



Evaluation

2016, Vol. 22(4) 394–409

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DOI: 10.1177/1356389016667889

evi.sagepub.com



Reconceptualizing regulation: Formative evaluation of an experiment with System-Based Regulation in Dutch healthcare

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Abstract

The Dutch Healthcare Inspectorate has recently tried out a new form of inspection: System-Based Regulation (SBR). This article explores how SBR was situated in the healthcare context through a process of ‘experimentalist governance’. A qualitative formative evaluation was undertaken involving two years of participative observation, numerous iterations between data gathering and feedback in order to orient the next steps of the process. The evaluation found that SBR could fit into the existing supervisory regime, but notwithstanding positive outcomes SBR was controversial and further implementation was delayed. The process of ‘experimentalist governance’ was strengthened by qualitative formative evaluation that documented and reflected on the process as it progressed. The evaluation also helped to translate and communicate learning so as to better understand regulation and to reform and reconceptualize SBR in today’s healthcare context.

Keywords

experimentalist governance, formative evaluation, inspection, qualitative research, System-Based Regulation

Introduction

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

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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)

Current regulation in the Dutch healthcare system is mostly prescriptive and performance-oriented (Gilad, 2011). Healthcare organizations complain about the quantity of performance indicators they have to supply due to this type of regulation. Both inspectorate and healthcare institutions are dissatisfied with the regulatory burden and the reflex to strengthen state regulation that arises out of incidents, mishaps and scandals that occur. In response to this dissatisfaction, the Dutch Healthcare Inspection (DHI) has recently experimented with a new form of supervision: System-Based Regulation (SBR). In contrast with the traditional application of prescriptive or performance standards, this approach invites organizations to develop and make explicit their own design and management of internal governance and control systems. Inspection then focuses on these self-designed ‘management systems’. Although SBR is defined differently by different inspectorates, it is most generally conceptualized as a form of public supervision where regulatory systems are assessed as well as the level of compliance to pre-set regulations. Thus this kind of regulation not only focuses on outcome and compliance to rules and prescriptions, but also assesses the efficacy of self-regulation systems in complex organizations (Gilad, 2011).

The DHI having only limited experience with a process-oriented way of regulating in the pharmaceutical industry, began a trial of SBR in healthcare organizations. In 2012–2013, a project group from the DHI sought to devise new ways of working in collaboration with healthcare organizations and experts from other regulatory sectors. This process was theoretically framed as ‘experimentalist governance’ (Dorf and Sabel, 1998; Sabel, 2004; Sabel and Zeitlin, 2008; Szysszczak, 2006). The findings for this article derive from a formative evaluation of this new way of developing and agreeing on a new approach to inspection. The aim of our evaluation was not only to describe the process of the reconceptualization of regulation, but also, by participating as ‘formative’ evaluators in the project, to uncover assumptions and clarify concepts.

In formative evaluation (Hansson et al., 2014) evaluators do not seek to be objective or keep a distance from the processes they evaluate. Rather, they are involved in the process, ask evaluation questions from the very start, and engage in an ongoing dialogue between participants, users and evaluators. Formative evaluation can in the view of its advocates return evaluation to its classical role as a means to learn and self-correct through dialogue. We used qualitative formative evaluation techniques in order to answer our research questions:

- Can ‘experimentalist governance’ and a non-traditional formative evaluation contribute to innovation of healthcare regulation?
- What do both the DHI and the healthcare organizations learn from the project to develop and implement SBR?

To answer the research questions, we first explore theories of regulation, in the relevant literature and how in particular SBR fits into existing models of regulation. Subsequently 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 as well as the positive and negative aspects of adding SBR to the external supervision of healthcare. The description of this project should both contribute to further development of theories

regarding the innovative renewal of regulation; while at the same time demonstrating the potential contribution of formative evaluation to processes of ‘experimentalist governance’.

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 by suggesting 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. Zeitlin (2013: 10) considers ‘regulation’ as an overarching concept covering the full policy cycle from rule-making through supervision, inspection, and enforcement to evaluation and review. The notion of ‘inspection’ refers to the daily work of the inspectors: checking behaviours and standards in real-time. It focuses on the competence of professionals, compliance with professional standards and outcomes for service users. We use these definitions in this article.

System-Based Regulation

Scholars of regulation describe SBR also as ‘management-based regulation’ (Coglianese and Lazer, 2003), ‘enforced self-regulation’ (Braithwaite, 1982), ‘reflexive regulation’ (Gunningham, 2012), ‘systems-based regulation’ (Gunningham and Johnstone, 1999) or governance-based regulation (Zeitlin, 2013). These 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 into a hybrid model of regulation that monitors the design, management and working of the internal quality and safety systems of an organization.

Healthcare is mostly organized in complex and constantly changing organizations (Hollnagel et al., 2013; Scott, 2000). The object of regulation by SBR is the formal and informal management system for patient quality and safety. A management system can be described as the set of procedures an organization needs to follow in order to meet its objectives. In some small organizations, there may not be an official system, just ‘our way of doing things’, which is mostly kept in the heads of the staff. But the larger the organization, the more likely that procedures need to be systematized to ensure everyone is clear on who does what.

We designate that part of a management system that helps an organization to meet objectives concerned with quality or risks, a quality management system or a risk management system.

The concept of risk includes the possibility and the probability of loss and injury (Kaplan and Garrick, 1981). Most definitions of risk include both the probability and the consequences of an event or development (Aven, 2011). We choose the term ‘integrated risk management system’ to indicate a management system used by an organization to control all risks that may threaten the realization of its objectives.

When an organization develops its own set of rules and internal controls in light of regulatory goals, this might be described as (enforced) self-regulation. SBR stimulates and assesses modes of organizational self-organization and encourages self-critical reflection at an organizational level (Parker, 2002). However, this self-management approach could not be possible without the prior development of performance indicators, standards and management tools (see Wiener, 2000) that involve the external assessment and control of risks, compliance, and the system of maintenance and review (Gunningham and Sinclair, 2009). Moreover, formal systems like audits and monitoring have been shown only to be effective when they are supported by informal ‘cultural’ systems (Alvesson, 2002; Gunningham and Sinclair, 2009; Parker and Gilad, 2011). SBR inevitably requires that the regulatee has considerable autonomy in how to organize the achievements of desired outcome and thus conflicts with a more traditional centralized ‘command and control’ approach to regulation.

Many scholars consider SBR to be a better situated form of supervision. SBR requires 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).

Model of responsive regulation

Due to the emphasis on organizational self-regulation, SBR fits into a model of responsive regulation whereby regulators can use a ‘pyramid’ of enforcement interventions (Ayres and Braithwaite, 1994). The situational approach that is embedded in the concept of responsive regulation leads beyond the dichotomy of either permissive or enforced supervision. Responsive regulation is concerned with designing regulatory institutions and processes that 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 strongly when necessary (Scott, 2004). The essence of the pyramid is that the ability to escalate to really tough responses at the top of the pyramid enables the more deliberative base. Furthermore, responsive regulation assumes that regulators would be able to identify which enforcement response would fit the regulatee. Consequently, regulators need the capacity to assess the validity of the information on the governance and performance of the organization and they have to be able make their own judgement (Gilad, 2011: 429). Heimer (2011) shows that performing responsive regulation in a layered system faces important challenges but also offers opportunities. In addition to responding with encouragement to those who comply and coercion to those who resist, regulators can also help regulatees solve problems so as to meet their regulatory objectives.

Experimentalist governance

The SBR pilot of the DHI can be considered as ‘experimentalist governance’ (Dorf and Sabel, 1998; Sabel, 2004; Szyszczak, 2006) that enables both the regulators and regulatees to be involved in the innovation of regulatory methods. 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 (1) central and local institutions jointly establish a framework of goals and measurements, (2) local units are then given discretion to situationally enact these goals, (3) as a condition of their autonomy they report on their performances and compare them through peer-review, and (4) local institutions reflect and act on the comparison allowing all the actors to reflectively revise goals, measurements and procedures. Experimentalist governance is consistent with a concept of pragmatism in which actions are assessed in the light of their practical consequences (Shields, 1998). Pragmatism focuses on inquiry in which experience is given meaning and where theory and practice meet (Salem and Shields, 2011). Experimentalist governance can be understood in these terms: as a mutual co-creation of regulation, a process of ‘simultaneous coupling’ (De Bree, 2005) in which regulators help regulatees to meet regulatory objectives while regulatees help regulators to construct more effective regulation (Gilad, 2011; Heimer, 2011).

The DHI project operationalized pragmatism and experimentalism by assembling experiences from other regulatory practices and translating them into the specific context and language of healthcare. A new kind of inspection was created and situated in the healthcare context over the course of a year. This was based on a pragmatic ‘learning by doing’ process in which inspectors, experts from other regulatory sectors, healthcare directors and quality managers were involved in devising innovative regulatory techniques.

Formative evaluation

Much of the scholarly literature on regulation is focused on *how* to better regulate markets, capitalism, and individuals. Parker (2013) emphasizes in addition the need to understand how regulation is used and experienced in the everyday life of both regulators and regulatees and with what consequences. Accordingly, the trial of SBR by the DHI was followed through with an observational study in order to come to a ‘grounded’ and pragmatic understanding of how a new form of regulation is, and can be, deployed in the everyday practices of inspection. The study was designed as a ‘qualitative formative evaluation’ where formative evaluation 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 et al., 2004). Formative evaluation 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 evaluation is aimed at giving feedback to project members and thus helps shaping the project (Bal and Mastboom, 2007). In this project, formative evaluation guided the development of the concept and the instruments as well as reflection upon the effects and consequences of this new kind of regulation.

The project lasted from December 2011 to November 2013. After gaining access and consent, we employed participant observation whereby the first author – the evaluator – followed the project group in all their activities; in total, 87 hours of observation were conducted. Observations were taped, transcribed and written up immediately after the event in order to produce a ‘thick description’ (Geertz, 1994). We made use of Atlas.ti to analyse the data inductively. Data and observations were regularly shared with the project group. The transcripts of the observations of six experimental inspections helped the project group in reporting their findings, and several reflective presentations stimulated thinking about the meaning of SBR,

the conceptions of regulation and the practicalities of inspection. Being both outsider and insider as an evaluator, gave the first author the opportunity to learn the practicalities of inspection and to collaborate in finding ways to translate the concepts of SBR from other sectors into healthcare and from policy into practice. Simultaneously, as an outsider, her reflections and 'disconcertments' (Jerak-Zuiderent, 2013) were discussed on different platforms: in the scientific advisory council, in the project group and in a colloquium of the inspectors of the DHI. The observations and reflections contributed to shape the experiment in a formative way in which not only knowledge of the content, operation and effects of SBR improved, but also a reconceptualization of regulation emerged.

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 of sense-making, experience and follow-up of consequences contributed to shaping SBR.

Results

Instrumentalizing System-Based Regulation

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 safety and a good quality of patient care; and to develop this new approach to inspection. The question was: How could an SBR inspection work in the regulation of healthcare?

This question was answered by developing a draft SBR, using knowledge and experience from inspections in other sectors and of internal and external experts. Four conferences with invited experts and involved healthcare directors were organized during the project in order to reflect on and make adjustments as required. The method consisted of a protocol for an audit visit, a list of information 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 to the DHI, seemed to have a well-functioning Quality and Safety (Q&S) management system. The draft method was tested in three trial inspections. The next three inspections were conducted after the evaluation and revision of the method. An important adjustment in the second series of three visits was that the project group, instead of analysing the information that was sent in advance, asked the board of the next three organizations to present their Q&S system at the time of the site visit. The project group consisted of six inspectors, one external consultant experienced with SBR projects in other sectors, and the evaluator, an organizational anthropologist. The external consultant was charged with transferring knowledge (e.g. introducing 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 situated 'practices' of healthcare. The project group undertook a great deal of 'conceptual' work during their meetings, which gradually made the significance of SBR clearer, giving it a more concrete and 'inspectable' form. What was the first step in the process, defining the meaning of SBR, lasted the whole project. The project group comprised inspectors from various DHI programmes. During the pilot, these inspectors

slowly gained a better idea of the meaning, significance and implications of SBR, and learned how to perform SBR. That was not easy because they were used to looking at specific indicators and were unaccustomed to the inspection of integrated management systems. They learned where to look in 'the system' for the root cause of performance rather than assessing the performance itself. Moreover, they improved their ability to make use of the overall information about the organization that was available in the DHI. The project group not only reconceptualized their regulatory work but also learned how to enact SBR in practice. During the project, the evaluator and the project group revised the SBR method and the assessment tool based on trial inspections, feedback and discussions at the by-invitation conferences. This allowed for revisions and retesting in a second series of trial inspections.

Trial inspections

Q&S were the key features of the inspections. The formal point of reference was the Quality of Care Act that covered responsibilities, systematic monitoring, control and improvement to quality of care, including risk management and other regulations concerning quality and patient safety. The trial inspections lasted one day. In the first series of trial inspections the project group tried to understand the organizations systematic approach to Q&S by reading documentation, a complex and time-consuming task. In the second series of inspections, the organizations were asked to present their own integrated Q&S management system including the following components:

- Database: legal frameworks/legislation
- Compliance: different roles and responsibilities
- Dashboard Safety and Quality
- Risk analysis
- Incident reporting and procedures
- Checks on the operation of quality systems (internal audits)
- Accreditations (external audits)

As not all organizations were ready to present their own Q&S system, the request to do so proved to be a learning incentive for the organizations concerned. After the first presentation and discussion with the board of directors, often accompanied by the manager of the quality department, various actors from the organization were interviewed by the project group to check how well the 'system' functioned. Six separate interviews of 60 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 and practices on site and by triangulating answers with other respondents. Following the interviews, inspections ('reality checks') took place in the departments, following a topic predetermined by activities of the organization concerned. Thus:

- in mental healthcare the topic was the prevention of suicide;
- in long-term care, it was medication errors and falls prevention;
- in the hospitals, it was medication errors and the care for frail elderly patients.

These topics helped to focus inspections but were necessarily amplified by open observation and questioning. The inspectors visited two or more departments or sites in each organization, spoke to employees, sometimes to clients or client representatives, and accessed files. Current issues in Q&S were selected in documents for verification during the inspection (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 behaviour
- 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 a baseline, a further scoring system allows for a quantified picture of the organization’s system. The quantification is then compared with the standard, and leads to a classification of the level of quality development at the organization. This is partly derived on work by Coglianesse and Lazer (2003), who proposed such 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 Inspectie, 2008, 2009) proposed a four-tier model based on the full Plan-Do-Check-Act (or Deming) cycle, with the levels arranged according to differences in design and operation of the Q&S management system. A supervisory arrangement is associated with each level.

The trial inspection established the organization’s level (on a scale of 1 to 4) of internal control and indicated matching supervisory arrangement. The findings of the visits were recorded in a report, using the checklist as a heuristic.

The contents of the classification levels and supervisory arrangements are as follows:

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 a sufficient level of internal control of safety and quality (integrated along with other risks from business-related fields) that the regulator can be confident.* 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 points for improvements of the individual systems. Although some Q&S management systems are functional, there is still no integrated risk management system although larger organizations are often certified by accreditation bodies. Although SBR as public supervision emphasizes other aspects in practice, certifications and accreditations – from private accreditors – it provide the organizational conditions to form the basis of the Q&S system. Since the selected organizations were, according to the information of the DHI gathered in other inspections and instruments, 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 those inspected

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 behaviour. 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. 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 provided the impetus for structural improvements. At the final invitational conference of the project, one of the directors noted that the inspections and the report 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 into contact 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 where we could position our work more clearly.

The directors indicated that they experienced the collaboration with the DHI as fruitful, not only for the development of this new supervision method but also for their own improvements; and healthcare organizations were eager to improve. The SBR inspections taught them what they could amend in their processes and systems, raising the possibilities of learning about best practices from both the private sector and the health and care sector.

The inspections paid attention to the doubts, dilemmas and choices to be confronted when prioritizing risks. SBR gave the organizations room to show how regulation was adapted to their individual circumstances. Healthcare directors appreciated the room for adaptation, but despite the added value of cooperation with the regulator, they understood that it could also lead to inconsistencies and uncertainty over the rating of their integrated management systems.

Experiences of the inspectors

During the pilot project, inspectors grew acquainted with the meaning, significance and practices of SBR. Not all of them were accustomed to the inspection of integrated management systems; they learned by doing: which questions to ask and where to look. 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;
- ensures 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. The DHI could use information on organizations that has already been collected through existing forms of supervision. However, during the trial, it proved difficult to access information on the organizations concerned. This was because the DHI distributed information across different forms of supervision, 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 defined SBR as an 'oversight umbrella'.

Nevertheless, 'fitting into the existing supervisory regime' meant that SBR operated alongside existing prescriptive and performance-oriented regulation. The precise positioning of SBR in relation to existing regulation has still to be worked out.

Contentious findings

Notwithstanding the positive experience discussed above, SBR was controversial. It was a rather 'vague concept' that on the one hand worked as a 'boundary object' (Bowker and Star, 1996; Star and Griesemer, 1989) On the other hand its technocratic labelling (as a 'system') led to resistance: some actors were afraid that SBR would turn out to be a new technocratic (or even bureaucratic) accountability method. In the first invited conference, one of the medical directors of a mental healthcare organization warned the project group:

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 not 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.

Experimentalist governance projects may achieve involvement but may also encounter resistance. The participants from the mental healthcare organization continued to be very critical of 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 furiously to the written report, in which they did not recognize the oral report. Yet, after the end of the project, we visited the respondents again for evaluation purposes and they reported that the mental healthcare organization had adjusted their Q&S management system to incorporate 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 during a period of several severe incidents in Dutch healthcare, in which the DHI was criticized for trusting the organizations too much. Media and politicians pushed for a more restrictive regime. SBR is (too) easily framed as 'based on trust' and trust was a contested concept at that time when there were political pressures for a tougher approach. These contextual circumstances impeded further use of the evaluation findings by the DHI. In the last invited 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: it is not realistic to expect 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 in terms of risk is performative; it rationalizes the work of care into the rhetoric of risk management. The concept of risk generates a language of quantification. 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 quoted above suggests that risk can be managed but it can never be totally avoided. Notwithstanding the known imperfections of these systems, the director is willing to take on the responsibility for the management of risk. We saw that SBR provokes two kinds of criticism often in tension with one another. On the one hand, SBR is assumed to be too much based on trust and, on the other hand, it is assumed to be too much based on control. In this context of motivated and responsible practitioners and a cautious DHI the question remained if SBR has a 'raison d'être'.

Discussion

From a critical perspective with respect, it can be argued that importing tools from the chemical sector and comparing existing compliance management systems to standards is a relapse to a universalistic rather than a contextualized or situated approach (Pichault, 2013) to the introduction of SBR. On the other hand, experimentalist governance focuses on translating regulatory goals to different local contexts rather than the enforcement of uniform fixed rules and sanctions. For example, the resistance of the participants of the mental healthcare organization could have been used more 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 holistic system to achieve this. SBR encourages organizations to develop a proactive policy to track down their own site-related risks. After evaluating the Q&S management system, the 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 drives 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 to consider in the choice of applying SBR should be further investigated – e.g. is it appropriate for a small private clinic? 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. 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 differentiating the sector in terms of sufficiently sophisticated intrinsic control.

The key to success of SBR appears to be that institutions should be responsive to the (new, system) stimuli. It is not yet clear whether the application of SBR can influence responsiveness by affecting aspects within the regulated organization like quality awareness, management system and culture. Future research is necessary to investigate to what degree SBR offers an effective approach to help improve organizational responsiveness.

SBR gives the DHI the opportunity to adapt its supervision methods to follow advances in the field. This presents challenges to both the field and the DHI. 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 the level of risk management. SBR appeared to bind together the various forms of supervision and thus enabled an integrated 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 the classification of organizations considered as performing at level 2 (basic Q&S management system), described as organizations that still need external control, is it then necessary to change the current practices of the DHI? The project group has recommended that the 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. Both the field, the DHI and policy makers need to work further on definitions, requirements and standards within a field-supported supervision framework.

In addition to an assessment of the level of control within the organizations, the pilot also provided 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 must ensure that 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 question of whether regulation should be enforced 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 that recognize a paradox in the desire to maintain rigorous control on the one hand and yet provide more space for self-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. The project both revealed and improved the responsibilities of the organizations to build into their operative structure as conditions for self-restraint (Selznick, 1985: 367). Both the DHI and the healthcare organizations learned from the project and it consequently established a constructive regulatory relationship that fits with 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 (Gilad, 2011; Heimer, 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.

Moreover, we found that the process of experimentalist governance was strengthened by qualitative formative evaluation. The evaluation helped the process in all stages by describing what happened and reflecting on why things happened, revealing underlying assumptions. This reflection supported by systematic evaluative research created opportunities to learn from the experiment both for regulators, regulatees and evaluators. The formative evaluative process also fits extremely well with experimentalist governance. All in all, we saw that the formative evaluation co-created 'experimentalist governance' and helped in jointly constructing and articulating the meaning of SBR. This resulted in a better understanding of regulation in order to reform and

reconceptualize it. This continuous ‘conceptual’ work sharpened the scientific and practical meaning of SBR and increased the effectiveness of SBR. Where experimentalist governance joins regulators and regulatees in innovation, formative evaluation adds the evaluators to the innovative process, enabling them to contribute to achieving the desired outcomes. Joining in real-time practices and reflections mediates the distance between the often separate fields of healthcare practice, regulation and research, and stimulates the co-creation of knowledge.

For other regulators the experiences with modernizing supervision by combining experimentalist governance with formative evaluation can be attractive and usable. It shows that it is possible to reconceptualize regulation incrementally and counters the undesirable effects of large and sudden changes.

Acknowledgements

We wish to thank the project group of the DHI and the healthcare organizations for their generosity to share their work with us. We also would like to thank the anonymous reviewers of this article, the editors of SS&M, as well as Kor Grit and the members of the Healthcare Governance team of the Institute of Health Policy and Management, the members of the DHI colloquium, Francois Pichault and Egosians of Sub-theme Reconceptualizing Contemporary Public Services Organizations, EGOS Colloquium 2014. We thank Ragini Werner for editing.

Funding

This research was funded by ZonMw, the Dutch Organization for Health Research and Development (project number: 80-83505-98-001).

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