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"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 paper 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.

1. 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 (Power, 2007; Macrae, 2014a). 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 wide-spread use of performance management and accreditation systems, the use of indicators, standardized protocols and rankings of best performing hospitals, are just some examples (Wallenburg et al., 2019; Dixon-Woods et al., 2012; Waring and 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 et al., 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. 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

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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, 2017). 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, 2017). 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 et al., 1999; Martin et al., 2018; Martin et al., 2015; Macrae, 2014a).

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' 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 – as: 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 into 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 (2015–19) 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 paper, 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 et al., 2018). To that end, the central research question guiding this paper 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 paper 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.

2. Theoretical framework

2.1. 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, pp. 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, Sutcliffe, & Obstfeld, 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.

2.2. 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 et al., 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 co-operative 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 et al., 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.

3. 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 (2015–19) 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 Kok et al., 2019; Kok et al., 2018) 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.

3.1. Setting, sampling, data collection and analysis

For this specific study, diverse qualitative methods were triangulated, including semi-structured interviews (n = 33, with 27 respondents), observations (n = 4 h) and document analysis. The study was built up in four phases. Table 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[2]) 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 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 our understanding of how signals are received and acted upon, we conducted 4 h of observation at the National Healthcare Report Centre (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 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 2). The cases concerned intensified supervision trajectories[3] 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-

[2] 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.

[3] 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.

Table 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?
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).	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?
4 h of **observations** at the National Healthcare Report Center (HYCI incident report center)	JK, IW		– 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	JK, IW		– 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?
4 **semi-structured interviews** with leaders from 4 Dutch hospitals (n = 6)	JK, IW, RB		– 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?

*** See Table 2 for a summary of this analysis.

Table 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.

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.

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 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', 'sense-making 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 (reference MEC-2018-054 MEX). Due to the sensitive nature of the narratives and confidential documents retrieved the interview transcripts as well as the case-studies were anonymized.

4. 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.

4.1. 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*, an 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 important: 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.

4.2. 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 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.

4.3. 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 (Kok et al., 2019) 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." (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.

5. 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, b).

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 et al., 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.

6. Conclusion

We started this paper 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.

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