

The proof of the pudding

The value of governmental regulation of healthcare
quality and safety

Prof.dr. Ian Leistikow

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De waarde van overheidstoezicht op kwaliteit en veiligheid van de gezondheidszorg

Prof.dr. Ian Leistikow

Motto

"All right, but apart from the sanitation, the medicine, education, wine, public order, irrigation, roads, a fresh water system, and public health, what have the Romans ever done for us?"

Life of Brian

Colophon

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Introduction

When I informed my colleagues at the University Medical Center Utrecht that I was going to work at the Health and Youth Care Inspectorate, Cor Kalkman asked me whether I was crossing over to 'the Dark Side'. Although Cor's reference to the 'Dark Side' was meant as a joke, there is nonetheless a serious undercurrent to it. Many healthcare providers have a negative view of the Health and Youth Care Inspectorate. They regard it as a sinister force that imposes regulations, increases administrative burdens and hands out penalties. Although patients have greater confidence in the Inspectorate,¹ they too have difficulty in understanding what it is for, and its actions do not always correspond to their expectations.² Political interest for the inspectorate mainly arises in the wake of a serious adverse event in the healthcare sector. In such cases the prevailing political reaction is that the inspectorate should take tougher action.

And I have to admit that my own image of the Inspectorate was not a very positive one either. Before applying for the position as inspector, I asked former chief inspector Jan Vesseur whether the Inspectorate actually contributed to quality and safety in healthcare. Jan looked at me in astonishment. "Of course it does, otherwise I wouldn't be working here," he replied decisively. And after I joined the Inspectorate, I saw that almost all employees are committed to contributing to healthcare quality. The employee satisfaction surveys show that inspectorate employees award a high score to the content of their work.³ Over time I have seen multiple examples of results that would never have been achieved without the Inspectorate, or would have been achieved to a far lesser extent. These include improvements in structures, such as opening a

help desk for side effects of implants. Improvements in healthcare procedures, such as a substantial decline in the use of restraints in mental healthcare. And improvements in results, such as a 50% reduction of mortality following pancreaticoduodenectomy, an operation carried out in patients suffering from pancreatic cancer. This reduction is due to implementation of the norm that hospitals are only allowed to perform this operation on condition that they perform at least 20 of these surgical procedures a year. So the Inspectorate makes a difference, but its added value is not always visible.

Challenges facing the Inspectorate

During the past decades, our society has attached increasing importance to governmental regulation of healthcare quality.⁴ The thematic legislative evaluation concerning governmental regulation of healthcare quality published by the Netherlands Organisation for Health Research and Development (hereafter: 'ZonMw') in 2013 states that modern society is developing into a risk society. People in this type of 'precaution-oriented culture' expect the government to protect them against risks. In the event of inadequacies in healthcare quality, the focus is no longer on the 'risk producer' alone, but also on the role of the regulator. This serves to fuel incident-driven politics and politicisation of regulation. The work of the regulator is scrutinised under a social microscope.⁵ My predecessor, Professor Paul Robben, described this as regulation in a house of glass in his 2010 inaugural lecture.⁶ In 2013 the Advisory Council on Government Policy (hereafter: 'WRR') advocated concentrating on the social function in governmental regulation, whereby the public interest constitutes the reference point.⁷ Our society is in a state of development, and governmental regulation is developing along with it. In many ways, today's Inspectorate is very different to the Inspectorate I started working at in 2011. Today, the Health and Youth Care Inspectorate is firmly and visibly positioned at the heart of Dutch society. This means that the Inspectorate must be able to demonstrate its public value. In this inaugural lecture, I will examine what the concept of public value means for a governmental healthcare inspectorate and how public value can be achieved.

Value

The government defines regulation as: "collecting information on the question of whether an action or an issue fulfils the relevant requirements, subsequently forming an opinion on the situation, and, if necessary, performing an intervention based on this opinion."⁸ This definition is instrumental and does not specify what the public value of the regulator's collecting, assessing and intervening should

be. In line with the theories on public value,⁹ I would like to argue that there are four perspectives that determine the public value of governmental regulation of healthcare quality. These are the perspectives of patients, professionals, politicians and the public.

Patients

Patients (or clients) and their loved ones are the ones who benefit the most directly from healthcare quality. A large part of the Inspectorate's activities are not visible for this group. Meetings held with umbrella organisations and scientific associations, input contributed to policy decisions, extensive inspections carried out on pharmaceutical companies, and regulation of pharmaceutical advertising are just a few examples. In most cases, patients only become aware of the Inspectorate if something goes wrong during healthcare provision. The expectations that patients, clients or their families have with respect to the Inspectorate's role at such times do not always correspond to what the Inspectorate is able or permitted to do, or what it considers relevant. For example, research conducted by Renée Bouwman at the Academic Collaboration for Research on Regulation on members of the public who report to the National Helpdesk for Customer Concerns revealed that these people consider it important for the Inspectorate to investigate complaints made about a disrespectful attitude towards patients. However, inspectors do not often investigate reports on attitudes; they give priority to reports that express concerns about medical technical issues.¹⁰ Often, the perspectives of patients and inspectors are aligned. In my role as inspector, I have experienced many examples of situations where patients, clients and their families attach great value to the Inspectorate's input. Explanations, mediation or sometimes just listening can be of immense help to them. During the past years, the Health and Youth Care Inspectorate has devised various strategies for involving patients' (or clients') perceptions in regulation, such as use of social media, deploying 'Experts by Experience' and organising 'citizens' panels'.^{11 12 13} The added value of governmental regulation of healthcare quality should always be assessed from the perspective of those who receive care.

Professionals

The regulator has the largest impact on the institutions and individuals that fall under the authority of the regulator. In the healthcare sector, these are the providers, administrators, traders and manufacturers of healthcare and healthcare related products and services. Since their roles in healthcare quality are of a professional nature, I will classify them under the umbrella term 'professionals'. The Inspectorate oversees that professionals comply with the relevant law, regulations and standards. However, this relationship is by no means a one-way street. The reputation enjoyed by the Inspectorate among these professionals has an impact on its influence on them. A good reputation makes informal,

non-legal supervisory tools - such as recommendations and persuasion - more effective, which in turn means that the Inspectorate does not need to resort to legal instruments as frequently. Moreover, a good reputation enables the Inspectorate to table matters with authority and to influence the social and political debate on healthcare.¹⁴ One extreme example of what can happen if professionals doubt the regulator's added value occurred in Denmark in January 2018. Thousands of doctors signed a petition of no confidence in the Danish healthcare inspectorate, since they felt that this institution was too repressive.¹⁵ Mutual respect between professionals and the regulator enables all parties to reinforce one another while maintaining the supervisory relationship. There are several examples of improvements in healthcare quality which would not have been achieved without this collaboration, at national as well as local level: I will be citing a number of these examples later on. The added value of governmental regulation of healthcare quality is dependent on the value perceived by professionals.

Politics

In the Netherlands, government regulation of healthcare quality is funded by public resources. Or, to put it more simply: the State forces all inhabitants to pay for regulation by imposing taxes. This leads to the question of whether the public would have paid for this voluntarily. Despite the fact that we cannot answer this question - after all, who is 'the public'? - it is worthwhile bearing this in mind if we want to determine the value of governmental regulation. When somebody considers a purchase, they think about what that product is worth to them. For example, how much money am I willing to spend on a bicycle? When a democratic constitutional state distributes the funds it has obtained through taxation, the elected representatives of the people are the ones who decide on the value. As Professor Mark Moore says: politics remains the final arbiter of public value just as private consumption decisions remain the final arbiter of private value.¹⁶ The world of politics is a world in itself, which sometimes appears to be at a considerable distance from the reality with which inspectors are confronted. At the Dutch Health and Youth Care Inspectorate, the Administrative Support and Policy Management Department forms the link between these two worlds. This department's role is essential in ensuring that the Inspectorate does not lose sight of the political perspective, because the added value of governmental regulation of healthcare quality is partly determined by the value perceived by politics.

The public

'The public' refers to the 17 million inhabitants of the Netherlands. Although 75% of these people have heard of the Inspectorate, most of them only know it by name. The public's expectations of the Health and Youth Care Inspectorate change over time. Recent research suggests that in 2011, Dutch people mainly envisaged the Inspectorate's role as monitoring compliance with legislation and regulations. Although the public still regarded this as an important task in 2017, they considered monitoring and supervising quality and safety improvement to be even more important.¹⁷ A large percentage of the population are not patients or do not regard themselves as such, they do not work in the healthcare sector, and they are not politically active. However, they do make financial contributions to healthcare and should be able to rely on receiving high-quality care if they need it. In his inaugural lecture entitled "Was Getekend", Professor Kim Putters describes how a certain group has developed within our population that is concerned about whether there will be sufficient healthcare for them in the future. If there is a group of people at the top who are more easily able to receive better quality of care with the resources at their disposal, this will erode public support for the social contract.¹⁸ The Health and Youth Care Inspectorate must be receptive to this situation; after all, the public's perspective invariably plays a role in assessing the public value of governmental regulation of healthcare quality.

There are four different perspectives that determine whether governmental regulation of healthcare quality creates public value or not. These are the perspectives of patients, professionals, politics and the public. But what course of action should the Inspectorate take in order to create public value? How can the Inspectorate decide what to focus on (and therefore what not to focus on), what type of interventions would be effective, how it should evaluate the consequences of its decisions, and how can it justify all this vis-à-vis the public? Or, to put it more simply: how can the Inspectorate respond to the question I once asked Jan Vesseur: whether the Inspectorate actually contributes to healthcare quality?

Introduction of a model

To answer this question, I would like to propose a model. This model endeavours to connect scientific knowledge on regulation with the practical reality of inspectors' everyday work. Its purpose is to serve as a guideline for designing regulatory strategies which contribute to healthcare quality and safety. The model comprises eight steps:

1. Explicitly clarifying the regulator's overarching mission;
2. Defining the risk or the problem to focus on;
3. Determining which actors the regulator can address;
4. Determining what is expected from this actor to decrease the risk or problem;
5. Clarifying the goal of the expected behaviour;
6. Design and execution of an intervention to achieve this goal;
7. Assessing the consequences of the intervention;
8. Disseminating the results and the lessons learned.

Step 1. Overarching mission

Foucault describes regulation as a disciplinary force which imposes compliant behaviour through hierarchical observation, normalizing judgment, and examination.¹⁹ Or, to put it more simply: the regulator ensures that actors adhere to the rules of conduct agreed upon. If an actor does not comply to the desired behaviour, sanctions are imposed, preferably those that encourage the actor to display the desired behaviour. This emphasis on compliance to regulations is increasingly accompanied by the perspective that regulation should also play a role in fostering improvements in the sector which it regulates.²⁰ In 2013 the Advisory Council on Government Policy (WRR) argued that unilateral emphasis on compliance and enforcement irrevocably results in political and social disillusionment on the way regulation functions. Regulatory agencies should look beyond the limits of legislation and regulations, and actively search for risks and threats to the entire system they are regulating. According to the WRR, regulatory agencies play a role in highlighting emerging issues and developing new standards in collaboration with the sector.²¹ In this respect, the WRR is challenging regulatory agencies to be more than just a disciplinary force.

This results in a dilemma for regulatory agencies. Should they focus on preventing negative outliers, or on improving the quality of the sector as a whole? Is the Health and Youth Care Inspectorate's core purpose to identify and correct dentists who provide substandard care, or to encourage and support continuous improvements in the quality and safety of dental care in the Netherlands? "Both", one might answer. However, since there are only 12 inspectors for more than 15,000 dental care professionals, the Inspectorate will have to make a choice. Moreover, the regulatory strategies required for promoting compliance are different to those required for promoting quality improvement.

In its Long-Term Policy Plan for 2016-2019, the Inspectorate states that its approach is based on a healthy sense of trust, and that it wants to focus on healthcare providers' capability to learn.²² This implies that healthcare providers should have room to make mistakes, provided that they learn from such mistakes. For healthcare professionals, this is an appealing approach; from a

political point of view, this seemingly 'soft' approach will be easier to digest by some political parties than others. A great deal will depend on social acceptance and the extent to which the Inspectorate is actually able to demonstrate improvements in healthcare quality. However, a patient who has been the victim of a serious adverse event may well find it unacceptable if a healthcare institution executes a mediocre root cause analysis, and the Inspectorate accepts this because the healthcare institution is at the start of its learning curve. This requires careful guidance on the part of the Inspectorate as well as the healthcare provider. The results obtained from a citizens' panel organised by the Inspectorate in January 2018 suggest that the public regards monitoring healthcare providers' capability to learn as one of the Inspectorate's primary tasks. Monitoring the capability to learn is quite a different ballgame to monitoring compliance and requires specific skills from the regulator. Research carried out by Joy Furnival in the United Kingdom showed that regulatory agencies sometimes lack improvement skills and experience, and that the emphasis on the capability to learn may result in confusion regarding regulatory roles and tensions in maintaining regulatory relationships with healthcare institutions.²³ Such an approach also raises the question how much opportunity an individual or an organisation should be granted to learn and at what moment the regulator should switch to a more stringent approach.

The first piece of the puzzle is also the most complicated one. The Inspectorate will have to maintain a dialogue with all four parties - patients, professionals, politicians and the public - in order to ensure that its mission remains in sync with the interests of these four groups.

Step 2. Risk or problem

Defining a specific risk or problem is more difficult than it might seem at first sight. In 2014, when the Inspectorate compiled an overview of the potential risks it could focus on, this resulted in a very diverse list. It included increased antimicrobial resistance, the impact of budget cuts on healthcare quality, inadequate healthcare due to poor professional performance, healthy patients being harmed as a result of cosmetic surgery, inadequate somatic care for psychiatric patients, incorrect licences for tissue banks and inadequate governance of healthcare institutions, to name just seven of the 70 or so issues cited. At that time these were all genuine risks whereby it could justifiably be argued that the Inspectorate should devote attention to them. This poses two problems. First of all, there are more issues than capacity, so a choice has to be made, i.e. selecting issue no. 1 means by definition that the Inspectorate will not be able to address issue no. 2. It also means that we must accept that a certain risk will remain in existence. This makes inspectors uneasy, not only because of the risk of negative impact if serious events arise in connection with this issue. Inspectors feel responsible because, as people in petrochemical industry risk

management say, "if you see it, you own it". Secondly, the way the potential risks are formulated often insufficiently address the actual problem. An issue that first seems like a risk may, on further examination, turn out to be a symptom of an underlying risk. If the Inspectorate fails to disentangle the risk in sufficient depth, there is a danger that the Inspectorate will be focusing on a symptom instead of on the real underlying problem. An example from Sweden concerned the problem of long waiting times at emergency departments. On further examination, it emerged that one standard for waiting times existed (a maximum of 4 hours), which was applied to every patient. Enforcing this standard for waiting times could be detrimental to care for acute patients, who would have to wait for longer so that the non-acute patients could be seen within 4 hours.

The possibility of harm lies at the core of the concept of 'risk'. In the healthcare sector, it is most often the patient who endures the harm. The possible types of harm are frequently referred to in terms of the 'Five Ds': Death, Disease, Disability, Discomfort and Dissatisfaction. I would like to add a sixth D to this list: Disrespect, since a disrespectful attitude of healthcare providers can have a tremendous impact on patients who depend on that provider. When considering which risks to focus on, it helps to examine the extent to which these Six Ds can occur.

Besides the type of harm that may occur, it is also important to ascertain the type of risk involved. In its report entitled 'Onzekere Veiligheid' (Uncertain Safety), the Advisory Council on Government Policy specifies four types of risks: simple, complex, uncertain and ambiguous.²⁴ In the case of simple risks, the standards which to adhere to in order to control this risk are known, or are relatively simple to establish. In the case of complex risks, the nature of the risk is known, but we first have to obtain additional information in order to understand how to reduce the risk. In the case of uncertain risks, the nature of the risk is still unknown. In the case of ambiguous risks, there is even discussion on the way in which the nature of the risk ought to be interpreted. In 2014 my fellow inspectors Sippie Formsma, Rian Vos, Sylvia Eland and I worked on the question of how the Inspectorate could re-design its Risk-Oriented Regulation. During this process, we compiled a flow chart to show how the Inspectorate could deal with these four different types of risks. It is of foremost importance that the Inspectorate is aware of the type of risk concerned, since each of the four types requires a different regulatory strategy.

Regulatory agencies are increasingly confronted with uncertain and ambiguous risks. As I have already described, these are situations in which it is unclear what risks are involved, and in which there are sometimes even normative discussions on the extent to which these risks are acceptable. In such cases, classic regulatory strategies focusing on sanctioning non-compliance to standards are

not feasible. This is because there are no clear standards, nor is there sufficient information for the regulator to be able to establish a standard. One example of such a situation is regulation of healthcare provided to children living in poverty. Suzanne Rutz, one of my colleagues at the Health and Youth Care Inspectorate who works to the Joint Inspectorate Social Domain, carried out doctoral research on the way in which inspectors cope with this situations.²⁵ In her research, Suzanne describes how 'reflexive regulation' provides guidelines for developing regulatory strategies that take account of the lack of knowledge concerning possible risks and of the fact that this knowledge is in itself also subject to debate. The primary focus in reflexive regulation shifts from the content of a problem to the process for interpreting the problem. In such cases, regulatory agencies do not pose the question: "how can we reduce the risks for children living in poverty?" The question here is: "who can help us understand the risks run by children living in poverty, and what would be the best way to address this issue?".

When defining a specific risk or problem, one should start with the question of whether this risk is a simple, complex, uncertain or ambiguous one. The type of risk involved is the deciding factor in whether the Inspectorate can directly address the question of how it can enhance compliance, or whether it first has to address the question of which actors it should engage to help understand the problem and come up with potential solutions to this problem.

Step 3. Addressee

After the regulator has selected the risk or problem it wishes to focus on, the question arises which actor is capable of reducing this risk . The inspectorate can address his actor, therefore called the 'addressee', to reduce the risk, or can engage the actor in interpreting the risk. In healthcare, the addressee might be a healthcare professional, the management or board of an institution, an association, an interest group, an umbrella organisation, a fellow regulator, or another entity. The art lies in making the correct choice between addressing the actor with the greatest influence and finding a working method requiring as few resources as possible. In other words: achieving the right balance between effort and impact.

During the past years, the Inspectorate has increased its number of addressees in its regulation of nursing homes. In the past, the Inspectorate regarded the board of directors of a healthcare organisation as the major addressee. Since the board bears ultimate responsibility, it seems logical for the Inspectorate to focus its efforts on this entity. In due course, boards of trustees were also involved as addressee, because they fulfil a monitoring role in the board of directors' actions. In their 'Good Management Framework', the Inspectorate and the Dutch Healthcare Authority state that they envisage a significant role for the clients'

participation council in the provision of good-quality client-oriented healthcare.²⁶ Over time, the Inspectorate has gained some experience with a so called 'good management inspection day' in which it engages with a management delegation and staff representatives as well as with the staff council in addition to the previously mentioned actors. The Inspectorate wishes to increase the influence of these groups on organisational improvement. Regarding them as addressees and addressing them as such contributes to their influence. In the past, when the Inspectorate exclusively engaged with the board of directors, this unintentionally restricted the Inspectorate's influence on the desired improvement processes. The Inspectorate has increased its impact by engaging other actors besides the boards, who have influence on quality improvement.

This example of regulating care for the elderly also reveals another mechanism. The Inspectorate can consciously contribute towards creating an addressee who did not previously exist as such. The Inspectorate asked boards to involve their Nursing Advisory Councils (VAR) in their talks with the Inspectorate. At those care homes that did not yet have a VAR, the Inspectorate's request resulted in establishing a VAR or a similar council.

Occasionally, no one sole addressee exists, such as a board with ultimate responsibility, who can be addressed on managing the risk, but responsibility for the risk is distributed among several actors. One example of such a situation is care provided to elderly people still living at home. In many cases this involves various care providers and other actors, who together form a care network around the client. These include for example GPs, pharmacies, home care agencies, municipalities and voluntary carers. The Inspectorate cannot address one sole actor that bears overall responsibility in such cases. In these situations, healthcare quality depends on collaboration among all these actors. Research conducted at the Academic Collaboration for Research on Regulation by the Netherlands Institute for Health Services Research (NIVEL) and Amsterdam Public Health (formerly EMGO) between 2012 and 2016 revealed that in many cases, collaboration in these networks was frequently insufficient.²⁷ The elderly people themselves were generally in control, and risks arose when these elderly people were no longer able to maintain control. In line with the recommendations of this research report, the Inspectorate extended its strategy from supervising individual care providers to supervising collaboration among all these providers. The Inspectorate's 'Integrated Care' team subsequently took the initiative to evaluate the pilot project for this new working method. The results are used to improve this working method further, including the implementation of mechanisms for interim feedback to be given to the Inspectorate by both clients and their care providers.

In other instances, the healthcare provider causing the risk may not be available to be held to account. One example of this is the sale of illegal pharmaceuticals on the Internet. These traders are often unknown or inaccessible to the Inspectorate. The research institution IQ Healthcare conducted research into this at the Academic Collaboration for Research on Regulation.²⁸ The researchers advised the Inspectorate to collaborate with the Public Prosecutions Department (OM), the Fiscal Intelligence and Investigation service (FIOD), Customs and other partners for the purpose of reducing trade in and demand for unreliable pharmaceutical products on the internet. If the Inspectorate is unable to address a care provider or network, it can focus on the care recipient. In the present case, this refers to the consumer wishing to purchase pharmaceuticals on the internet.²⁹

The choice of which addressee the Inspectorate engages has a considerable influence on the potential added value of the Inspectorate's actions.

Step 4. Expected behaviour

After the regulator has decided which actor it intends to engage, the subsequent question is: what does the Inspectorate expect from this actor? In the event of simple or complex risk problems, this generally comes down to compliance of the actor to laws, rules and standards.. Examples of this include whether a manufacturer of a medical product conducts its post-market surveillance compliant with legislation, or whether a nurse adheres to the infection prevention protocols. In cases of uncertain or ambiguous risks, where no standard yet exists, the 'expected behaviour' refers to conduct that contributes towards understanding and/or reducing the risk. Examples of this include whether a director is making sufficient efforts to the potential risks during a merger, or whether a care institution involves the patient's family members in adverse event investigations.

Making it clear what type of conduct the regulator expects is the step that has the greatest impact on the potential added value of regulation. It also involves the greatest risk for regulatory agencies, since an ill-considered choice can unintentionally result in negative effects. If the regulator's judgement of providers' actions can lead to consequences for that provider, this induces the providers to make strategic choices.

Research conducted in the wake of the Stafford Hospital (UK) crisis in 2008 revealed that the gravity of the problems was underestimated due to the 'gaming' of quality data and objectives. The 2013 Berwick report describes this clearly: "If the system is unable to be better, because its people lack the capacity or capability to improve, the aim becomes above all to look better, even when truth is the casualty."³⁰ For example, the publishing of quality data may tempt

healthcare institutions to focus on making this data appear good, instead of on actually improving the way care is delivered. I know of at least one hospital in the Netherlands where this happened when the HSMR was published. HSMR stands for Hospital Standardised Mortality Ratio and refers to the ratio between the actual mortality rate at a hospital and the expected mortality rate on the basis of the patient profiles. A score of 100 indicates that the number of patients who have died is just as expected, while a score of 110 indicates that 10% more patients have died than expected. This might be a sign of problems relating to healthcare quality. The way in which the expected number of deceased patients is calculated involves some complicated arithmetic.³¹ One of the factors that influences the outcome is the number of secondary diagnoses for each patient. A secondary diagnosis is, for example, that a patient has diabetes in addition to cardiac disease. Theoretically speaking, these secondary diagnoses are registered in the patient record. I say theoretically, since this is not always done carefully in practice due to the fact that not all secondary diagnoses are equally relevant for the attendant physician. If these secondary diagnoses are not recorded, they are not taken into consideration in the HSMR, which makes it appear as if the hospital is treating patients with a less complicated medical history than is actually the case. This increases the HSMR score, which makes it appear as if a greater number of patients die than anticipated. When the hospital management realised this, some of them urged their medical staff to be more thorough in registering secondary diagnoses. This led to a situation in which doctors were more or less obliged to fill in secondary diagnoses in some hospitals. This did not improve healthcare quality; the sole object of the exercise was to make the HSMR score appear more favourable and thereby enhance the hospital's image. Since inspectors are very well aware of this type of strategic conduct, they do not regard the HSMR as an absolute factor, but as only one of the many indicators they can discuss with hospital boards.

The situation becomes even more serious if a hospital's strategic behaviour is detrimental to healthcare quality. An example of this is a quality indicator entitled 'unscheduled re-interventions after resection of a primary colorectal carcinoma'. This means the number of times that a patient who has been operated on for colorectal cancer has to undergo an unforeseen secondary surgical procedure. One well-known reason for a secondary operation after this type of surgery is anastomotic leakage. If a tumour is removed from an intestine, the two outer ends of the intestine can be re-attached to one another. But if, for whatever reason, the suture between these two parts of the intestine does not remain intact, the content of the intestines may spill into the abdominal space. This is known as anastomotic leakage, and frequently results in a secondary operation because it can result in life threatening consequences for the patient. The simplest way of preventing this for all patients is not to connect the two ends of the intestine, but to create a stoma. Creating a stoma reduces the likelihood of

having to perform a secondary operation, and therefore has a favourable effect on the hospital's outcome for this quality indicator. However, a stoma can have a negative impact on the quality of the patient's life. In this case, a good outcome for the patient can come into conflict with a good outcome for the hospital. The fact that surgeons were felt judged on the number of re-interventions after intestinal surgery resulted in an incentive to make fewer anastomoses and create more stomas. The regulator has to be able to foresee these types of consequences, or, else has to be able to recognise them promptly. In this case, the undesirable incentive was identified during the biannual meeting of the Inspectorate and the Dutch Society for Surgery. The indicator was adjusted to 'failure to rescue'. This indicator provides insight into the extent to which hospitals are able to identify surgical complications in time and take adequate action. This way, the Inspectorate has implicitly altered the message from 'hospitals must limit unplanned secondary surgical procedures to a minimum' to 'hospitals must identify and treat surgical complications as soon as possible'. As a result, satisfactory results for the patient are once more in line with satisfactory results for the hospital.

When clarifying the desired behaviour, regulatory agencies must always take unintentional side effects of such behaviour into consideration. Regulators must be able to differentiate between actual compliant behaviour and pretending to comply. They must also have measures in place to quickly spot potentially adverse consequences of the desired behaviour. For this reason, it is important to clarify not only the desired behaviour, but also the underlying purpose of that behaviour.

Step 5. Goal of governmental regulation

The ultimate aim of regulation is to create added value. Regulation must make a difference from the perspectives of both patients, professionals, politicians and the public. This added value does not have to be earth-shattering; it could also comprise a modest first step which would not otherwise have been taken, or which might have taken more time to accomplish. The objective does not have to equal the ultimate objective (e.g. 'safe healthcare'). In the same way as in the previous steps, the arts is again achieving the correct balance between effort and impact.

In 2013 I participated in a meeting with the team responsible for assessing hospitals' root cause analysis reports. It was a difficult time for everyone working at the Inspectorate because its functioning had been severely and publicly criticised. We asked each other why we chose to remain with the Inspectorate; the answer was that we all felt the Inspectorate could make a significant contribution to healthcare quality. And this in turn gave rise to the question of what our specific value as the team might be. After all, we were only a small

part of a bigger entity and we had no direct influence whatsoever on healthcare quality. We eventually realised that our potential added value lay in the way in which hospitals investigated adverse events. We were of the opinion that if hospitals carry out adequate investigations into adverse events, this would decrease the likelihood of such events recurring, which in turn would contribute towards improving healthcare quality. With this objective in mind, we adjusted the working method. The focus shifted from assessing the content of adverse events to the process hospitals organised to learn from their adverse events. To this end, we devised new assessment criteria which enabled us to quantify the quality of the adverse event investigation reports and monitor the hospitals' learning capability over time.³² And we saw some hopeful results: the average score for hospitals' investigation reports increased from 6.3 out of 10 in 2013 to 8.5 in 2017. Other effects were even more impressive. For example, we observed that the percentage of reports in which the patient was involved in the adverse event investigation increased in two years from 15% to 70%. The goal we set, that hospitals are able to conduct adequate adverse event investigations, appeared to be attained at the end of 2017. The time has now come to determine the next objective that brings us even closer to our ultimate goal: safe healthcare.³¹

Defining a clear goal is a crucial step in determining the added value a regulator wishes to achieve. This goal must contribute to the quality of healthcare and medical products if it is to create public value. In its current documents, the Inspectorate often refers to its own results as goal, e.g. "ensuring an increase in the number of youth care providers we examined in terms of percentage", or "making more public announcements", or "commencing an investigation", or "developing a risk model for the efficient deployment of inspection capacity". Only one or two goals in the Inspectorate's action plan for 2018 are not focussed on its own results. An example is the department that regulates dental care, who stated as goal encouraging the sector to establish at least two enforceable standards relating to healthcare quality. The Dutch Health and Youth Care Inspectorate is not unique in this respect. Discussions with our international sister organisations revealed that they also have difficulty in expressing goals related to healthcare quality instead of their own organisational productivity. Professor Malcolm Sparrow of Harvard University describes how this works in his book entitled 'The character of harms'.³³ The regulator cites a problem it wishes to concentrate on, but this problem is too big so it is parsed into smaller, more actionable parts. The regulator then designs working procedures in order to tackle these smaller problems, and subsequently devotes all its energy to managing these internal working procedures. These procedures unconsciously become a goal in themselves, which is expressed in objectives focusing on executing the regulator's own working procedures instead of on reducing the original problem. This deviating process is predictable and that is exactly why regulatory agencies have to remain alert to it. This certainly applies to the

Inspectorate and its international sister organisations, since objectives focusing on healthcare quality make it clear to patients, professionals, politicians and the public what the regulator's added value is.

There are four generic goals to strive for as regulator, by which they can contribute to improving healthcare quality. Depending on the type of risk and the phase the sector is in, these goals are:

- Creating recognition for the risk;
- Development of a standard to mitigate the risk;
- Recognition and acceptance of the standard within the sector;
- Increased compliance with the standard.

With "Creating recognition for the risk" I mean all actions that contribute towards an improved understanding of the risk. This includes the many different strategies the Inspectorate can apply for complex, uncertain or ambiguous risks. The subsequent steps can only be used for simple risks. Although the Inspectorate is frequently unable to achieve these four goals by itself, it often does have the capacity to influence other actors in achieving these goals.

Regulators should make sure they define their goal before they initiate an intervention. Not just long-term goals such as 'enhanced healthcare quality', but especially specific goals that can be achieved in the shorter term. A tool that can be of help with identifying short term goals is the 'Driver Diagram'. A driver diagram shows the relationship between the overall aim of a project, the primary drivers (sometimes called "key drivers") that contribute directly to achieving the aim and the secondary drivers that are components of the primary drivers.³⁴ Regulators can demonstrate their added value by specifying regulatory goals, especially when these goals are aligned with the perspectives of patients, professionals, politicians and the public.

Step 6. Intervention

An intervention is any action taken by a regulator for the purpose of achieving its goals. Interventions can focus on individual healthcare providers, manufacturers or distributors. They can also focus on a group, such as umbrella organisations, networks or an entire sector. The Dutch Health and Youth Care Inspectorate's previous long-term policy plans classified the various types of intervention as follows: encouragement, correction, adopting administrative measures, and using punitive or disciplinary measures in the most serious cases.

A large part of a regulator's legitimacy depends on its authority as laid down by law. The Inspectorate's contributions would be just another opinion if it were not for its legal mandate, and it would be powerless without legal authority. Thanks to the possibility to scale up to administrative, disciplinary or punitive measures, less severe interventions can already be effective. The Inspectorate's Legal Affairs Department fulfils a crucial role in making the most out of its legal authority. Interaction between inspectors and legal staff drives the selection of the most effective intervention in accordance with the principles of 'responsive regulation'.³⁵ Responsive regulation means that regulatory agencies always endeavour to apply the type of intervention that achieves the greatest possible impact with the least possible pressure. If the impact proves insufficient, regulators can take the next step up on the scale and continue doing so until the desired effect has been achieved. They can then move down the scale until they observe that the desired effect is diminishing.

In view of increasing attention for learning capability, it is not only important for the Inspectorate to verify whether or not an addressee is adhering to the rules, but it is also important to comprehend why this addressee is able or unable to do so. An understanding of the underlying mechanisms helps in selecting the right type of intervention. Since 2017, the Dutch Health and Youth Care Inspectorate uses the 'Trust Framework' - devised by my colleague Sandra Spronk - to help choose the right intervention in the regulation of healthcare providers.³⁶ This framework helps the Inspectorate to make it explicitly clear why it does or does not trust that a certain healthcare provider is sufficiently capable of providing good quality care. The results of this choice help the Inspectorate to select the most effective intervention for dealing with that particular provider.

I already mentioned that in the past, the Inspectorate classified interventions under the following headings: encouragement, correction, administrative measures and punitive or disciplinary measures. In practice, a potential additional intervention has been discovered: feedback without recommendations. In 2014 the Inspectorate carried out the first pilot project using a new monitoring tool to observe clients in long-term care institutions. This pilot formed part of research into capturing well-being of people with dementia and care providers' handling of their challenging behaviour. With this new monitoring tool, called SOFI, inspectors sat with clients suffering from dementia in their living rooms for 45 minutes in order to observe how these clients experienced the care provided. Since this was a new method, the Inspectorate had agreed with the care institutions that, although the inspectorate would provide the care providers with feedback on the results of its observations, it would not form any opinions based on its observations. The pilot project was investigated by the research institute NIVEL.³⁷ A secondary finding that emerged from the research was that the relevant care institutions had used the inspectors' observations to improve

the quality of the care they provided. In some cases not only at the actual location visited, but also at other locations of the same care institutions. A similar result has meanwhile been observed in the inspections within the social domain. This has resulted in the hypothesis that reporting the Inspectorate's findings to a healthcare provider without formulating an opinion or recommendation might in itself be an effective intervention. This hypothesis fits in with my own experiences with the improvement project at the University Medical Centre Utrecht around 2010. During this project, we filmed care providers during handovers and asked them to watch fragments of the videos we had made. This was incredibly effective, resulting in structural improvements in handovers that would never have been accomplished through external pressure. This method is also used elsewhere under the name of 'video reflection'.^{38 39} To me this is one of the cleverest patient safety interventions I have ever encountered. It's actually quite logical that people are more enthusiastic about working on improvements they themselves have devised than on externally imposed measures. For regulatory agencies, however, specifying a risk without indicating what the party responsible should do about it is counterintuitive. Giving feedback without judgement or recommendations is an intervention that surfaced by chance and that the inspectorate became aware of thanks to research within the Academic Collaboration for Research on Regulation. Currently, the inspectorate is cautiously gaining further experience with this intervention. In my opinion, this is a promising inspection intervention that merits additional research, certainly in the case of uncertain or ambiguous risks.

In line with the generic goals mentioned earlier, there are four generic interventions the inspectorate can use to promote compliance:

- Creating recognition for the risk;
- Encouraging the development of a standard to mitigate the risk;
- Encouraging recognition and acceptance of the standard;
- Monitoring compliance with the standard.

The Inspectorate has to adjust its strategy for each step in order to ensure that the relevant actors join the negotiating table, establish common objectives that all actors can support, and maintain the correct balance between pressure and momentum. The extent to which the Inspectorate can be effective by using encouraging, corrective, administrative, punitive and/or disciplinary measures differs according to each situation. Lack of pressure can result in lack of commitment, while too much pressure can have an adverse effect on the intrinsic motivation. The rules for process management as specified by my PhD supervisor Hans de Bruijn offer useful guidance in this respect.⁴⁰ A translation takes place between establishing a standard and monitoring this standard. In 2016 the Inspectorate - in collaboration with Zorginstituut Nederland

(formerly known as the Healthcare Insurance Board) - commissioned research to be carried out on how healthcare standards are translated into regulatory standards. The results revealed that communication and collaboration with the actors concerned are a decisive factor for the efficacy of this procedure. The direct involvement of all the parties concerned by the Inspectorate, in an open and structured manner, serves to enhance the Inspectorate's transparency and predictability, as well as support for its regulatory activities.⁴¹ If done right, the development process of such an intervention can become a regulatory intervention in itself.

Step 7. Measuring the consequences of the intervention

William Demming's PDCA cycle - Plan-Do-Check-Act - is classic in quality improvement literature and practice.⁴² In regulatory practice, carrying out a 'Check' in order to verify the impact of an intervention is not always customary. The Dutch Health and Youth Care Inspectorate is an exception to this rule. Our European sister organisations regard the Inspectorate with some envy because of the Academic Collaboration for Research on Regulation (AWT) that we have set up in order to conduct scientific research into the effects of regulation. But this could be improved even further. Studying the effects of regulatory interventions should become an integral part any regulatory activity, instead of an independent academic exercise. I envisage a spectrum with a simple check at one end which does not require any scientific knowledge. For example, if the Inspectorate's objective is for the actors concerned to establish two enforceable healthcare quality standards, the test will consist of determining whether these two standards have in fact been established. The research conducted into complex and ambiguous regulatory issues is at the other end of the spectrum. For these issues, the Academic Collaboration for Research on Regulation provides the infrastructure to perform research in a multidisciplinary approach within various theoretical frameworks: epidemiological, legal, socio-scientific and administrative. One example of this is the AWT's umbrella project on regulation in uncertainty, led by Kor Grit, which examined how the Inspectorate can operate in situations where there is a lack of clarity in respect of the risk, the standard or the addressee.⁴³ I have included many of the results from this research in this inaugural lecture.

In some cases, an issue appears to be simple at first sight, but closer examination reveals an underlying layer. More in-depth research is then required in order to really understand the consequences of the intervention. One example of this is the inspectorate's intervention to encourage care institutions to involve patients or their families in the investigation of serious adverse events. The Inspectorate works with a PDCA cycle in this example. The idea was to encourage patient involvement through feedback on adverse event investigation reports. This was carried out in the regulations of hospitals from mid-2013.

When assessing the adverse event investigation reports, inspectors check whether the patient was involved in the investigation. If the patient was not involved, the inspectorate sends the hospital board a letter stating that they must engage the patient in future adverse event investigations. There is a plan carried out by the inspectorate, the inspectorate continually checks the results and, and subsequently acts upon them. This way the PDCA cycle is completed.

The Inspectorate saw that the percentage of reports stating that the patient was involved increased from 15% in 2013 to 80% in 2017. This is an example of a check at the easy end of the research spectrum. However, there is a great deal more to explore behind these percentages. The inspectors discovered that the way in which patients were involved differed from one hospital to another, and that the new working method could have unintentional consequences at certain hospitals. Research into the consequences of the policy requires expertise, time and qualitative research methods that are not available at the Inspectorate. For this reason, ESHPM doctoral candidate Josje Kok was asked to carry out research on this topic. Her research revealed that only a few hospitals have succeeded in maintaining a balance between patients' viewpoints and those of the healthcare professionals. Or, to put it more simply: the majority of hospitals regard patients' input as the final phase of the research. They can only process this input if it fits in with input from their own staff. So the answer is Yes, patients are involved, but at the same time it is No, their involvement does not lead to patients' input being regarded as equal to the input of healthcare professionals. This is relevant for the Inspectorate, since it helps to devise a new intervention to improve patient involvement further.

In order to argue the added value of regulation, the consequences of the regulator's interventions must be made visible. Research can help achieve this. The type and complexity of the research can differ from case to case; basic wherever possible, in-depth wherever necessary. For the Inspectorate, this means that inspectors have to be able to make the results of their work visible themselves. In cases where this is more complex or where it takes more time than is available, the Risk Detection & Development Department can provide support. And if thorough scientific research is required, the Academic Collaboration for Research on Regulation enters the picture.

Step 8. Disseminating the results of the intervention

Malcolm Sparrow summarises the regulator's work as follows: find a problem, solve it and tell everybody. Stephan Grimmelikhuijzen of Utrecht University investigated the best way for government institutions to communicate their policy.⁴⁴ In collaboration with Femke de Vries and Wilte Zijlstra of the Dutch Authority for the Financial Markets (AFM), he investigated how communication on the part of the AFM affects public confidence in the AFM. From this research, it emerged that it generates greater public confidence if the AFM informs the

public *why* it came to a certain decision, that *how* it came to that decision.⁴⁵ In 2017 the Health and Youth Care Inspectorate replicated this research in collaboration with the AFM and the Education Inspectorate. This research showed that it does not make much difference *how* the Health and Youth Care Inspectorate communicates, as long as it *does* communicate.⁴⁶ Communicating on the Inspectorate's work helps to increase public confidence in it, even if it communicate that it is adopting a 'wait and see' attitude towards a high-risk situation.

It is likely that communication also influences the perceived added value of the Inspectorate. If patients, professionals, politicians and the public are unaware of what the Inspectorate accomplishes, they will not be able to form a substantiated opinion on its added value. And this brings us back to the beginning of this inaugural lecture. Before I started working at the Inspectorate, I had hardly any idea of what the inspectorate achieved. As an outsider, I erroneously assumed that the Inspectorate's main task was to hand out penalties, and I doubted whether this contributed to improving healthcare quality. The Inspectorate's communication strategy has changed substantially since that time. The way in which it currently interacts with the public very different to seven years ago. The Inspectorate's Communications Department fulfils a major role in helping people understand what the Inspectorate does, and why. But this department also plays a role in the regulatory interventions. Communication has a performative function: it not only specifies the reality, but it can also change it. One example of this is a publication in the 'Medisch Contact' medical journal, in which the Inspectorate wrote that the percentage of hospitals providing peer support to staff who had been involved in a serious adverse event increased from 40% in 2014 to 80% in 2016. This not only described the reality, but it also changed this reality. From that time on, offering peer support was no longer an option, but it had become part of high-quality care provision.⁴⁷

Communication on the effects of regulation is the final component in each regulatory strategy. It not only fulfils an informative function, but it is also an intervention in itself. It can contribute to public confidence in regulatory agencies and to compliant behaviour of professionals.

This finishes my demonstration of the eight steps of the model.

Summary and impact on the Chair

Regulation is a team sport, both within the regulatory agency as outside of it. Internally, collaboration is essential between inspectors, the Helpdesk, the National Helpdesk for Customer Concerns, legal staff, policy support staff,

researchers and communication experts in order to design and communicate regulatory policy in such a way as to make its added value clear to patients, professionals, politicians and the public. This collaboration depends upon organisational support from managers, supervisory staff, HR, finances and many more. By collaborating with external actors such as umbrella organisations, scientific societies, insurance companies, Zorginstituut Nederland and fellow supervisors, the Inspectorate enhances the reach and impact of its efforts. The Inspectorate plays its role within a continually developing society. Ensuring that its regulatory activities stay in sync with societal developments requires a great deal of effort on the part of the Inspectorate and its staff. New regulatory strategies sometimes require new skills for inspectors. The Inspection Academy has already demonstrated its ability to fulfil a supportive role in this respect. The Inspectorate is developing into a learning organisation, and evaluating its own actions is becoming increasingly normal. By showing its added value the Inspectorate can increase the trust within society in both the regulator itself and in the quality of youth care and health care.

In this inaugural lecture, I have endeavoured to give you an insight into the tremendous variety of issues that the Inspectorate regulates. I have argued that the public value of governmental regulation of healthcare quality and safety is determined by four perspectives: those held by patients, professionals, politicians and the public. I have specified eight steps that are essential in order to attain added value:

1. Explicitly clarifying the regulator's overarching mission;
2. Defining the risk or the problem to focus on;
3. Determining which actors the regulator can address;
4. Determining what is expected from this actor to decrease the risk or problem;
5. Clarifying the goal of the expected behaviour;
6. Design and execution of an intervention to achieve this goal;
7. Assessing the consequences of the intervention;
8. Disseminating the results and the lessons learned.

As the holder of this Chair, I will make every effort during the coming years to help the Inspectorate achieve continuous improvement in following these steps. Science can help the Inspectorate to make unconsciously applied strategies perceptible, to develop new strategies, and to improve its communication of the public value of regulation. This way, the Chair will contribute to the development of evidence-based regulation. At the same time, this Chair will contribute to embedding the practice of regulation in the research and educational programs of Erasmus School of Health Policy & Management. I regard educating the current and future leaders of the healthcare sector in the Inspectorate's role as a supervisory intervention in itself. This will result in improved mutual

understanding and thereby in more effective regulation. My predecessor, Professor Paul Robben, has laid a solid foundation for this Chair and I am grateful that I have been granted the opportunity to build on this further. In a few years' time, I can look back with satisfaction if my successor finds him- or herself in a situation in which demonstrating the public value of regulation is a normal part of the Inspectorate's activities. After all, whatever course of action the Inspectorate adopts, the creation of public value is the ultimate 'proof of the pudding'.

Conclusion

Medicine is humanity's epic battle against nature. We carved caves out of mountains to protect ourselves from the wind, we made fires to protect ourselves against the cold, and we created healthcare to protect ourselves against pain, illness and death. Respectful of the limited role regulation has, it can and must contribute to this overall goal.

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Ian Leistikow is endowed professor at Erasmus School of Health Policy & Management on behalf of the Dutch Health & Youth Care Inspectorate. He is a non-practicing physician and combines his work at the Inspectorate with a research at Erasmus University into the effect of governmental regulation of healthcare quality and safety.

During the past decades, our society has attached increasing importance to governmental regulation of healthcare quality. Today, the Health and Youth Care Inspectorate is firmly and visibly positioned at the heart of Dutch society, which means that the Inspectorate must be able to demonstrate its public value.

In his inaugural lecture entitled 'The proof of the pudding', Professor Ian Leistikow examines ways in which the Inspectorate can face this challenge and design regulatory interventions that create public value. He argues that the public value of governmental regulation of healthcare quality is determined by the perspectives of both patients, professionals, politicians and the public.

Professor Leistikow introduces a model comprising eight steps which endeavours to connect scientific knowledge on regulation with the practical reality of inspectors' everyday work. Its purpose is to serve as a guideline for designing regulatory strategies which contribute to healthcare quality and safety. By showing its added value the Inspectorate can increase the trust within society in both the regulator itself and in the quality of youth care and healthcare.

Erasmus University Rotterdam
Erasmus School of Health Policy & Management
Bayle (J) Building
Burgemeester Oudlaan 50
3062 PA Rotterdam, the Netherlands
T +31 10 408 8878
E communicatie@eshpm.eur.nl
W www.eur.nl/eshpm