

# The mutual shaping of governance and regulation of quality and safety in Dutch healthcare

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## Abstract

Developing the concepts of governance and regulation is path dependent: working with the complexity of governance and regulation shapes and reshapes both their meaning and form. We conducted a case study on governance and regulation of quality and safety in Dutch hospitals to reveal these processes. We found that governance was given meaning in several phases, ranging from a focus on institutional design (e.g. corporate governance) through coping with incidents and using quality measurements, to prospective risk management. Governance changed incrementally in form and practice. We also saw that governance and regulation are intertwined; regulation shapes governance and is simultaneously shaped by changes in the meaning of governance. Insight into these processes is important to better understand what is defined as “good governance” and “good regulation” in a certain context. Understanding the mutual development of these concepts and practices reveals potential pathways to continuous shaping of good governance.

## Keywords

Governance, healthcare, hospitals, quality and safety, regulation

## Introduction

*I'd say that governance includes internal management, accountability, and oversight in an organization and is the responsibility of all concerned, the supervisory board, board of directors and others. (Respondent, Dutch Healthcare Inspectorate 3)*

The governance of healthcare organizations is on the agenda in many countries. Quality incidents have been an important driver for this since failing governance is regarded as an important cause of these incidents.<sup>1</sup> The emphasis on governance in healthcare not only affects the responsibilities of hospital boards, it also changes the work of state regulators, responsible for the supervision of quality of care because they have to supervise whether the organization's governance is up to standard.

As the above quote points out, governance is about the responsibilities of various actors active on different levels: professionals on the micro level, boards of directors and supervisory boards on the meso level, and state regulators on the macro level.<sup>2</sup> Despite the common use of the word governance, what governance means and how it should be put into practice is not that

clear. As a concept, governance is often perceived as “so thoroughly institutionalized that it requires no further elaboration”<sup>3</sup> even though it is still a struggle for both researchers and practitioners to come to terms with its complexity.<sup>4–6</sup> Ezzamel and Reed defined governance as “a multi-level, multi-dimensional regulative practice and form that is always mediated through particular socio-historical and spatial contexts.”<sup>7</sup> This definition was our starting point in studying the development of governance in Dutch healthcare with the aim of clarifying the meaning given to the concept in healthcare practice and the consequences for quality regulation.

In the Netherlands, the governance of quality is set in regulation. The Quality of Care Act (1996) gave the board of directors of healthcare organizations ultimate legal responsibility for quality and safety

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(Q&S) of care provision in their organization. The internal supervisory board has to supervise the board of directors. The boards' responsibilities are often considered the governance of healthcare organizations. The assumption is that if both boards live up to their responsibility, external regulation by the Dutch Healthcare Inspectorate could be limited to monitoring the governance of Q&S.

In this paper, we aim to understand how the Dutch context shaped the meaning and content of governance and the relation between boards and regulator. Our research question is *How did the meaning and content of governance in Dutch healthcare develop and how does this relate to the development of regulation?* We conducted a qualitative case study focused on the development of governance and regulation of Dutch hospital care.

First, we frame the theoretical concepts of governance and regulation. The method section describes how we conducted the study. The results discuss how the concept of governance has gained meaning through the years and how regulation evolved. Our findings show how governance and regulation are interrelated and mutually shape each other. In the conclusion, we reflect on the mutual, path-dependent development of both concepts.

## Theoretically framing governance and regulation

The term "governance" is popular but imprecise.<sup>8</sup> Literally, it means the act of governing, but it is often used to indicate the shift from government ("the state") as a central and powerful actor to broadly dispersed plural "network" forms of governing.<sup>9</sup> From this perspective, governance points to a wide variety of steering mechanisms used to coordinate the individual, collective, and corporate actors at different levels of the healthcare system. Governance of healthcare organizations has become an especially important subject in many Western countries. The internal governance of healthcare organizations has been attributed a particularly important responsibility for quality of care. Despite this emphasis on organizations, national governments carry responsibility for the Q&S of healthcare in general. The most important instruments to enact this responsibility are regulation and supervision. With the emerging emphasis on the responsibility of internal governance of healthcare organizations, both regulation and supervision are subject to change as well, since the object of regulation and supervision changes. Governance and regulation are therefore interrelated.

Numerous contrasting views on governance give, in their variety the concept its theoretical richness and

multifaceted organizational identity. What is clear is that what governance means partly depends on context. The approach by Ezzamel and Reed is helpful to understand governance and do justice to this context. They state that we should understand governance both as a practice and as a form.<sup>10</sup> The concept points at the multifarious institutional forms and organizational routines and practices through which we "order" our lives. The specific form of governance, according to these scholars, emerges through particular socio-historical and spatial contexts. They define governance as an "ordering regulative practice." Therefore, to better understand the governance concept, it is important to study how the concept is given meaning in a particular context.<sup>11,12</sup>

Similar to the concept of governance, regulation means different things to different scholars. The most widely cited and long-lasting definition of regulation is "a sustained and focused control exercised by a public agency over activities that are valued by the community."<sup>13</sup> Expressing a definition comparable to the governance discussion, Levi-Faur stated that regulation involves a continuous action of monitoring, assessment, and refinement of rules that it is exercised not by one agency but by many.<sup>14</sup> Walshe and Shortell distinguish three dimensions of conventional regulatory regimes: *direction*, meaning how regulators set out their expectations and requirements; *detection*, how they measure and monitor performance; and *enforcement*, meaning the interventions regulators use to make organizations change their behavior (penalties, shaming, controls, more regulation).<sup>15</sup> Walshe recently added "developmental regulation" to the regulatory regime toolkit.<sup>16</sup> Developmental regulation is based on a dynamic perspective on organizations in which the regulatory diagnosis goes beyond measurement and monitoring into judgment and sense-making in which the interventions are focused on improvement and organizational development.

To conclude, in this paper we approach governance and regulation as a mutual relation, emerging as practice, form, and context in order to better understand how the Dutch context shaped the meaning and content of governance and the relation between boards and regulator.

## Methods

Rhodes pleads for studying "the everyday practices that arise from agents whose beliefs and actions are informed by traditions and expressed in stories" to better understand the changing meaning and shifting practices of governance and regulation.<sup>17</sup> When we consider governance and regulation as a mutual relation emerging as practice, form, and context, we need

profound case studies to understand the iterative construction of their meaning.

We applied a qualitative research design in this study. We assembled policy documents to unravel the socio-historical evolution of governance and regulation in Dutch healthcare, specifically in the governance of Dutch hospitals. Key figures emerged from our document analysis and were approached. We used a snowball method to find other respondents who were acquainted with the emergence of governance and regulation in Dutch hospital care. The respondents ( $n=18$ ) provided narratives from various angles. We selected the following respondents: directors of hospitals ( $n=5$ , some were also healthcare professionals), a quality manager ( $n=1$ ), advisors/governance experts ( $n=3$ ), a representative of the branch organization for healthcare directors ( $n=1$ ), a representative of the branch organization for healthcare regulators ( $n=1$ ), (former) inspectors ( $n=5$ ) and policy-makers in the Ministry of Health ( $n=2$ ). We visited respondents in their own surroundings for semi-structured interviews of 1.5-h duration. The interviews were recorded with the permission of the respondents and were transcribed verbatim. We analyzed the data (documents and interview transcripts) first by coding how the concept of governance evolved and then searched for different meanings of governance. Inductively, we found four phases in which governance was given meaning (corporate governance; coping with incidents; using quality measurements; and risk management). The development of governance is path dependent: working with the complexity of governance shaped and reshaped its meaning. The third step of data analysis coded the respondents' opinions of the fit between governance and regulation.

## Constructing the meaning of governance

### *Governance: corporate governance*

Although the concept of governance is old, only in 1990 did it become a topic of debate in Dutch healthcare when the government introduced a two-tier governance model. The two tiers refer to the board of directors and the supervisory board. It was not clear right away what the precise function of the two boards was.<sup>18</sup> In the following years, several attempts were made to clarify these issues.

Legislation, drawn up after consultation with the field in four so-called 'Leidschendam conferences', introduced in the late 1990s partly clarified the role of the boards. The Individual Healthcare Professions Act (1997) made healthcare professionals legally responsible for providing good quality care to their patients. However, the Quality of Care Act (1996) made the

boards of healthcare directors legally *ultimately responsible* for quality of care. This act stipulates that healthcare organizations must systematically monitor, control, and improve quality of care.<sup>19</sup> As the external regulator of quality of care, the Dutch Healthcare Inspectorate (DHI) was intended to supervise whether this responsibility was taken up in practice.

Subsequently in 1999, some of our respondents initiated a Committee of Healthcare Governance that drew up a code of conduct and recommendations for "good governance." The code was expected to serve as a guideline for the improvement of the professional relation between both boards. Several committees and recommendations followed, all pointing at the importance of a clear division of responsibilities and at "good governance" through the development of a system of "checks and balances." In the opinion of respondents, those committees and reports influenced the field of healthcare. The conceptual meaning of governance was constructed into "corporate governance," with responsibilities legally allocated and relations between responsible parties defined in written codes of conduct. However, what it meant in practice and what the boards should focus on and do exactly with quality of care were not apparent from the start.

### *Governance: coping with incidents*

The legal changes introduced in the 1996 Quality of Care Institutions Act did not cause an immediate change of behavior among healthcare directors or the DHI. Although healthcare directors were made legally responsible, they did not know how to systematically monitor, control, and improve quality of care and the DHI did not know how to supervise the work of the boards. In 2005, a severe incident in one of the biggest hospitals made this very apparent. The evaluation blamed not just the individual doctor but the whole management of the hospital. Several other incidents evaluated after 2005 consistently pointed out that not only the internal control on quality and safety of care was inadequate, but that the wider healthcare system was involved.<sup>20</sup> All respondents referred more than once to the role these incidents had played. The DHI's analysis of these incidents emphasized the roles and responsibilities of the directors and the supervisory boards in healthcare. The political consequence was that the DHI had to strengthen its methods of detection and enforcement. The incidents were seen as wakeup calls to start thinking about *how to govern* quality and safety of care. Security experts from other sectors were consulted:

*A big safety and quality agenda emerged years ago. As director of Shell, Rein Willems and several other*

*business people introduced the notion of safety.*  
(Executive 4)

According to the respondents, political accountability following the incidents hardened the relationship between providers, DHI, and politicians, creating a repressive atmosphere. Nevertheless, they acknowledge that pressure from the press and politics helped clarify the ultimate responsibility of the boards.

*Boards now see and understand that it can happen to them too.* (Respondent DHI 2)

Executive boards are addressed directly on their responsibility for quality of care, which makes them feel vulnerable and leads them to put quality of care firmly on their agenda. This process gave further meaning to the governance of healthcare organizations. The next step was finding the instruments to govern quality effectively.

### Governance: using quality measurements

*The reason for so many Q&S problems was malfunctioning governance. Healthcare professionals didn't take up their responsibility, executive boards didn't know where to look, and supervising boards were totally absent.*  
(Respondent DHI 2)

Governance of quality means governing healthcare professionals. It proved difficult for executives to find ways to be accountable for the work of professionals who were used to self-regulation and autonomy. To enable managerial responsibility, it was necessary to organize accountability in a way that made quality of care transparent, measurable and through that governable.<sup>21</sup> To stimulate quality improvement, the DHI initiated the development of quality indicators. This helped healthcare executives gain control over the quality of the care provided in their organization.

*In my opinion, the DHI did a good job on indicators. It led to improvements. In the beginning, there was some resistance but now everybody joins in.* (Executive 3)

The executive boards learned to use the measurements to improve quality, stimulated by national quality programs.<sup>22</sup> There is evidence that the overall quality of hospital care improved because of all the initiatives.<sup>23</sup> Nevertheless, in the opinion of respondents, there are currently far too many quality indicators.

*The transparency that indicators created helps implement governance. Yet the multitude of indicators is its own problem.* (Executive 3)

The bureaucracy that accompanies large numbers of indicators creates resistance in both healthcare professionals and boards of directors. They consider it “box ticking” that turns performance measurement systems into a kind of virtual reality. The indicators constitute a system, often called a “dashboard” that facilitates an abstract image of the quality of care. The dashboard shows only a part of the reality of care, and it can become a risk in itself.

*It [the dashboard] was getting way too complicated, with all those indicators. I thought, if I had this dashboard in my car, I'd never be able to drive.* (Advisor 3)

The multitude of indicators and other quality instruments such as audits, rankings, visitations and guidelines not only created a bureaucracy of “tick boxes,” executives complained that it drove up the costs too. Extra indicators were added, or indicators were slightly modified causing extra work and thus extra costs.

Indicators and other quality measurements became the administrative form that defined the control of quality of care. From this perspective, governance meant “controlling quality of care.” This is how the meaning of governance became entangled with quality measurements and, consequently, a bureaucratic burden.

### Governance: risk management

The concept of governance first referred to the division of responsibilities for the provision of healthcare. Following several incidents, the content of the responsibilities changed and quality of care became an issue on the agenda of the board of directors; the financial & business focus was combined with (administrative) responsibility for quality of care. In the next phase, the efforts to control quality focused on safety and more specifically on risk reduction.<sup>24</sup> One of the executives indicates that managerial insight into safety matters and risk is necessary to be able to talk with healthcare professionals about quality of care.

*I don't want to know what happens in the consulting rooms, but I do want to know that the medical specialist and his department are working on quality. Do they register and discuss complications? How do they report incidents?* (Executive 3)

Organizing internal reporting of incidents and “near incidents” is the first instrumental step toward risk management.

*The reporting culture arose after we started digital reporting and after we created decentralized teams for*

*safe incident reporting [VIM]. Reported incidents are now discussed in the units, and we insist on reporting near incidents. (Executive 2)*

Hospitals can learn from incidents occurring in other hospitals (that are made public) and use these to improve their own internal monitoring. This is how an incident is converted into a “possible risk” that another hospital follows up with a risk assessment. According to one respondent, a proper risk management system is the core of managing a healthcare organization and thus forms the core of governance. Hospital management uses more than incident reporting and analysis to design a risk management system. It also searches for a proactive form.

*We don't just use incident reporting, because that's based on hindsight. We use complaints to get a picture, and we learn from case studies of deceased patients. We try to apply our best practices in a number of safety themes, because when you're well on the way to doing that, you run less risk. That ultimately determines the overall probability that an incident will occur, and the impact it will have. Then you are at the heart of our risk management system. (Executive 2)*

According to a respondent, this proactive form, termed “prospective risk management,” has a great potential for implementing improvements, but according to other respondents, prospective risk management is not commonplace yet.

*It's shocking to see that many organizations really have no idea where their risks are, and what could be their downfall. (Respondent DHI 1)*

Other respondents are skeptical about how risk is governed in care organizations because of the influence of societal actors, such as government and insurers. When incidents occur, the societal reflex is to tighten regulation and look for perpetrators to blame. Many respondents are afraid of the repressive demotivating atmosphere that is generated like this. Moreover, they worry that more regulation and inspection will lead to even more bureaucratic burden.

The focus on risk management conceptualizes the internal governance of Q&S in hospitals in a certain way. It gives a specific meaning to quality; namely it defines quality in terms of risks. Moreover, it prescribes the actions of boards of directors in a certain way; namely to build risk management systems. It can be seen as a present phase in giving meaning to governance, building on the previous phases.

## Regulation and governance

The increased focus on the governance of hospitals not only influenced the role and activities of the board of directors and supervisory boards, but it changed the role and activities of the DHI too. We have already shown examples of this in the previous sections (e.g. its response to incidents and stimulating the development of quality indicators); here we go deeper into this interrelation.

Since the Quality of Care Institutions Act (1996) made boards of healthcare directors legally ultimately responsible, the external regulator the DHI had to supervise whether the boards had taken up this responsibility in practice. The DHI scrutinized quality incidents, yet they still meant a wakeup call for the DHI too. In fact, external regulation, or the lack thereof, was publically and politically considered part of the problem. In response to this, the DHI has taken a more stringent role in the supervision of quality; it has increasingly closed wards which did not comply with Q&S standards, put increasing numbers of organization under “stringent supervision,” used unannounced visits more often and made it easier for citizens to report on failing quality.<sup>25</sup> The DHI also searched for ways to control and simultaneously stimulate the governance of hospitals. For example, the DHI initiated the development of quality indicators and stood firm on collecting information.

*Once a year we have a meeting with the DHI. Everything gets discussed, incidents too. Something always doesn't go well. We must of course provide all the info, and they explore it and ask questions about it. ... Furthermore, indicators, they just want to know. (Quality Manager 1)*

Healthcare providers are urged to share information on their structure and administration with the DHI. They have to report systematically on indicators and incidents. So, the DHI was one of the drivers of giving meaning to governance in a way that entangled governance with quality measurements and consequently with the bureaucratic burden. At the same time, however, this influenced the DHI's own activities and role. The subsequent focus of hospitals on building Q&S systems to govern quality and safety implied that the DHI had to incorporate this into its supervisory framework. The assumption is that if healthcare organizations take on their responsibility, public/external supervision can be limited to inspecting an institution's governance system to guarantee Q&S of care. This became an option only recently, after governance of quality had been given further meaning and was put into practice.

The DHI recently experimented with process-oriented regulation: governance-based regulation.<sup>26</sup> In contrast to traditional prescriptive standards or

performance standards, this new approach invites organizations to develop their own processes to enable Q&S management system standards.<sup>27</sup> The emphasis on self-regulation and responsible autonomy of the organization seems to fit in a situational approach that leads beyond the dichotomy of either permissive or repressive supervision. Governance-based regulation focuses prospectively on risks in the governance of the organization.

*Interestingly, process-oriented regulation is proactive. In my opinion, that's an advantage. I think it's a big gain compared to, yes, reacting afterwards in response to incidents. (Executive 2)*

This could lead to a justification of the trust of the DHI in organizations and could strengthen the DHI in their relation to citizens, media, and politics. The question is how the DHI can supervise internal governance of a healthcare organization.

*You can't put it in a tick box; it's lots of soft information. That's actually the core of everything. Each organization's governance is all different because it is so situational, it depends so much on the type of institution, the kind of people. [...] It's very hard for us to create a regulatory framework. (Respondent DHI 1)*

The organization's integrated risk management system can be the DHI's object of inspection. A risk management system refers to structural, financial, and cultural aspects, and includes accreditation systems, safety management systems, and internal audits. The culture of the organization is very important to make an integrated risk management system work, because formal systems such as audits and monitoring have shown to be effective only when they are supported by informal "cultural" systems.<sup>28,29</sup>

When used in healthcare, supervisory authorities can use governance-based regulation to monitor integrated risk management systems, the structure, and culture of the organization and ensure that these do not remain "paper realities," but are properly implemented. This way of working connects to the idea of developmental regulation that focuses not on prescribing, but rather on judging the formal and informal systems and strives for organizational development. This shows how internal governance and regulation can jointly construct "good governance."

## Conclusion

Although governance in healthcare is often talked about as if its meaning is self-evident, we have shown in this article that this is not the case. The meaning of

the concept evolves, mediated by context. Similarly, regulation involves a continuous action of monitoring, assessment and refinement of rules, and is exercised through a network of actors. We found that governance was given meaning in several phases, ranging from a focus on institutional design – e.g. corporate governance – through coping with incidents to using quality measurements, and, currently, to prospective risk management. Governance changed incrementally in form and practice. We also saw that governance and regulation are intertwined; regulation shapes governance and is simultaneously shaped by changes in the meaning of governance. For instance, the DHI experiments on governance-based regulation stimulate and assess modes of organizational self-organization and encourage organizational self-critical reflection and development. However, this self-management approach could not be possible without the previous development of performance indicators, guidelines and management tools that involves the assessment and control of risks, compliance, and the system of maintenance and review.

Both governance and regulation are evolving further. Healthcare boards and regulators are both trying to find ways to gain control over quality through integrated risk management systems that can be used to ensure Q&S proactively. In conclusion, to better understand the concept of governance, it is important to study how the concept is given meaning in a particular context. Insight into this factor is important to better understand what is defined as "good governance." The same goes for the regulation of quality. Understanding the mutual development of these concepts and practices reveals potential pathways to a continuous shaping of "good governance."

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