Title: Reconceptualizing regulation: Evaluating the experimental project of System Based Regulation in Dutch healthcare

Abstract *(word count: 98)*

The Dutch Healthcare Inspectorate (DHI) has recently experimented with a new form of inspection: System Based Regulation (SBR). This paper explores how SBR was situated into the healthcare context through an experimental process. A qualitative formative evaluation was provided based on 2 years of participative observation with numerous iterations between data gathering and feedbacks to the project members in order to orient the next steps of the process.

Gradually it became clear if and how SBR could fit into the existing supervisory regime. Notwithstanding the positive outcomes, SBR was controversial. Contextual circumstances impeded further implementation of the findings.

Keywords: System based regulation; experimentalist governance; qualitative formative evaluation

Introduction *(word count 7.550, ref. included)*

Regulation entails respect for and reference to the system of private ordering.

Philip Selznick 1985:363

As I see it, the fundamental objective is to create responsible organizations, that is, to build into the operative structure of the enterprise the conditions that make for self-restraint. My impression is that sustained attention to this problem can be a promising focus for organization theory as well as for the study of regulation.

Philip Selznick 1985:367

Worldwide, there is a growing emphasis on regulation and supervision in various ways, across both private and public sectors. One of the instruments most commonly used is inspection. Inspection is mainly based on national or regional statutes, focusing on competence of professionals, compliance with professional standards and outcomes for service users. In the Netherlands, as in other countries (Ferlie & Shortell 2001), emphasis is being given to improving the quality, safety and outcomes of the healthcare system. As the position of professionals in the healthcare sector has

historically been strong, instruments were introduced to intervene in their self-regulation (Harrison & Pollitt 1994; Freidson 2001). To improve quality of Dutch healthcare two lines have been followed. On the one hand professional self- regulation has changed through the accountability instruments that have been introduced in healthcare (Timmermans 2005; Helderman, Schut, van der Grinten & Van de Ven 2005; Martin, Leslie, Minion, Willars & Dixon-Woods 2013). On the other hand boards of directors have been made end-responsible for the quality of care by law, under external supervision of the Dutch Healthcare Inspectorate (DHI). The Quality of Care Act of 1996 stipulates that healthcare institutions must systematically monitor, control and improve the quality and safety of their care. Directors and supervisory boards, the internal supervisors, are primarily responsible for the quality and safety of care in their institutions, which includes ensuring correct procedures and culture.

Both internal and external governance of healthcare organizations was strengthened and the institutional context of Dutch healthcare has become more layered (Van de Bovenkamp, De Mul, Quartz, Weggelaar – Jansen & Bal, 2013). The introduction of regulated markets in the public sector was not accompanied by the demise of professional self-regulation but pre-existing arrangements have become incorporated in and conditioned by regulated markets instead. One of the important consequences of layering is institutional fragmentation, because a multitude of actors become

involved in steering a certain policy. (Van de Bovenkamp et al. 2013; Van de Bovenkamp & Stoopendaal forthcoming). Nevertheless this multi-level approach (Ferlie & Shortell 2001) in governing healthcare quality seems to have had an impact, according to the positive results of recent research on Dutch quality of hospital care (De Blok, Koster, Schilp & Wagner 2013). However, although responsibilities of professionals and managers seem to have become more shared in a 'responsible autonomy' (Degeling, Maxwell & Iedema 2004), in occurring incidents around quality of care the state regulator increasingly is called upon to supervise the governance of quality, a phenomenon described as the 'regulatory paradox'[1] (WRR 2013; Zeitlin 2013; Van de Bovenkamp & Stoopendaal, forthcoming).

Current regulation in the Dutch healthcare system is mostly prescriptive and performance oriented. Healthcare organizations complain about the huge amount of performance indicators they have to supply due to this type of regulation. Both inspectorate and healthcare institutions are not satisfied with the regulatory burden and the reflex to strengthen state regulation that arises out of the occurring incidents. In answer to this, the DHI has recently experimented with a new form of supervision: System Based Regulation (SBR). In contrast to traditional prescriptive standards or

[1] the tendency for policy makers and the general public to focus on reducing the costs and burdens of regulation when things are going smoothly in a particular field, but to shift abruptly towards a stricter and more interventionist approach as soon as a major incident of regulatory failure occurs that spurs public outcry.

performance standards, this approach invites organizations to develop and reveal their own design and management of the primary processes and their internal governance and control systems. Although SBR is defined differently by several inspectorates, it is most generally conceptualized as a form of public supervision where the level of regulatory compliance assurance is assessed rather than only the level of compliance (De Bree 2010).

The DHI had only limited experience with a process-oriented way of regulating in the pharmaceutical industry. Therefore, they began a trial with SBR in healthcare organizations. A project group of the DHI experimented with new ways of working that were creatively invented and experimented together with healthcare organizations and experts from other regulatory sectors. The findings in this paper derive from the observational study coupled to the pilot that the DHI conducted in 2012-2013.

The present study was aimed to show how, in fact, regulatory techniques were devised. The main research question was: How is a new form of supervision constructed?

To answer the research question, we first explore in the theoretical part of this paper what regulation and particularly SBR means in literature and we introduce the concept of 'experimentalist governance' to frame the innovative work of the DHI. Using the

empirical findings of the SBR pilot, we then describe how SBR was instrumentalized and what occurred as the pros and cons of adding SBR to the external supervision of care. The scientific description of this project may contribute to further development of theories regarding experimental renewal of regulation.

Theoretical framing

Regulation

According to Levi-Faur (2011:3) regulation is hard to define, because it means different things to different people. 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' (Selznick 1985:363). Levi Faur (2011:5) adds some pluralism to this definition stating that regulation involves a continuous action of monitoring, assessment and refinement of rules and that it is exercised not by one agency but by many. This pluralism fits to the layered institutional context of Dutch healthcare. Zeitlin (2013:10) reveals three different concepts of regulation that are used in scholarly literature: regulation, supervision and inspection. He considers 'regulation' as an overarching concept covering the full policy cycle from rule-making through supervision, inspection, and enforcement to evaluation and review.

'Supervision' is, according to Zeitlin, pointing at 'implementation, oversight and enforcement'. The notion of 'inspection' refers to the daily work of the inspectors, the real life check. It focuses on competence of professionals, compliance with professional standards and outcomes for service users.

System Based Regulation

SBR stimulates and assesses modes of organizational self-organization and encourages organizational self-critical reflection (Parker 2002). However, this self- management approach could not be possible without the former development of performance indicators, standards and management tools (see Wiener 2000) that involves the assessment and control of risks, compliance, and the system of maintenance and review (Gunningham & Sinclair, 2009). Moreover, formal systems like audits and monitoring only have shown to be effective when they are supported by informal 'cultural' systems (ibid.). SBR inevitably requires that the regulatee has more autonomy in how to organize the achievements of desired outcome and thus conflicts with a traditional centralized command and control approach of regulation.

Healthcare is mostly organized in complex and constantly changing organizations (Scott 2000).The object of regulation by SBR is the formal and informal organizational system for patient quality and safety. Scholars of regulation describe SBR also as

'management-based regulation' (Coglianese & Lazer 2003), 'enforced self-regulation' (Braithwaite 1982), 'reflexive regulation' (Gunningham 2012), 'systems-based regulation' (Gunningham & Johnstone 1999) or when it is embedded in processes of 'experimentalist governance' it is called governance-based regulation (Zeitlin 2013). These new kinds of regulation can all be qualified as 'process-oriented regulation' that mandates and monitors an organization's capacity for self-evaluation, design and management of their primary processes and their internal governance and control systems (Gilad 2011:423). Process-oriented regulation combines prescriptive, technology-based and outcome-oriented regulation[2] into a hybrid model of regulation that monitors the design and management of the internal quality and safety systems of an organization. When an organization develops a set of rules and internal controls in light of regulatory goals, this is termed (enforced) self-regulation. Many scholars consider SBR to be a more situational form of supervision. SBR asks for high levels of expertise and regular monitoring by supervisory authorities to ensure that risk management systems do not remain 'paper realities' but are properly implemented in practice (Zeitlin 2013). And moreover, as Selznick stated: *Regulation entails respect for and reference to the system of private ordering*.(1985:363). However, empirical

[2] Prescriptive regulation is a limited tool for managing complex and dynamic social realities because detailed rules can never match all possible scenarios; technology-based regulation specifies the technologies to be used and outcome –oriented regulation is based on specific measures.

literature on SBR as a kind of 'process-oriented regulation' is still in its infancy; in particular, data is lacking on regulators and regulatees perceptions of, and experiences with SBR (Coglianese & Lazer 2003; Gilad 2011).

By the emphasis on self–regulation and the responsible autonomy of the organizations, SBR fits perfectly into a model of responsive regulation in which regulators can use a 'pyramid' of enforcement interventions (Ayres & Braithwaite 1992). The situational approach that is embedded in the concept of responsive regulation leads beyond the dichotomy of either permissive or repressive supervision. Responsive regulation is concerned with designing regulatory institutions and processes which stimulate and respond to the regulatory capacities of the regulatees (the subjects of regulations), attempting to keep regulatory intervention at a minimum while retaining the capacity to intervene more and stricter (Scott 2004). The essence of the pyramid is that the ability to escalate to really tough reponses at the top of the pyramid enables the deliberate base of the pyramid . This idea theoretically connects with the Foucauldian concept of self-disciplining. But is self-disciplining to be trusted or controlled? Six (2013) states that the use of trust and control in the pyramid of responsive regulation needs to be re-conceptualized. She shows that trust and control are not substitutes but complements. Trust and control may be applied simultaneously and may reinforce each other and this has effect on regulatee compliance. When

regulatees internalize and integrate the values of the regulators, then the regulatees are more likely to comply with the regulation in a self-determined way, on their own volition. The quality of the compliance will then be higher. Yet, SBR and its embeddedness in the concept of responsive regulation invites it to be criticized as at the one hand to much based on trust and at the other hand to much based on control.

Furthermore, responsive regulation assumes that regulators could be able to identify which enforcement response would fit the regulatee. Consequently, regulators need the capacity to assess the validity of the information of the governance, and performance of the organization and they have to be able make their own judgment (Gilad 2011:429). Heimer (2011) shows that performing responsive regulation in a layered system faces important challenges but it offers opportunities too: in addition to responding with encouragement for compliers and coercion for resisters, regulators could respond by helping regulatees solve problems so that they could meet regulatory objectives.

Experimentalist governance

The SBR pilot of the DHI can be considered as 'Experimentalist governance' (Dorf & Sabel 1998; Sabel 2004; Szyszczak 2006) that enables both the regulators and regulatees to be involved in the innovation of regulatory techniques. According to

Zeitlin (2014;13) experimentalist governance is ‘a recursive process of provisional goal-setting and revision based on learning from the comparison of alternative approaches to advancing these goals in different local contexts’. Experimentalist governance focuses on translating regulatory goals to different local contexts rather than the enforcement of uniform fixed rules and sanctions. It involves a multilevel architecture in which four elements- are iteratively linked. The idea is that central and local institutions jointly establish a framework of goals and measurements (1); local units are then given discretion to situationally act upon these goals (2); as a condition of their autonomy they report on their performances and compare them by peer-review (3); the local institutions reflect and act on the comparison and then all the actors reflectively revise goals, measurements and procedures (4). Experimentalist governance arises from the concept of pragmatism as it was founded by C.S. Peirce and J. Dewey. Pragmatism is the philosophy of common sense, because actions are assessed in the light of practical consequences (Shields 1998). Karen Evans (2010) argues that public administration is dominated by an overemphasis on efficiency. Pragmatism could provide an alternative to efficiency-thinking because it focuses on inquiry in which experience is given meaning and where theory and practice meet (ibid.; Salem & Shields 2011). Experimentalist governance can be understood as a mutual co-creation of regulation. In this process of ‘simultaneous coupling’(De Bree

2005) regulators can not only help regulatees to solve problems in order to meet regulatory objectives; regulatees can also help regulators to construct more effective regulation (Heimer 2011; Gilad 2011).

The project of the DHI can be placed in the pragmatist, experimentalist stream. Experiences from other regulatory practices were assembled and translated into the specific context and language of healthcare. A new kind of inspection was creatively constructed and situated into the healthcare context in a one year process based on 'learning by doing' in which inspectors, experts from other regulatory sectors, scientists, healthcare directors and quality managers were involved in the innovation of regulatory techniques.

Research design

Much of the scholarly literature on regulation is focused on "how" to regulate markets, capitalism, and individuals better (see Braithwaite 2008). Yet, Parker (2013) finds it still necessary to keep on seeking to understand how regulation is used and experienced in everyday life of both regulators and regulatees and to what consequences? Present study adds another component: it scrutinizes how new forms of supervision are constructed. Accordingly, the trial of SBR by the DHI was followed through an

observational study in order to come to a 'grounded' and pragmatic understanding of how regulatory discretion is, and can be, deployed in the everyday practices of inspectors. The project lasted from December 2011 to November 2013. The study was meant to be a 'qualitative formative evaluation'. Formative research is defined as: A type of systematic inquiry focused on context, conducted with the goals of developing, monitoring, and critically assessing all interventions throughout their development, implementation, and evaluation phases (Nichter, Quintero,Mock, & Shakib 2004). Formative research is process-driven and iterative. Data collected at one point in time influences research conducted at a subsequent point in time as new research questions emerge. Moreover, formative research is aimed at giving feedback to project members and thus helps shaping the project (Bal & Mastboom 2007). In this project, formative research guided the development of the concept, the instruments as well as reflection upon effects and consequences of this new kind of supervision.

After gaining entrance and consent, we used participant observation as the first author followed the project group in all their activities; in total, 87 hours of observation were conducted. Observations were taped, transcribed and written down immediately after the event in order to aim at 'thick description' (Geertz 1994). The original Dutch material was translated. We made use of Atlas.ti to analyze the data inductively. Data and observations were eventually shared with the project group. The transcripts of

the observations of six experimental inspections, and several reflective presentations helped the project group in reporting their findings. Being both outsider and insider as a researcher, gave the first author the opportunity to learn the practicalities of inspection and to collaborate in finding ways to translate the concepts of SBR into practice. Simultaneously, as an outsider, her reflections and 'disconcertments' (Jerak-Zuiderent 2013) contributed to shape the experiment in a formative way in which knowledge on the content, operation and effects of SBR developed.

The project group developed a conceptual framework, tools and methodologies and then tested them experimentally in selected institutions. Following the evaluation of the first three trial inspections, the SBR concept, tools and methodologies were adjusted and then re-applied in a second series of inspections, a process that gradually refined the conceptualization and instrumentation. Development was thus an iterative process during which several meanings, experiences and consequences contributed to shaping SBR.

Results

Instrumentalizing SBR

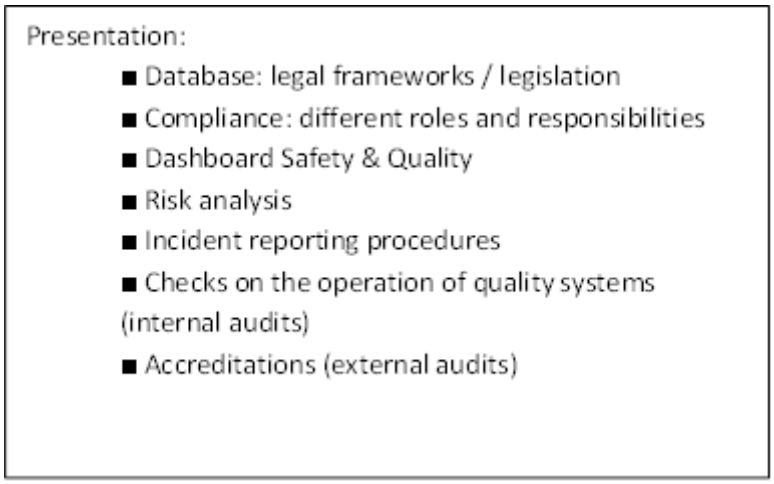
The pilot SBR was commissioned to explore the possibilities for SBR in healthcare. Its main goal was to determine whether SBR could contribute to public oversight of safe and good quality of patient care. An additional question was to try out how SBR inspection could work in practice. This question was answered by developing a draft SBR, using the knowledge and experiences from inspections in other sectors and of internal/external experts. Four invitational conferences with experts and involved healthcare directors were organized during the project in order to reflect on and make adjustments to steps taken.

A method was developed consisting of a protocol for an auditing visit, a list of information that has to be collected prior to the visit, and an assessment tool. The experiment involved six different organizations (two hospitals, two organizations for long term care and two organizations for mental healthcare) that, according the DHI, seemed to have a well-functioning Q&S management system. The draft method was tested in three trial inspections. After an evaluation and a revision of the method the next three inspections were conducted. An important adjustment in the second series of three visits was that the project group instead of questioning the information that was sent beforehand asked the board of the next three organizations to present their Q&S system on the spot. The project group consisted of six inspectors, one external consultant experienced with SBR projects in other sectors, and the researcher, an

organizational anthropologist. The external consultant was charged with transferring the knowledge collected in other sectors. He introduced the inspectors to tools and findings from other sectors. The inspectors visited companies in the chemical industry and attended an SBR inspection of a chemical factory. The project group started investigating the possibilities of translating SBR into the context of healthcare and into situated 'practices'. The project group did a lot of 'conceptual' work, which gradually made the significance of SBR clearer and gave it a more concrete and 'inspectable' form. What seemed to be the first step in the process, defining the meaning of SBR, lasted the whole project. The project group comprised inspectors from various DHI programs. During the pilot, these inspectors slowly gained a better idea of the significance of SBR. That was not easy because they were not accustomed to the inspection of integrated management systems. The project group learned from the trial inspections, the feedback process, and the discussions of preliminary results at the invitational conferences, as well as from the observations and questions that emerged from the accompanying research study. During the project, the SBR method and assessment tool were revised and then retested in the second series of trial inspections.

Trial inspections

Quality and safety were the key aspects of the inspections. The formal point of reference was the Quality of Care Act (responsibilities, systematic monitoring, control and improvement to quality of care, including risk management) and other regulations concerned with quality and patient safety, such as links between guidelines and agreements, professional groups, legal regulations, hospital contracts and protocols, and work instructions. The trial inspections lasted one day. In the first series of trial inspections the project group tried to understand the organizations systematic approach of Q&S by reading the documents. During second series of, the organizations were asked to present their own integrated Q&S management system that could include the following components:



The very question of presenting their own Q&S system worked out as a learning incentive. Not all organizations were fully prepared for this command. After the first

presentation and discussion with the board of directors, often companied by the manager of the quality department, various actors from the organization were interviewed to check how well the 'system' functioned. Six separate interviews of sixty minutes were conducted with representatives of the following types of respondents:

- Quality Manager / Quality Department
- Medical staff / medical director / Nursing Advisory Council
- Line managers
- Staff from the primary process

Between the interviews, information given orally was checked by reviewing the documentation on site. Following the interviews, inspections (reality checks) took place in the departments, following a predetermined topic from the quality audit. In mental care this topic was the prevention of suicide, in long term care medication errors and falls prevention, in the hospitals medication errors and the care for frail elderly. The topic helped to focus but was necessarily amplified by open observation and questioning. The inspectors visited two or more departments or sites in each organization. They spoke to employees, sometimes to clients or client representatives, and they accessed files. Current issues in quality and safety were selected for

verification (e.g. a unit of the Safety Management System or a recent update to a directive or guideline).

Near the end of the day, the findings of the DHI team were fed back to the respondents, and the inspection concluded with a mutual evaluation of the visit. A checklist, called 'the instrument', and an observational transcript supported the written report to be prepared by the inspectors. As the project was a trial, the written reports were not used for 'real' supervision purposes. This was communicated to the respondent.

Scoring system

The project group deployed a proven checklist from the chemical industry as a tool to assess Q&S management systems in the organizations visited (De Bree 2005). Several items and the language that was used in the checklist were adapted to healthcare. The following elements of the system were studied:

- Legal frameworks
- Vision and behavior
- Thinking on quality, self-critical attitude and ongoing improvement
- Internal control and pro-activity
- Openness and annual reports
- Screening employees
- Incident reporting and analysis

Each element contains a number of questions based on pre-set requirements. The instructions describe how each requirement is verified during the inspection: points are given if documentation is present (stage 1), if it is effective (stage 2), and if it is implemented (stage 3). Using this first score as baseline, a further scoring system allows for a quantified picture of the organization's system to be obtained. The quantification is then compared with the standard, and thus leads to a classification of the level of quality development at the organization. This classification is partly derived from work by Coglianese and Lazer (2003), who proposed a classification system based on how an organization carried out its planning or implemented a compliance system. In the Netherlands, the Inspectorate of Housing, Spatial Planning and the Environment (VROM 2008, 2009) proposed a four-tier model based on the full PDCA cycle, with the levels arranged according to differences in design and operation of the Q&S management system. A supervisory arrangement is coupled to each level.

The trial inspection established the organization's level (on a scale of one to four) of internal control and indicated the matching supervisory arrangement. The findings of the visits were recorded in a report, using the checklist as heuristics.

Contents of the classification levels and supervisory arrangements:

1. Organizations without a Q&S management system do not have trustworthy internal controls. Supervision of these organizations will be traditional and will occur at the maximum frequency. It is believed that these organizations are so far removed from implementing a good Q&S management system that it would make no sense to expect it to happen within a reasonable time span.

2. Organizations with basic Q&S management systems, but no integrated risk management system, that do not have a verified level of sufficient mastery. These organizations are usually certified by accreditation bodies and their systems have been tested. Supervision will still be traditional and occur at maximum frequency. However, the presence of a working and tested management system means that there is the potential for improvement to level 3.

3. Organizations with Q&S management and integrated risk management systems demonstrating such a level of internal control of safety and quality (integrated along with other risks from business-related fields) that the regulator can be confident about it. This does not mean that these organizations will no longer be inspected, but that fewer inspections are needed than in other supervision arrangements. The regulator will periodically audit the Q&S and risk management systems and check the compliance of the organization to verify that the system continues to function well.

4. Organizations with an integrated Q&S and risk management system that has proven to work well for a long time. The organizations manage their risks well, organize compliance, and thus guarantee safe and quality care. This makes them eligible for further reductions in the number of inspections. The periodic reviews remain in force, as well as random verification inspections using other supervision methods such as incident monitoring.

Outcome of the trial inspections

All six organizations visited were classified in level 2, with some institutions nearly ready to step up to level 3 and others further away. The reports clearly indicate the points of improvements for the individual systems. Although some Q&S management systems are functional, there is still no integrated risk management system. The larger organizations are often certified by accreditation bodies and thus their systems are tested. Although SBR as public supervision emphasizes other aspects in practice, certifications and accreditations- from private accreditors- provide the organizational conditions to form the basis of safety and quality.

Since the selected organizations were well- performing healthcare organizations, the overall score indicates that the general health sector operates under or on level 2. Those findings suggest that a high frequency of external monitoring is still needed in

Dutch healthcare. However, the presence of a well-functioning and properly tested Q&S management system means that there is potential for individual institutions to improve to level 3 or 4 where surveillance can proceed to a more self-regulating and responsive supervision model for which SBR is appropriate.

Experiences of the inspectees

Both written and oral reports of the trial inspections attend to the specific situation of each organization, discussing not only specific laws, regulations and risks, but also cultural aspects such as vision, leadership and concrete behavior. The directors of the participating organizations confirm that this process gave a reasonably complete picture of the performance and outcomes of their Q&S management system. Attention was given during the inspections to the doubts and dilemma's that are met and choices that were made in prioritizing risks. According to the participants, the DHI project group's oral and written reports provided meaningful feedback on the design and operation of their Q&S management system and formed the impetus for structural improvements. At the final invitational conference of the project, the directors noted that the inspections had made them think about their own Q&S management systems:

> *It functioned as a mirror for us. We realized that this is an area where you mostly do not come in the contacts with the inspection. In that respect, this*

> *really added something to the things that we normally learn from the inspection. At the system level, we saw where we could make better connections and were we could position our work more clearly.*

They indicated that they experienced the collaboration with the DHI fruitful, not only for the development of this new supervision method but also for their own improvements. The healthcare organizations that had scored best in the SBR classification scheme certainly were eager to ameliorate. The SBR inspections taught them what they could amend in their processes and systems. They discussed the possibilities of learning of best practices from both the private sector and the industry. The project ended with a joint excursion - a gift from the DHI to the organizations involved - to a 'best practice' large chemical company where the integrated risk management system was presented and the management of formal and informal processes was explained.

Experiences of the inspectors

During the pilot project, inspectors grew acquainted with meaning, significance and practices of SBR. Not all of them were accustomed to the inspection of integrated management systems, they learned by doing. The inspectors experienced the SBR

inspections as a more situational and proactive form of supervision. The project leaders reported that SBR:

- contributes to the objectives of the inspectorate
- provides an instrument to proactively work on patient safety and quality
- provides insight into the degree of risk of the institution itself
- enables that the focus of the inspection can be concentrated on those settings where patient safety and quality of care are inadequate.

Gradually it became clear to them that SBR could fit into the existing supervisory regime of of risk-based regulation. With SBR, the DHI can use information on organizations that has already been collected through existing forms of supervision. However, it proved difficult to gather information on the organizations included in the trial. This was because the DHI distributed information across different forms of supervision, and the supervision of different sectors is not always organized in the same way. Increasingly, the project group regarded SBR as an opportunity to better integrate the information collected by the DHI. In its final report, the group thus defined SBR as an ‘oversight umbrella.’

The project group found some well-functioning Q&S management systems, nevertheless the experiment showed that really integrated risk management systems were scarce. The reports gave clear indications to which the individual systems could be improved.

Controversial findings

Notwithstanding the positive outcomes, SBR was controversial. It was a rather 'vague concept' that on the one hand worked as a 'boundary object' (Star & Griesemer 1989; Bowker & Star, 1999). On the other hand its technocratic naming (system) led to resistance: some actors were afraid that SBR would turn out to be a new technocratic (or even bureaucratic) accountability method. One of the medical directors of an organization for mental care warned the project group in the first invitational conference:

> *I wonder: what will SBR replace and for whom is it a profit? For the Inspectorate it seems logical, for the patient it is hopefully profitable but for the organization I see a bureaucratic burden. We are that busy with accreditation, audits, reporting incidents. We think we are in control, we can always be better, but compliance management and compliance officer are no terms we use in mental*

health. The burden on institutions seems to increase. It has to decrease. It should not come on top of existing quality systems.

An experimentalist governance project may achieve involvement but may encounter resistance as well. The participants of the organization for mental healthcare continued to be very critical to the way SBR was shaped during the project. The director criticized the words 'system' and 'compliance'. They were afraid to be confronted with another 'Checklist Rating'. They appreciated the DHI project group's oral report but they reacted furious on the written report, in which they did not recognize the oral report at all. In comparison with the other organizations they were not 'bench-marked' as a leading practice. Yet, after the ending of the project, the management of the organization for mental care rearranged their Q&S management system and incorporated a specific 'mental care' risk management system.

Politically it turned out to be risky for the DHI to introduce SBR as a new supervisory practice. The experiment took place in a period of several severe incidents in Dutch healthcare, in which the DHI was criticized of trusting the organizations too much. Media and politicians urged for a more restrictive regime. SBR is easily framed as 'based on trust' and trust was a contested concept at that time as the political winds urged for a tougher approach. Those contextual circumstances impeded further

implementation of the findings into the regular work of the DHI. In the last invitational conference one of the inspectors complained:

> *We (the DHI) have trouble to reassure politics. We want to give some counterweight to the incident-driven regulation. We previously had a very difficult discussion on this subject with the ministry.* One of the directors reacted: *It is the only good solution: you cannot pursue that there is no risk at all, but you can show that you are trying to reduce risks as much as possible. You have to use risk management as a focus, you must explain how risk management and legislation are related. This is the responsibility of directors of the organizations.*

Framing healthcare into risk is performative, it rationalizes the work of care into the rhetoric's of risk management. The concept of risk generates a quantifying language. Risk emphasizes what goes wrong and not what is being done to prevent failures. Is safety realized when there is no risk? The reaction of the director shows that risk can be managed but it can never be totally avoided. Notwithstanding the known imperfectness of the systems the director is willing to take up the responsibility for the management of risk. We can see that SBR provokes two kinds of critics: at the one hand is assumed to be too much based on trust and at the other hand too much based

on control. In this context of a motivated and responsible field and a cautious DHI the question remained if SBR has a ‘raison d’etre’.

Discussion

From a critical view on SBR it can be posed that importing tools from the chemical sector and comparing existing compliance management systems to standards is a rather a relapse to the universalistic view instead of using a contextualist view (Pichault 2013) on the introduction of SBR as a new content. As stated in the theoretical part of this paper experimentalist governance focuses on translating regulatory goals to different local contexts rather than the enforcement of uniform fixed rules and sanctions. The resistance of for example the participants of the organization for mental healthcare could have been used to find a ‘better fit’.

The Q&S management systems of organizations do not have to be optimal to apply SBR, if we can assume that SBR will give those organizations an incentive to learn. Organizations are doing a lot to optimize safety and quality assurance, but they are still searching for a suitable and integral system to achieve this. SBR encourages organizations to develop a pro-active policy to track down their own site-related risks. After evaluating the Q&S management system, DHI places the responsibility back in

the hands of the organization to implement improvements to risk management and thereby improve the safety and quality of its patient care. The organization should be able to produce tangible evidence of the results in a subsequent inspection. This would mean that SBR provides a learning incentive that would drive steady improvements to the organization's management system, until it finally attains the level of inspection that just involves periodic system checks and verification in practice.

It follows from the above that SBR is not necessarily applicable in all organizational settings. The size and type of organization (e.g. private clinic) to consider in the choice of applying SBR should be further investigated. The organization should have a certain level of (potential) intrinsic control through a Q&S management system for it to make sense to apply SBR. More generally said, the organization should be responsive to stimuli aimed at its system. In the absence of this, SBR would be unhelpful. The four-level model that the DHI used in the pilot seems like a good starting point for interpreting differentiation in the sector in terms of sufficiently sophisticated intrinsic control.

SBR gives the DHI the opportunity to adapt its supervision methods to follow advances in the field. This presents challenges to both field and DHI. The framework of the Quality of Care Act provides ample space to apply SBR. The method applied in the pilot

proved suited to quick collection of relevant information on the design and operation of the Q&S management system and level of risk management. SBR is intended to bind together various forms of supervision and thus enables an integral assessment of the organization.

Nevertheless it remains to be seen how SBR inspections can be applied in the DHI's current processes. A critical question arises from the findings: if the trial inspections lead to classify organizations considered as well-performing at level 2 (basic Q&S management system), is it then necessary to change the current practices of the DHI? The project group has recommended that DHI management set up an implementation trajectory to proceed to the next phase of the project, to answer new questions and go on developing the actual form of SBR. The suspicions of policy makers and the criticisms expressed in the mental healthcare organization can be considered as a lack of translation and enrolment (Callon 1986). Both field, DHI and policy makers need to be enrolled to work further on definitions, requirements and standards within a field-supported supervision framework.

In addition to an assessment of the level of control at the organizations, the pilot also gave a picture of the role and structure of the DHI itself. The question is how the DHI maintains an overview of the whole field of healthcare organizations that it must

regulate. SBR seems to hold up a mirror to the organization of the inspectorate itself. This implies that the DHI should take care it has professional staff in-house as well as an effective management system that guarantees the quality of supervision.

An important question is how commensurate SBR is with political and social developments and whether SBR fits in with the attitude that the DHI wants to present to the field. Often this choice is combined with the query whether regulation should be repressive or responsive. SBR offers the opportunity to move beyond this dichotomy by seeing various forms of regulation as a continuum. SBR can be compelling to those who need it and can give space to those who take up their responsibility. This is consistent with recent policy recommendations to make better use of supervision in the governance structures of the sector (WRR 2013) and which recognize a paradox in the desire to maintain rigorous control on the one hand and yet provide more space for own responsibility on the other.

Conclusion

This project enabled both the regulators and regulatees to be involved in the innovation of regulatory techniques. ‘Experimentalist governance’ realized a co-creation of a future healthcare regulation. Both DHI and the healthcare organizations

learned from the project and it consequently established a constructive regulative relationship that fits to the concept of responsive regulation. In the mutual process of experimentalist governance regulators can not only help regulatees to solve problems so that they could meet regulatory objectives; regulatees can also help regulators to construct regulation (Heimer2011; Gilad 2011). The reconceptualization of regulation in this particular project included both a process -experimentalist governance- and a product -a method to apply SBR in healthcare. As language matters and words can be performative, the word 'system' in SBR could be reconsidered. For other inspections the experiences with modernizing supervision can be attractive and usable. It shows that it is possible to reconceptualize regulation incrementally and prevents undesirable effects of large and sudden changes.

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