instrumental utility:

> "For a regulator ... factual, hard findings are crucial because an [intervention] report or letter [issued by the HYCI] needs to withstand the administrative court's judgment." (HYCI Legal officer)

To make soft signals actionable they are pieced together with other forms of data to substantiate and validate HYCI's actions, to the healthcare organization and the greater public. The earlier mentioned meetings play a key role in this process, as accountholders and other involved inspectors contemplate the seriousness of the problem or risk and decide what intervention should take place. This risk appraisal is guided by the inspectors' assessment of and trust in the capability of the organization's leaders' ability and willingness to comply to regulatory standards at hand:

> "Look, scaling up the enforcement strategy will have little use if the leader just isn't competent. (...) When you scale up, you [the HYCI] expect the director to be able to [successfully] address the issues with a nudge in the right direction." (HYCI Accountholder 3)

Informal knowledge about the behavior and leadership quality from the directors 'at the helm' colors the deliberation; if a leader is not considered competent, disciplinary measures may be more effective than cooperative approaches. The assessment of the competence of an organization's leader(s) is founded on soft signals. These are picked up 'live' during inspections and face-to-face meetings but can also be stored in memory from the experiences build up over time:

> "I know how she [hospital CEO] works, ... from five years ago at the head of a different organization. I think she is very transparent and honest and she has guts; dealt with all the bad apples and the media attention that came with it." (HYCI Accountholder 1)

> "I knew him [hospital CEO] from before, from a different hospital where he left when things got ugly, so there was history there that shaped my perception." (HYCI Accountholder 2)

Memories and experiences continuously feed into each other, coloring the assessment of the organization as a whole. They form the context to which other signals – hard or soft – are weighed and interpreted. This process of sensemaking translates into regulatory strategies; strategies that, depending on the trust in and assessments of the leadership capabilities, can take diverse forms. Our case study analysis demonstrated this clearly: two hospitals were placed under intensified supervision because HYCI inspectors felt the Board members provided an unsatisfactory response when confronted with safety problems in their hospital (table 4.2). The sensed 'lack of urgency' from these hospital leaders, a soft signal for the HYCI inspectors, added to the risk – and carried more weight – than the actual non-compliance to guidelines (a hard fact) observed during the inspection visits. During the intensified supervision period the CEO from hospital A was held 'on a short leash' as inspectors' earlier experiences with this leader's behavior (see quote from accountholder 2 above) made them weary of his ability to achieve improvements. Accordingly, the inspection visits were intensified and the CEO was given strict instructions. In hospital B, the CEO quickly regained HYCI's trust by being transparent in his communication style as he honestly shared his concerns and was open about ongoing problems. In an interview the CEO recounted his strategy:

> "I was very alert and punctual in my way of communicating, the timing, the style. [I was] attentive of the quality and readability of the documents we sent [to the HYCI], aware of their limitations. I spend a lot of time thinking about the reports and the questions they asked and how to translate all the transformations into our daily work processes." (CEO Hospital B)

As an effect, this CEO was granted more managerial leverage to work towards solutions as he saw fit. The same regulatory measure (intensified supervision) can thus take on very different shapes owing to the soft signals that have framed the inspectors' assessments.

The role of soft signals for constructing supervision strategies then is a dominant one. This role is explicit by acting on these signals directly, but also implicit as soft signals help to feed HYCI's (informal) knowledge about regulatees, becoming part of the Inspectorate's collective memory:

> "It [the soft signal] doesn't always need to be confirmed... but it does feed into the image we have of that organization." (HYCI Team coordinator 1)

Soft signals, especially about the behavior of hospital boards, informs regulatory activities it seems even more than 'hard' ones and are built into the reputation of a hospital or CEO. In turn, as a continuous process of crafting and recrafting, this reputation is used to make sense of (future) signals arriving at, or filtered out, by the HYCI.

In sum, soft signals play a key role but often do not by themselves hold instrumental utility. That is, they are pieced together with other types of signals to come to regulatory action. Action can take place directly, i.e. in the form of an immediate decision, or in the future, as the soft signals feed into the HYCI's collective memory about regulatees and their ability to manage and attend to safety risks. In this process of collective sensemaking, signals also get their quality of either hard or soft, that is: the hardness of a signal – its actionability – is the result of such sensemaking processes.

Soft signals and regulatory effectiveness

In this final empirical section, we present some of the challenges of utilizing soft signals in light of a regulator's institutional effectiveness. This is an important matter to attend to for, as discussed in the theoretical framework, regulators increasingly use 'responsive regulation' to interact with regulatees. How this is done in practice is however understudied and poses several dilemmas.

For instance, 'scaling up' on the regulatory pyramid is often time intensive and getting the 'right' response is crucial for the effectiveness of regulatory interventions and thus also for the reputation of the regulator.

'Scaling up' the responsive regulation pyramid of interventions, for instance by placing a hospital under intensified supervision, our data show, is a collective endeavor. In a team meeting, inspectors weigh all the available data and signals against the backdrop of internal and external contexts in which hospitals operate. In so doing the soft signals that have alarmed inspectors are substantiated or 'made hard', as inspectors called it. Participants stressed that the decision to scale up on the pyramid is not taken lightly. Disciplinary approaches are 'a lot of work' for the Inspectorate, pressed to allocate scarce resources wisely. Furthermore, soft signals carry with them a danger of reputational damage and hence a legitimacy risk if interpreted or filtered out wrongly. Additionally, as part of the responsive regulatory strategy of the Inspectorate, disciplinary interventions sometimes conflict with the HYCI's pedagogic reasoning (chapter 3) as they prevent organizations to learn and solve problems for themselves. Intervening at the top of an organization obstructs this ideal.

A recurrent matter in the interviews was the importance of maintaining the institutional effectiveness and legitimacy of the Inspectorate; a legitimate and credible regulator is more effective. Accordingly, participants recognized the potential value of soft signals but also stressed the vulnerability that lies within these signals. Their diffuse and ambiguous nature makes them complex in relation to the regulatory legitimacy of the Inspectorate. If soft signals are missed or not pieced together properly, patient safety may be at stake and so is HYCI's reputation:

> "We are alert (...) we take action if there is a worrying signal. Then we look at it thoroughly. And, depending on who the signal is from and what it is about we conduct an unannounced visit, speak to a director, a doctor. Also because if you ignore the signal, or you don't manage to uncover it and it blows up, you [the Inspectorate] suffer the consequences as well." (HYCI Accountholder 5)

Interviewees explained that the practices of sensemaking, as well as the subsequent decision of what to do with that soft signal, are always made on the backdrop of that (political) vulnerability:

> "The moment that it [a soft signal that has been received by the regulatory authority but has not been acted on] receives press coverage then it is too late. Then the image can arise that you haven't done your job properly." (Inspectorate of Education inspector)

How signals, soft or hard, are pieced together and made sense of is therefore not a neutral act. The institutional environment influences the way signals are assessed and this filters down through to the devised strategies and actions taken. What is soft or hard then is situated and evolving.

Within the HYCI the pressure and necessity felt to 'harden' soft signals in a timely manner was evident, but these signals cannot always be 'made hard'. The earlier introduced UMCU case illustrates this: anonymous complaints from professionals where sought out by inspectors but did not match up with the other pieces of information available. In other words, sometimes the diverse signals come together as a hazy sketch rather than a clear picture of performance. Coming to intervention decisions then becomes difficult. Strikingly, our analysis showed that it is in these 'hazy' situations that the softness of earlier experiences, collective memory and gut-feelings play a pivotal role. The trust in leadership qualities as well as the assessment of the risk to one's own institutional reputation shape the road to action. In the UMCU case, the trust in the leadership served as a tin-closer; a decision that backfired. Yet, in most cases it works out well, for all parties involved. Like in the case where a hospital was placed under intensified supervision, and the CEO was granted freedom to address problems by himself:

> "We [HYCI] gave space [for him] to solve the problem. Space based on trust that the leader would solve the problem in a good way. But you always think about how you can explain that [to the public]. Because what if something goes

> wrong during this trajectory? What if someone makes a mistake, and a patient dies? Then they [the public] will all think it is because you are in this trajectory." (HYCI Accountholder 4)

Here it is important to note that the CEO in question did not necessarily experience the trajectory as one filled with 'space' and 'trust'. When interviewed, he looked back on a period filled with extensive reporting and felt a high administrative burden. In light of the legalized context, for a regulator, providing room and trust does go hand in hand with collecting 'hard' evidence to protect institutional reputation.

To sum up, soft signals and the way they are made sense of and are acted upon in regulatory work can only be understood when reflecting on the broader institutional environment in which the regulator operates: the regulator-regulatee relationship, the dialogue between inspectors when decisions have to be taken on the 'right' regulatory strategy and the possible consequences of proposed regulatory strategies. Softs signals play a role in these decision processes; they are simultaneously visualized risks to patient safety and clues for designing appropriate regulatory action.

DISCUSSION

In this article we analyzed how a regulatory body labels, interprets and utilizes the diverse array of signals about safety risks it receives and picks up, with the aim to understand how soft signals have their place in daily regulatory practices. Gaining an insight into these practices is relevant when recognizing the complex nature of managing and addressing risks and safety problems. It is also particularly relevant in the advance of process-based systems of supervision, such as responsive regulation, as such systems no longer only rely on rule-following behavior but are concerned with the willingness and capability of organizations (and their leaders) to improve performance. In this

light, soft information or signals have been put forward as a means to assess this willingness and capability. Our study therefore focused on the use of such signals in the regulatory practice of the HYCI.

Our analysis revealed several things. First, signals are layered. A concrete (hard) incident or problem, is often coupled to a softer sign, namely: how is the risk perceived or problem being managed? Moreover, what is hard and soft, is not always so clear-cut and the labels provided are the outcome of sensemaking and deliberation processes. Contrary to what is often assumed in literature, signals are not by themselves hard or soft, but their hardness is a consequence of sensemaking practices. Third, such sensemaking is a collective undertaking in which many different signals – hard and soft – are gathered together. And finally, this sensemaking is embedded in an institutional context that structures deliberations. In the case of the HYCI this is a context in which making individual healthcare organizations responsible for quality as well as scaling up regulatory measures must be balanced.

Our empirical analysis showed that, as 'tin-openers', soft signals can point to safety risks or fallibilities in a healthcare organization but they may also function as 'tin-closers', instilling an inspector with a sense of trust and confidence that the organizational leaders are competent and in control. Study participants provided diverse examples, ranging from a hospital CEO being proactive and transparent about an ongoing conflict within the organization ('positive signal') to an organization's complaints register not being in order or rude doctors ('negative signal').

Soft signals about safety risks 'arrive' at the HYCI through different channels. Many soft signals are picked up through formally established platforms; report centers that process and attend to thousands of questions, complaints, formal notifications and reports from the healthcare sector and public at large. Alongside the established platforms, soft signals are also picked up by inspectors through more implicit means: by listening, reading and observing 'between the lines' in formal documentation and in face-to-face contact when visiting regulatees. Successfully filtering out the 'important' signals is difficult

and time-consuming work, as they need to be distilled from noise and marked as significant in an environment confronted with masses of complex information, much of which appears to be urgent and all of which is competing for finite resources (Macrae, 2014a, 2014b).

Our study shows that distilled signals do not automatically have meaning, rather meaning is attributed in social processes of sensemaking, wherein a signal is comprehended to determine 'what is going on here?' and 'what will we do next?' (Weick et al., 2005, p. 412). HYCI's periodic multidisciplinary meetings serve as a good 'sensemaking' example, where inspectors weigh and triangulate different pieces of information about a regulatee and jointly deliberate on fitting regulatory actions. That is to say, sensemaking is a collective activity. As inspectors piece different fragments of information together they attempt to make the soft signals 'hard'; to give them instrumental utility. It is this actionability, rather than the material realization of harm, which makes a signal hard or soft. 'Soft' and 'hard' thus do not so much refer to the actual realization of harm – and in this sense, soft signals don't necessarily precede hard ones – but rather refer to their usability in regulatory practice. Preferably, signals have to be made tangible (and hence discussable) in order to play a role in regulation. In line with the concept of sensemaking, our analysis shows this process is not about acquiring an exact truth, rather it is about crafting and recrafting an emerging story or picture, so that it becomes more comprehensive, incorporates more of the existing data and is more resilient in the face of criticism (Weick et al., 2005). Attempts to make soft signals 'hard' are not always successful: some signals remain or become soft, but then, participants explained, they often become part of the HYCI's collective memory. In turn, this collective memory acts as an interpretive lens through which inspectors assess future pieces of information and come to regulatory action. This leads us to conclude that even in a 'soft' state, soft signals have implicit instrumental utility, as soft signals may be loud – in the alarming sense – or carry serious weight when inspector's decide on regulatory action(s).

Soft signals thus have an important role in regulatory work; helping inspectors to unravel the often ambiguous nature of safety problems. This is an important point to acknowledge, as regulators operate in a context increasingly pressured to produce and work with 'hard facts' (Goddard et al., 1999). Our study therefore adds to the growing body of knowledge underlining the potential of utilizing softer forms of knowledge in health care governance (Francis, 2013; Goddard et al., 1999; Macrae, 2014b; Martin et al., 2015). Additionally, it provides an empirical glimpse into the relational character of responsive regulation and how this regulatory model is enacted in practice. To be able to decide what enforcement actions are appropriate, inspectors are required to make assessments about the willingness and capability of an organization – and its leaders – to successfully work towards practices of good and safe care. This forces inspectors to be sensitive to the context in which an organization is operating and appraise the leadership qualities of organizational leaders.

Soft signals play a key role in these assessment practices; they color an inspectorate's appraisal and subsequently also steer the enforcement actions taken. Like the case studies demonstrate: less coercive enforcement strategies were imposed once a hospital CEO (re)established a relationship of trust with the HYCI, by being transparent and proactively communicating problems. This case also illustrates that images of 'good' and 'bad' leaders, colored by the HYCI's collective memory, are not necessarily fixed; they too evolve and are continuously recrafted in processes of sensemaking. Moreover, sensemaking as we have shown in the analysis is a collective socio-material practice in which many different departments of the Inspectorate are involved and in which different regulatory practices come together. Guidelines informing the ways in which complaints are handled, standardized reporting of adverse events, meetings of inspectors from different departments, the strategies of having conversations with hospital boards all go into the sensemaking process. Whilst in the literature it is sometimes suggested that data analysis can solve many of the filtering problems of assessing data (Griffiths, Beaussier, Demeritt, & Rothstein, 2017), our study shows the informal 'backstage' work that is needed in these processes.

On a final note, our study shows that this crafting process is not neutral, as it is driven by normative and political choices. The recurrent theme in our interviews about the HYCI's 'institutional effectiveness' underlines this finding. Like Baldwin and Black (2016) have illustrated in their work on regulatory risk appraisal, regulators, in their assessments and actions, are also driven by political, communicative and reputational factors, stemming from their need to maintain their reputation and legitimacy in eyes of their political overseers and the greater public. As a consequence, these factors also filter through and influence the relational and communicative character of the responsive regulatory strategy.

Cleary, the Dutch healthcare regulatory context, and in particular the regulation of hospitals, has unique characteristics. With 'only' 90 hospitals to monitor and a relatively small community of healthcare CEO's, HYCI inspectors are possibly better acquainted with regulated organizations and their leaders than in other countries. We call for further research to be done in broader contexts, to help advance our understanding of the layered nature of soft and hard signals in safety regulation.

CONCLUSION

We started this chapter with the question what role soft signals play in the assessment of patient safety risks and how these signals are employed in everyday regulatory practices. On the basis of our analysis of the use of signals by the HYCI we conclude that the softness or hardness of a signal is the outcome of collective sense-making processes in which the actionability of signals is assessed. Soft signals play a central yet often implicit role in regulatory practice. They are vital to the everyday processes of making sense of and weighing risks and encouraging quality improvement. For a regulator, as we have shown, soft signals serve as 'tin-openers' and 'tin-closers'; initiating a search for safety risks or problems that may have otherwise remained obscured from sight or (rightfully) sparing valuable resources when such a search is not necessary. Soft signals furthermore serve as 'context information' and in doing so give meaning to 'hard' measures. Based on our findings we encourage

policy makers and inspectorates to start a dialogue on their use of soft signals and develop work models and working routines for discussing them as well as their implications. Particularly the collective nature of piecing signals, hard and soft, together, is crucial and should thus be a central pillar when developing (responsive) regulatory work models.

5

HOW INCIDENT REPORTING SYSTEMS CAN STIMULATE SOCIAL AND PARTICIPATIVE LEARNING: A MIXED-METHODS STUDY

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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 adverse events. 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 adverse events. Healthcare inspectors scored all investigations to assess hospitals' learning process following adverse events. We analyzed 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 adverse event 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 professionalization 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., 2015). Research has shown, however, that IRSs struggle to foster learning (Macrae, 2016; Mitchell et al., 2015; Peerally, Carr, Waring, & Dixon-Woods, 2017; Stavropoulou, Doherty, & Tosey, 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 & Marang-van de Mheen, 2015). IRSs fail to demonstrate progress, suggesting that learning has not occurred (Baines et al., 2013; Shojania & Thomas, 2013). We argue that such evaluations are problematic as they work with impoverished conceptualizations of what learning is – generally confusing learning with performance (Ramanujam & Goodman, 2011)– , neglect how definitions of what constitutes incidents shift (Leistikow et al., 2017; Vincent & Amalberti, 2015) and are inattentive to how more reported incidents might be reflective of a safety minded organizational culture rather than poor performance (IGZ, 2016d; 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 adverse events 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 5.1 for the type of incidents reported in the Netherlands and the role of the Inspectorate. Rather

than assessing *what* hospitals learn from adverse events, the Inspectorate monitors *how* hospitals learn from adverse events, inquiring if hospitals *learn to learn* from adverse events (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 adverse events (box 5.2). In line with this instrument, the Inspectorate published a guideline, informing hospitals on what the Inspectorate expects from an investigation (IGZ, 2016c). Since July 2013, every adverse event reported and investigated by hospitals is scored by the Inspectorate (Leistikow et al., 2017; chapter 3).

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 reorganizing shared knowledge, technologies and practices. It is these processes of action and reorganization 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 & Goodman, 2011, p. 85). Our study is guided by the question: How does the Dutch IRS stimulate social and participative learning from incidents?

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,

Benjamin, & Goodyear, 2001; Johnson, Onwuegbuzie, & Turner, 2007). We present and integrate quantitative data on scored adverse event investigation reports and qualitative data on how adverse event investigators perceive the effects of the IRS on their investigation practices and learning processes.

Box 5.1. Adverse 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 adverse events (IGZ, 2016a). In the case of incidents and adverse events, the Inspectorate notes, 'something was not done right' – in contrast to complications, that are categorized 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 adverse events alike, hospitals only have to report their adverse events to the Inspectorate – for reporting and investigating incidents, hospitals should have organizational reporting procedures in place. Incidents and adverse events, then, are distinguished based on severity in terms of patient outcome. An adverse event 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 adverse event to the Inspectorate, as they are legally required to do, hospitals conduct their own investigation into the adverse event 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 adverse events 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 (IGZ, 2016d). These interventions, true to the responsive regulation framework (Ayres & Braithwaite, 1992), range from providing critical feedback to organizations, to require organizations to re-do the investigation or for the Inspectorate to conduct their own inquiry with specialized inspectors (IGZ, 2017b).

Box 5.2. Scoring instrument to assess the quality of the adverse event investigation 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
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

Data collection

Database of adverse event investigation reports

As researchers, we were granted access to an Excel-export that listed 4667 scored adverse event reports, from all 96 hospitals in the Netherlands, between 1 July 2013 and 31 March 2019. We received an anonymized version and could not link hospitals to individual adverse event reports. The database shows how inspectors scored each of the 25 items for each adverse event 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 (chapter 3). Given our interest in how an IRS might stimulate social and participative learning, the database with scored adverse event investigation reports potentially provides an indication if and on what items hospitals improved their capability to investigate adverse events. 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, Grit, & Bal, 2019; Grit et al., 2018; chapters 3 and 6). All of these projects included qualitative, ethnographic research. In all, we conducted 73 semi-structured interviews and 36 hours of ethnographic observations. In this chapter, we present data collected within two projects specifically (table 5.1). In the first project, the objective was to explore how hospitals organize their adverse event investigation practices, how managers and incident investigators perceive the effects of investigating adverse events 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 synthesize 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.

Table 5.1. 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 adverse events: 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 anonymized. 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 in more depth elsewhere (see chapter 6).
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 adverse event 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 anonymized. 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 analyzed in order to understand the historical development of the IRS. We have discussed methods used to conduct this study in more depth elsewhere (Grit et al., 2018).

Data analysis

Database of adverse event investigation reports

Descriptive statistics were applied analyzing the 4667 scored adverse event investigation reports. To study changes over time, we obtained how adverse event 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 adverse event 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 adverse event reports by each of the 96 hospitals. Hospitals that reported less than three adverse events 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 5.2). 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 adverse events (Leistikow et al., 2017). For one, the Inspectorate "tailors its regulatory practices to the learning capabilities and the developmental stages of healthcare providers (IGZ, 2016d, p. 10)." Second, conducting good adverse event investigations is thought to be a skill that hospitals develop over time (Leistikow et al., 2017). So, while hospital performance – in terms of adverse event investigation 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 adverse event 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 adverse event scores during the first year serves as an approximation of hospital's learning capabilities and the developmental stages they are in.

Table 5.2. Information on hospital groups, reported and scored adverse events (01-07-2013/01-07-2014)

Groups	Cut-off points of the groups (average adverse event report scores)	Reported adverse events	Average of adverse event report score	StdDev of adverse event 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

Semi-structured interviews

The transcribed interviews were analyzed with the aim to identify themes, performing thematic analysis (Green & Thorogood, 2006). 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 analyzed 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 adverse event 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 adverse events; 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 organization. For that to happen, it helps to investigate adverse events, because you'll force yourself to dig deep. (Investigation committee chair, 10-08-2015)

Adverse event 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 adverse events.

> R1 When I compare where we were five, six years ago with today, we've really developed. Also just in terms of the adverse events we report. We never had adverse events...
>
> R2 (laughs)

R1 You had nothing to worry about when you visited our hospital; things did not go wrong... Now we report 12 adverse events each year. (Investigation committee chair and incident investigator, 20-9-2016)

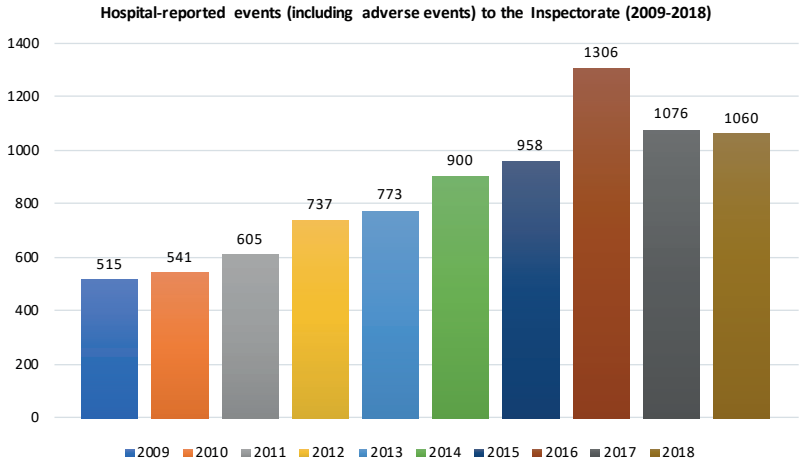

Figure 5.1. In addition to adverse events, hospitals are also required to report 1) violence or sex in professional-patient relationships or in patient-patient relationships when violence has severe consequences and 2) when hospitals dismiss professionals because of poor professional performance. These two events were added to the requirement to report adverse events on 1 January 2016. The Inspectorate reported that of the 1306 events reported in 2016, 1272 were reported as adverse events. Of the 1076 events reported in 2017, 1035 were reported as adverse events. Of the 1060 events reported in 2018, 1030 were reported as adverse events (IGJ, 2019; IGZ, 2016b). An inspector told us the peak in reported adverse events in 2016 can be attributed to considerable and sustained national media attention at the end of 2015 on (unreported) adverse events and a wanting safety culture in the UMC Utrecht, one of the nation's academic hospitals (NRC, 2015, and chapters 2 and 4). Many of the adverse events hospitals reported in 2016, the inspector noted, the Inspectorate judged not to qualify as adverse events.

Many hospital respondents state that they report and investigate more adverse events now than in the past. This is supported by data of the Inspectorate that shows how, since 2009, reported adverse events have steadily increased

(figure 5.1). The quote also shows that what (the number of reported) adverse events tell us has changed. "Before," an inspector told us "no adverse events meant you were the best organization. Now, when an organization reports no adverse events, something's not right" (Inspector, 30-05-2017). Thought of as reflective of an organizational safety culture, the amount of reported adverse events becomes a quality metric in its own right, but one that says little about how organizations are able to learn from them (Macrae, 2016; Vincent, 2002).

Improved adverse event investigations

A key aim of the Dutch IRS was to have hospitals improve their capability to investigate adverse events as an important step towards learning from adverse events (Leistikow et al., 2017). For how adverse event reports are scored by inspectors since 2013, see figures 5.2-5.7.

We might conclude that the high scoring group of hospitals already did fairly well, having many of the conditions for conducting adverse event analysis in place and that, particularly, the low scoring group of hospitals developed. From Q4 2015 onwards, some two years after adverse event reports were scored in accordance to the new scoring instrument, the development of the average adverse event 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 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 adverse event investigations. As to the weight attributed to these items by inspectors, one inspector notes:

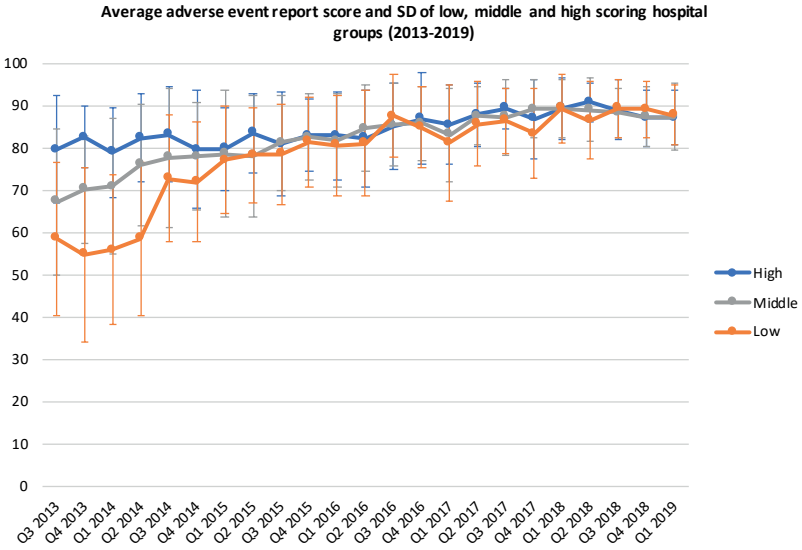

Figure 5.2. Presented here are the average score and standard deviation of those average scores of the low, middle and high scoring group of hospitals between 1 July 2013 to 31 March 2019 (n = 4406). There is no big difference in the extent to which the high, middle and low scoring groups account for the number of reported adverse events; low scoring hospitals reported 1118 adverse events 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.

> What happened [leading up to and during the adverse event] 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 emphasize 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 5.3)—so that the root causes might be identified (figure 5.4) and corrective actions devised that address those root causes (figure 5.5).

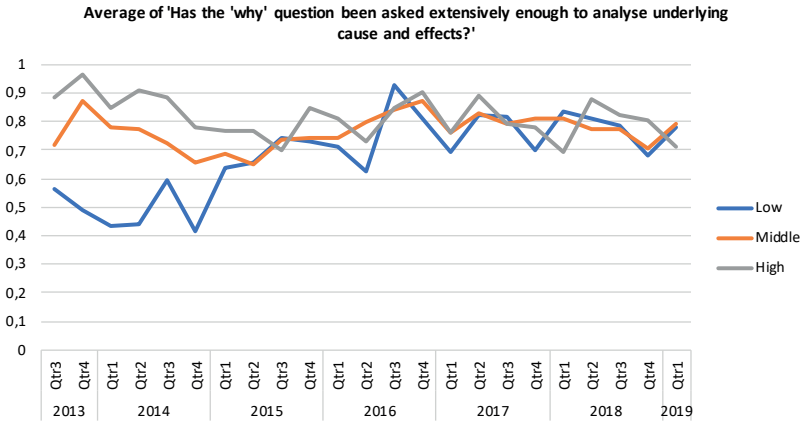

Figure 5.3. Across all items scored, this item is both pivotal according to inspectors (De Kam et al., 2019) – as their assessment of the adverse event report builds upon the investigation's ability to address the why-question thoroughly – and challenging for hospitals to do well on. The overall development mirrors that of the average adverse event 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.

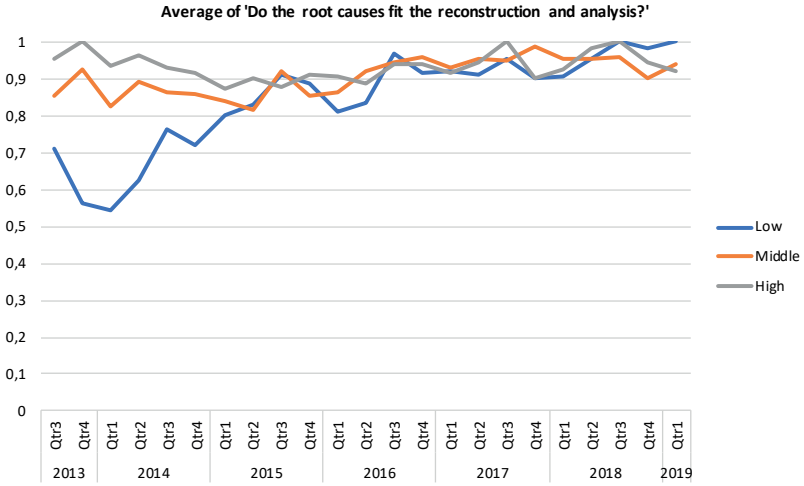

Figure 5.4. This item, that scores the consistency of/link between the causes identified and the preceding analysis of the adverse event, demonstrates a similar development to figure 5.3 and the average scores of adverse event reports. Interestingly, hospitals groups average 100% on this item at some points in time – e.g. in Q3 2017 all 38 adverse event investigation reports by high groups of hospitals addressed this item adequately.

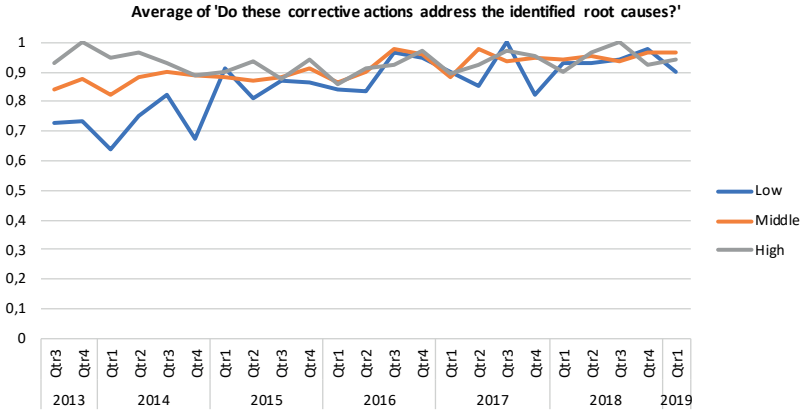

Figure 5.5. This item assesses whether or not the corrective actions formulated address the earlier identified root causes.

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 adverse events or if hospitals have become more adept at writing adverse event 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 adverse event report. Also, the score awarded to adverse event 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)

Hospitals have invested in the professionalization of investigation teams – emphasized and argued for in multiple studies (NHS 2019; Peerally et al., 2017) – by training them in methods on how to conduct adverse event investigations and by keeping teams consistent, allowing investigators to develop expertise. But, dedicated teams are also needed due to the increased numbers of adverse events 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 adverse event 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 adverse events that need to be investigated, coupled to the desire to 'score' well, conducting adverse event investigations becomes a particular organizational 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 recognized and is spurred by the idea that healthcare can learn from the patients' and families' perspectives (Fitzsimons & Cornwell, 2018; Iedema & Allen, 2012; O'Hara et al., 2018, and see chapters 6 and 7). In the Dutch IRS, hospitals are expected to involve patients and families in adverse event investigations and as such, it encouraged hospitals to widen the circle of people able to participate in and contribute to adverse event investigations.

> Yeah, [involving patients and families in adverse event 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 adverse event investigations was no customary practice (figure 5.6). Similarly, the IRS assessed and contributed to the degree to which adverse event investigation reports are shared with patients and families afterwards (figure 5.7). The IRS contributed to the normalization of a practice – the increased involvement of patients and families – that is widely argued for.

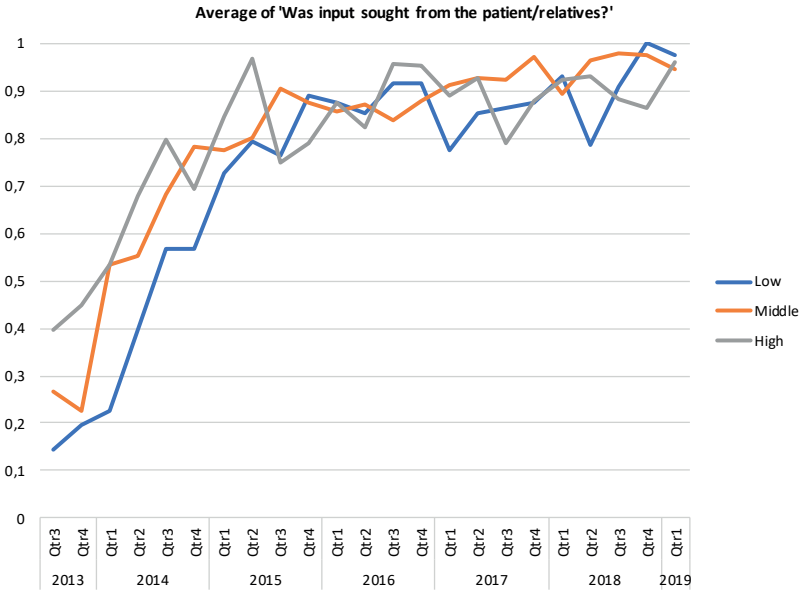

Figure 5.6. In contrast to the other items presented (figures 5.3-5.5), asking patients and families for input in an adverse event investigation was not a customary practice for either of the two hospitals groups. Currently, Dutch hospitals routinely ask patients and families for input in adverse event investigations.

But involving patients and families in adverse event investigations is not the same as learning from them. The IRS operationalizes the need "to engage the patient or a patient representative in adverse event 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 organizing said involvement. Typically, however – and we report on practices of patient and family involvement in adverse event investigations more extensively in our other work (chapter 6) – incident investigators predetermine the scope and the questions the investigation needs to provide answers to.

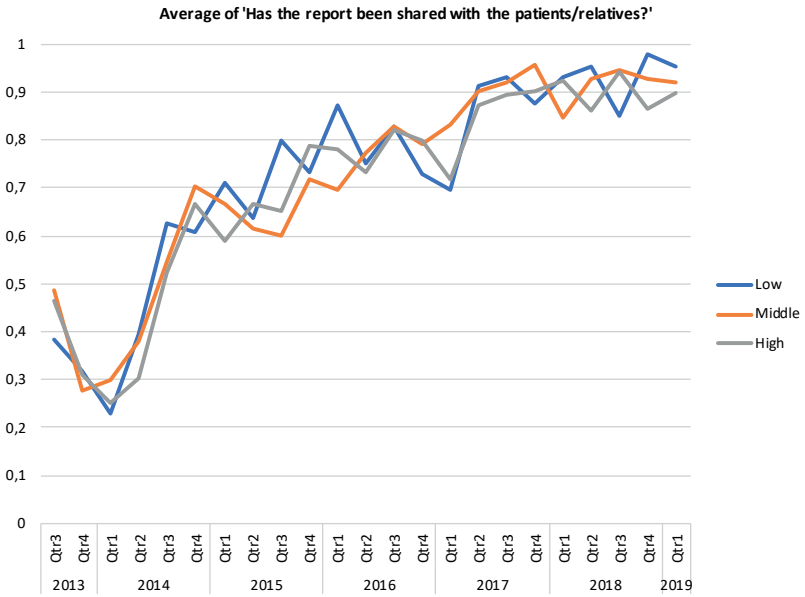

Figure 5.7. Much like figure 5.6, when the IRS started asking hospitals to report if they shared the adverse event report with patients or relatives, hospitals of either of the two groups did not often do this. Now hospitals of both groups report they routinely share the adverse event report with patients 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.

> [In case of an adverse event] we [the investigation 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 adverse events 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.

> 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 adverse event], 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 adverse event] or really played a part in the process that led to the adverse event, 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 adverse event 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 adverse event 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 adverse event investigations generally happens on the hospital's terms (see also chapters 6

and 7). 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 adverse event investigations.

Local learning

While investigating adverse events is expected to generate learning, the need to investigate adverse events is not prompted by the potential learning opportunities an adverse event holds but because it is severe in terms of patient outcome (see box 5.1). This, respondents point out, means that organizational resources and time are committed to investigating adverse events 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 [adverse event investigations] to a higher level and then I saw three more adverse events 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 adverse events that need to be investigated by hospitals comes at the cost of reflecting on what singular adverse events 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 adverse events, inspectors have to keep scoring them.

> What do all these adverse events tell us? How might other organizations 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 adverse events 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 5.5 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 acknowledge that it is a challenge to keep track of all the recommendations adverse event 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 organizational investment into investigating adverse events 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 adverse events, 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 & Goodman, 2011, p. 85). Our study finds that while hospitals invest in the

training of incident investigators and while hospital adverse event 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 gatekeepers of the investigative process; investigations are organizationally 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 adverse events. This is a trend we can expect to continue as reporting behavior has become a quality metric in its own right, that is said to be indicative of a hospital's 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 adverse event 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 organizations invest in practices that are externally monitored (Dahler-Larsen, 2014; Wallenburg et al., 2019) it is hardly surprising

that hospitals consistently deliver higher scoring adverse event 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 organize for and value such involvement differently (chapter 6). Here we want to point out that the involvement of both patients and professionals in adverse event investigations is instrumental to the objective of learning from an adverse event and that the emotional impact of adverse events, on both patients, families and professionals, is not accommodated for in these investigations (Nicolini, Waring, & Mengis, 2011). As Nicolini and colleagues already pointed out, failing to engage with and make room for the emotional impact of an adverse event in favor of the quest for facts and evidence can actually hamper learning (Nicolini et al., 2011). In chapter 7, we explore how 'being emotional' renders patients and professionals prone to being disqualified as contributing valuable input in an adverse event investigation. Now, the IRS does inquire into aftercare practices of hospitals following an adverse event, 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 organized and valued by those who make use of them. The professionalization of adverse event 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 adverse event 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 & 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 adverse events seem

in place, the IRS should redirect its focus to encourage reflection, monitor how shared understanding develops after an adverse event and stress the linkage between investigating and learning. We propose two ways in which an IRS might further encourage shared and participative learning from adverse events.

First, there is a need to rethink the emphasis on investigating singular adverse events. Investigations are prone to become stand-alone activities, disconnected from wider organizational safety practices and learning opportunities (Hibbert et al., 2018; Peerally et al., 2017; Stavropoulou et al., 2015). In the Netherlands, as in other countries, "the perimeter[s] of patient safety" (Vincent & Amalberti, 2015, p. 539) keep expanding as more events qualify as adverse events (Leistikow et al., 2017). As both hospital respondents and inspectors struggle with the number of adverse events that have to be investigated and assessed, a continued focus on singular adverse events might become untenable. Especially for hospitals that consistently demonstrate the ability to adequately investigate singular adverse events, the IRS would do well to accommodate an aggregated level of analysis, encouraging hospitals to reflect on and learn from adverse events in connection to their wider safety policies and practices (Hibbert et al., 2018; Peerally et al., 2017; Stavropoulou et al., 2015). Second, there is a need to move beyond the investigation practices and monitor how hospitals use adverse events to improve daily care practices. Following Ramanujan and Goodman, the IRS can monitor how hospitals work to link the analysis of an adverse event 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 adverse event? How do you link the learning process of the investigation team to the professionals working with their solutions? How do you institutionalize and normalize the solutions identified so that they are used in practice (Ramanujam & Goodman, 2011)? Such open questions encourage hospitals to reflect on how investigation practices (of singular adverse events 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 adverse events 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 organizational 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 adverse event involved healthcare professionals as well as patients. In our focus on how the IRS encourages practices of social and participative learning, we foregrounded the accounts of incident investigators and committee chairs; the professional groups that, in hospitals, organize the investigative practices that aim to support such learning. By conceptualizing 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 sets, 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

PATIENT AND FAMILY ENGAGEMENT IN ADVERSE EVENT INVESTIGATIONS: EXPLORING HOSPITAL MANAGER AND INCIDENT INVESTIGATORS' EXPERIENCES AND CHALLENGES

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ABSTRACT

There is growing recognition among healthcare providers and policy makers that when things go wrong, the patient or their families should be heard and participate in the incident investigation process. This chapter explores how Dutch hospitals organize patient or family engagement in adverse event investigations, maps out incident investigators' experiences of involving patients or their families in adverse event investigations and identifies the challenges encountered. We conducted semi-structured interviews with managers and incident investigators in 13 Dutch hospitals. Study participants (n = 18) were asked about the adverse event investigation routines and their experiences of involving affected patients or family members. Interview transcripts were coded and analyzed using thematic content analysis. Our findings reveal that patient or family involvement in adverse event investigations is typically organized as a one-time interview event. Interviews with patients or their families were considered to be valuable and important in their own right and seen as a way to do justice to the individual needs of the patient or their family. Yet, the usefulness and validity of the patient or family perspective for adverse event investigations was often seen to be limited, with the professional perspective afforded more weight. This was particularly the case when the patient or their family were unable to provide verifiable details of the adverse event under investigation. Study participants described challenges when involving patients or family members, including in relation to the available timeframe for adverse event investigations, legal issues, managing trust and working with intense emotions. We propose that by placing patient and family criteria of significance at the center of adverse event investigations (i.e. an 'emic' research approach), hospitals may be able to expand their learning potential and improve patient-centeredness following an incident.

INTRODUCTION

Patient-centeredness in healthcare has become a widespread goal. Initiatives to achieve patient participation vary widely and can be found in many aspects of healthcare delivery, including patient safety. Emerging incident disclosure frameworks highlight the importance of the patient's or their family's experiences, needs and rights (ACSQHC, 2013; NIVEL, 2016; NPSA, 2009; Ocloo & Matthews, 2016; Powell, 2006). There is growing recognition among healthcare providers, policy makers and scholars that when things go wrong (Powell, 2006), patients or their families should also be heard and participate in the incident investigation process (Etchegaray et al., 2014; Grissinger, 2011; Iedema & Allen, 2012; Peerally et al., 2017; Zimmerman & Amori, 2007).

The literature discusses two main lines of reasoning as to why patients or their families should be involved in incident investigations. First, a moral justification emphasizes the rights and needs of an affected individual and their family. It argues that their involvement is an ethical imperative, is necessary for acceptance, supports the grieving process and reestablishes bonds of trust (Birks et al., 2014; Iedema & Allen, 2012; Legemaate, 2015). The second is an epistemological justification which recognizes the epistemic value of the patient or family perspective; that is, the existence and validity of knowledge attributed to their experience. The epistemological justification draws on concepts of system-based learning and patient-centered healthcare. It recognizes that all actors are experts in their own right and that patients and their families bring valuable knowledge that can inform learning from what has gone wrong, thereby improving patient safety (Etchegaray et al., 2016; Liang, 2002). It also explicitly recognizes that there is a patient or family perspective and that this can differ from the professional perspective (Iedema, Allen, Britton, & Gallagher, 2012; Rowley & Waring, 2011; Vincent & Amalberti, 2016). The patient or family experience can thus offer key insights that might otherwise be overlooked (Amori & Popp, 2007).

While recognized as an important issue, there are few published descriptions of processes that explicitly consider the patient or family perspective in responding to patient safety incidents (Herrin et al., 2016; McDonald et al., 2010). Empirical data on how hospitals organize and experience patient or family engagement in incident investigations remain scarce (Grissinger, 2011), and the degree to which the moral or epistemological justifications resonate through these practices remains unclear. This study aims to contribute to closing this gap by exploring how Dutch hospitals organize patient or family involvement in adverse event investigations and how this is experienced by those responsible for adverse event investigations.

Patient and family engagement in adverse event investigations in the Netherlands

In the Netherlands, a newly passed law (January 2016) mandates hospitals to involve patients and their families in adverse event investigations (NIVEL, 2016). Dutch hospitals are required to implement internal incident monitoring systems and to report adverse events to the Dutch Health and Youth Care Inspectorate (HYCI), the national regulatory body. Dutch law defines adverse events as unintended or unexpected events that are related to the quality of care and that have caused the death of or serious harm to the patient. They are internally investigated by root cause analysis (RCA), or similar form of investigation in an attempt to learn from what went wrong. Hospitals have eight weeks to investigate the event and submit the investigation report to the HYCI. The HYCI actively monitors patient and family engagement, seeing it as 'a necessary ingredient for hospitals to optimally learn from what has gone (IGZ, 2016b) (epistemological justification) while also considering involvement to be 'an external check on the investigation's validity' (Leistikow et al., 2017).

The legislative framework in place means patient or family adverse event investigation engagement rate in Dutch hospitals is likely to be high. Indeed, HYCI data show that the proportion of adverse event investigation reports that documented some form of input from the patient or their family increased from 15% in 2013 to almost 85% in 2016 (figure 6.1). However, what remains

unclear is what precisely patient and family engagement in adverse event investigations in Dutch hospitals entails, how the patient or family perspective is being used in investigations and the challenges that are being encountered by managers and incident investigators[25] in involving patients or their families.

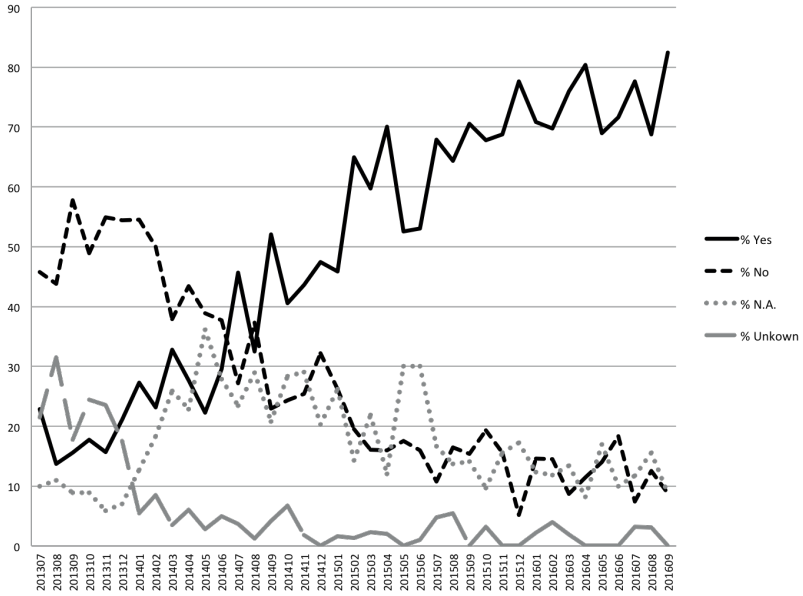

Figure 6.1. Documented involvement of patients and/or families in adverse event investigations in the Netherlands

x-axis: time (year/month). y-axis: % of RCA investigation reports. Solid black line denotes percentage of adverse event investigation reports received by the Inspectorate, that have received input from the afflicted patient and/or patient's family. (Source: HYCI's incident investigation monitoring database, accessed December 2016, unpublished data.)

25. *In the Netherlands 'incident investigators' are usually trained in Root Cause Analysis (RCA) techniques. They may be involved in the investigation of different types of safety incidents. The incident investigators participating in this study were specifically asked to reflect on their adverse event investigations.*

METHODS

Sampling

Sampling was conducted in two stages. In the first stage, we purposively selected 10 (out of a total of 93) hospitals. These were geographically evenly spread throughout the country and included academic teaching, tertiary and general hospitals. Included hospitals scored excellent, average or poor with regard to the quality of their adverse event investigation reports, as documented by the HYCI (table 6.1). Our initial aim was to continue sampling until no new insights emerged from the data (Green & Thorogood, 2006), but preliminary analysis suggested that saturation had already been reached within the small initial sample of 10 hospitals. We randomly approached three additional hospitals; this did not reveal any further insights, confirming that we had reached data saturation.

Data collection

This study targeted individuals responsible for or involved in adverse event investigations in Dutch hospitals. Secretariats from the sample were contacted by telephone to inquire who was responsible for adverse event investigations within their organization. Following this, we approached 19 eligible individuals for an interview via email, which provided details of the study's objective and specified confidentiality standards, namely, that all data would be fully anonymized to facilitate open and transparent communication. Stressing these norms was particularly relevant as one of the authors (IL) is employed by the HYCI. One potential study participant declined participation. Interviews were conducted by the first author (JK), who had no prior relationship with study participants, but had met one participant at an international patient safety conference. Interviews followed an interview guide, exploring key topics of interest (table 6.2).

Table 6.1. Study participants and interview details

Hospital details			Study participants			Interview details	
No.	**Hospital type**	**Average quality of adverse event analysis report vs. national average (0-100%) ***	**Gender**	**Occupation**	**Role in RCA investigation process**	**One-on-one/ duo**	**Length (min.)**
1	Academic	75/78	Female	Manager	RCA investigator / Committee member	o	80
			Male	Director / medical professional	Committee chair	o	63
2	Tertiary	90/82	Female	Manager	Committee chair	o	75
3	Tertiary	88/80	Female	Manager	RCA investigator	o	87
			Female	Manager	Committee chair	o	58
4	Tertiary	91/81	Female	Quality and Safety advisor	RCA investigator	o	59
5	Tertiary	84/81	Female	Medical professional	RCA investigator	o	91
6	General / Tertiary	78/81	Female	Manager	Committee chair	o	62
7	Tertiary	78/81	Female	Assistant manager	RCA investigator / Committee member		
			Female	Manager	Committee chair	d	61
8	Academic	76/81	Male	Manager / medical professional	Committee secretary		
			Male	Assistant manager	RCA investigator / Committee member	d	70

Table 6.1. Continued

Hospital details			Study participants			Interview details	
No.	Hospital type	Average quality of adverse event analysis report vs. national average (0-100%) *	Gender	Occupation	Role in RCA investigation process	One-on-one / duo	Length (min.)
9	General / Tertiary	76/81	Male	Manager / medical professional	Committee chair	o	52
10	General	70/80	Female	Manager	Committee chair	o	76
11	Tertiary	70/82	Female	Legal advisor	Committee secretary / RCA investigator	o	72
12	General / Tertiary	75/81	Female	Manager	Committee secretary / RCA investigator	o	75
13	Tertiary	83/82	Female	Manager	Committee secretary		
			Female	Assistant manager	RCA investigator / Committee member	d	75

** Adverse event analysis reports are scored by the HYCI (0-100%) to monitor the quality of the adverse event investigation. To monitor a hospital's overtime performance the HYCI calculates moving averages for each hospital; the mean score derived from a hospital's past five reports. Because moving averages change overtime and our interviews have taken place over a period of several months this column denotes a hospital's moving average as recorded by the HYCI during the month of the interview. Source: HYCI's adverse event investigation monitoring database called "digiBAN" [cited Feb-Aug 2015], unpublished data.*

Table 6.2. Interview guide

Introduction	**Topic 1** Adverse event investigation team/ incident investigators	**Topic 2** Adverse event investigation routine/work protocol	**Topic 3** Patient/family engagement	**Wrap up**
• General acquaintance • Repeat purpose study • Repeat confidentiality norms • Informed consent/ permission auto-recording	1. Participants: how many? Who is involved? Etc. 2. Organization: formal/ informal activities 3. Own role/ responsibilities	1. Process description (incl. disclosure & peer-support practices) 2. Experiences 3. Challenges	1. Process description 2. Experiences 3. Challenges	• Other points to discuss? • Member-check appointment made

We carried out a total of 15 semi-structured interviews, involving 18 participants in 13 hospitals (table 6.1). Interviews were carried out face-to-face; they lasted between 50 and 90 minutes. Interviews were audio recorded following consent and transcribed verbatim. Participants were invited to receive a copy of the transcript to validate or amend their accounts. Nine respondents did request the transcript, but none requested any changes.

Data analysis

Data were analyzed using thematic content analysis. This involved categorizing data based on recurrent pat- terns and deviant cases found within the earlier defined topics from the interview guide (table 6.2) (Green & Thorogood, 2006). Transcripts were first coded inductively (open coding) in Microsoft Word by JK. The inductive codes were transferred to tables, ordering related interview extracts. In the second coding phase, the content in these tables was reexamined to search for and define patterns. The identified patterns were discussed (JK and RB) to agree on the credibility of our interpretations.

Our analysis was presented at the Third International Disclosure Conference (Amsterdam, October 2016), attended by many of the study participants. The presentation and succeeding discussion provided a member-check platform as participants publicly reflected on our analysis. The discussion established that our analysis reflected the reported involvement practices and experienced challenges.

Quotes presented in this chapter were translated into English. They were selected to illustrate our analytical findings. The selected quotes were shared with study participants to obtain permission for use and validate our translation.

Ethical approval

This study did not require approval from national or local ethical committees as Dutch law (WMO act) determines such approval is not required for reflective interview studies (CCRIHS, 2017).

RESULTS

Study participants from all 13 hospitals (n = 18) included in the study reported that they would seek patient involvement during adverse event investigations and all but one actively sought input from family members when the patient was (emotionally) not able to participate or was deceased. All study participants noted that the majority of patients or their families wished to be involved in the investigation process. Our analysis of the data identified a number of key themes. These were: the practical organization of patient or family involvement; motivations for involving patients or families; and experienced challenges of involving a patient or their families in adverse event investigations. We report on each theme in turn.

Patient or family involvement is a one-time event

Study participants explained that it was a common practice for an investigation team to be formed within the hospital immediately after an adverse event had been discovered. Teams would typically comprise of two to five RCA trained incident investigators with diverse clinical (doctor, nurse) and non-clinical (administrative support staff) backgrounds. Most study participants reported that incident investigators on these teams would conduct these investigations on a voluntarily basis, in addition to their day-to-day work. A typical investigation would start by examining medical file(s) to describe the problem, followed by defining the questions that the investigation should answer and the sources to be consulted to understand the causal factors that have contributed to the problem:

> Depending on the type of adverse event we decide what it is we need to know. General research questions are formulated. And (. . .) we determine who we need to speak to. We plan interviews with these actors and (...) we involve the patient or their next of kin. (. . .) We contact them and ask if they would like to be interviewed or just wish to receive the end report. (RCA Investigator, no. 7)

There was widespread agreement that patient or family involvement in the investigation process would generally constitute a one-time interview event

rather than ongoing engagement. Study participants noted that a patient or family interview may last anywhere between 30 minutes and two hours. Practices vary between hospitals, however, for example in the way they communicate with patients or their families affected by the adverse event. Some formally invite the patient or their family by sending a letter or leaflets to inform them about the investigation process and purpose. Others use a more informal approach, communicating with the patient or their family face-to-face or on the phone. Interviews with patients or their family are conducted at the hospital, in people's own homes or by telephone. Some hospitals strictly adhere to one location while others are more flexible, choosing the location of the interview in line with the patient's or their family's preferences. Also, hospitals differ in sequencing the process; that is, the point when the patient or their family is being interviewed. Study participants from two hospitals expressed a strong preference for starting the process with input from the patient or their family to allow them to share their experiences first, while the majority would conduct the interview at a time of practical convenience i.e. when personal schedules of involved participants matched. Hospitals also vary in the range of hospital staff involved in the interview of the patient or their family. Typically, interviews comprise two incident investigators and the patient or a family member. Occasionally, a quality manager, member of the hospital board or medical specialist who was not involved in the adverse event may join. The presence of a complaints officer is also becoming more common, to lead the interview or serve as a support person for either the patient/their family or investigator(s).

Motivations for patient or family engagement in adverse event investigations

All study participants stated that they valued patient and family engagement in adverse event investigations. Several participants specifically highlighted their appreciation of the HYCI, which had helped or forced hospitals to overcome the 'hurdle' of engaging patients and their families during investigations:

> R: We must compliment the HYCI, (...) it is a good thing they enforce this [patient and family engagement]. It has really improved the quality.

> I: In what way?
>
> R: Well you do hear [during the patient or family interview] several things that you won't find in the official internal documentation or hear from the medical staff. They [patient and family] have a different perspective.
>
> (Committee Secretary, no. 8)

This quote also speaks to one of four motivations that incident investigators identified for involving the patient or their family in adverse event investigations, which we discuss in turn.

(1) Verifying operational details and/or inspiration to 'look further'.

Patient and family engagement was considered meaningful when it allowed investigators to verify technical details or when patients or their families were able to offer new 'facts':

> We often receive information from patients that place the doctors' or nurses' accounts in new light. Just the other day we had a case in which they [the nurses] said 'Those people [patients or their families] did not call the hospital' but then the patient handed us [investigators] a phone bill specifying that he [the patient] did call. (...) So the nurses' accounts were verifiably incorrect. (Committee Secretary, no. 13)

Such 'verifiable' input could then "push investigations into new directions" (Committee Secretary, no. 13). The interviews revealed that when patients or their families were not able to provide or confirm such details, that is, they had not 'witnessed' the actual adverse event, their input was perceived to be less useful for the investigation. Study participants from only two hospitals (notably the same two hospitals where the investigation process begins with an interview with the patient or their family) argued that patient or family input was always seen to be relevant. Firstly, where there are large discrepancies between the patient's or family's account and that of professionals, recommendations could

be made towards improving internal communication practices. Secondly, a patient's or their family's account of the adverse event can sometimes prompt investigators to look further than the 'factual' technicalities of the adverse event:

> R: The other day we investigated an adverse event, which was brought to our attention via a complaint. (. . .) The central research question in our investigation was, 'was care delivered according to protocol?' Obviously the patient wasn't happy. (...) Everyone [investigators] was zooming in on the protocol but it was vague, could be interpreted from different angles. One professional thought this, the other expert and complains commission thought that. (. . .)
>
> I: The investigators were stuck?
>
> R: Yes. Our focus on the protocol just wasn't going to help. So we turned it around and asked: 'did we place this patient's needs first? And did we follow up on those needs?' (Committee Chair, no. 4)

In this example, the patient's experience prompted the investigators to move beyond the technical specifics of the adverse event and embraced it as a driver for broader improvements.

Interview participants from other hospitals appeared to place less weight on individual patient's (or their family's) emotions, opinions or observations. An exemplary quote conveys this tendency:

> Sometimes we identify discrepancies [between what the patient or their family and the healthcare professional says] but yeah, that's where it ends because, well you can't verify it with facts, it's something someone says, it's the patient's point of view. (Committee Chair, no. 6)

Embracing the patient's or their family's story and learning from their accounts appear to be difficult. As the quote reveals, incident investigators do recognize that there is such a thing as a patient or family perspective, but in most cases the professional perspective seems to carry more weight.

(2) Providing space to share experiences and emotions.

All study participants emphasized the value of patient or family involvement to provide a platform that allows them to share their experiences and feelings.

> It is of particular importance that you provide patients or family members with space to share their experience. Because you want them to be satisfied, despite what has happened. (Committee Chair, no. 7)

Clearly, inviting patients or their family for an interview does not only serve the purpose of gathering (practical) information for the investigation; the interview functions as a space for the recollection of events. However, in line with our earlier observation, the recollection of events by patients or their families is not always framed as 'useful' input for the adverse event investigation:

> What I've noticed is that the information provided by the patient is mostly not taken up in the report (...). They just share their experiences. (Committee Chair, no. 6)

(3) Providing information and answering questions.

Many study participants explained that the interview with patients or their families also functions as a formal opportunity to respond to questions and/or provide information. Depending on who is present at the interview, queries regarding the investigation process and goal, as well as related medical questions, can be answered:

> It [the patient or family interview] is a moment to inform them [patients or their families] that the hospital is doing an investigation and why this investigation is done. We explain that we wish to learn from what has happened and are not out to assign blame. It's sort of like expectation management, so that when they [patients or their families] receive the end report they know what to expect of it and won't be like 'but the report doesn't tell me if I also have an increased risk of

> having a brain hemorrhage'. That's not what the investigation is for but patients or their families don't know this. (. . .) So we take the time to attend to questions. (RCA Investigator, no. 3)

(4) Displaying empathy and regaining trust.

Study participants highlighted the value of interviews with the patient or their family as providing an opportunity to show empathy, which may help to restore trust:

> Purely the fact that we [hospital], that you listen to them [patients or their families] and that we make the effort to listen to them. That works therapeutically. They [patients or their families] feel like they are taken seriously, like 'well, that our hospital does all this for us'. (Committee Secretary, no. 13)

The interview provides an opportunity where hospital representatives can demonstrate sincerity. One study participant noted that doing this well can be a way to help restore or improve a hospital's reputation, and a means to avoid legal claims: "It's worth gold!" (Committee Secretary, no. 8). Thus, engaging patients and their families serves the hospital's own interests as well as that of affected patients and their families.

Challenges faced by hospital incident investigators

Although patient and family engagement were believed to be important and valuable, study participants highlighted several challenges. First, patient and family engagement can create legal challenges as adverse event investigations can take place in parallel to financial claims and complaints proceedings. Study participants reported the challenge of the need to keep all parties informed of various proceedings that occur in parallel. It may also impose considerable strain on patients and their families, as well as investigators, to deal with the wide range of actors involved in different processes and proceedings.

Second, the timeframe within which an investigation is to be carried out can be problematic. As noted earlier, hospitals have to report to the HYCI within

eight weeks from when the adverse event has been discovered. While incident investigators interviewed for this study were positive about the strict timeline, this can pose challenges for effective patient and family engagement as it leaves little room for working at the patient's (or their family's) pace (Amori & Popp, 2007). Several study participants explained that in case of a patient's death they would "wait for the funeral to pass" (Committee Secretary, no. 8; Committee Chair, no. 10) but then they would "really have to get going" (RCA Investigator, no. 3). This may result in patients or their families not being willing or able to take part in the investigation. The restricted timeframe may also limit opportunities for effective learning from the patient's or their family's stories, as it allows investigators to speak to them only once.

Third, study participants highlighted the challenge of managing patients' and their families' expectations about how their input will be used. Failing to do so may cause additional distress or even distrust. Study participants noted that this can be problematic when patients or their families seek answers from the investigation that it may not be able to provide. Moreover, as one participant explained, where patients or their families share personal experiences or provide alternative accounts to those of the professionals, but this input is not considered in the final investigation report, this may make patients or their families feel unheard (Committee Chair, no. 6).

Finally, study participants highlighted the challenges of having to deal with emotions. Managers interviewed for this study noted that interviews with patients or their families were not difficult as such, as incident investigators are often clinical staff that are equipped with the tools to give "bad news" (Committee Secretary, no. 11; Committee Secretary, no. 12). However, incident investigators themselves noted the difficulty of dealing with their own emotions, as well as those of patients and their families, which can range from anger, sadness, guilt, betrayal and helplessness. One investigator recalled a particularly emotional interview:

> For me it almost felt as a threatening situation. I was relieved that we [the investigators] were with the two of us. He [bereaved family member] looked at me in a way that made me think 'I hope he doesn't find out where I live'. You know? But at the same time, I also felt so sorry for him. (RCA Investigator, no. 13)

Our findings suggest that the diverse emotions surfacing during interviews with patients and their families may require (additional) support or improved investigator competencies.

DISCUSSION

Our study set out to explore how patient and family involvement in adverse event investigations is organized in a sample of Dutch hospitals and how hospital staff involved in investigations experience this involvement. We found that patient and family involvement is typically limited to a single interview event. Patient or family interviews confront incident investigation teams with several challenges, but they are largely regarded as adding value to the investigation process. Motivations for patient engagement in adverse event investigations include that consulting the patient or their family allows investigation teams to verify operational details and/or prompts investigators to look for further information or beyond the incident under investigation. Further, the patient or family interview provides space for patients and their families to share their experiences and emotions; allows hospital investigators to provide patients and their families with information and/or to answer outstanding questions; and it creates a platform where the hospital, through the investigation team, can demonstrate empathy and regain trust.

The nature of participation

The supportive governmental regulatory policy (Ocloo & Matthews, 2016) has led to patient or family involvement becoming a routine part of adverse event investigations in the Netherlands. This is a positive development that aligns with the norms set by open disclosure frameworks and the patient-centeredness

movement more generally (ACSQHC, 2013; Arnstein, 1969; Etchegaray et al., 2016; Etchegaray et al., 2014; Grissinger, 2011; Herrin et al., 2016; Iedema & Allen, 2012; Iedema et al., 2011; McDonald et al., 2010; NIVEL, 2016; NPSA, 2009; Ocloo & Matthews, 2016; Zimmerman & Amori, 2007). Patients or their families are consulted on and provided with information, but they are not actively taking part in the investigation process. Indeed, participation in terms of reviewing data, providing feedback about (preliminary) findings and reports are increasingly called for in literature (Grissinger, 2011; Herrin et al., 2016; Ocloo & Matthews, 2016; Zimmerman & Amori, 2007), is not common. Although patient participation is predominantly viewed from within this 'more is better' paradigm (Arnstein, 1969; Ocloo & Matthews, 2016; Van de Bovenkamp & Zuiderent-Jerak, 2015), we would argue that whatever the nature or intensity of involvement, the underlying justifications for patient or family participation must be considered first.

Justifications for engaging patients or their families in adverse event investigations

We have suggested that engaging patients or their families in adverse event investigations provides opportunity for patients and their families to share their experiences and emotions and for hospital investigators to provide further information and/or answer outstanding questions. It also creates a means to demonstrate empathy and regain trust. These motivations reflect what has been described as the moral justification, whereby hospitals aim to do justice and cater to the individual needs of patients and their families. Patient and family engagement is seen to be important based on the underlying principle that it is the right thing to do. The patient interview provides an opportunity, a space where the hospital can 'do the right thing' in a difficult and emotionally charged situation.

We have also shown that engaging patients and their families allows investigation teams to verify operational details, a motivation that is more closely linked to the epistemological justification. This considers the patient or family perspective as valuable to help understand and learn from things that have

gone wrong. However, we find that existing processes and routines do not fully do justice to the 'learning from' aspiration. Incident investigators interviewed for this study recognized that there is a distinct patient or family perspective on the adverse event and that this perspective differs from a professional perspective, but it is the latter that is typically accorded more weight in an investigation. This was particularly the case where patients or their families were unable to provide or verify 'facts' related to the adverse event; here, the epistemic value of their input was deemed to be limited.

Emic versus etic research approach

The anthropological concepts of 'emic' and 'etic' research approaches may help us understand why the epistemic value of the patient (or their family's) voice in adverse event investigations is accorded a lower weight. An etic research approach emphasizes the observers' (researchers'; the outsider) rather than the insider's explanations, categories and criteria of significance (Kottak, 2004). Preconceived notions of what is 'true' and relevant to know lead the fieldwork and are used to decipher a phenomenon. In contrast, an emic research approach emphasizes the insider's perspective with a focus on the explanations and criteria of significance provided by the members of the phenomenon, i.e. the actors involved (Kottak, 2004). Emic approaches seek to understand a phenomenon 'from within' (Kottak, 2004).

Our findings suggest that in most cases, hospital incident investigators appear to adopt (implicitly or explicitly) an etic research strategy: the investigation team decides what it is they need to know and whom they need to speak to, to understand and learn from what has gone wrong. Such an approach devalues the epistemic significance of the patient or family perspective. While adverse event investigations seek to support the healing process and cater to individual needs, the experiences or patients and their families, their reconstructions of events and 'low level' concerns (Iedema & Allen, 2012) are predominantly framed as less valid or important for the analysis of the adverse event, unless

their insights 'fit' with or contribute to the predetermined investigation route. Moreover, most investigations take the investigators' research questions as a starting point rather than those posed by patients or their families.

The patient or family interview, conducted within an etic researcher strategy, reflects a moral rather than the epistemological justification. Adopting an emic research approach in adverse event investigations, for instance by interviewing patients or their families at the beginning of the investigation process and maintaining continued involvement and using patients' questions and concerns to be the starting point of the investigation, would emphasize the epistemic significance of patient (or family) knowledge. However, an emic approach may not necessarily meet all needs of patients or their families, but it would support investigators to embrace the patient or family perspective and help inform their learning from patient or family input, which is likely to provide insights that were previously unrecognized patient safety issues.

Study limitations

The scope of this study is limited as we have focused our exploration on a specific type of healthcare organization (hospitals) and our sample size was small. Broadening the scope could have possibly furthered our understanding of patient and family involvement processes and the challenges different types of healthcare organizations are facing in terms of adverse events and involvement approaches. However, the balanced diversity of our sample, including participants from different hospitals across the Netherlands and the member-check performed at the Open Disclosure conference to validate our analysis, gives us confidence that our findings provide a trustworthy exploration from within Dutch hospitals. Importantly, we also recognize that patients and families 'being heard' and actually 'feeling heard' are not necessarily the same thing. This study did provide insights from an institutional perspective but did not include patients and families affected by adverse events. Future research should focus on the patient and family views of adverse event investigations.

CONCLUSIONS

Our findings provide a better understanding of the practices and challenges of engaging patients or their families in adverse event investigations in Dutch hospitals. A key finding is that patient and family voices are heard but the value of their input is often downplayed and not used widely as a driver for broader learning.

Implications

Complementary to earlier calls to investigate how patient or family engagement can play an effective role in patient safety (Etchegaray et al., 2016; Iedema et al., 2012; Iedema et al., 2011; Ocloo & Matthews, 2016), we recommend that hospitals actively evaluate their patient engagement approaches to understand the degree to which they are meeting the expectations and needs of patients and their families. This is a necessary step to encourage learning from the patient perspective and provide patient-centered care more broadly. It will be essential for policy makers and incident investigators to recognize the approach taken to investigate patient safety incidents. The nature of the approach, emic or etic, determines how investigators assess what it is they see and hear, what they think is important and relevant to learn. Our findings highlight that patient or family engagement on its own does not necessarily lead to increased patient-centeredness (Van de Bovenkamp & Zuiderent-Jerak, 2015), or enable broader learning from mistakes. The patient's and their family's experiences and perspectives must be recognized as valuable in their own right and should be considered as a core part of the investigation process.

7

EPISTEMIC INJUSTICE IN INCIDENT INVESTIGATIONS: A QUALITATIVE STUDY

UNDER REVIEW AT

Health Care Analysis

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ABSTRACT

Adverse event investigations – often conducted by means of Root Cause Analysis (RCA) methodologies – are increasingly seen as platforms to learn from multiple perspectives and experiences: professionals, patients and their families alike. Underlying this principle of inclusiveness is the idea that medical staff and service users hold unique and valuable knowledge that can inform learning, as well as the notion that learning is a social process that involves people actively reflecting on shared knowledge. Despite initiatives to facilitate inclusiveness, research shows that embracing and learning from diverse perspectives is difficult. Using the concept of 'epistemic injustice', pointing at practices of someone's knowledge being unjustly disqualified or devalued, we analyze the way adverse event investigations are organized and executed with the aim to understand why it is difficult to embrace and learn from the multiple perspectives voiced in adverse event investigations. We draw from 73 semi-structured interviews with healthcare leaders, managers, medical professionals, incident investigators and inspectors, document analyses and ethnographic observations. Our analysis identified several structures in the investigation process, that can promote or hinder an actor's epistemic contribution in the process of incident investigations. Rather than repeat calls to 'involve more' and 'listen better', we encourage policy makers to be mindful of and address the structures that can cause epistemic injustice. This can improve the outcome of adverse event investigations and can help to do justice to the lived experiences of the involved actors in the aftermath of an adverse event.

INTRODUCTION

While the value of incident investigations as a driver for learning and improving healthcare has been contested (Anderson et al., 2013; Macrae, 2016; Mitchell et al., 2015; Peerally, Carr, Waring, & Dixon-Woods, 2017), they have become a consistent – sometimes legally mandated – component of national and local incident reporting systems around the world (Leistikow et al., 2017). In the American, Australian, English and Dutch healthcare systems, adverse event investigations are routinely conducted by means of Root Cause Analysis (RCA) methodologies (Iedema et al., 2006; Mengis & Nicolini, 2011); a family of approaches that consist of a structured, retrospective analysis to identify the latent and root cause(s) of an adverse event. Based on the root causes, improvement measures are formulated in an attempt to minimize the risk of reoccurrence (Nicolini et al., 2011).

RCA methodologies adopted by healthcare organizations stimulate incident investigators[26] to collect input from all actors who are most familiar with, have knowledge about and/or were part of the incident (WHO, 2011) professionals, patients and their families alike. Underpinning such broad inclusiveness are the widely embraced ideals of patient-centered care and system-based learning, wherein all actors are seen as experts in their own right, who bring valuable knowledge that can inform learning from what has gone wrong and improve healthcare services more generally (chapter 6; Birkeland, 2019). Particularly patients and their families are increasingly recognized as invaluable informants when it comes to healthcare improvement. It has been noted they make important observations that are different from those of managers and healthcare staff (Adams, Maben, & Robert, 2018; Birkeland, 2019; Gillespie & Reader, 2018; Iedema, Allen, Britton, & Gallagher, 2012), fueling calls to take user experiences – their complaints and ideas for service improvements

26. *As noted earlier in this thesis, incident investigators can be involved in the investigation process of many different types of safety incidents. The incident investigators interviewed for this study were specifically involved in adverse event investigations.*

– seriously. Harvesting different experiences in adverse event investigations is also an imperative when learning is conceived of as a social and participative process that involves people actively reflecting on shared knowledge and practices (Macrae, 2016). Alongside this learning perspective, involving and hearing all knowledgeable actors is also presented as the right thing to do – for patients, their families and caregivers, – facilitating healing and closure (De Vos & Hamming, 2018; Dekker, 2012; Wu, 2000; chapter 6). Importantly, within this latter ideal, allowing participants to provide testimony is not about who is right or more reliable, but about providing room for the perspectives of all those involved.

Even though the value of involving multiple actors in incident investigations is increasingly recognized, it does not always happen (Etchegaray et al., 2016; Grissinger, 2011). Moreover, where there is multi-voiced involvement to improve healthcare services and quality of care, research has shown that gathering, processing and assigning value to multiple perspectives is a challenging endeavor. A recent interview study has shown that medical staff often view patients as unreliable commentators on the quality of care given, as well as lacking insight on their own care and treatment priorities. These opinions, negatively influence the way patient narratives – specifically patient complaints – are assessed and used by medical professionals to reflect on services (Adams et al., 2018). A study in English National Health Service (NHS) hospitals reported that dissent and conflict between different professional voices harvested in the investigation was frequently edited out of the final investigation report (Nicolini et al., 2011). Similarly, a study in Dutch hospitals concluded that although patient and family members were routinely involved in adverse event investigations, their input was often downplayed and when the contributions of patients and families contradicted that of professionals, the professional perspective prevailed (chapter 6).

Muting or underrating voiced experiences, as demonstrated in the above-mentioned studies, potentially hampers social learning and improving health services. What's more, not feeling heard or listened to in the aftermath of an

adverse event can inflict intensified grievance (De Vos & Hamming, 2018; Iedema et al., 2011), inhibit reconciliation and cause patients and their families to go on a 'legal crusade'(Moore & Mello, 2017). To understand why it is difficult to assign value and learn from all perspectives, we (re)examined qualitative data collected in research projects on adverse event investigation practices in Dutch healthcare organizations. We studied these investigation practices to identify instances where professionals, patients and their families are prone to experience 'epistemic injustice'.

Developed by Fricker, 'epistemic injustice' refers to a wrong done to someone specifically in their capacity as a knower (Fricker, 2009). Fricker identifies two types of epistemic injustice: testimonial and hermeneutical. Testimonial injustice occurs when prejudice causes a hearer to give a deflated level of credibility to a speaker's word. An example would be if a police officer does not believe a man's testimony because he is black (Fricker, 2009). In this example, the man suffers a credibility deficit, not because he has been observed to be unreliable in the past but because of the negative stereotypes – in this case racial – attributed to him by the hearer (Hookway, 2010). Due to the officer's prejudice – Fricker argues – the black man is unjustly discredited as a knower (Fricker, 2009; Hookway, 2010). Hermeneutical injustice occurs when a lack of resources, usually conceptual resources, puts someone at an unfair disadvantage when it comes to making sense of, and sharing, their experiences (Fricker, 2009; Hookway, 2010). Fricker tells the story of a woman who suffered injustice as she battled depression succeeding the birth of her son. For years she blamed herself and was blamed by her husband, until she attended a meeting in the late 1960s where postpartum depression was discussed. Here the unveiled conceptual resource – the linguistic label 'postpartum depression' – enabled the woman to understand her condition, previously ill-understood by herself as well as others. In this example, the woman's husband – the hearer – may not have been unwilling to believe his wife's testimony, but he could simply not understand what she was saying as he may have lacked the same concept (Fricker, 2009). Certain groups of people, Fricker adds, are more prone to be hermeneutically disadvantaged – and suffer hermeneutical injustice – for

social norms, cultural practices, structural social inequalities and institutional arrangements prevent them equal access to the resources to make sense of and articulate their experiences (Anderson, 2012; Carel & Kidd, 2014; Fricker, 2009). In a related vein, when someone is not granted access to participate in epistemic activities at all, this is called epistemic exclusion (Carel & Kidd, 2014; Hookway, 2010). Taken together, the notions of epistemic injustice and exclusion are insightful when studying quality and safety improvement efforts, as they allow us to recognize how potentially valid knowledge is undervalued and/or not shared (Reed & Rishel, 2015).

The concept of epistemic injustice has been used in empirical studies in healthcare before. These studies mainly focus on care related encounters between health professionals and patients – in pregnancy and childbirth (Freeman, 2014) or surrounding the contested medical status of chronic fatigue syndrome (Blease, Carel, & Geraghty, 2017). They show how power imbalances between both groups renders patients prone to suffer epistemic injustice in these encounters (Carel & Kidd, 2014). In addition to the social interactions in healthcare, epistemic injustice can also be triggered through the structures of contemporary healthcare practices, as organizations and procedures privilege certain styles of articulating testimonies, certain forms of evidence, and certain ways of presenting and sharing knowledge (Carel & Kidd, 2014). When we recognize that the specific structure of adverse event investigations encourages a specific way of talking about, thinking about and doing safety (Anderson, 2012), we expect that some actors invited to contribute to incident investigations are prone to suffer epistemic injustice when their testimonies do not suit this structure. Fueling this expectation are the earlier described studies demonstrating that incident investigators occasionally neglect or silence different interpretations offered during the investigation process (chapter 6; Nicolini et al., 2011). Moreover, other scholars have reported that professionals and patients sometimes feel frustrated and unjustly treated because their accounts are not (fully) sought out (Moore & Mello, 2017), are misrepresented or missing entirely in the final

reconstruction, drawn up by incident investigators (Dekker, 2012; Iedema & Allen, 2012; Iedema et al., 2011; Iedema et al., 2006; Nicolini et al., 2011; Peerally et al., 2017).

In the policy domain of patient safety improvement and incident investigations, studies often reiterate calls to value the input of patients and families, to take them seriously (Iedema et al., 2011; Peerally et al., 2017), and to do justice to the experiences of professionals (Dekker, 2012), without adequately taking into account the structural characteristics of healthcare that might thwart such efforts. In what follows we thus use the concept of epistemic injustice to help us understand and identify the specific instances in incident investigation routines where participants are prone to experience an unjust disqualification of their testimony. To be clear, it is not our intent to make normative judgments or injustice claims on behalf of patients, families or professionals, rather we seek to identify the structural elements in adverse event investigations that may make these groups suffer epistemic injustice.

METHODS

Setting

Adverse event investigation practices in the Netherlands provide a fitting setting for our analysis, for the Dutch Health and Youth Care Inspectorate (HYCI) mandates healthcare organizations to engage all 'knowledgeable actors' of an adverse event in the subsequent investigation (table 7.1) (chapters 5 and 6; Leistikow et al., 2017). As an effect, Dutch healthcare organizations – in particular Dutch hospitals – report high engagement levels of knowledgeable and involved staff members as well as patients and their relatives (chapters 5 and 6).

Between 2015-2018 the authors were engaged in a research program studying the incident investigation system of the HYCI. In this chapter we draw from qualitative data gathered in five projects within this program, which examined

different elements of Dutch adverse event investigation practices and HYCI's supervision of these practices. Project details are summarized in table 7.2. Combining the insights obtained from these different projects provided us a unique insight into incident investigation practices from the perspective of the actors responsible for organizing and executing adverse event investigations as well as assessing the epistemic value of a testimony: healthcare leaders, RCA investigators and HYCI employees.

Table 7.1. Explanation of Dutch national incident reporting system and definition of an adverse event

Internationally incident reporting systems and investigation activities vary. In the Netherlands, healthcare organizations are legally required to have internal incident monitoring systems in place and to report adverse events to the Dutch Health and Youth Care Inspectorate (HYCI) within three days of discovery.

Dutch law defines an adverse event as an unintended and/or unexpected event related to the quality of care, having caused the death of, or serious harm to the patient. The European Commission upholds a similar definition (EU, 2014). Adverse events are internally investigated by means of a Root Cause Analysis method, or similar form of investigation, in an attempt to learn from what went wrong. Healthcare organizations have eight weeks to investigate the event and send their incident investigation report to the HYCI. Upon request, the HYCI grants a six week extension if the eight week deadline is not feasible.

The legally binding 'adverse event investigation report' guideline dictates that all professionals involved in or with the incident should be involved in the investigation. Moreover, Dutch law obligates healthcare organizations to involve patients/family members in these incident investigations and disclose the findings. The HYCI oversees this process and monitors if all professionals/patients/families are indeed involved. The HYCI does not dictate what the involvement should look like but does stress the importance of involvement, framing it as a necessary ingredient to optimally learn from what has gone wrong (IGZ, 2016b).

Study approach and analysis

We analyzed data collected in five qualitative studies of the Dutch incident reporting system. We draw from a total of 73 semi-structured interviews, 36 hours of ethnographic observations at the HYCI and document analyses of

policy documents collected at the HYCI and healthcare organizations. In all projects, respondents were purposely sampled (chapter 5; Green & Thorogood, 2006). Interviews were recorded with permission and transcribed verbatim. Observation field notes were transferred to observation reports and findings from the document analysis were processed into detailed written summaries.

Data analysis, conducted by JK and DdK, comprised of two phases (see table 7.2). First, data was ordered and analyzed inductively (open coding) (Hardon et al., 2001), to construct an overview of the structures and social processes involved with adverse event investigations, such as the sequential organization of all the investigation activities, who is involved and what are the tasks and responsibilities of the involved actors. These results were schematically mapped out in figure 7.1. Building on this overview, in the second phase, we specifically searched for examples of what constitutes as knowledge, who is thought to have relevant knowledge, who is actively heard, how testimonies are organized and how investigators value and interpret the different testimonies in the investigation process. Data was then coded deductively (Green & Thorogood, 2006; Hardon et al., 2001) using themes that were informed by our review of the literature on epistemic injustice (Anderson, 2012; Blease et al., 2017; Carel & Kidd, 2014; Freeman, 2014; Fricker, 2009; Okasha, 2018). See table 7.2 for an outline of these themes. In a 'low technology approach'(Green & Thorogood, 2006), selected quotes and extracts were transferred into tables within Microsoft Word, ordering related findings. Lastly, the content in these tables was discussed with all authors to verify interpretations.

Research ethics

The type of research conducted in the overarching research program (anonymized observations, document analysis and retrospective interviews) are not subject to the Dutch Medical Research Involving Human Subjects act (Dutch abbreviation: WMO). For verification we refer to the guideline by the Central Committee on Research Involving Human Subjects as well as the waiver issued by the Erasmus MC Medical Ethics Committee (reference MEC-2018-054) (CCRIHS 2017). All projects were performed in accordance with

Table 7.2. Overview collected data and analysis approach

Research project & fieldwork activities	**Fieldwork conducted by (author initials)**	➔	**Data analysis phase 1**	**Data analysis phase 2**
Project 1 (Feb – Aug 2015) 33 hours of observations incl. informal interviews at HYCI with inspectors responsible for overseeing adverse event investigation reports Document analysis of protocols, guidelines and internal communication	JK JK		Insights obtained from the policy documents, interview transcripts and observation reports, were used to construct a detailed overview of adverse event investigation practices in the Netherlands. Special attention was paid to map out: • Social processes: actors involved, their tasks, responsibilities and interactions • Structures: formal and informal processes / organization of activities (i.e. how are actors approached, how and where are interviews organized etc.), legal framework	Transcripts were coded deductively using a coding schedule, organized around the following themes: • What constitutes as 'knowledge' in adverse event investigations? • Who is thought to have knowledge? And why? / What are the "markers of credibility?" • How are testimonies collected, valued and processed? • Challenges / hurdles in the way, to embrace a testimony
Project 2 (Apr 2015 – Sept 2016) 15 semi-structured interviews with diverse respondents (n = 18) in 13 Dutch hospitals. Respondents incl. healthcare professionals, incident investigators, quality managers Document analysis of adverse event investigation protocols	JK JK			
Project 3 (May – Nov 2016) 31 semi-structured interviews with respondents from 4 Dutch elderly care and mental healthcare facilities, incl. organization leaders, quality managers, incident investigators and (external) incident investigation chairs (n = 24)	DdK, KG			

	Project 4 (Jan 2017 – May 2018) 8 semi-structured interviews with (former) HYCI inspectors involved in designing or monitoring the Dutch incident reporting system (n = 10) Document analysis of HYCI policy documents on the development and aims of the incident reporting system	DdK, KG DdK, KG			
	Project 5 (Feb – Sept 2018) 19 semi-structured interviews with diverse HYCI employees (n = 21), incl. inspectors, legal officers, program managers 4 hours of observations at the National Healthcare Report Center (HYCI incident report center)	JK, RB JK			

the Declaration of Helsinki research ethics principles. In all studies participants provided informed consent before the observations and interviews took place and were provided with the opportunity to review the transcripts. Data was anonymized.

EMPIRICAL FINDINGS

The first part of the analysis allowed us to draw up a generalized overview of adverse event investigation practices in Dutch healthcare organizations, see figure 7.1. The overview displays the sequential order of activities that are geared into motion once an adverse event has been detected. Moreover, it shows which actors are involved, how they are involved and at what stage of the investigation process.

The second part of our analysis revealed that there are several structures in the investigation process that make professionals, patients and their families prone to suffer epistemic injustice. It is difficult to capture and translate these elements into rigid, clear-cut categories. In practice these structural elements overlap and, as we will show, permeate into each other. For the purpose of clarity, we use the sequential investigation order, as documented in figure 7.1, to present the elements we found.

Investigation preparations: the gatekeepers search for 'facts'

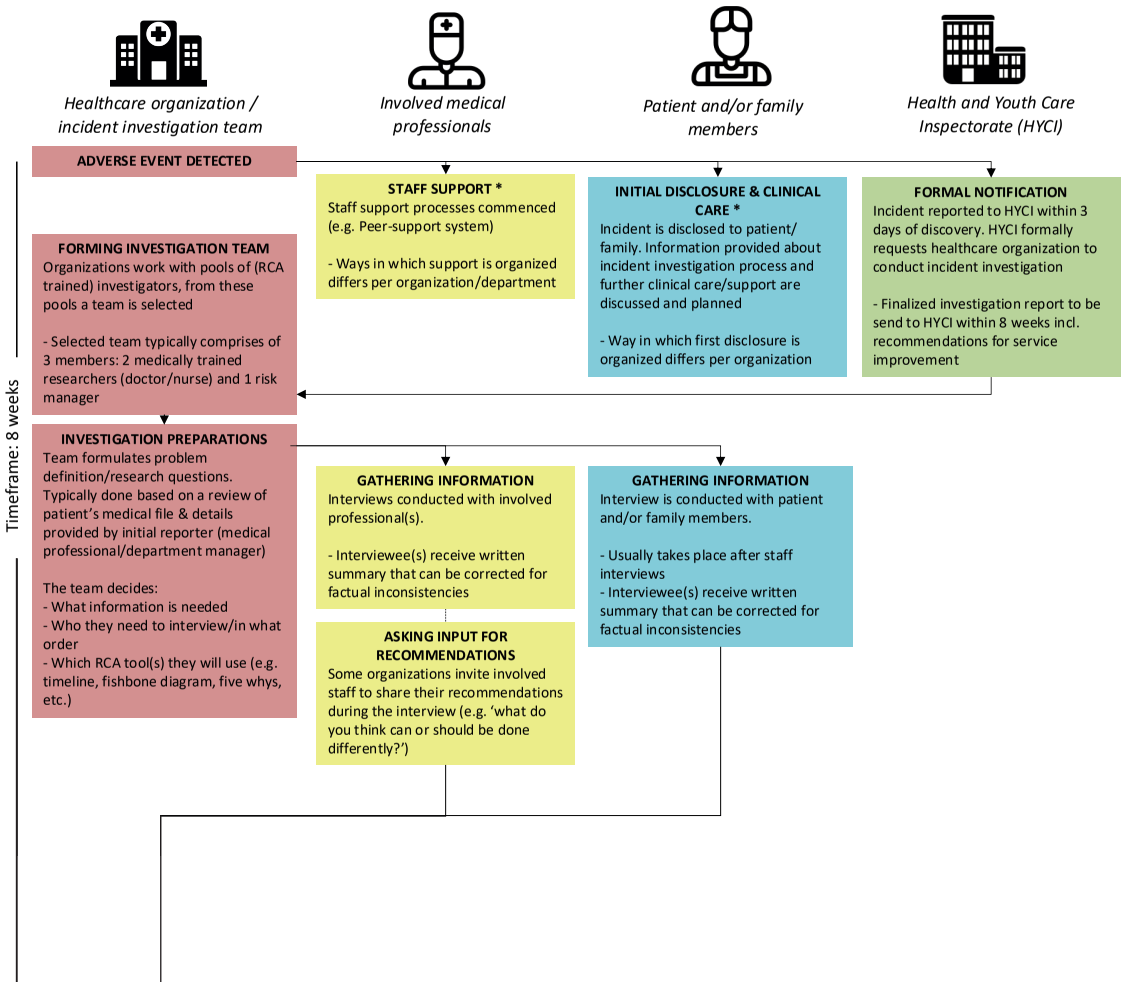
Shortly after an adverse event is detected, the organization where the incident has occurred forms an investigation team. This team – mandated by their organizational leaders – independently drafts a problem statement and decides: (1) what questions are central in the investigation, (2) what information they need to answer their question(s), (3) who they need to interview to retrieve this information, (4) in which order they wish to interview these people and (5) which RCA tool (e.g. timeline, fishbone diagram etc.) they will use to organize and interpret their findings. The independent status of the investigation team is reinforced by HYCI's guidelines, which dictate that investigators should have no

ties to the incident (see also chapter 5 and Leistikow et al., 2017). Document analysis of HYCI policy documents revealed that this 'distance' is associated with the ideals of securing impartiality.

It is specifically in the preparation phase of the investigation process that the epistemic privilege of the investigation team is clearly visible, for – by virtue of their mandated task – they act as gatekeepers and decide what questions and information are relevant. Moreover, they determine who holds relevant information, and who gets to speak up first. The team members, in other words, are the 'interpreters' of knowledge as they work towards shaping a linear narrative of the adverse event within the legal timeframe of eight weeks.

The quest for root causes guides the investigators to look for and speak to all actors involved. In practice this translates to a search for 'witnesses'; actors that have first-hand knowledge about the adverse event and/or the specific care process the adverse event relates to. Witnesses have to be reliable in the sense that they know what they talk about and can talk about it in meaningful ways. Other types of input or sources may be harvested but at the onset this input is seen as less valuable to the investigation. Examples are family members that are heard, to give them a chance to share their stories but "they do not necessarily have a clear image of what has happened, what the facts are" (Executive director elderly care facility, 06-10-2016) and they may not "know how things go around here, what is normal" (Quality & Safety manager mental care facility, 04-10-2016). Or, in another example regarding the input of professionals: when a senior doctor is heard instead of a junior doctor, because the first was perceived to be more experienced with the care process (Quality & Safety manager hospital, 12-07-2016). Here then, when there are multiple witnesses, investigators evidently consider some witnesses as more knowledgeable or credible – and thus reliable – than others.

Our interviews revealed that testimonies provided by actors that share verifiable facts to help determine the underlying root causes of the adverse event, are considered to be most knowledgeable. The emotions that interviewed actors may have, are frequently framed as problematic for a team's fact-finding quest.


Healthcare organization / incident investigation team
Involved medical professionals
Patient and/or family members
Health and Youth Care Inspectorate (HYCI)
ADVERSE EVENT DETECTED
STAFF SUPPORT *
Staff support processes commenced (e.g. Peer-support system)
- Ways in which support is organized differs per organization/department
INITIAL DISCLOSURE & CLINICAL CARE *
Incident is disclosed to patient/ family. Information provided about incident investigation process and further clinical care/support are discussed and planned
- Way in which first disclosure is organized differs per organization
FORMAL NOTIFICATION
Incident reported to HYCI within 3 days of discovery. HYCI formally requests healthcare organization to conduct incident investigation
- Finalized investigation report to be send to HYCI within 8 weeks incl. recommendations for service improvement
FORMING INVESTIGATION TEAM
Organizations work with pools of (RCA trained) investigators, from these pools a team is selected
- Selected team typically comprises of 3 members: 2 medically trained researchers (doctor/nurse) and 1 risk manager
Timeframe: 8 weeks
INVESTIGATION PREPARATIONS
Team formulates problem definition/research questions. Typically done based on a review of patient's medical file & details provided by initial reporter (medical professional/department manager)
The team decides:
- What information is needed
- Who they need to interview/in what order
- Which RCA tool(s) they will use (e.g. timeline, fishbone diagram, five whys, etc.)
GATHERING INFORMATION
Interviews conducted with involved professional(s).
- Interviewee(s) receive written summary that can be corrected for factual inconsistencies
GATHERING INFORMATION
Interview is conducted with patient and/or family members.
- Usually takes place after staff interviews
- Interviewee(s) receive written summary that can be corrected for factual inconsistencies
ASKING INPUT FOR RECOMMENDATIONS
Some organizations invite involved staff to share their recommendations during the interview (e.g. 'what do you think can or should be done differently?')

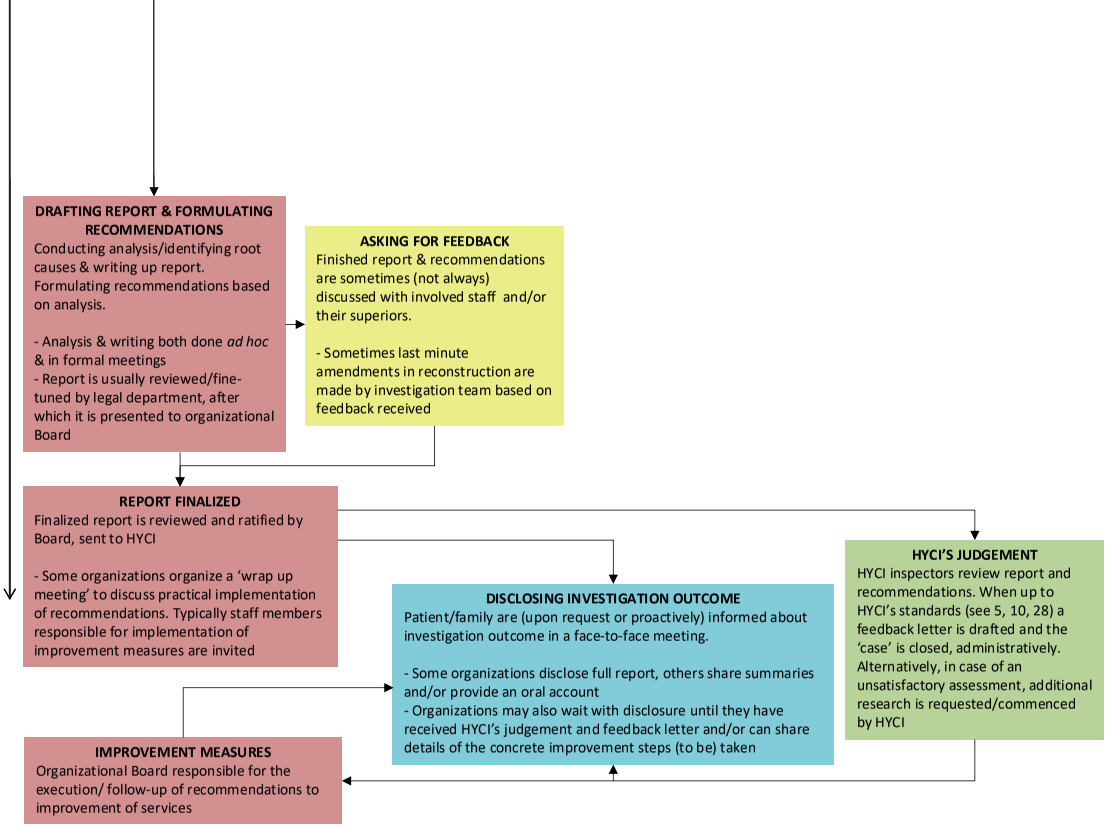


Figure 7.1. Overview of adverse event investigation practices in Dutch healthcare organizations
** Although these stages are – strictly speaking – not part of the actual investigation process, they must be described in the final report. The HYCI monitors these steps. As a result, 'staff support' and 'initial disclosure' practices have become an integral part of adverse event investigation protocols in most Dutch healthcare organizations.*

R: Sometimes they [patients/family members] are angry. Mad at everyone. Or they are dealing with a complex grieving process. Emotions like 'they let my father die'. And then it becomes very difficult for us [as investigation team].

I: Can you tell me a bit more about that?

R: (...) Yes, well for example we had this case. A patient. He was filled with rage and grief. One minute he was here, the other he was there [pointing at different places in the room], literally, like in the room but also in his story. Just all over the place. (...) I mean it was terrible, ter-r-ible what happened to him, but he, eh, was also very stuck in these emotions. He had a [negative] opinion about everything.

I: Was his testimony useful?

R: Well it was, because he had a chance to share his story. (Quality & Safety manager hospital, 20-09-2016)

Here listening to the patient is seen as useful to allow him to voice his experience but he is not judged to be a knowledgeable participant in the collective practice of interpreting and understanding what went wrong (Carel & Kidd, 2014). Him being 'all over the place', angry and in grief makes his story not only less intelligible but also less credible – emotions create distance from, or possibly distort, the facts. The quote sheds light on the way emotional patient and family testimonies are assessed. Providing space to let the emotions out is seen as useful, for purposes of healing and regaining trust (see also chapter 6), but being emotional might mean being perceived as less reliable, risking one's testimony to be devalued.

For professionals the same 'logic' applies. Our respondents noted that it is understandable if professionals feel sad, nervous and/or anxious, but these emotions must be contained as much as possible. "You don't want those emotions in the investigation" (Quality & Safety manager hospital, 12-07-2016). Emotions are thought to cloud someone's vision, contaminating their testimony. These findings resonate with other studies on epistemic injustice that

report how emotional testimonies are often discredited and perceived to have little or less epistemic value. Moreover, claiming someone is too emotional is a common way – at times even a deliberate strategy – to downplay the value of someone's input (Blease et al., 2017; Carel & Kidd, 2014; Freeman, 2014).

Gathering information: providing the right format?

As Peerally et al. have noted, a key problem surrounding RCA investigations is that the information obtained from the interviewed actors is influenced by their willingness and ability to provide relevant data as well as the nature of the relationships between interviewees and investigators (Peerally et al., 2017). Aside from this being a challenge in itself to attain 'high quality RCA investigations' (Peerally et al., 2017), our analysis revealed that the fact that the investigators decide what is relevant and dictate the format in which information should be provided and collected, are obstacles to achieving epistemic justice for professionals, patients and their families. With respect to format, four different points came to the fore.

First, the predefined eight-week timeframe in which investigation teams are to conduct their investigation and produce a final report, can give rise to epistemic exclusion. Respondents mentioned that most patients and family members are willing to contribute to the investigation process, but in practice some are not ready to provide their testimony within eight weeks after the event because they are still processing the emotional impact of the incident. As a result, these testimonies are excluded entirely. Moreover, when we recognize that framing someone as 'too emotional' can be a deliberate strategy to discredit someone's epistemic contributions (Blease et al., 2017; Carel & Kidd, 2014; Freeman, 2014), actors run the risk of being excluded or undervalued if other parties, in this case the investigation team, assesses such 'emotional readiness'.

Second, the composition of the incident investigation team sitting across an interviewee, influences the way in which that interviewee is at ease, how a story is shared and what is shared. Our respondents noted that nurses and

junior doctors were often visibly more nervous than interviewed doctors "who sit there talking to their peers, so there is less pressure" (Medical doctor/RCA investigator hospital, 18-08-2016). A professional recalled:

> "It was really daunting [to be interviewed]. Just because I knew that I would be sitting across our medical director [one of the investigators]." (Personal Care attendant mental care facility, 12-10-2016)

Quality and Safety managers and organizational leaders stressed that incident investigators are trained to conduct interviews in an open and non-judgmental manner. What's more, these respondents explained that, especially in the case of complex adverse events, the investigation teams are strengthened with an extra member and/or a 'very experienced investigator' to ensure information is collected according to high standards. In practice these experienced investigators are often in positions of authority (De Kam et al., 2019). As the earlier quote reveals, this can make interviewees nervous and careful in what words to use. A 'daunting' setting where actors feel affected by interpersonal power-imbalances might inhibit someone to clearly express him- or herself.

Also, knowing that the final report will be sent to the HYCI can make some professionals wary about giving information:

> "I know for a fact that if I ask a nurse 'do you feel any barriers to phone the on-call doctor during a night shift?' that there will be nurses that say: 'yes, there are doctors that are difficult to approach.' (...) Once we start an incident investigation and I ask that same question, there is not a single nurse that's going to tell me that these difficulties exist. I'm just not going to get that on record, because this is an investigation. The report will go to the Inspectorate. You're [the nurses] not going to say that!" (Quality & Safety manager hospital, 10-08-2015)

These relationships and power dynamics can influence the way testimonies are given and can render particular actors prone to suffer epistemic injustice, e.g. when actors self-censor their testimonies because they do not feel safe enough to share openly. To be clear, the relational setting does not automatically trigger

epistemic injustice, but relational power dynamics have the potential to impact some groups in particular (i.e. nurses or junior doctors), hampering their ability to articulate their stories. On top of that, actors' testimonies might be unjustly discredited given their position (as being 'just' juniors or nurses) or when their nervousness is interpreted as uncertainty or doubt.

A third point with regard to format is the nature in which the 'collection of information' is shaped. The investigators have usually prepared an extensive list of (closed) questions before the interview commences; questions in line with their quest for root causes. Such a strict interview guide may not provide the appropriate amount of space for an actor to share all he or she wants to share:

> "I had the feeling I couldn't really say what I wanted to say. (...) They [investigators] did explain that the goal was to learn, they explained that well. And it wasn't their tone or anything, but the way we kept going over the same points, going back to their specific questions. While I had the feeling that I had already answered their questions and all my other points, the things I contributed, didn't receive any attention. When we were finished, I was like 'this wasn't a pleasant conversation'. That was just my experience, even though they were really friendly." (Personal Care attendant mental care facility, 12-10-2016)

For patients and family members similar experiences are likely. Most teams, we learned, decide to speak to the patient and family after the team has drafted their first RCA timeline or fishbone diagram. A draft based on the input from involved professionals and a review of medical file(s). Inviting patients and families to 'confirm' elements on the predefined timeline and/or only inviting testimony on specific parts of the care process, may not do justice to the complexity and richness of their stories. Moreover, respondents explained that investigators often have to manage patient and family expectations. When they share experiences and concerns about issues – which investigators interpret as 'side-issues' that are not part of the team's investigation focus – investigators struggle to take such testimonies into account.

The fourth point on format relates to the setting in which the interview takes place, for this too can influence an actor's (emotional) ability to share what he or she wants to share. Interestingly, our analysis revealed that patients and families are often asked where the interview can best take place; at home or the healthcare facility. In comparison, professionals are not offered an option. A nurse shared an anecdote, of when she was asked to re-enact her actions with a colleague, in the same room the adverse event had transpired. The investigators watched, took notes and ran through their pre-formulated questions:

> "At that moment, the questions they asked, I felt it was so inconsiderate. The investigators didn't realize how intense this confrontation was. They were just trying to solve a 'thing', but I don't think they were aware what the impact of their approach was. (...) In your mind you've gone over it, over and over; how could this have happened? And then you stand there in that room, and they bring in the stretcher [the 'prop' needed to show the investigators what had happened]. We couldn't hold back our tears." (Nurse elderly care facility, 13-10-2016)

The quote reveals that in the interviews, investigators create or search for spaces where causes and 'facts' can be observed and documented. The emotions that are triggered by the same place or setting, as we have shown earlier, can influence the way in which a testimony is valued by investigators.

(Not) Asking input for recommendations

When incident investigators 'gather information' to construct their narrative of the event, the interviews with involved professionals are sometimes embraced as a moment to ask input for recommendations towards service improvements. Some healthcare organizations have made this an integral part of the adverse event investigation process; stimulating professionals to 'speak up' and 'think along'. There are, however, also organizations that avoid asking input for recommendations, stressing the importance of the investigation team's independence.

> I: Who formulates the recommendations?

R: The investigation team.

I: Ok. And do you ask for input from the actors involved?

R: No. No. Noo. We are independent investigators. So, as a team you really have to do that yourself. (Medical doctor, incident investigator hospital, 18-08-2019)

The importance of having – or maintaining – independence also plays a role in organizations that do encourage voice:

"We do ask for input, but if that input is used is another matter. That's up to the investigators." (Quality & Safety manager hospital, 28-06-2016)

In this phase of the investigation process, independence was not only thought of as an imperative for validity and reliability. Rather, the team's task to formulate SMART (Specific, Measurable, Attainable, Related and Timely) recommendations in line with their defined root causes – one of HYCI official requirements (chapter 5; Leistikow et al., 2017) – is often interpreted by them as stressing the team's autonomy. As an effect, the regulatory requirements make it difficult for the team to assign equal value and/or 'really listen' to suggestions for recommendations. Moreover, even when input is sought, treating proposed ideas for improvement as mere input that needs to be weighted by the investigation team, this one-way approach of gathering and weighing/interpreting data from involved actors does not stimulate a process of shared learning and improving.

Ultimately then, in both scenarios, the investigation team's epistemic privilege is underscored, which inhibits a shared practice of learning. In practice, as Iedema and colleagues have shown, this can cause a disjunction between recommendations and their workability and implementability at the sharp end (Iedema, Jorm, & Braithwaite, 2008). But, aside such practical implications, entirely excluding or ignoring parts of someone's ideas for improvement(s) are suggestive of epistemic injustice.

(Not) Asking for feedback and disclosing investigation outcome

Our analysis revealed that organizations struggle with the ways in which feedback loops and dialogues between investigators and involved actors can be organized and processed in the last phase of the investigation routine. Interviewed professionals are typically asked to review the final version of the report and subsequent recommendations, but like the feedback requested on the earlier interview summaries in the 'gathering information' phase, their feedback should – ideally – be geared towards rectifying factual inconsistencies. It is common, however, that professionals do not agree with (parts of) the finalized narrative and/or feel their testimonies were misunderstood, not taken seriously or ignored entirely.

> "I thought the report was one sided, to be honest. Because the points I had made, about broader policy issues and stuff like that, those were not in the report." (Personal Care attendant mental care facility, 12-10-2016)

Professionals who disagree with the conclusions are sometimes described as "not being that far along with patient safety thinking" (Quality & Safety manager hospital, 29-06-2016). Or, in another telling example, one healthcare organization purposely did not invite the interviewed professionals to the 'wrap up meeting' to discuss the final report because "they are too emotional; (...) doctors are just not used to hearing, in the presence of lay people, that something hasn't gone right" (Assistant manager Quality & Safety hospital, 20-09-2016). A narrow feedback loop or lack of dialogue then can cause or amplify feelings of frustration and injustice.

Patients and family members are usually not asked for feedback on the final report. Respondents note that this is partly due to time constraints, but they also argue that they fear patients and/or families will feel the investigation is corrupt or a hoax if preliminary conclusions are changed in the final stage of the investigation. Dutch healthcare organizations do increasingly disclose the investigation reports to patients and families (redacted or not), once it has been sent to the HYCI (chapter 5). Our interviews show, however, that patients and

families do not always agree with the conclusions of the report. Voicing these concerns can cause investigators to label them as 'difficult', 'unintelligent' and/or 'looking for someone to blame'.

The stereotypical labels attached to actors voicing concerns or actors with a dominant take on what has happened can deflate their input earlier on in the investigation process. The illustrative anecdote below reveals this risk: a mother carrying the label 'difficult parent' felt her testimony was not taken seriously and protested once the finalized report was disclosed to her:

> She [the patient's mother) was a 'difficult' parent, like you just come across in healthcare sometimes. Perceived as difficult in the sense that she had her own vision and I don't know what else. (...) [T]he parent objected to our conclusions (...) We concluded that the anesthesiologist had "acted professionally" during a cardiopulmonary resuscitation, [but] the parent disagreed. Listening to her, I thought "You're right". The anesthesiologist 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." (External Chair investigation committee mental care facility, 13-10-2016)

This quote hints at the potential value for investigators to ask for and listen to feedback, even if the experience that is shared (or objection made) does not specifically relate to 'hard', verifiable facts. The 'difficult parent' label had prevented the investigators from taking the mother's earlier voiced experiences seriously. In epistemic exchanges, continued dialogue can help actors to further their understanding and facilitate learning (Anderson, 2012). Moreover, it can help to do justice to the epistemic contributions that have been shared.

DISCUSSION

Earlier studies have shown that the HYCI has successfully stimulated healthcare organizations to collect input from all knowledgeable actors in their adverse event investigations; professionals, patients and their families (chapters 5 and

6). Our analysis shows however that providing testimony does not always mean that this testimony is heard, understood or valued. What's more, who is recognized as a knowledgeable actor and seen as holding relevant information for the adverse event investigation is not a 'given'. Rather, this is determined by incident investigators and the institutionalized structures in which these investigators work. We identified several structures that can promote or hinder an individual participant's knowledge contribution in the process of an adverse event investigation. First, the RCA tools used in these investigations steer investigators to map out timelines and fishbone diagrams to work towards a linear narrative of the incident. The construction of a linear narrative makes investigators prone to displace or disregard different interpretations to how events have unfolded and have been experienced (Nicolini et al., 2011; Peerally et al., 2017). Moreover, the RCA tools used, drive investigators to search for verifiable facts or other forms of 'hard' evidence. As a consequence, actors that provide testimony outside the scope of such a timeline and/or share experiences that are not verifiable, risk being seen as less credible. Also, the format used to collect testimony, i.e. only asking specific questions, the setting in which the interview takes place, the relationships between the actors involved, may not suit the kind of testimony an actor wishes to share and pose a barrier for a speaker to articulate their story clearly (Carel & Kidd, 2014). The incident investigators formal task to formulate recommendations towards service improvements in line with the identified root causes, – a regulatory requirement – can inhibit the team to use ideas for service improvement(s) provided by professionals. Lastly, investigators also carry – slumbering in the background – personal and structurally induced biases towards professionals, patients and families, judging them to be 'too emotional', 'unintelligent' or 'not committed to patient safety'. These biases influence how investigators assess and value an actor's testimony. The process of assessing and valuing testimonies by an independent investigation team can transform the participation of professionals, patients and families into a one-way process, instead of a social process of shared learning from incidents, like adverse events. Taken together it is evident that, even though the HYCI has provided an – arguably successful – impulse

to multi-voiced engagement in adverse event investigations, in practice institutionalized structures at the local and national (regulatory) level, pose barriers to do justice to and facilitate shared learning from all testimonies.

Epistemic injustice in adverse event investigations, then, can be triggered through the prejudice of incident investigators but also by the way in which an adverse event investigation is structured, hindering testimonies from being articulated or heard clearly, or not at all. The structures we have presented in the analysis, are mostly likely to trigger testimonial forms of injustice. That is, specific groups of actors risk to suffer from a credibility deficit due to the stereotypes attributed to them during the different stages of the investigation process, i.e. a junior doctor is less reliable than a senior doctor, or testimonies are too emotional etc. Hermeneutical injustice may also rise but our study does not allow us to come to that conclusion for we do not know if testimonies are deflated as a result of lacking (conceptual) resources. Nonetheless, in whatever form, the identified structures can be problematic as epistemic injustice can hinder learning from adverse events and prevent doing justice to the lived experiences and ideas from healthcare professionals, patients and their families. In a time when healthcare organizations are seen to have a duty to learn about what happened from multiple perspectives (Etchegaray et al., 2014), and there are popular calls to 'better involve patients' (Etchegaray et al., 2016; Iedema et al., 2011), to 'take patients seriously' (Ocloo & Matthews, 2016), and 'value everyone's language equally' (Sibley, 2019), an important contribution of this chapter is to illustrate the institutionalized structures that can complicate such efforts. Calling for practices of individual testimonial and hermeneutical justice is understandable, but such calls have to be accompanied by an awareness for the structural conditions that allow for such practices (Anderson, 2012).

Epistemic injustice is problematic beyond the scope of learning from incident investigations, for – as Fricker explains – if someone has the experience of not being taken seriously as a source of information, they can lose their confidence in their ability to obtain and transmit knowledge (Fricker, 2009; Hookway,

2010). They may silence their own voice or undermine their own experience, which can be detrimental for efforts to further patient safety and organizational safety cultures more generally, as both rely on open communication.

Tackling epistemic injustice is challenging but being familiar with the concept itself can be a first step to understand what is required in practice to operate in a way that works against it (Fricker, 2009). In any given situation, being mindful of our own prejudice and how this influences our ability to understand and (under)value what someone is saying, is important. Initiating policies to train incident investigators to stimulate such reflective thinking and challenge their biases can be helpful. Clearly though, personal reflectivity and/or genuine willingness to do justice to someone's testimony is not enough. For, as we have shown, there are social and institutional structures that promote biases, cause epistemic exclusion and prevent actors from being seen as credible.

In light of our analysis we have three recommendations for healthcare regulators, policy makers and incident investigation practices. First, map out the organizational structures that can make actors prone to suffer epistemic injustice. In line with Carel and Kidd, recognizing structural epistemic asymmetries – between doctors and nurses, doctors and patients, investigators and interviewed actors, etc. – is crucial when one wishes to equally solicit their contributions within epistemic practices like incident investigations (Carel & Kidd, 2014). Critically appraising the practical elements in these structures, such as the format in which actors are to voice their experiences, and how these formats can possibly be more accommodating, may be a good first step. For example, it could help if the involved medical professionals are interviewed by their peers. So, a junior doctor by a junior doctor, instead of by senior doctor to whom the junior might not disclose his/her experiences in the same manner. Also, at the start of an investigation, investigators may want to seek input for the research questions with all those directly concerned, to prevent an all too narrow framing of the problem statement. Any controversies or conflicting experiences voiced in the interviews can be captured in the report rather than edited out. Second, building on the first recommendation and Dekker's notion

of 'just culture' (Dekker, 2012) it is crucial to ask the actors involved: what do you need to be able to share your testimony? Instead of simply inviting actors to tell their story, or only asking for specific details of their story. For example 'replaying' an incident can be helpful but investigators should recognize that this puts emotional burden on the professionals involved. Assisting them in this and maybe also interviewing them on another occasion might be helpful in preventing their testimony to be discredited. Investigations can then also be a part of the recovery process instead of only a process of fact-finding. Third, encourage and organize continued dialogue and feedback loops, for learning from mistakes is an on-going social practice (chapter 5; Macrae, 2016). For example, we found that the timeframe of the RCA poses barriers to continued epistemic exchanges. This is something that could be negotiated with the external regulator. Also, the practice of having the committee set the epistemic boundaries of the RCA—i.e. by posing the questions that need answering—instead of involving concerned professionals and patients in this creates tensions for including their testimonies later on in the process. This can be easily remedied by having a more inclusive process at the start as well as the wrap-up of the investigation.

In our quest to understand how testimonies are collected and knowledge is appraised in adverse event investigations, we have focused the main part of our analysis on 'the hearer's point of view', i.e. incident investigators, managers and healthcare leaders. We have a limited understanding of experiences of epistemic injustice of people giving testimony. This is an important limitation of our study. More research should be done to explore and understand how patients, families and involved professionals experience epistemic injustice as such insights can help strengthen efforts to address these issues. Also, comparative research can be useful to further our understanding of the structural mechanisms that trigger epistemic injustice in different healthcare settings.

CONCLUSION

In this chapter we have shown that inviting someone – whether a healthcare professional, patient or family member – to share their experience about healthcare encounters or service delivery, does not automatically guarantee that this testimony is understood or valued by the hearer(s). Institutional structures can prevent someone's testimony from being recognized as relevant knowledge. As we have rendered epistemic injustice in adverse event investigations tangible, we hope our analysis does not discourage. Rather, we encourage healthcare providers, policy makers and regulators to use these insights to further their commitments to multi-voiced engagement in healthcare. This can improve learning from adverse events and – more broadly – facilitate quality and safety improvements that do justice to the experiences of healthcare professionals, patients and their families.

DISCUSSION: STANDARDS AND THEIR CONSEQUENCES

Danny Dog:	It's gone dark!
Suzy Sheep:	We're in a tunnel.
Children:	(collective laughter)
Narrator:	The tunnel is the last thing on the activity sheet
Peppa Pig:	(ticks off the box on the activity sheet)
Children:	Hurray![27]

27. *Screenshot & screenplay text taken from YouTube, Peppa Pig, Episode "The Train Ride". Peppa Pig, Astley Baker Davies Ltd / Entertainment One UK Limited 2019.*

As we reach the final chapter of this thesis, having explored the nature and use of standards in the regulation of adverse events and more, it is time to step back and shed light on how these standards work and what they mean in terms of the consequences that they have on behavior and organizational learning. The Introduction of this book explained that standards are a central element of regulation and regulatory activities. Regulatory standards come in all shapes and sizes but have in common that they are used to translate, and preferably operationalize (De Kam, 2020), a public interest purpose into something that can be steered and monitored (Black, 2002; Walshe & Boyd, 2007). In that sense, standards – inscribed with norms or aspired principles – are crucial for a regulatory authority in order to secure compliance with the public interests it is commanded to protect and encourage.

In the Netherlands, the common interest of safe healthcare is regulated by the Dutch Health and Youth Care Inspectorate (Inspectorate). To monitor safe care and stimulate the continuous development of quality and safety in Dutch healthcare organizations, the Inspectorate introduced a regulatory framework for its adverse event regulation,[28] in the form of guidelines and a scoring instrument with coupled monitoring system to harness learning from adverse events. Along with this goal, these standards were also introduced to standardize the Inspectorate's own work practices as a way to be predictable, consistent and transparent to regulatees and to account for the impact of their activities to an increasingly critical public (Dute, 2015; Leistikow, 2018). Both the idea that the implemented standards steer learning *and* standardize work practices, presume the natural ability of standards to regulate behavior (Lampland & Star, 2009). Existing literature, however, draws a conflicting picture on the regulatory power of standards (Slager et al., 2012), in the sense that standards seem to direct or underdetermine practices. What's more, as regulatory authorities are pressed to account for their impact (Dute, 2015; Leistikow, 2018; Rutz, 2017; WRR, 2013),

28. To be clear, as noted in the Introduction of this book, and as detailed in chapter 4, the Inspectorate also has other regulatory programs in place and undertakes a wide range of supervision activities.

it is crucial to find out if and how the standards that they use produce effects (Weenink et al., 2020). The scholarly dispute as well as the necessity for a regulator to know how regulatory standards work, underline the theoretical and practical relevance of this study.

To further our understanding of the workings and consequences of standards, I conducted an ethnographic study. In this chapter I revisit and discuss the main findings and lay out the script that has been inscribed into the standards used by the Inspectorate and reflect on how this script is enacted. I have chosen to use this script metaphor, first introduced by Madeline Akrich (1992), for it attunes us to the idea that we must look at what it is that standard(s) explicitly and/or implicitly requests the actors (regulatees and regulator) to do, how they are to act and what skills they must have to perform. Specifically, the metaphor allows us to conceptualize standards as relationally enacted instruments that are not stable in terms of the meaning attributed to them by the actors working with them. Standards then, are not "dead lists" (Star, 1999) or lifeless "things" (Bateson, 1978) and as such must be studied as they are performed in a localized setting. My analysis was guided by the following research questions:

1. What script has been inscribed in the regulatory standards that are used in the regulation of adverse events?
2. How is this script enacted by the regulator (Inspectorate) and regulatees?
3. What are the consequences of this script and the way that it is enacted, for the actors involved and for organizational learning in hospitals?

With regards to organizational learning, I was specifically interested how the script in use influences: what learning is; who must learn and who is involved in that process; and what is seen as valid input for the learning process.

In what follows I answer each question in turn. When reflecting on how the script is enacted (question 2) I will also point to the external factors that appear to influence the enactment. Then, using these answers, I discuss the implications of these findings for the theory on the consequences and workings of standards and regulatory practice, and I wrap up with some concluding thoughts.

THE STANDARDS AND THEIR SCRIPT

If one wished, the standards in use in the regulation of adverse events can be printed. Words printed on paper that you can hold in your hand as tangible lists of instructions; just like the activity sheet Peppa Pig is instructed to check off during her train ride. But, for however dry and tangible these lists of instructions are, the piece(s) of paper alone will not tell us much about their workings and consequences. Rather, mapping the underlying framework of action that is inscribed into the pieces of paper (Akrich, 1992), with all sorts of expectations about the roles actors must play and their subsequent responsibilities, is an instructive first step to understanding how the standards are performed and produce effects.

To unveil this script, let me start by reflecting on the three standards that have been looked at in this thesis (summarized in table 8.1): a law, a guideline and a scoring instrument. These standards are part of a nested system (Lampland & Star, 2009), and jointly constitute the Inspectorate's regulation program for adverse events. First, the law (Healthcare Quality, Complaints and Disputes Act) dictates that healthcare providers are responsible for the quality and safety of care. The law lays out the definition of an adverse event[29] and mandates that these events must be reported to the Inspectorate. This report must provide the Inspectorate with the "relevant facts to allow [the regulator] to determine whether there is a situation that could pose a threat to the safety of patients/ clients as well as broader healthcare delivery, that may give rise to the taking of measures" (VWS, 2016). What's more, the law determines that the Inspectorate can sanction in the case of non-compliance. It is noteworthy that the goal of 'learning from safety incidents' is not explicitly mentioned in the law,[30] rather

29. *It has been argued that this definition leaves (too much) room for interpretation, is not clear or precise enough (Bal et al., 2017; Grit et al., 2018; Leistikow & Robben, 2016).*
30. *Indeed, the words learning (leren) or learning potential (lerend vermogen) are not mentioned at all.*

investigating an adverse event appears to carry the purpose of providing external accountability and open up the possibility of retribution (when legally warranted).

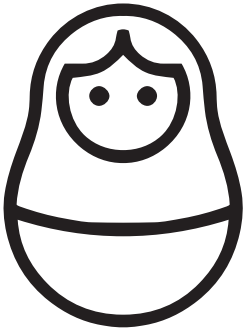
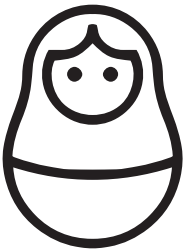
Nested standards in the Inspectorate's regulation of adverse events		
		
Law & implementing order	**Guideline**	**Scoring instrument & coupled performance management database**
Healthcare Quality, Complains and Disputes Act *(Wet Kwaliteit Klachten en Geschillen Zorg, WKKGZ)*	Guideline adverse event investigation report *(Richtlijn calamiteiten-rapportage)*	BAN & digiBAN
Establishes that healthcare professionals and their leaders are responsible for the quality and safety of healthcare. Provides the definition of an adverse event (AE) and dictates that AEs must be reported to the Inspectorate **	Sets out how an AE should be reported to the Inspectorate and how it should be investigated by healthcare organizations	Allows inspectors to 'mark' or score the AE investigation reports and the database allows the Inspectorate to monitor safety related trends and overtime (learning) performance (see box 5.2, chapter 5)

Figure 8.1. The nested system of standards in the regulation of adverse events
*** The law encompasses many more healthcare related matters, but these are the most relevant ones to point out with regard to (the regulation of) adverse events*

Linked to this law, we find the second standard: the guideline for an adverse event investigation report. This standard concretizes how an adverse event is to be reported to the Inspectorate and what elements an investigation report must comprise of. Also, it dictates that the investigation must be conducted by independent professionals, should include input from different stakeholders (chapters 6 and 7) and the outcomes must be shared with patients and their families (chapters 5 and 6). As such, learning is framed as a participative and social affair, in which the input from the involved stakeholders is seen as an imperative for healthcare organizations "to optimally learn from what has gone wrong" (IGZ, 2016b; chapters 6 and 7). The multi-voiced investigation must be conducted within an 8 week timeframe, after which (SMART) improvement measures must be formulated that are endorsed and implemented by the organization's Board of Directors (IGZ, 2016c).

Linked to this guideline we find the third standard: the BAN scoring instrument (chapter 5, box 5.2). An instrument that has been founded to allow inspectors to score the received adverse event investigation reports and monitor overtime (learning) performance and risks more broadly. The latter two standards – the guideline and scoring instrument – have been developed by the Inspectorate based on the World Health Organization's 'Concise Incident Analysis Protocol'[31] (chapter 3). This protocol determines that incident analysis "is a structured process for identifying: what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer, and what was *learned*" (WHO, 2012, emphasis added). Accordingly, these standards radiate the ideal that learning from safety incidents is a prerequisite to good and safe care. What's more, both, as De Kam explains, are instruments that – based on the law – translate a quality issue (an adverse event) into an object of regulation (learning from the event), rendering it inspectable through a set of activities that the Inspectorate can document and monitor (De Kam, 2020). Importantly, this process of monitoring not only provides the Inspectorate with

31. *Another standard! Once more demonstrating that standards are nested in complex systems and carry many linkages.*

the opportunity to steer and (when necessary) prosecute regulatee behavior, it also allows the Inspectorate to provide accountability over their own activities to external stakeholders.

In sum, the organized process of reporting, investigating and learning from safety incidents to improve the quality and safety of care and be accountable,[32] is the overarching framework of action inscribed in these standards. Accordingly, this action plan allocates specific roles and responsibilities to the regulator and regulatee, which I discuss next.

To start with: the Inspectorate. In line with the multifaceted action plan, the Inspectorate must take up two distinct roles. First, based on the law, the Inspectorate is responsible for monitoring risks, sanctioning non-compliance (i.e. providers not reporting adverse events, not doing so on time) and taking action when regulatees are struggling to learn (i.e. not investigating an adverse event properly). The data collected through the BAN system, in theory, allows the Inspectorate to do this. These responsibilities cast the Inspectorate into the role of what Bardach and Kagan have called stern "rule-bound bureaucrat" (1982) or classical watchdog. To be sure, this is precisely the role that is expected of the Inspectorate by the general public (Bal et al., 2017; Dute, 2015; Legemaate et al., 2013; chapter 1). At the same time, because the Inspectorate has set the 'rules of the game' for learning from adverse events and provide organizations feedback on that reported process (chapter 3), inspectors are also scripted into the role of a teacher or mentor, as they must develop pedagogical strategies to encourage and support the learning process. Lastly, on top of these two roles, the guideline and BAN system embodies two promises. First, the promise of a regulator that uses the (structurally) gathered data to demonstrate the effects of their work. And second, the promise of a regulator that objectively assesses adverse event investigation reports and takes regulatory action along the

32. *A true Safety-I approach to attaining and furthering safety in healthcare (Hollnagel et al., 2013).*

lines of the standard; limiting 'street-level discretion' (Lipsky, 2010), making inspectors predictable and trustworthy. Thus, the script contains conflicting roles that somehow have to be managed by the Inspectorate.

For healthcare organizations, the script implies that they are the 'owners' of safety incidents. As such, they are responsible for investing in the processes and necessary skills to allow them to investigate incidents, including adverse events, and learn from them (the 'learn to learn' ideal, see chapter 5 and Leistikow et al., 2017), formulate improvement measures and implement these measures. At the same time, the standards – and especially the BAN scoring instrument – implicitly inscribed the necessity for regulatees to invest in the skills to write 'good', legible investigation reports, along the lines of the standard (a list of 25 criteria, see chapter 5, box 5.2). This task is not spelled out but originates from the relational nature of the standards; the Inspectorate makes regulatory decisions and provides feedback on the documented narrative in the investigation report written by regulatees. Lastly, the script emits an underlying trust that healthcare providers – professionals and organizations alike – are intrinsically motivated to deliver safe care,[33] are open and honest when things go wrong and embrace these unfortunate events as learning opportunities to further the quality and safety of the care they provide.

To sum up, what the above shows is that there are layered expectations, roles and responsibilities inscribed in the nested system of standards for the regulation of adverse events. This script (summed up in table 8.1) has been shaped in the hope to steer behavior and (organizational) processes into a certain direction, on both the side of the regulator and the regulatee, but it also carries conflicting demands. The question is whether the inscribed roles and tasks actually materialize, and/or how they are acted out. This is discussed next.

33. *In 2016 the Inspectorate explicitly communicated to the public that their regulatory practices were rooted on a "healthy sense of trust" in their multi-year policy plan (IGZ, 2016d), and during the course of my research trajectory it was the opening slogan used at all the Inspectorate's official presentations and inspection visits I observed.*

Table 8.1. Summarized overview of the standards' inscribed roles, tasks, responsibilities and expectations

Actor	Insights from study
	Inscribed roles, tasks, responsibilities and expectations
Inspectorate	Role: watchdog; will sanction/take action in the case of non-compliance (i.e. if AEs are not reported, not reported on time or not investigated along the lines of the standard) Role: teacher/mentor; the Inspectorate has set the 'rules of the game' for learning and provides feedback on this process Task: uses data garnered through the system of reporting/investigating to monitor risks and safety trends at the level of individual organizations and nationally Expectation: the Inspectorate is disciplined by the standards (i.e. assesses AE investigation reports using the guideline, limiting discretion/inspector variation and uses data to target/address weak and underperforming regulatees Expectation: uses collected data to be accountable/demonstrate value to external stakeholders
Regulatee	Responsibility: responsible for quality and safety of care, and as such also 'owners' of the safety incidents that happen, including AEs Task: be open and accountable to patients and the greater public (particularly when safety incidents have occurred) Task: report AEs to the Inspectorate within legal timeframe and investigate AEs in a standardized manner using independent in-house investigators (that is: investigation is not a tick box exercise, but the investigation report must include all the elements as dictated by the guideline), and use findings/root causes to formulate and implement improvement measures Task: invest in the (internal) processes and skills to allow investigations to be conducted along the lines of the guideline or put differently: invest in the 'things' that allow you to learn to learn from AEs. Task: invest in (writing) skills, to produce legible investigation reports Expectation: learning from safety incidents is an important aspect of (providing) good and safe care (safety-I paradigm) Expectation: intrinsically motivated to deliver safe care, report AEs and learn from AEs to minimize the risk of reoccurrence Expectation: learning is a participative and social activity in which all involved stakeholders (professionals, patient, family etc.) are heard, and their input is used to learn from what has happened

THE SCRIPT'S ENACTMENT

Enactment by the Inspectorate

I start by outlining the Inspectorate's enactment of its inscribed tasks and roles. First, to be able to materialize, or work towards the materialization of the inscribed action plan, the Inspectorate introduced a new or "sharpened" (Schippers, 2013; VWS, 2012) work routine to monitor and score the adverse event investigation reports. As documented in chapter 3, this included the formation of LMO teams,[34] the standardized routines in which inspectors score the adverse event investigation reports, et cetera. This then, was a very practical impulse to rearrange work practices in line with the standard, but also a performance that was politically driven, for inspectors were pressed to put an end to societal distrust after years of turmoil and accusations of regulatory capture (chapter 3).

The Inspectorate monitors trends, radiating from the digiBAN database. On the 25th of January 2018, approximately five years after the introduction of the BAN scoring instrument with coupled performance management system, the Inspectorate published a press release titled "More attention for patients and family in the wake of an adverse event" (IGJ, 2018b). The article stated that hospitals and providers of elderly and mental care facilities increasingly involve patients and relatives in adverse event investigations. It argued that this involvement "improves the quality of the investigation as well as the transparency after an adverse event, which improves [public] trust in healthcare" (IGJ, 2018b). The press release accompanied the report "Learning from mistakes in openness (*in openheid leren van fouten*)", that disclosed

34. *LMO teams (Landelijk Meldingen Overleg) are the Inspectorate's national adverse event reporting consultation teams (IGZ, 2013b; Legemaate et al., 2013). These teams comprise of a mix of 'general inspectors' (i.e. former nurses, lab technicians and biomedical scientists) and 'specialized inspectors' (i.e. non-practicing medical specialists). Each LMO team was made responsible for a different part of the healthcare sector, for example, hospitals, long-term elderly care, and general practitioners. Chapter 3 elaborately discusses the work of the LMO team responsible for monitoring adverse events in hospitals.*

numerous BANscore developments, including the increased patient/family participation figures presented in this thesis (chapters 5 and 6) (IGJ, 2018a). A year earlier, a similar report was published by the Inspectorate, accompanied with the justification that the report serves the purpose of encouraging learning across the healthcare sector as well as facilitating transparency through clear and accessible information "for everyone" (IGZ, 2016b, p. 4). What healthcare organizations can and should learn from the disclosure of these figures, or even the publication of anonymized investigation reports and generalized overviews, as has been called for by the Dutch government, is however not exactly clear and the subject of ongoing debate (see for instance Meurs, 2019). But my point here is, that the publication of these reports[35] indicate that the introduced standards, and the ranking/benchmarking data that is garnered through them, indeed serve as an instrument for the Inspectorate to account for their work and demonstrate their societal value to the public.[36]

The publication of the number of administrative fines imposed on healthcare organizations that did not report adverse events and/or did not report them within the set timeframe (see IGJ, 2018a; IGZ, 2016b), demonstrates that the Inspectorate performs its rule-bound bureaucrat or watchdog role. During the fieldwork I also observed the other, teacher/mentor role enacted as inspectors carefully weigh the feedback they give to hospitals about their investigations and think of strategies to help get their (pedagogic) instructions across and keep regulatees motivated to report and learn (chapter 3). Inspectors are sometimes more inclined to reach out to regulatees that seem eager to learn and hold great learning potential (a subjective appraisal), than the 'bad apples'; for "it's just not worth flogging a dead horse" (chapter 3). This latter point demonstrates that the inscribed promise of disciplining the regulator to be objective and take

35. *From 2018 onwards, these figures have been published on the Inspectorate's website, on the online dashboard 'Inspectorate in numbers (IGJ in cijfers)', see https://www.igj.nl/over-ons/igj-in-cijfers/cijfers-over-meldingen.*
36. *If it is fair that the Inspectorate uses these figures for such legitimization purposes is a matter for thought and consideration, as I have shown in this thesis that what these figures actually say about what really happens inside hospitals can be questioned (chapters 5 to 7).*

action along the lines of the standard, does not (fully) materialize. In practice, the inspectors' emotions and personal convictions are never far away. This coincides with findings from other studies wherein inspectors voice that they feel some items on the BAN scoring instrument are more important than others (De Kam et al., 2019; Grit et al., 2018). Crucially, also, as chapter 4 reveals, inspectors need to – and continuously do – read between the lines and use their informal knowledge about and experiences with healthcare organizations and their leaders, to make sense of the possible quality and safety risks radiating from formal (adverse event investigation) reports. This is a direct consequence of the Inspectorate's responsive regulation approach (Ayres & Braithwaite, 1992), wherein regulatory decisions and actions are attuned to the context in which they are applied (Mascini & Wijk, 2009; Van Erp et al., 2018). Chapter 4 also underlines that the possible risks to the Inspectorate's own legitimacy and institutional reputation continuously color the assessments made by inspectors and the actions that they take, further emphasizing the difficulty for inspectors to be disciplined by the standards introduced to keep their personal judgements, institutional circumstances, and existing relationships out. In what follows I outline how the script is enacted by hospitals.

Enactment by regulatees

In line with the observations at the Inspectorate, hospitals also invested in organizational structures and skills to meet – or at a minimum work towards – the requirements of the (new) standards (chapters 5 to 7). As such they seem to perform in the spirit of the inscribed responsibility to safeguard the quality and safety of healthcare delivery. To be clear, Dutch healthcare organizations were already legally mandated to report and investigate adverse events (chapter 1), but the new guideline and BAN performance management system further professionalized those routines, stimulated "safety thinking" and led to an increase in the number of adverse events reported to the Inspectorate (chapter 5).

The findings do not allow me to determine if regulatees were intrinsically motivated to report adverse events and learn.[37] I spoke to seemingly dedicated respondents, who were invested in "doing it [the investigation] well for the Inspectorate" (chapters 5 to 7), but as the fieldwork unfolded there were plenty of signals that 'being open' about, and publicly accountable for safety incidents – as an organization[38] – does not always come easy. For instance, Dutch investigative and news media communicated that hospitals underreport adverse events and attempt to silence affected patients or their families, by having them sign silencing clauses in settlement agreements (chapters 2 and 4). The media's accusations were later confirmed by the Inspectorate and other independent inquiries (IGZ, 2017a; Meurs et al., 2016) and generated societal and political turmoil (chapter 4). Also, when then inspector-general, Ronnie van Diemen, was asked on national TV if it was true that the conclusions in adverse event investigation reports were toned-down or rewritten by – or by order of – hospital CEOs before they were sent to the Inspectorate for review, she confirmed this "shouldn't, but does happen" (EenVandaag, 2016b).[39] As scholarship has shown (Baldwin et al., 2012; Hatcher, Jaffry, Thébaud, & Bennett, 2000), there can be many underlying reasons that hamper transparency: institutional or personal reputations, fear of (sanctions by) the regulator, negative publicity. But these same factors can also contribute to the felt urgency or wish to do well, i.e. report events and learn – or, if not learn at

37. *This is arguably something that is difficult to establish in any study.*
38. *Chapter 5 shows that healthcare professionals, as individuals, also find it difficult to talk about safety incidents or safety issues, particularly if their narrative accounts are sent to the Inspectorate.*
39. *The case discussed in the television program concerned an adverse event investigation report that, according to the members of the hospital's incident investigation committee was rewritten by the Board of Directors before it was sent to the Inspectorate. The new version of the investigation report was, according to the anonymous whistleblowers, rewritten behind the committee's back and no longer reflected the root causes that they had documented in the initial report. This example illustrates the fine line for CEO's between being publicly accountable and managing this responsibility, on the one hand, and on the other hand keeping enough distance to safeguard the independent nature of the investigation process. This delicate balancing act fuels the Inspectorate's LMO inspectors to 'read between the lines' of these reports and search for the soft signals radiating from these reports, as illustrated in chapter 4.*

least document and account for some form of action taken in the wake of an adverse event. For example, the Inspectorate witnessed a flood of adverse event reports in 2016 (chapter 5, figure 5.1), which was the year the news broke on Adrienne Cullen's 'case' (chapter 2), "the attempted 'death-cover-up'" in the Tergooi hospital (chapter 2), as well as Zembla's series on the unsafe working climate at the UMCU (chapter 4 and 5). Likewise, Weenink and colleagues have reported, that the feared risk of being caught or reprimanded by the Inspectorate gears Dutch hospitals into action to implement and work along the lines of regulatory standards (Weenink et al., 2020). In sum, multiple external drivers – the media in particular (chapter 2) – can stimulate the enactment of the inscribed responsibilities in regulatory standards, both in a negative and positive sense.

With regard to the investments that have been made to professionalize the process of adverse event investigations, I found that resources have been allocated to professionalizing the investigation teams' Root Cause Analysis and writing skills; to allow them to produce 'good' reports. The importance of legible reports is illustrated in chapter 3, as inspectors award 'points' to reports when they "understand what has happened here". Also, hospitals have invested in the formation of dedicated teams that build up experience conducting adverse event investigations and the writing of reports. Interview respondents noted that they want to do well; "want to score "100%", as the Inspectorate's score awarded to (their) report, is experienced as a formal grade (chapter 5). It seems as though those investments have paid off: hospitals have indeed received higher scores overtime. But, as explained in chapter 5, this does not allow one to conclude that regulatees have learned to learn, for it is likely that the investigation teams in hospitals have become more adept at writing adverse event reports in line with the demands of the guideline.

The different steps taken by hospitals in the investigation process are detailed in chapter 7, figure 7.1, and coincide with the Inspectorate's guideline. It is clear that the participative nature of the investigations has been encouraged by the standard – through the inscribed ideal that learning is a participative and social

affair – as involved professionals are heard and almost all hospitals invite voice from patients and/or their families. What's more, participants are sometimes asked for input for improvement measures and are occasionally awarded the opportunity to provide feedback on the finalized version of the report (chapters 5 to 7). The nature in which this involvement is organized and what is done with invited input does vary across organizations. What's more, in practice investigators find it difficult to assign equal value to the input of the different stakeholders for the (medical) professional perspective and/or narratives that provide verifiable facts, carry most weight (chapters 6 and 7). In other words, multi-voiced involvement does not automatically lead to social and participative learning (chapter 7).

Taken together, some of the tasks, roles and responsibilities inscribed in the nested system of standards for the regulation of adverse events, are materialized (e.g. the Inspectorate using BAN data to publicly account for their work) but others are not acted out as intended (e.g. hospitals not learning from patient experiences in the wake of an adverse event). Also, socio-political factors including the media (chapter 2) influence the enactment of the script. In the next, and final step of the analysis, I explicate what the consequences are of the script and its enactment for the work of the Inspectorate and regulatees. I also unravel what the consequences are for the desired organizational learning in the wake of an adverse event.

THE CONSEQUENCES OF THE SCRIPT AND ITS ENACTMENT

For the Inspectorate I can discern four distinct consequences. First, as mentioned, in a very practical sense, the Inspectorate was forced to start working in a new way and rearrange its work processes to be able to work with the guideline and BAN system. In terms of output the standard has not fully objectified the work of inspectors but at the same time, work processes have been changed and, in many ways, become routinized and standardized in line with the standard.

Second, as chapter 3 explained, the BAN standard and subsequent scoring system has practical advantages for the Inspectorate, as it helps to organize a "messy reality" (Lampland & Star, 2009) and aids inspectors to read through the investigation reports in a systematized manner. This is practical, but because of the procedural focus of the BAN, Inspectors can easily neglect content-related details (just like Peppa Pig and her friends, riding the train: they do notice 'things' that are not on the activity sheet but their focus is steered towards the boat, the tunnel and signal box), generating unintended blind spots (Espeland & Stevens, 1998; Martin et al., 2015; chapter 4). By concentrating on ticking off the BAN criteria boxes, inspectors risk losing sight of content related details, as well as other safety- or quality associated elements, that are not part of the guideline but may have been important. This poses risks for the Inspectorate's institutional reputation, as chapter 4 explained. Alongside the standardization work of the standards, they then also – quite paradoxically – feed the non-standardized interpretative work that inspectors perform to determine what actions they need to take. Inspectors search for signals and clues that help them to make sense of the data collected through their formal instruments (chapter 4).

Third, the dual role inscribed in the standards causes inspectors to face dilemmas in their daily work. As said, the Inspectorate enacts its watchdog role but for a regulatory body that is faced with increased expectations of a strict enforcement policy (Bardach & Kagan, 1982; Dute, 2015; Legemaate et al., 2013; Rutz, 2017), it is hardly an interesting observation that the Inspectorate utilizes its disciplinary armory (and communicates imposed sanctions to the public). More interesting are the dilemmas that inspectors face behind the scenes; to be a stern watchdog in light of the other inscribed role: the teacher/mentor. For chapter 3 shows that the inspectors find themselves in a continuous process of pedagogic reasoning. That is, because it is the Inspectorate's goal to stimulate regulatees to report and learn from adverse events, inspectors feel it is best – in most cases – not to be too stern. Sternness may cause regulatees to become demotivated and frustrated, possibly hampering their learning process or willingness to report and learn from adverse events altogether. As an effect, inspectors think of ways to keep 'their pupils' motivated and nurture the continuing relationship of

dependance between regulator and regulatee (Hawkins, 1983). For instance, by wrapping their reprimanding feedback to investigation reports with "red ribbons" to soften their tone (chapter 3).

Fourth, as the new standard – possibly alongside other external drivers – has successfully stimulated or nurtured safety thinking in hospitals, the growing number of reported adverse events has amplified the already existing work-pressure inside the Inspectorate (chapters 3 and 5, and see Grit et al., 2018). This, then, has also affected hospitals, that reportedly experience immense pressure to investigate the adverse events internally reported (chapter 5). We know that organizations invest in practices that are externally monitored (Dahler-Larsen, 2014; Wallenburg et al., 2019) and indeed, hospitals have, in line with their inscribed responsibility to do so – professionalized their investigation routines. As a consequence, they have less time and resources to learn from other types of incidents that potentially hold valuable learning opportunities; there is less time for (the organization of) informal 'backstage' learning practices (Waring & Bishop, 2010); less time to implement, follow up on and evaluate the improvement measures that are formulated in adverse event reports (chapter 5); and less focus on or investments in sectoral broad learning, as is often called for (EenVandaag, 2016b; Vincent, 2010; Waring & Bishop, 2010). Clearly then the script has forced learning from adverse events in a certain direction – and constrained it in others (Ponte et al., 2011). What's more, the earlier described wish of regulatees to score "100%" or "do well for the Inspectorate" (chapter 5) – irrespective of the underlying motivation – has further channeled the process of learning in a specific performance; one I will discuss next.

As noted, the script dictates that learning from adverse events is a social and participative process; one that invites input from different stakeholders. This approach to learning stems from system-based and patient-centered care thinking (introduced in chapter 1), that recognize that all stakeholders are experts in their own right and bring valuable knowledge that can inform learning from what has gone wrong (chapters 6 and 7). Importantly then,

the script also carries the assumption that an organization – particularly the professionals that work inside these organizations – *can* (and should) learn from safety incidents. But, chapters 5 to 7 reveal that while hospitals have invested in the skills of incident investigators and seem determined to learn, and while the adverse event investigation reports are scored higher over time, the learning process of the investigation team is not, or poorly connected to, the healthcare professionals or organization at large. While patients and family members are increasingly involved, their epistemic contribution is not always heard, understood or valued by investigators. This is because the input and perceived value of patients, family members and professionals is linked to the extent to which it helps investigators conduct the investigation, determine root causes and formulate improvement measures to meet the demands ensuing from the regulatory standards (chapter 5 and 6). The script stimulates investigators – as independent and trained specialists, commissioned by their Board of Directors – to act as gatekeepers of the investigative process, and as such (usually) formulate the investigation's research questions and decide who must be heard and what is important (chapter 6). The team 'draws the line' of inquiry (Dekker, 2012) and frames the problem under investigation (Behr et al., 2015). Other concerns or possible lessons and lines of inquiry, as posed by involved professionals or patients and their families, then are deemed less relevant. What's more, the input provided to investigations must not be emotional, for emotions are thought to cloud someone's vision, contaminating their testimony (chapters 6 and 7).

In sum, in an attempt to encourage and measure social and participative learning, the demands in the script (i.e. for independent investigators, for the identification of root causes, the formulation of SMART improvement measures, etc.), have elicited investigation practices that (sometimes) prevent the inclusion of relevant stakeholders and can cause the downgrading of epistemic contributions that are deemed 'too emotional', 'not factual', or simply 'not relevant' in light of the quest for a linear narrative of the event (chapters 6 and 7). So, although the standards have pushed the – arguably very positive –

'new normal' for multi-voiced involvement, the actual process of learning from an adverse event has become one that allows the boxes of the BAN scoring instrument to be ticked.

IMPLICATIONS FOR THEORY AND PRACTICE

Theoretical implications

What, then, does this 'standard story' teach us about how standards work and their consequences? In the Introduction of this thesis I explained that the theory on the workings of standards is unclear, or at a minimum undecided. On the one hand standards are said to be normative boundary objects that constitute organizational practices and directly dictate or constrain behavior; they carry in them the power to regulate (Slager et al., 2012) and are instruments of control (Brunsson & Jacobsson, 2000). On the other hand, there is literature that shows that standards are gamed and ignored, and as such do not determine behavior and organizational work (Hollnagel et al., 2013; McGlynn et al., 2003)

My analysis shows that standards do carry the power to regulate. They can steer and standardize behavior and work practices, but this does not just happen. I can pick almost any point in my analysis to illustrate this. For instance: internally, the standards for the regulation of adverse events have had a profound influence on the way inspectors carry out their work, in many ways standardizing work. Regulatees too have been steered to develop new work routines and invest in the processes and skills to meet the requirements of the standard; and this is exactly what the standard-maker (in this case the regulator) wanted them to do. From a distance then, one could conclude that standards have a natural ability to regulate. They have been introduced and enforce a new or changed way of working towards the set principle. However, when looking closer, we see that is not the whole story. A standards directive to be open about mistakes can be thwarted if regulatees have concerns about negative publicity by the media (chapter 2). Also, inspectors have in some ways been disciplined and steered in their behavior but not in others. For example, the inspectors' informal knowledge

and emotions – that the standard intended to keep out – have not been filtered out. On the contrary: informal knowledge and active interpretative work in the form of collective sensemaking practices (Weick et al., 2005), appear to be crucial to making a standard produce effects. That is, due to the Inspectorate's responsive regulation strategy, the seriousness of the risk or problem is not leading and therefore assessments have to be made about the capacity and willingness of an organization – and its leaders – to take responsibility for and address the issue(s) at hand (chapter 4). Whether a regulatee complies to the regulatory standard, is not the only or even the most important matter of concern. This pushes inspectors to continuously deliberate about how they should act within and along the lines of the standards. This deliberation is influenced by external drivers such as the political climate and the media. And, importantly, the deliberations are also driven by the nested system in which standards appear; as the interlinked standards produce a layered script that forces the actors to decide on the enactment of conflicting roles and tasks. This means that making a standard 'do' something, requires continuous work as well as a social organization to embed the standard in. Standards then, are not by definition instruments of control. They produce unique effects as a result of their nested system and enactment in a complex socio-political constellation. This is not just a 'standard' story.

The analysis in this thesis underlines the theoretical notion that standards are normative instruments for they do not act neutrally (Lampland & Star, 2009). They carry in them implicit norms that dictate what is important and what not. What's more, they do not simply describe pre-excising realities, rather: they actively produce them (Dahler-Larsen, 2014; Mulcahy, 2011). For, through the creation of a standard to monitor if regulatees learn from adverse events, the standard has skewed the focus of learning towards the criteria that have been set. This is not an innocent process because it leads, for instance, to the devaluation of emotional narratives in the investigation process or the deflation of epistemic contributions that do not contain verifiable facts to help with the determination of root causes (one of the set criteria)(chapters 6 and 7).

Lastly, when standards do produce effects, whether performative or not, these effects can level off or at some point stop to produce the earlier documented consequences (chapter 5). This demonstrates the dynamic character of a standard: rather than being a dry document, it is an instrument with a life course and many linkages. Therefore, for the study of standards, researchers must be mindful of the socio-political context, the timeframe and nested system, in which the consequences of the standard have presented themselves. Each standard has a unique story, that develops over time.

The script metaphor has been such a central concept in my analysis, that a short reflection on the exact merit of this approach for the study of standards is called for. As Nicolini has explained, an object of study (in this case regulatory standards) can always be studied from different angles and interpretative frameworks; the framework or 'lens' of choice determines what it is that you see (Nicolini, 2009), or what story a researcher can document. If I would have performed a – say – historical or a content analysis[40] of the Inspectorate's standards in their regulatory program for adverse events, I would have been able to discern interesting developments in the definition of healthcare quality and safety, as well as the operationalization of 'learning from safety incidents', and the way that the Inspectorate intends to regulate these principles. This then would tell me a lot about what a standard-maker hopes to achieve but not so much about what standards actually 'do'. In regulation (as in other domains), standards are introduced as an intervention. To enforce and facilitate some sort of organizational or behavioral *movement*; someone or something has to *act* towards a set principle. As such a standard is not static but has a relational property. By using Madeline Akrich's script approach, I have

40. *See Bowker and Star, for a thought-provoking account of how a historical analysis of seemingly flat and dry documents like standards, phonebooks and the yellow pages can be instructive. They argue that historical changes in phonebooks, including names and locations of services, for example, reflect political and social movements and the ways that society thinks about 'things'. Like the first listing of a Gay and Lesbian Pride Parade, next to the Garlic Festival, as an annual event in Santa Cruz, California, reflects the acceptance of homosexuality after years of activism and conflict (1999).*

explicitly foregrounded this relational characteristic of standards and the norms and values that they carry. Combining this script approach to the theoretical notion that standards appear in nested systems (Lampland & Star, 2009), has given me a useful analytical framework to map the conflicting roles, tasks and demands embedded in the Inspectorate's standards. This map then, helps explain how these standards have produced effects and where their enactment comes with hiccups and strain. Standard enthusiasts, who make it their mission to understand what it is that a standard does in a specific context, will find it helpful to use a script approach, for it sensitizes them to the 'things' to look out for when tracing the enactment of a standard.

Practical implications and recommendations for regulation practices

What I have observed raises some points that can be considered in the execution of daily regulatory work. First, the observed sensemaking practices at the Inspectorate, wherein informal knowledge, experiences and memories as well as pedagogic strategies color the decisions made, and actions performed by inspectors is not entirely surprising. This has been documented before (De Kam, 2020; Hawkins, 1983; Rutz, 2017) and is, as argued, an important facet of the responsive regulation approach (chapter 4). But it is an interesting finding in light of the looming NPM-spirit (chapter 1), and its heavy reliance on quantified, scientific and technical knowledge to justify the actions and legitimize public policy actions and decisions as being 'impartial', 'objective' and 'just' (Bardach & Kagan, 1982; Moes, 2019, p. 125; Porter, 1996). In this spirit, regulatory standards serve as an important instrument for a regulator to demonstrate its legitimacy and trustworthiness (Porter, 1996; Power, 2000). The Inspectorate actively uses their standards in that way: to be transparent and predictable it publishes the standards it uses, such as inspection frameworks, to inform regulatees and the greater public, about the way they work (Weenink et al., 2020). This then has an important function for accountability purposes, but

also risks society to get an unrealistic view of regulatory practice,[41] in the sense that it is framed as an entirely objective, standardized machinery. This thesis has shown that inspectors are required to make assessments about the willingness and capability of an organization and its leaders to successfully work towards practices of 'learning from adverse events', 'good' and 'safe' care. In this process inspectors are not only guided by the standards that they use. Their informal knowledge and the piecing together of different types of signals and information sources – as I have shown – is crucial in the assessment process. As such I would recommend that the Inspectorate thinks of ways in which they *also* communicate about this 'soft' part of their work to the greater public. If regulators do not do this, or do not do this enough, they risk shaping the myth that inspectors are infallible.[42] This recommendation is complementary to the advice articulated in chapter 4, namely: develop work models and work routines, like that of the existing LMO teams (chapter 3) and other multidisciplinary team meetings (chapter 4) – where tacit knowledge, information and performance data is triangulated, weighed and made sense of, collectively. The 'softness' of regulatory work should not be proceduralized (further) but rather be recognized and embraced as a central element of regulatory work.

Second, this thesis has hopefully attuned the Inspectorate and regulators more broadly that the standards they use can carry in them structures that inhibit the very practices they aim to stimulate and measure (chapters 6 and 7). This recognition is instrumental to stimulating the type of regulatory reflexivity increasingly called for (Bal et al., 2017; Rutz, 2017; WRR, 2013), wherein regulators do not only ask 'do our instruments work?' but actively seek out 'how and why do they work?' (De Kam, 2020; Dixon-Woods, Bosk, Aveling, Goeschel, & Pronovost, 2011; Jones, 2018). These insights can help to develop and adapt (existing) standards in response to the continuous developments in the regulatory field and the socio-political constellation in which regulators operate. At the Inspectorate, qualitive research has proved to be a helpful way

41. Or possibly, the already existing unrealistic view is fueled further.
42. As chapter 2 discusses, doctors are also confronted with this myth.

to answer these contextualizing 'how' and 'why' questions, and I recommend that they – as well as regulators more broadly – continue to invite such research as a reflexive tool.

Third, because standards can have unintended consequences and can lose their effects – or their effects can level off over time, there is a need to monitor the movement they create and develop them further (see chapter 5 and De Kam, 2020; Grit et al., 2018). Chapter 5 provides some recommendations for the development of the Inspectorate's BAN scoring instrument. Determining what the focus of a new or adapted standard ought to be, should be done with regulatees and other stakeholders. As mentioned in the Introduction, such co-construction is not unique for regulatory standards (Timmermans & Epstein, 2010; Windholz, 2018). For such co-construction initiatives I would advise regulators to not only invite input from their 'best pupils', i.e. the best scoring regulatees. First, because the 'best pupils' may not necessarily be the best at learning from adverse events. And, second, because convening dialogue with different regulatees, in terms of their level of performance or compliance to standards, can be insightful to understand how a regulatory instrument is internalized in different ways and what diverse modes of understanding organizations have concerning the instrument. To illustrate: a researcher evaluating a health program will select a research site where – according to the performance data – the program has been successful. The researcher will also find it instructive to visit a site where the program has had less of an effect or has not been effective at all. The insights obtained at all sites can help analyze the factors that have contributed to the success and which factors constrain success (Hardon et al., 2001, pp. 267-268). For a regulator, heterogenous input is imperative to develop and/or adopt standards that fit the conditions that are necessary for success. To be sure, I am not suggesting that a regulator is responsible for shaping the conditions to make their standards produce desired effects, but being mindful of the necessary conditions for success can help prevent decoupling; when policy is officially introduced but not actually implemented effectively (De Bree & Stoopendaal, 2018). Thus, regulators

should not only be concerned about creating an internal context in which standards can be embedded, they should also take into account the contexts in which they are to be used in (healthcare) practice.

LIMITATIONS OF THIS STUDY

The strengths and weaknesses of the different studies presented in this thesis have been discussed in each empirical chapter. However, there remain two important limitations that stretch beyond the boundaries of these chapters and warrant further reflection.

First, as chapter 2 depicted, adverse events in healthcare are a sensitive matter; a subject infused by an aura of distrust, heightened emotions and sharp opinions. Certainly, since the commencement of my research in 2015 I have witnessed a transparency trend equivalent to other European countries (see also Wiig et al., 2018), as, amongst other activities, more and more hospitals are making their adverse event rates public.[43] And indeed, throughout the research, I barely received any interview declines. *But,* when wishing to take a closer look, in person, I experienced firsthand that healthcare organizations sometimes find it difficult to be fully open about what happens behind the scenes. As such, the longed-for tracer project never took flight. An observational study to map 'work as done' (Hollnagel et al., 2013) inside healthcare organizations, would have strengthened the validity of my analysis. For, clearly, the observations conducted at the Inspectorate allowed us to appreciate the nature and importance of informal dynamics and tacit knowledge in the performance of regulatory standards (see chapters 3 and 4). In my interviews I worked around this limitation by explicitly leaving room for, and inviting talk on, the concrete struggles and dilemma's that the respondents faced in the realm of incident

43. RTL Nieuws' six year legal battle (2010-2016) to gain access to the adverse event numbers reported to the Inspectorate (Van Yperen, 2016); figures that are now often openly published on hospital websites arguably clearly showcase this trend.

investigation practices, their contacts with the media as well as their relationship with the Inspectorate. By not only talking about (imagined) work routines but specifically foregrounding the experienced blemishes and stains in this work, I hope to have come as close as possible to 'work as done' as well as limiting socially desirable answers surrounding this sensitive topic.

Second, aside from the argued for 'learning opportunities', adverse events are first-and-foremost a deeply tragic event in the life of a patient and his/her loved ones. As such, patients and their families are important stakeholders (see also Bouwman, 2016; Bouwman et al., 2018; Iedema & Allen, 2012; Van de Bovenkamp & Zuiderent-Jerak, 2015), that are affected by the representations and norms inscribed in the standards used by the Inspectorate. As my research unfolded, I often spoke about patients and their families, but not with them. This book has not included their unique experiences. These do deserve attention and scrutiny.[44] Now that I have mapped the institutional practices, I am hopeful that the findings presented in this thesis – particularly chapters 6 and 7 – sensitize researchers and policy makers to the specific constrictive structures and themes that can serve as a starting point for such research.

FINAL THOUGHTS

As noted in the Introduction of this book, regulators of high-complex industries tend to use a combination of regulatory approaches and standards to monitor and steer towards desired behavior (Gilad, 2010; Levi-Faur, 2011; Windholz,

44. *Quite recently the Netherlands Institute for Health Services Research (NIVEL) published a report documenting the experiences of 11 patients/their next of kin with adverse event disclosure and investigation practices in Dutch hospitals (see Merten, Portegijs, Dückers, & Wagner, 2019). It is an insightful report that reveals that patients and their loved ones have some shared desires with regards to (the organization of) their involvement in incident investigations and disclosure practices (for example: open and clear communication) but their personal preferences, wishes and needs also vary greatly. Some of the negative experiences reported by the respondents reveal instances of epistemic injustice (chapter 7), that stem from the structures posed by the BAN standard.*

2018). Currently, highly prescriptive standards are – and will undoubtably remain – an important tool in a regulator's toolbox to safeguard the quality and safety of products and services. However, in the healthcare sector we are witnessing a rise of many ambiguous, difficult to quantify ideals, that are framed as an integral part of the quality and safety of healthcare delivery. Examples are the concepts of 'resilience', 'good governance', 'just culture', 'patient-centeredness', 'medical leadership', 'network collaboration', et cetera. To illustrate such thinking: today, many readers will recognize that a patient that has successfully received a technologically advanced, evidence-based treatment in a state-of-the-art facility, can still have received mediocre care, if the patient's wishes were not heard or recognized or aftercare by other health services faltered. With the rise of these ideals and new ways of appraising quality and safety, I predict we will witness an intensification of the development and utilization of standards that broadly articulate the outcome or principle to be achieved without depicting how to achieve it (standards that Winholz calls outcome-orientated standards, see chapter 1, table 1.1). This changes the work of healthcare regulators and demands new skills from inspectors, or put differently, redefines 'regulatory craftmanship' (Sparrow, 2000). Let me explain why, using the example of patient-centeredness.

Earlier chapters in this book have discussed that patient-centered care has become a widespread ideal, called for by the public, policy makers and regulators. What the principle entails exactly in the daily practice of healthcare, is open for discussion and arguably also something that is, like the very concepts of 'safety' and 'quality', continuously evolving (Reinders, 2019; Stoopendaal, 2020; Vincent & Amalberti, 2015). What's more, for a regulator there is uncertainty about the associated risks if patient-centeredness is not achieved or organized effectively (Rutz, 2017). What then, in light of patient-centeredness, is the object of regulation and how can 'it' be translated into something that is rendered visible and as such inspectable (De Kam, 2020)? To answer these questions, a regulator must intensify its utilization of soft signals and convene in an ongoing dialogue with stakeholders. This demands regulators to diversify the traditional forms of communication in regulation practices (i.e.

inspection visits, yearly meetings with organizational leaders, etc.) (Hartman et al., 2020; Burgess et al., 2019). An open dialogue that welcomes different epistemic contributions to come to a joint understanding of a concept that is evolving and multifaceted in nature, is difficult – all the more so because of the public's diminished acceptance of risks and uncertainty (chapters 2 and 3; Power, 2007). I pose that for an inspector inviting dialogue on quality and safety principles, is not the same as communicating with regulatees about compliance practices, giving feedback or advice along the lines of prescriptive (legal) frameworks.[45] The former will be aided by the development of a different skillset, or what I would call 'anthropologic sensibilities'; a curious and reflexive mindset, attuned to and accommodating for the ideas and interpretations of others.

During my fieldwork at the Inspectorate I noticed that in terms of methodological practice, inspectors operate like anthropologists; they perform fieldwork, observe (organizational) rituals, gather documents and conduct interviews. All in an attempt to map how work is done. An important difference to the work of an anthropologist, however, is the underlying goal of these activities: an inspector is there to assess, to cast a judgement. And indeed, that is the job description. An anthropological researcher conducts fieldwork and 'comes up close' to daily practice with the goal to understand the meaning of people's ideas and practices (Hardon et al., 2001), without the necessity to determine if something is right, or wrong or should be going differently.[46]

A regulator that houses anthropological sensibilities is interested in what it is organizations do, but also wishes to understand how and why it is done, the way that it is done, and how the people in that organization make sense of what they are doing. The Inspectorate, as other healthcare regulators in

45. *As noted in chapter 6, the same goes for a medical professional: having a 'bad news' conversation with a patient is not the same as disclosing an adverse event to a patient. The latter requires a different skillset.*
46. *Or, I could also say: the luxury of not having to determine if something is right, or wrong or should be going differently.*

Europe, are already beginning to cultivate these sensibilities with, for example, the introduction of the Short Observational Framework for Inspection (SOFI), or by inviting more narrative accountability formats through the Rapid Ethnographic Assessment Procedure (REAP) in long term and elderly care (CSCI, 2007; Reinders, 2019; Stoopendaal, 2020). An important part of this process is – based on the earlier posed emic/etic dichotomy (chapter 6) – the bracketing (Bernard, 2002) of one's own assumptions, theories and criteria of significance (Kottak, 2004). Such a mindset, or work ethos, will aid the process of a reciprocal dialogue with different stakeholders (Burgess et al., 2019) as healthcare is becoming increasingly complex and assessed along the lines of ambiguous ideals. To be sure, this does not mean I am opposed to the development of standards (in whatever form they come), but with the rise of the afore mentioned norms, a continuous dialogue is needed on what the performance of these norms looks like in practice, how healthcare providers can account for their level of performance (Leistikow & Bal, 2020) and what types of regulatory instruments – including standards – would be suitable to monitor and stimulate this. For a regulator to maintain its institutional legitimacy it is crucial that when stakeholders are 'invited in' (chapter 2), they feel heard and seen in these (new) communication rituals. Embedding qualitative research in regulatory practice, as the Inspectorate has done for many years now, can help to nurture and mature these anthropological sensibilities as well as draw up the unique stories regulatory standards produce.

R

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APPENDICES

SUMMARY

Standards[47] are all around us. They are often introduced to steer behavior and organizational work by defining boundaries and enabling interaction through the provision of a common language and norms. Standards then *do* a lot, but how this actually works in practice and to what effects has rarely been the direct topic of study. Scholarship that does engage with the topic of standards draws a conflicting picture on their workings and consequences. Some studies suggest that standards direct behavior and work, in other studies standards do not seem to determine behavior and work practices.

This undecided academic debate calls for more research because there are many societal and institutional contexts in which standards are explicitly used to regulate the outcome or performance of daily work. One of these contexts is healthcare regulation. This book aims to further the academic debate on the workings and consequences of standards as well as help the daily practice of (healthcare) regulation by uncovering how the standards that regulators use – in the form of guidelines, checklists, regulatory frameworks etc. – produce effects. For regulators understanding these effects is crucial as regulatory bodies are increasingly pressed to demonstrate their societal value and account for the effectiveness of their work.

Chapter 1 explains that standards come in all shapes and sizes and are nested inside one another like a set of Russian Matryoshka dolls. I explicate that – when studying standards – it is useful to approach them as relationally enacted. This is key notion underpinning this thesis. Rather than envisioning standards as stable lifeless 'things', I approach them as dynamic instruments that carry a script. A script that implicitly holds aspired principles and assumptions about

47. *Specifically, in this thesis 'standards' refer to the instruments that have been developed to manage risks and steer behavior, through the description of norms or principles for (good) conduct and/or by explicating measurement criteria for the quality and performance of goods, processes and practices. Examples are guidelines, checklists and protocols, that carry – implicitly or explicitly – norms and directions to what constitutes as 'good, 'true' or 'correct'.*

the actors who use them; that dictates specific roles, tasks and responsibilities to these actors; that is interpreted and enacted by the actors in a specific context. As such, to understand how standards work, I argue that it is necessary to empirically study the standard makers, the standard users and context(s) in which standards are used.

The chapter goes on to introduce the research setting and discusses some recent developments in this setting, namely: the Dutch Health and Youth Care Inspectorate's (*Inspectie Gezondheidszorg en Jeugd*, hereafter Inspectorate) regulation program for adverse events[48] (*calamiteitentoezicht*) in hospitals. In 2013 the Inspectorate introduced a regulatory framework – including a guideline, scoring system and coupled monitoring database – with the goals to stimulate and monitor learning from adverse events in Dutch hospitals. Alongside these goals, the standards were also introduced to standardize the Inspectorate's own work practices as a way to be predictable, consistent and transparent to regulatees and to account for the impact of their activities. Both the idea that the implemented standards steer learning *and* standardize work practices, presume the natural ability of standards to regulate behavior. This thesis explores if that is the case, and if so, how that happens and to what effect(s).

The research in this thesis was guided by three overarching research questions: (1) What script has been inscribed in the regulatory standards that are used in the regulation of adverse events? (2) How is this script enacted by the regulator (the Inspectorate) and regulatees? And, (3) What are the consequences of this script and the way that it is enacted, for the actors involved and for organizational learning in hospitals? These questions are answered through ethnographic fieldwork, including observations, in-depth interviews and document analyses. The empirical findings are presented in chapters 2 to 7. These chapters have been written as individual academic articles and foreground different aspects

48. *Dutch law defines an adverse event as an unintended and/or unexpected event related to the quality of care, having caused the death of, or serious harm to, the patient.*

of the use, altered and non-use, of regulatory standards at the Inspectorate and in diverse Dutch hospitals. The chapters also shed light on the dynamic socio-political context in which healthcare regulation, and its use of standards, unfolds.

Chapter 2 was written as a short essay, that does not specifically discuss the standards or standardized practices we come across in the Dutch healthcare sector but reports on the social-political context in which the Inspectorate's regulation of adverse events is enacted. An appreciation for this context is relevant because we know that regulatory programs, like that for adverse events, are not performed in a social-political vacuum. Scholars have pointed to the influence of the institutional constellation – including the media – on regulatory practice. From a relational perspective, the standards used in a regulatory program, then are also influenced by this social-political context.

Based on insights obtained throughout the multi-year research project, the chapter unveils the strained relationship between healthcare organizations and the (news) media. It explains how this relationship hampers transparency and open dialogue about mistakes and safety incidents in healthcare; precisely the argued for preconditions for reporting, investigating and learning from adverse events.

Chapter 3 describes the introduction of the standards and coupled performance management system in the Inspectorate's regulation program for adverse events. Based on ethnographic observations of meetings where adverse event investigation reports are discussed and scored at the Inspectorate and interviews with inspectors, this chapter illustrates what theory of learning is inscribed inside the standards that are used, i.e. what and how the Inspectorate wants hospitals to learn in the wake of an adverse event. Moreover, it illustrates how the standards are enacted inside the Inspectorate and discusses the consequences of these standards for the Inspectorate's own work practices. The chapter shows that the introduced standards have had a profound influence on the way that the inspectors work and, in some ways, manage to standardize their daily work. But there are limits to the standards' (internal) regulatory power, for the

empirical work illustrates that informal knowledge and emotions – precisely the 'things' that the standards needed to keep out – have not been filtered out of regulatory work. This points to the importance of taking the relationships into account, in which regulatory standards are enacted, for these relationships influence the way standards 'work' in practice.

Chapter 4 discusses how the Inspectorate labels, interprets and utilizes the diverse array of signals about safety risks it receives and picks up in the field. The chapter outlines the social processes and activities that take place inside the Inspectorate alongside its use of formal standards and standardized practices. It shows that soft signals, i.e. the ambiguous pieces of information that are difficult to commensurate and are not easily classified within existing data management systems, are vital for inspectors to perform their everyday work, for they provide context to the 'hard' data and findings collected in the Inspectorate's performance management system, adverse event investigation reports, etc.

Importantly, the chapter also reveals that inspectors continuously read between the lines and use their informal knowledge about and experiences with healthcare organizations and their leaders, to make sense of quality and safety risks. This, the chapter concludes, is a direct consequence of the Inspectorate's responsive regulation approach wherein regulatory decisions and actions are attuned to the context in which they are applied. The chapter also underlines that the possible risks to the Inspectorate's own legitimacy and institutional reputation continuously color the assessments made by inspectors and the actions that they take. This emphasizes the difficulty for inspectors to be disciplined by the standards introduced to keep their personal judgements, institutional circumstances, and existing relationships out.

Chapter 5 explores how the Dutch incident reporting system (IRS), i.e. the institutionalized process of reporting and investigating adverse events as directed by the Inspectorate's regulatory framework, has contributed to social and participative learning in Dutch hospitals. Using quantitative data from the Inspectorate's performance management system, the chapter examines if and

on what aspects of the Inspectorate's scoring instrument hospitals have improved over time. Using qualitative data (semi-structured interviews with stakeholders, including incident investigators, quality managers, etc.) we illustrate and reflect on the actual organizational practices and developed routines behind these figures.

The mixed-methods approach allows this chapter to show that healthcare inspectors score incident investigation reports better over time. The qualitative data suggests that while the IRS stimulated organizational practices that support social and participative learning, it also contributed to practices that do not. The IRS, then, both hits and misses the mark and we argue that IRSs need to be responsive to the (developing) capabilities of healthcare providers to investigate and learn from incidents, if the IRS is to (continue to) stimulate social and participative leaning from incidents.

Chapter 6 specifically foregrounds one of the elements of the Inspectorate's adverse event investigation framework, namely: the directive to involve patients and/or their families in adverse event investigations. The chapter explores how Dutch hospitals organize patient and family engagement in adverse event investigations and maps their challenges with involvement. The analysis shows that even though hospitals do involve patients and/or their families, their epistemic contributions are not always seen as valid input for learning from an adverse event. The chapter demonstrates that – under certain conditions – standards can stimulate organizational processes and concludes that the supportive regulatory policy (the introduced standard) has led to more patient and family engagement. This is an important development, but the current nature of involvement does not necessarily do justice to the standard's underlying goal, namely: that patients and families should be involved to further learning from adverse events.

Chapter 7 again discusses the practice of multi-voiced involvement in adverse event investigations. Using the concept op 'epistemic injustice' – the idea that someone's knowledge is unjustly disqualified or devalued – the chapter reflects on how the standards that have been introduced by the Inspectorate

(their scoring instrument and incident investigation framework) may favor the contribution of some actors over others, ultimately influencing what is and can be learned from adverse events. The analysis, for example, reveals that the Inspectorate's standards steer adverse event investigators to search for 'hard' and 'verifiable' facts in de wake of an adverse event. As an effect, the involved patients, family members or professionals are sometimes framed as 'too emotional'. This frame risks their testimonies to be (unjustly) discredited. In a time when healthcare organizations are seen to have a duty to learn from adverse events using the input from multiple perspectives, alongside the continued calls to 'take patients seriously' and 'value everyone's language equally', this chapter points to the institutionalized structures that can complicate such efforts.

Chapter 8, the discussion of this thesis, revisits the findings presented in the empirical chapters to answer the three overarching research questions. It also reflects on the theoretical and practical implications of this research project.

First, the chapter starts by unraveling the script that has been inscribed in the regulatory standards that are used in the regulation of adverse events. It shows that the script carries layered expectations, roles and responsibilities, on both the side of the regulator and regulatees. These different expectations, roles and responsibilities sometimes come with conflicting demands. By answering the second and third research questions, it becomes clear that these conflicting demands cause dilemmas in the daily work of the Inspectorate. For instance, because the script dictates that the Inspectorate needs to be both a watchdog and mentor; two roles that require different communication techniques and regulatory strategies. What's more, the empirical work demonstrates that some of the inscribed tasks, roles and responsibilities are acted out as envisioned (for example, the Inspectorate using the data collected through performance management system, to publicly account for their work) but others are not acted out as originally intended (for example, hospitals not learning from patient experiences in the wake of an adverse event). The analysis furthermore shows that socio-political context and the media influence the enactment of the standard's script.

Theoretically this analysis is valuable for it demonstrates that standards do *not* have the natural ability to regulate behavior or work. Making a standard 'do' something, requires continuous maintenance and interpretation work as well as a social organization to embed the standard in. Standards, therefore, all have their own story: they produce unique effects as a result of the relationships and contexts in which they are enacted. Researchers must map these relationships and contexts in order to understand and explain how a standard works and what consequences it has in practice.

This study has practical relevance for the work of a regulator. It shows that standards have and important function for accountability purposes, but by actively showcasing their standards as disciplining and objectifying instruments, the Inspectorate – like any other regulatory body – also risks the public to attain an unrealistic view of regulatory work in the sense that it is framed as an entirely objective, standardized practice. This – as this thesis shows – is not the case and therefore I recommend that regulatory bodies think of ways to actively communicate about the 'softer' parts of their work, including the relational and informal interpretive work and sense-making practices, to the greater public.

This study has also illustrated that regulatory standards can have unintended consequences, for instance because they carry in them structures that inhibit the very practice that they aim to stimulate and measure. What's more their effects can level off over time. As such, I conclude that there is a need to continuously monitor the movement standards create and (further) develop them attuned to the context in which they are used. Regulators, I argue, should do this with regulatees and other stakeholders. This requires regulators to be reflexive and develop open and curious sensibilities.

SAMENVATTING

Standaarden[49] zijn overal om ons heen. Ze worden vaak geïntroduceerd om gedrag en organisatiewerk te sturen, om grenzen te definiëren en interactie mogelijk te maken. Dit doen ze door het aanbieden van een gemeenschappelijke taal en normen. Standaarden *doen* dus veel, maar hoe dit in de praktijk werkt en wat de effecten zijn, is zelden het hoofdonderwerp van wetenschappelijk onderzoek geweest. Onderzoeken die zich wel met het onderwerp 'standaarden' bezighouden, laten een tegenstrijdig beeld zien van hun werking en gevolgen. Enerzijds lijken standaarden het gedrag en werk in organisaties te bepalen, anderzijds lijken ze het gedrag en werk in organisaties juist niet te bepalen.

Dit onbesliste academische debat vraagt om meer onderzoek omdat er veel maatschappelijke en institutionele contexten zijn waarin standaarden expliciet worden ingezet om de resultaten of prestaties van het dagelijkse werk te reguleren. Een van deze contexten is het overheidstoezicht op de gezondheidszorg. Dit proefschrift heeft als doel om het academische debat over de werking en gevolgen van standaarden te bevorderen en om de dagelijkse praktijk van (gezondheidszorg)toezicht te helpen door duidelijk te maken hoe de standaarden die toezichthouders gebruiken – in de vorm van richtlijnen, *checklists*, toezichtkaders enz. – effecten genereren. Voor toezichthouders is het van cruciaal belang deze effecten te begrijpen, omdat publieke toezichthouders steeds meer worden gedwongen om hun maatschappelijke waarde aan te tonen en verantwoording af te leggen over de effectiviteit van hun werk.

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49. Concreet verwijzen 'standaarden' in dit proefschrift naar de instrumenten die zijn ontwikkeld om risico's te beheersen en gedrag te sturen, door het beschrijven van normen of principes voor (goed) gedrag en/of door de uiteenzetting van meetcriteria voor de kwaliteit en prestatie van goederen, processen en werkpraktijken. Voorbeelden zijn richtlijnen, checklists *en protocollen die - impliciet of expliciet - normen en aanwijzingen bevatten over wat als 'goed', 'waar' of 'correct' is aan te merken.*

Hoofdstuk 1 legt uit dat standaarden in allerlei varianten voorkomen en vaak met elkaar verweven (*nested*) zijn als een stel Russische Matroesjka poppetjes. Ik stel dat het, bij het bestuderen van standaarden, nuttig is om ze als een 'relationele uitvoering' te beschouwen. Dit idee is een belangrijk vertrekpunt in dit proefschrift. In plaats van standaarden te zien als stabiele, levenloze 'dingen', benader ik ze als dynamische, relationele instrumenten die een script bezitten. Een script dat impliciete principes en aannames bevat over de actoren die er gebruik van maken; dat specifieke rollen, taken en verantwoordelijkheden aan deze actoren oplegt; dat door de actoren in een specifieke context wordt geïnterpreteerd en uitgevoerd. In die hoedanigheid beargumenteer ik dat het, om inzicht te krijgen in hoe standaarden werken, noodzakelijk is om de makers van standaarden, de gebruikers van standaarden en de context(en) waarin ze worden gebruikt, op empirische wijze te bestuderen.

Het hoofdstuk gaat verder met het introduceren van de onderzoeksetting en enkele ontwikkelingen hierin, te weten het toezicht op calamiteiten[50] in Nederlandse ziekenhuizen (formeel 'incidententoezicht', maar steeds vaker aangeduid als 'calamiteitentoezicht') van de Inspectie Gezondheidszorg en Jeugd (hierna 'Inspectie'). In 2013 introduceerde de Inspectie voor het toezicht op calamiteiten een nieuw toezichtkader, inclusief een richtlijn voor calamiteitenonderzoek, beoordelingskader en een gekoppeld prestatiebeheersysteem, met als doel het leren van calamiteiten in Nederlandse ziekenhuizen te stimuleren en monitoren. Naast deze doelen werden deze standaarden ook geïntroduceerd om de eigen werkwijzen van de Inspectie te standaardiseren als een manier om voorspelbaar, consistent en transparant te zijn naar de ondertoezichtstaanden en om de invloed van de eigen activiteiten te verantwoorden. Het uitgangspunt dat de geïmplementeerde standaarden het leren van calamiteiten én standaardiseren van werkwijzen bewerkstelligt,

50. De Nederlandse wet definieert een calamiteit als een niet-beoogde of onverwachte gebeurtenis, die betrekking heeft op de kwaliteit van de zorg en die tot de dood van of een ernstig schadelijk gevolg voor een patiënt heeft geleid.

veronderstelt dat standaarden over het natuurlijk vermogen beschikken om gedrag te reguleren. In dit proefschrift wordt onderzocht of dat het geval is en zo ja, hoe dat gebeurt en met welk(e) effect(en).

Het onderzoek in dit proefschrift werd gestuurd door drie overkoepelende onderzoeksvragen: (1) welk script is opgenomen in de toezichtstandaarden die worden gebruikt in het toezicht op calamiteiten? (2) Hoe wordt dit script uitgevoerd door de toezichthouder (de Inspectie) en de ondertoezichtstaanden? En (3) wat zijn de gevolgen van dit script en de manier waarop het wordt uitgevoerd voor de betrokken actoren en voor het organisatorisch leren in ziekenhuizen? Deze vragen zijn beantwoord op basis van etnografisch veldwerk, waarbij naast observaties ook diepgaande interviews en documentanalyses zijn uitgevoerd. De empirische bevindingen zijn gepresenteerd in de hoofdstukken 2 t/m 7. Deze hoofdstukken zijn geschreven als losse academische artikelen. Ze bespreken verschillende aspecten van het gebruik, gewijzigd gebruik en niet-gebruik van wettelijke standaarden – bij de Inspectie en in diverse Nederlandse ziekenhuizen. In de hoofdstukken wordt ook een licht geworpen op de dynamische sociaal-politieke context waarbinnen het toezicht op de gezondheidszorg en het gebruik van standaarden plaatsvindt.

Hoofdstuk 2 is geschreven als een kort essay, waarin niet specifiek is gekeken naar de standaarden of gestandaardiseerde werkwijzen die we tegenkomen in de Nederlandse gezondheidszorg, maar naar de sociaal-politieke context waarin het toezicht op calamiteiten van de Inspectie zich ontvouwt. Enig begrip voor deze context is relevant omdat we weten dat toezichtprogramma's, zoals dat voor calamiteiten in ziekenhuizen, niet in een sociaal en politiek vacuüm worden uitgevoerd. Wetenschappers hebben reeds gewezen op de invloed van de institutionele constellatie – inclusief de media – op de uitvoering van toezicht. Vanuit een relationeel perspectief, worden de standaarden die in toezichtprogramma's worden gebruikt, dan ook beïnvloed door deze sociaal-politieke context.

Op basis van inzichten die zijn verkregen tijdens het meerjarige promotieonderzoek wordt in dit hoofdstuk de gespannen relatie tussen

gezondheidszorgorganisaties en de (nieuws)media onthuld. Het essay legt uit hoe deze relatie de transparantie en open dialoog over fouten en incidenten in de gezondheidszorg belemmert; en dat zijn nu juist de bepleitte voorwaarden voor het rapporteren, onderzoeken en het leren van calamiteiten.

Hoofdstuk 3 beschrijft de introductie van de standaarden en het gekoppelde prestatiebeheersysteem in het calamiteitentoezicht van de Inspectie. Op basis van etnografische observaties bij de bespreking van calamiteitenrapportages binnen de Inspectie en interviews met inspecteurs, illustreert dit hoofdstuk welke pedagogiek is opgenomen binnen de standaarden die worden gebruikt. Met andere woorden: wat en hoe wil de Inspectie dat ziekenhuizen leren in de nasleep van een calamiteit? Daarnaast illustreert het hoofdstuk hoe de standaarden binnen de Inspectie worden uitgevoerd en wordt besproken wat de gevolgen van deze standaarden zijn voor de eigen werkwijzen van de Inspectie. Het hoofdstuk laat zien dat de ingevoerde standaarden een grote invloed hebben gehad op de manier waarop de inspecteurs werken en erin slagen, op bepaalde wijzen, om het dagelijkse werk te standaardiseren. Maar er zijn grenzen aan de (interne) regulerende invloed van de standaarden; het empirische onderzoek illustreert dat informele kennis en emoties – net die 'dingen' die de standaarden buiten de beoordeling van het calamiteitenrapport moeten houden – niet uit het toezichtwerk zijn gefilterd. Aangetoond wordt hoe belangrijk het is dat rekening wordt gehouden met de relaties waarbinnen de toezichtstandaarden worden toegepast, omdat deze relaties beïnvloeden hoe standaarden in de praktijk 'werken'.

Hoofdstuk 4 analyseert hoe de Inspectie de diverse signalen over veiligheidsrisico's die zij uit het veld ontvangt, categoriseert, interpreteert en gebruikt. Het hoofdstuk geeft inzicht in de sociale processen en activiteiten die achter de schermen bij de Inspectie plaatsvinden, naast de gestandaardiseerde werkwijzen en het gebruik van formele standaarden. Het hoofdstuk toont dat 'zachte signalen', ofwel de ambigue stukken informatie die moeilijk te vergaren zijn en niet gemakkelijk in bestaande gegevensbeheersystemen kunnen worden geclassificeerd, van cruciaal belang zijn voor inspecteurs om hun dagelijks

werk uit te voeren. De signalen bieden een context voor de 'harde' data en bevindingen die de Inspectie verzamelt in haar prestatiebeheersysteem of voortkomen uit formele rapporten zoals calamiteitenrapportages.

In dit hoofdstuk blijkt voorts dat inspecteurs voortdurend tussen de regels door lezen en hun informele kennis over en ervaringen met gezondheidszorgorganisaties en hun bestuurders gebruiken om kwaliteits- en veiligheidsrisico's in te schatten. Dit gepuzzel met signalen is een direct gevolg van de responsieve toezichtsaanpak van de Inspectie, waarbij de beslissingen van de inspecteurs worden afgestemd op de context waarin de toezichtsacties moeten worden ingezet. Het hoofdstuk onderstreept ook dat de mogelijke risico's voor de eigen legitimiteit en institutionele reputatie van de Inspectie de beoordelingen van inspecteurs en de acties die zij ondernemen doorlopend kleuren. Hierdoor wordt nogmaals benadrukt hoe moeilijk het voor inspecteurs is om gedisciplineerd te worden door de standaarden die zijn ingevoerd om hun persoonlijke oordelen, institutionele omstandigheden en bestaande relaties buiten de deur te houden.

Hoofdstuk 5 bespreekt hoe het Nederlandse incidentrapportagesysteem (IRS), ofwel het geïnstitutionaliseerde proces van het rapporteren en onderzoeken van calamiteiten zoals wettelijk is vastgelegd, heeft bijgedragen aan sociaal en participatief leren van calamiteiten in Nederlandse ziekenhuizen. Aan de hand van kwantitatieve gegevens uit het prestatiebeheersysteem van de Inspectie wordt in dit hoofdstuk onderzocht of en op welke elementen van het in 2013 geïntroduceerde scoringinstrument om calamiteitenrapportages te beoordelen, ziekenhuizen beter zijn geworden. Met behulp van kwalitatieve data (semigestructureerde interviews met stakeholders, zoals calamiteitenonderzoekers, kwaliteitsmanagers, enz.) illustreren we welke organisatorische praktijken schuilgaan achter deze cijfers.

Middels deze *mixed-methods* analyseaanpak laat het hoofdstuk zien dat inspecteurs de calamiteitenrapportages in de loop der tijd positiever zijn gaan beoordelen en ziekenhuizen op bepaalde onderdelen van de standaard beter zijn gaan scoren. De kwalitatieve gegevens suggereren dat het IRS weliswaar

organisatorische werkwijzen stimuleerde die sociaal en participerend leren in ziekenhuizen ondersteunen, maar ook heeft bijgedragen aan werkwijzen die dat juist niet doen. Het hoofdstuk bepleit dat als het IRS sociaal en participatief leren van calamiteiten wil (blijven) stimuleren en bevorderen, het systeem (met haar standaarden) tijdig moet worden doorontwikkeld om in te spelen op het reeds ingezette ontwikkelde vermogen van zorginstellingen om calamiteiten te onderzoeken en daarvan te leren.

Hoofdstuk 6 zet specifiek één van de elementen uit de richtlijn voor calamiteitenrapportages centraal, namelijk de instructie om patiënten en/of hun families te betrekken bij calamiteitenonderzoek. Het hoofdstuk beschrijft hoe Nederlandse ziekenhuizen dergelijke betrokkenheid vormgeven en brengt de uitdagingen daarbij in kaart. Uit de analyse blijkt dat hoewel ziekenhuizen de patiënt(en) en/of hun familieleden inmiddels wel uitnodigen om mee te werken aan het calamiteitenonderzoek, hun inbreng niet altijd wordt erkend als waardevolle input om van te leren. Het hoofdstuk laat zien dat – onder bepaalde omstandigheden – een hiervoor ingezette toezichtstandaard organisatorische processen in gang kan zetten en concludeert dat het toezichtbeleid, d.m.v. de in 2013 nieuw geïntroduceerde standaard, zeker heeft geleid tot meer betrokkenheid van patiënten en familieleden. Dit is een belangrijke ontwikkeling, maar de huidige aard van de betrokkenheid doet niet noodzakelijk recht aan het onderliggende doel van de standaard, namelijk dat patiënten en familieleden moeten worden betrokken om optimaal te kunnen leren van wat er niet goed is gegaan in het zorgproces.

In **hoofdstuk 7** wordt opnieuw het betrekken van meerdere partijen in calamiteitenonderzoek (*multi-voiced involvement*) besproken. Met behulp van het concept '*epistemic injustice*' – het idee dat iemands kennis ten onrechte wordt gediskwalificeerd of gedevalueerd – wordt in het hoofdstuk onderzocht hoe en waardoor de standaarden van de Inspectie de inhoudelijke bijdrage van sommige actoren de voorkeur geven boven die van anderen. De calamiteitenrapportage richtlijn stuurt er juist op aan om verschillende partijen tijdens calamiteitenonderzoek te horen, vanuit de visie dat er dan zo optimaal

mogelijk kan worden geleerd van wat er niet is goed gegaan. De vraag is of alle partijen, als ze betrokken worden, ook echt gehoord worden. Uit de analyse blijkt o.a. dat de richtlijn van de Inspectie calamiteitenonderzoekers aanzet om te zoeken naar 'harde' en 'verifieerbare' feiten. Als gevolg hiervan worden de betrokken patiënten, familieleden of professionals soms als 'te emotioneel' weggezet. Deze beoordeling dreigt (onterecht) afbreuk te doen aan hun getuigenissen. In een tijd waarin zorgorganisaties worden geacht te leren van calamiteiten door gebruik te maken van de input vanuit meerdere perspectieven en er voortdurend wordt opgeroepen om 'patiënten serieus te nemen' en 'ieders taal gelijk te waarderen', wijst dit hoofdstuk op de geïnstitutionaliseerde structuren die dergelijke inspanningen kunnen compliceren.

Hoofdstuk 8, de discussie van dit proefschrift, reflecteert op de bevindingen die zijn gepresenteerd in de empirische hoofdstukken en beantwoordt de drie overkoepelende onderzoeksvragen. Het hoofdstuk bespreekt ook de theoretische en praktische implicaties van dit onderzoek.

Het hoofdstuk begint met het ontleden van het script dat is opgenomen in de standaarden die worden gebruikt in het calamiteitentoezicht van de Inspectie. Het laat zien dat het script gelaagde verwachtingen, rollen en verantwoordelijkheden heeft, zowel aan de kant van de toezichthouder als aan de kant van de ondertoezichtstaanden. Deze verschillende verwachtingen, rollen en verantwoordelijkheden stellen soms tegenstrijdige eisen. Door het beantwoorden van de tweede en derde onderzoeksvraag wordt duidelijk dat deze tegenstrijdige eisen dilemma's veroorzaken in het dagelijkse werk van de Inspectie. Bijvoorbeeld omdat het script dicteert dat de Inspectie zowel een waakhond als mentor moet zijn; twee rollen die verschillende communicatietechnieken en toezichtstrategieën vereisen. Het empirische onderzoek laat ook zien dat sommige van de beschreven taken, rollen en verantwoordelijkheden worden uitgevoerd zoals beoogd (bijvoorbeeld de Inspectie die de gegevens uit het prestatiebeheersysteem gebruikt om publiekelijk verantwoording af te leggen over het uitgevoerde werk), maar dat andere rollen, taken en verantwoordelijkheden niet worden uitgevoerd

zoals oorspronkelijk bedoeld (bijvoorbeeld ziekenhuizen die de ervaringen van patiënten niet gebruiken om te leren van een calamiteit). De analyse toont bovendien aan dat de socio-politieke context en de media, de uitvoering van het script – en daarmee ook de consequenties van de standaarden – sterk beïnvloeden.

Theoretisch is deze analyse waardevol omdat ze aantoont dat standaarden *niet* een natuurlijk vermogen hebben om gedrag of werk te reguleren. Een standaard iets laten 'doen' vereist zowel voortdurend onderhouds- en interpretatiewerk als een sociale organisatie om de standaard in te bedden. Standaarden hebben dus allemaal een eigen verhaal: ze produceren een uniek effect als gevolg van de relaties en contexten waarin ze worden toegepast. Onderzoekers moeten deze relaties en contexten in kaart brengen om te begrijpen en uit te leggen hoe een standaard werkt en welke gevolgen de standaard in de praktijk heeft.

Dit onderzoek heeft praktische relevantie voor het werk van een toezichthouder. Het toont aan dat standaarden een belangrijke functie hebben voor verantwoordingsdoeleinden. Echter, door actief de gebruikte standaarden te presenteren als disciplinerende en objectiverende instrumenten, riskeert de Inspectie – net als andere toezichthouders – dat zij de maatschappij een onrealistisch beeld geeft dat toezichtwerk volledig objectief en gestandaardiseerd kan zijn. Toezichthouden – zo laat dit proefschrift zien – is juist geen volledig objectieve en gestandaardiseerde activiteit. Daarom adviseer ik toezichthouders om manieren te bedenken om naar het publiek actief te communiceren over de 'zachtere' onderdelen van het toezichtwerk, zoals het relationele en informele interpretatiewerk evenals de onmisbare betekenisgeving (*sense-making)* praktijken.

Daarnaast heeft deze studie laten zien dat toezichtstandaarden onbedoelde consequenties kunnen hebben, bijvoorbeeld omdat ze structuren bevatten die juist de werkwijze(n) die moet(en) worden gestimuleerd en gemeten, belemmeren. Ook kunnen de effecten van standaarden in de loop der tijd afvlakken. Als zodanig concludeer ik dat er voortdurend moet worden gemonitord hoe een standaard in de praktijk werkt en welke gedragsbeweging

een standaard bewerkstelligt, om ze ook tijdig te kunnen doorontwikkelen. Ik stel dat toezichthouders deze doorontwikkeling samen met de ondertoezichtstaanden en andere belanghebbenden moeten doen. Dit vraagt van toezichthouders reflexiviteit evenals de ontwikkeling van een open en nieuwsgierige houding.

ACKNOWLEDGEMENTS

I am driving.
05.24 a.m., the sun not yet awake.
Andrea Bocelli on repeat; a family tradition when
heading to snowy peaks or sunny vineyards.
A recipe for nostalgic reflection.

The smooth dark asphalt of the Route du Soleil holds little resemblance to my colorful, meandering PhD journey. In my mind I list people who helped me along the way.

"*... per sempre grato!*", Bocelli bursts.

Oh, the Italian drama! But I agree: forever grateful.

This book has been a long time in the making, and I owe so many people and organizations so much for helping me to complete it.

It feels appropriate to begin my list of acknowledgments with the organization that – through its financial contribution – has made my PhD journey possible: the Dutch Health and Youth Care Inspectorate (*Inspectie Gezondheidzorg en Jeugd*). Thank you for opening the doors for my curious eyes and questions. I know the political nature of regulatory work often demands quick and straightforward answers, so I am greatly appreciative of your patience with my lingering qualitative research. Although the identities of most my research participants remain anonymous there are some (former) Inspectorate employees who *must* be named for their fantastic support and commitment to my work: Ronnie van Diemen, Paul Robben, Sandra Mulder, Franske Keuter, Maurice Vlemminx, Hugo Solleveld, Jan Maarten van den Berg and Sipko Mülder.

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A warm thank you to the doctoral committee members, the NIG-community and all the critical reviewers for taking the time to read and think about my work.

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Iris, we immersed ourselves in a world of 'soft signals' and literally ended up lost on the streets of Utrecht. Teaming up with you was a good decision! You've gone out of your way to help me to get this 'thing' done. Honestly, I can't thank you enough for your extraordinary support and generosity.

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To my twin sister, Renske, free-spirited brother, Marijn, and my parents, Job and Hermine: I am so grateful for your unconditional support and love. Mom and dad, from a young age you introduced me to languages, symbols, traditions and repertoires of understanding that were not my own. Undoubtedly this cultivated the habit of reflecting on my own ways of knowing: the anthropologist was born! There are not enough words to thank you for your unfaltering help and encouragement throughout my life. I am thankful *for* you.

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ABOUT THE AUTHOR

Josje Kok (1984) studied Interdisciplinarity Social Sciences (bachelor) and Organizational Psychology (post-bachelor) and obtained a master's degree in Medical Anthropology and Sociology at the University of Amsterdam. She worked as an HR advisor in a commercial trade company, before shifting back to academia when she was employed as a PhD researcher at the Erasmus School of Health Policy and Management (ESHPM) in Rotterdam.

At ESHPM she was involved in the bachelor, premaster and master programs, teaching courses in Qualitative Research Methodology, Policy Sciences and Quality and Safety in healthcare. She also coached student-mentors and supervised theses. As part of her doctorate training, Josje attended the Netherlands Institute of Governance (NIG) graduate school in Utrecht.

Through her work and research Josje developed an interest in how people and organizations make sense of, govern and organize quality and patient safety matters in everyday healthcare delivery. Her PhD research specifically zoomed-in on the effects of regulatory practices by the Dutch Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*). Keen to speak to a broad public, Josje published her work in diverse international peer reviewed journals and research reports addressing (health) practitioners, policy makers as well as social scientists.

Josje currently works at the Antoni van Leeuwenhoek/Netherlands Cancer Institute as a policy advisor. After a childhood full of travel, she has settled down in Haarlem where she lives in a crooked-but-charming house with her husband and two children.

PHD PORTFOLIO

Name:	Josje Kok
Institute:	Erasmus School of Health Policy & Management (ESHPM)
PhD period:	2015 – 2020
Supervisors:	Prof.dr. Roland Bal
	Prof.dr. Ian Leistikow

Courses

Time and project management	2015
Atlas-ti	2015
Teaching workgroups	2015
Presentation skills and techniques	2015
NIG Classics in public administration and political science	2016
NIG Answering explanatory research questions	2016
Basic teaching didactics	2017
NIG Network governance	2017
NIG Getting it published	2017
NIG Integrity and responsibility in research and advice	2017
Leadership skills 'leadership of the heart'	2018

Teaching activities

Tutor workgroups Qualitative Research Methods (BA)	2015, 2016, 2018
Tutor workgroups Qualitative Research Introduction (BA)	2015, 2016, 2017
Tutor workgroups Policy & Administrative sciences (BA)	2015, 2016
Supervisor and co-evaluator theses (BA)	2016, 2019
Lecturer Qualitative Research Methods (BA)	2016, 2018
Tutor workgroups Quality & Safety (MA)	2016
Tutor workgroups Advanced Research Methods (MA)	2018, 2019
Coach student-mentors (BA)	2018
Supervisor 'Serious game' (BA)	2018, 2019

Presentations at/contributions to conferences and symposia

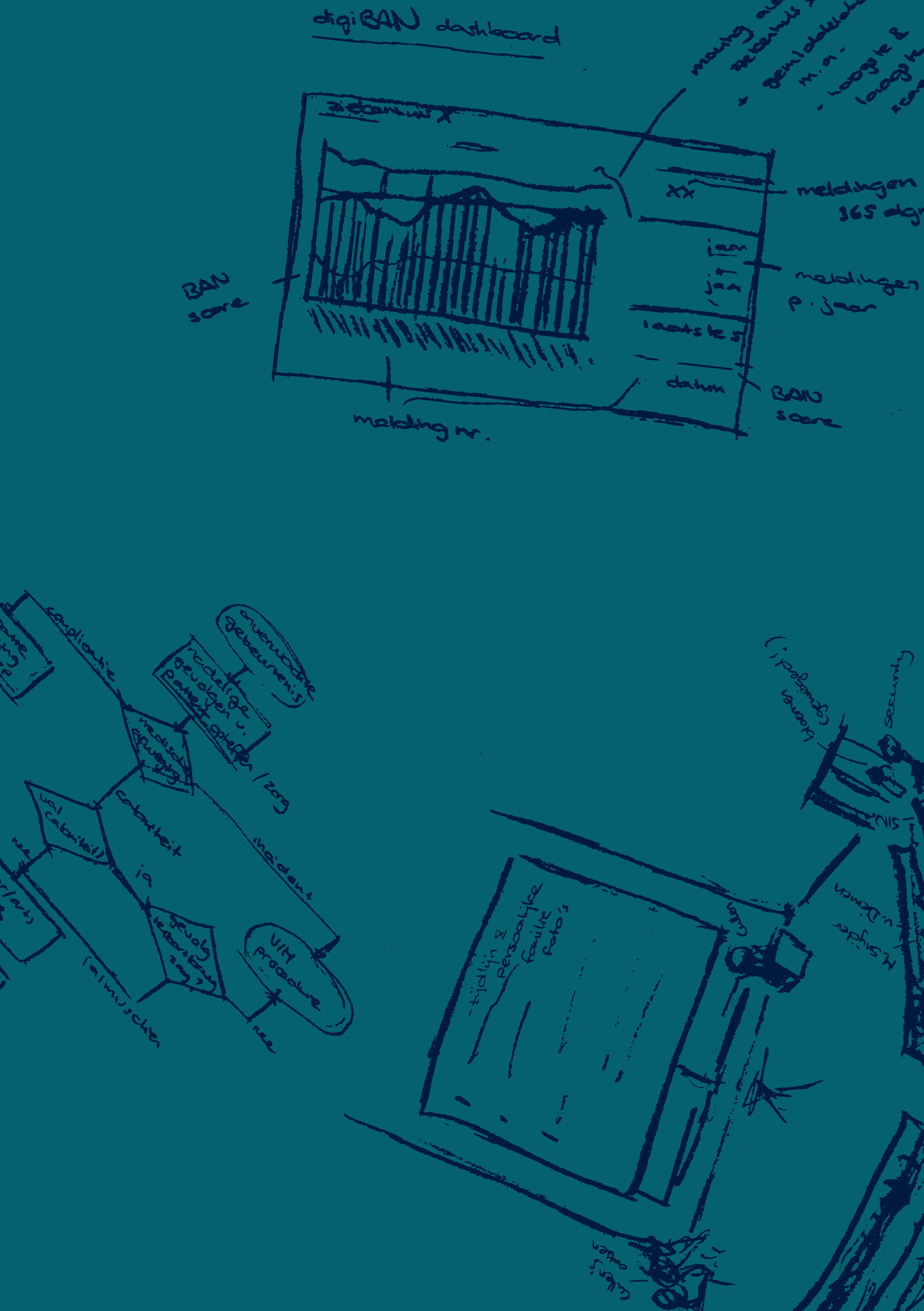
Contribution to presentation BMJ International Forum Quality & Safety in Healthcare, London	2015
Contribution to workshop BMJ International Forum Quality & Safety in Healthcare, Gothenburg	2016
Presentation at regulation workgroup, Stavanger	2016
Presentation at Inspectorates meeting, Copenhagen	2016
Presentation at International Incident Disclosure Conference, Amsterdam	2016
Presentation at HYCI colloquium, Utrecht	2016
Presentation at ESHPM symposium, Rotterdam	2018
Presentation at BMJ International Forum Quality & Safety in Healthcare, Amsterdam	2018
Presentation at HYCI for Norwegian delegation visit, Utrecht	2019
Presentation at ESHPM seminar, Rotterdam	2019

Published international peer reviewed articles (in this thesis)

- Kok, J.H., Leistikow, I.P. & R.A. Bal (2018). Patient and family engagement in incident investigations: exploring hospital manager and incident investigators' experiences and challenges. *Journal of Health Services Research & Policy*. doi: 10.1177/1355819618788586
- Kok, J.H., Leistikow, I.P. & R.A. Bal (2019). The pedagogy of regulation: Strategies and instruments to supervise learning from adverse events. *Regulation & Governance*. doi: 10.1111/rego.12242
- De Kam, D., Kok, J.H., Grit, K., Leistikow, I.P., Vlemminx, M. & R.A. Bal (2020). How incident reporting systems can stimulate social and participative learning: a mixed-methods study. *Health Policy*. doi: 10.1016/j.healthpol.2020.05.018
- Kok, J.H., Wallenburg, I., Leistikow, I.P., & R.A. Bal (2020). The doctor was rude, the toilets are dirty. Utilizing 'soft signals' in the regulation of patient safety. *Safety Science*. doi: 10.1016/j.ssci.2020.104914

Contribution to research report

- Wallenburg, I., Kok, J.H. & R.A. Bal (2019). *Omgaan met Soft Signals in het Toezicht: Signaleren, Interpreteren en Duiden van Risico's in de Zorg door de IGJ*. Rotterdam: Erasmus School of Health Policy & Management.


digiBAN dashboard
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laatste 5
datum
BAN score
complicatie
onverwachte gebeurtenis
nadelige gevolgen v. patiënt opleveren
calamiteit
ja
incident
VIM procedure
nee
tijdlijn & persoonlijke familie foto's

A STANDARD STORY

Standards – in the form of guidelines, protocols, scoring instruments, and so forth – are all around us. They are said to have a reverberating influence on our lives. But how do standards manage to exert such an influence? This question has rarely been the direct topic of study, but it is a relevant concern when we recognize that there are many institutional contexts in which standards are explicitly introduced to direct and monitor behavior and organizational work. One of these contexts is governmental regulation.

A Standard Story takes a close look at the use and enactment of standards in the regulation of healthcare, in an attempt to further our understanding of how standards work and to what effects. The book presents and discusses the findings from ethnographic fieldwork at the Dutch Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd) and numerous hospitals in the Netherlands. It will be of interest to regulators, policymakers, and standard enthusiasts, as well as anyone curious about the backstage practices of (healthcare) regulation.