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1. Introduction

Although many governments use external inspections to assess the quality of care, the actual effect of these inspections remains debated (Allen et al., 2020). Hovlid et al. make an important contribution to the scholarly knowledge on how external inspections can have positive impact on healthcare quality, which they define as: "improved clinical care after inspection" (Hovlid et al., 2022). Their study provides insight into how inspections do, or do not, contribute to this outcome and how this could be improved. The empirical findings presented by Hovlid et al. build on, and strengthen, earlier research showing how regulators can play a role in recoupling practice and intended outcomes within healthcare organizations, thus promoting healthcare quality (de Bree and Stoopendaal, 2020). For this, they argue, "there must be contextual structures present supporting accountability and engaging staff in improvement work." The regulator can then "hold the inspected organizations accountable for continuously assessing whether care is delivered in a way that produces the intended outcomes for the patients." Although the choice for 'improved clinical care' as measure of impact is understandable, it excludes a variety of other outcomes that could arguably also be considered as 'impact on quality of care'. In this commentary we will consider these other outcomes by reflecting on how regulation of healthcare quality can create societal value, and how external inspections – as one of the many possible regulatory interventions - can contribute to this.

Based on the scholarly literature and our experience in both designing and researching regulatory policy and practice at the Dutch Health and Youth Care Inspectorate, we developed and use a framework for 'value driven regulation'. We will use this framework to reflect on Hovid et al.'s findings and discuss the potential effects of external inspections. We will conclude with some suggestions for future research on the effectiveness of regulatory interventions.

2. Characteristics of regulation and regulatory object

Regulation means different things to different people, with definitions varying according to professional discipline, political ideology and even geography (Levi-Faur, 2011). The diverse definitions of regulation (see Fig. 1) distinguish four key characteristics. First, there is a societal value for which behavior by individuals and organizations must be influenced and (structurally) monitored (Black, 2002; Selznick, 1985; Walshe and Boyd, 2007). Second, there are standards reflecting what needs to be done to achieve the desired societal value (Black, 2002; Windholz, 2017). Third, there are one or more addressees that have influence on the societal value and can be influenced by a regulator (Selznick, 1985; Black, 2002; Windholz, 2017). And fourth, there is a regulatory agency with a mandate to exercise control on behalf of society (Windholz, 2017; Walshe and Boyd, 2007). In summary, regulation is defined by the combination of societal value, standards, addressees, and an organization mandated to influence addressees to uphold the standards needed to realize the intended societal value. See Tables 1 and 2.

The intended societal value constitutes what is also called the 'regulatory objective' (de Kam, 2020), which is what the regulator ultimately tries to contribute to. But this objective in itself does not provide guidance for regulatory policy as it is usually stated in rather broad

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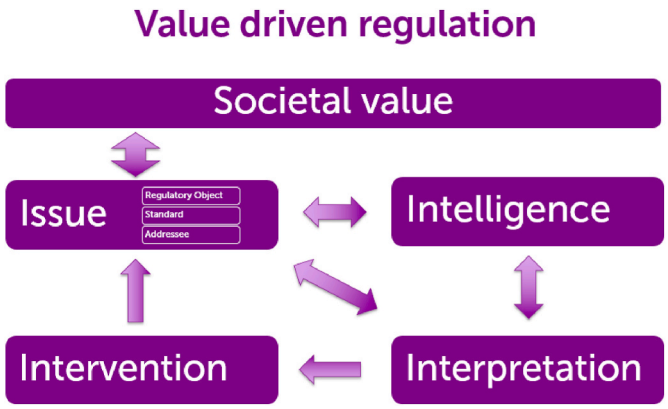

Fig. 1. Value driven regulation.

Table 1
Definitions of regulation.

sustained and focused control exercised by a public agency over activities that are valued by a community Selznick, P. (1985).
the sustained and focused attempt to alter the behavior of others according to defined standards and purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standardsetting, information-gathering and behavior-modification Black, J. (2002)
those cases where an agency, in the public interest, has been granted centralized powers to act as a third party to transactions or inter-organizational relationships. Walshe (2003).
A structured process undertaken by or under the auspices of government designed to modify the behavior of persons or entities according to defined standards Windholz, EL (2017)

Table 2
4 defining characteristics of regulation in the context of health and care provision.

Societal value	That what is deemed of value by the user (patient, resident, etc), the care provider (professional, manager, organization etc), the government (national, local, municipality etc) and/or the community (local, regional, national). The regulator must weigh all these four perspectives when considering what is of value to regulate.
Standards	That what (should) guide the providers behavior, e.g. legislation, professional standards, ethical/moral standards, Hippocratic oath, norms etc. Not all standards are written documents and standards can change over time.
Addressees	Those who have influence on achieving the societal value, e.g. care providers, users, professional educators, payers, insurers, interest groups, media etc. Not all addressees are regulatees.
Regulatory agency	The organization mandated to regulate, bounded by legal forms, powers, funding, governance, relation to government etc.

terms such as 'good quality of care', 'ensuring safety', or 'expanding accountability'. As De Kam explains, based on the work of Dahler-Larsen (2019): "the regulatory objective of quality and safety in healthcare needs to go through a series of translations before it might mobilize or regulate the behaviour of others." That is, in order for a regulatory objective to become inspectable, it needs to be translated in "a particular quality issue as the (legitimate) object of regulatory scrutiny." (de Kam, 2020) A 'regulatory object' is the operationalization of a specific aspect of a regulatory objective. This operationalization sometimes also provides for a standard and an addressee. For example, if the 'objective' is that providers should learn from their mistakes, the 'regulatory object' could be 'the extent to which adverse event analysis reports show that providers are learning'. This object then needs further translation into a regulatory instrument with which the regulator can monitor and influence the desired behavior. In line with the previous example, this could be a checklist to score items in adverse event reports that reflect learning. Regulatory objects and instruments together mobilize quality agents, the people that realize the desired change within regulated organizations. It is through the actions of these quality agents that a regulatory instrument ultimately affects healthcare quality (de Kam, 2020).

This can be illustrated with the empirical findings of Hovlid et al. (2022). Take for example the six case studies they used regarding treatment of sepsis. One could describe the regulatory objective as "healthcare services should be safe and effective and provided in accordance with sound professional practice." This can be further specified in a regulatory object (adequate antibiotic treatment for patient with sepsis), a standard (administration of antibiotics within 1 h) and addressees (hospital board and staff). In case-study 7, for example, the hospital employees that gathered performance data and made this accessible to clinicians and managers could be seen as the 'quality agents'. The translation of regulatory objective into regulatory object offers the regulator guidance for a regulatory strategy: it could monitor and/or promote that the hospital board and staff make sure patients with sepsis are administered antibiotics within 1 h. But it also shows that the regulator could make other choices: it could choose between monitoring, promoting and enforcing, it could choose another element than timeliness from the professional sepsis guideline to focus on and it could address the board only or (also) address other actors within the hospital organization. For example, instead on focusing on the question whether antibiotics are administered within the specified time-frame, the regulator could define the regulatory object to focus on the process through which the hospital organizes and monitors the correct administration of antibiotics.

Besides the options a 'regulatory object' creates for the regulator, there is also another mechanism that should be considered when understanding the dynamics described above: so-called 'performativity'. This refers to how instruments meant to describe a reality can come to shape that reality (Law, 2009; MacKenzie, 2007). Instruments can 'perform' (MacKenzie, 2007) or 'constitute' (Dahler-Larsen, 2013) social realities. For example, when the regulatory instrument used to score the quality of adverse event reports includes an item on 'patient engagement', the engagement of patients can start to be perceived as essential for good adverse event analysis and maybe even for healthcare providers' learning capacity. This then becomes a new reality and quality agents will be set out to comply to this new reality. Performativity can be used intentionally, as it might be in the former example, but is often unintentional and hard to detect. In a study on patient engagement during incident investigations, we for example found that whereas most hospitals changed their practice to accommodate this, the majority did so in a rather tokenistic way (Kok et al., 2018). Performativity thus can have both positive and negative impact. An further example of a negative impact from Dutch healthcare is how surgeons performed more colostomies in response to a national quality indicator on 'unscheduled re-interventions after resection of a primary colorectal carcinoma' (Leistikow, 2018). A frequent reason for re-intervention after this type of procedure is anastomotic leakage. By creating a stoma, instead of an anastomose between the two parts of the colon where the tumor was removed, surgeons eliminated the chance of anastomotic leakage and thus diminished the risk for re-intervention. The indicator, meant to improve surgical colorectal care, was interpreted by some surgeons as a call to reduce anastomotic leakage. This created a new reality in which colostomies became 'good care', unintentionally impeding the regulator's intention to improve healthcare quality. If the Dutch Health and Youth Care Inspectorate had not consulted the Dutch Society for Surgery to help interpret the indicator data, this unforeseen effect would have probably remained invisible for the regulator (Leistikow, 2018). Once it did become visible, the indicator was changed to 'failure to rescue'.

To summarize: for a regulator to have impact on a societal value, this value first needs to be translated into a regulatory object with one or more standards and addressees. Thus, the primary question in the

development of any regulatory policy is: WHO should be doing WHAT to achieve WHICH societal value. Answering this question might seem straightforward but is in our experience arguably the most difficult challenge for a regulator. Addressees can be hard to identify (e.g. who has the informal power to really drive change), standards can be ambiguous or contested (e.g. what exactly is 'sepsis') and values can differ between actors (e.g. relative importance of timely sepsis treatment in relation to other life-threatening diseases presented at the emergency room) and be subject to change (e.g. increased attention for safety of personnel during the pandemic). On top of this, the regulatory policy and practice that is developed in line with this answer, can lead to unforeseen consequences compelling the regulator to reconsider its policy or practice. Regulatory reflexivity is needed to continuously assess whether the answer formulated yesterday is still applicable today, and whether the regulatory policy and practice it ensues remains beneficial to the intended societal value.

3. Choosing a regulatory intervention

When the regulator has defined its regulatory object, standards and addressees the follow-up question is HOW the regulator can monitor and influence these. Hood et al. (2001) state that any risk regulation regime must contain at least three components: (1) information gathering, (2) standard-setting and (3) behavior modification. The legal mandate to set standards, in the sense of creating standards and/or deciding which standards apply, differs per regulator. But all regulators use standards to assess whether regulatee behavior contributes to the aspired societal value (Kok, 2021).

Based on the scholarly literature and our experience in both designing and researching regulatory policy and practice at the Dutch Health and Youth Care Inspectorate, we identify four components that interact to create a regulatory policy. We refer to these as the 4 I's: Issue, Intelligence, Interpretation and Intervention. For a regulator to achieve societal value, it must first define the 'Issue' it wants, needs, or is expected to focus on. The Issue derives from the aspired societal value and is the combination of regulatory object, standards and addressees. In other words: WHO should be doing WHAT to achieve WHICH societal value Next, the regulator uses a regulatory instrument to gather data with which it can inform itself on the status of this Issue. But data is not the same as information. Information is created by giving meaning to data. Because gathering data and giving meaning to data are two different activities, requiring distinct strategies and competencies, we set them apart in 'Intelligence' and 'Interpretation'. Intelligence refers to all forms of data, quantitative and qualitative, that the regulator has or can get access to. Examples of Intelligence are complaints, performance indicators, financial data, adverse event reports or data gathered during inspection visits. Without Intelligence, a regulator cannot inform itself on the Issue. To make sense of this Intelligence, it must be interpreted along the lines of available standards. Based on this interpreted intelligence, the regulator then applies 'Interventions' targeted at the addressee, for example enforcement, to modify addressee's behavior in regard to the Issue. By monitoring and Interpreting the Intelligence gathered after the regulatory Intervention, the regulator can establish its effect on the Issue, and thus on the underlying societal value. This enables regulatory reflection, which can lead to a further round of defining the Issue, what type of Intelligence should be gathered, how this should be Interpreted etc. In practice, the four components not only interact in a circular sequence of first Issue, then Intelligence, then Interpretation, then Intervention and then back to Issue. They also interact with each other in other ways. While gathering Intelligence, the regulator can come to redefine the Issue, for example because certain Intelligence is unavailable thus forcing the regulator to focus on another value, standard or addressee. Interpretation of data can prompt the regulator to gather other forms of Intelligence, for example when it learns that the gathered Intelligence insufficiently reflects the Issue. Or it can prompt the regulator to redefine the Issue, when for example it learns that the chosen addressees have little impact on the societal value. The Issue also directly influences the way Intelligence is Interpreted, as this interpretation is based on the 3 elements on the Issue (regulatory object, standards, addressees). See Fig. 1.

Although only the Interventions are specifically designed to influence addressees' behavior, the other three elements – defining the Issue, gathering Intelligence, and Interpreting the data – can also influence addressees. For example, by announcing which data the regulator will gather, it can already influence regulatee behavior to improve the care processes reflected in this data. For example, as we found in a study looking at the role of inspection frameworks, the publication of these frameworks (the 'regulatory instruments') already had an effect on some addressees before the regulator had undertaken any formal 'intervention' (Weenink et al., 2021). Of course, these effects include unintended behavior, like 'gaming' the data to make a good impression on the regulator, as we described above in the example of the surgical indicator. This influence also calls for reflexivity of the regulator, as it can impact its intended effects.

The iterative and reflexive (re)design of the 4 I's - Issue, Intelligence, Interpretation and Intervention - can be called 'Value Driven Regulation', as the driver behind the regulatory activities is always the aspired societal values and the regulator's contribution to these values. See Tables 3 and 4 and Fig. 1.

4. Theoretical underpinning of value driven regulation

The concept of Value Driven Regulation is based on a combination of existing theories on regulation. The three components Intelligence, Interpretation and Intervention fit with the notions of (really) responsive regulation, risk-based regulation, smart regulation and system-based regulation (Ayres and Braithwaite, 1992; Black and Baldwin, 2010; Stoopendaal et al., 2016). The regulator interprets the intelligence it has on regulatees to develop an intervention that is best suited for the specific situation, and then adjusts that intervention as compliance increases or decreases or when unintended effects come to the fore. For Value Driven Regulation, achieving compliance is not a goal in itself, and is always critically appraised in its relation to the intended societal value. Although responsive regulation is "less interested in rule-compliance than in pursuing the reason behind the rule" (Baldwin and Black, 2007: 17) and really responsive regulation adds to this by also taking, amongst others, the broader institutional environment and regulatory logics into account (van Erp et al., 2020), these approaches do not question the rule, in other words the 'standard', itself. Value Driven Regulation adds to these approaches by not just pursuing the reason behind the standards, but also questioning whether this reason still contributes to societal value. And while these approaches focus on influencing the regulatee, Value Driven Regulation broadens the regulator's toolkit by considering all addressees that could influence the societal value, independent of their relationship with the regulator. Value Driven Regulation not only helps regulators consider how to best achieve compliance but offers a framework which broadens its options and keeps the intended societal value at the heart of the regulatory policy and practice.

Table 3
The 4-Is model of Value Driven Regulation.

Issue	The aspect of 'WHO should be doing WHAT to achieve WHICH societal value' that the regulator sets out to influence
Intelligence	Data which can help understand the Issue, e.g. notifications from users, inspection outcomes, quality indicators, financial data, adverse event reports, media items, 'soft signals' etc.
Interpretation	The process of making sense of the data, often by assessing data along the lines of a standard
Intervention	A deliberate action (or inaction) by the regulator aimed at positively influencing the Issue, e.g. informing the public, addressing providers directly or through media, announcing inspection themes, enforcement, influencing legislation etc.

Table 4
Examples of value driven regulation.

4-I's model – practice examples		
	Acute care	Long-term care
Issue	Hospitals should administer thrombolysis within 1 hour to stroke patients	Community care providers should have up-to-date care plans for every client to ensure client-centered care.
Intelligence	'Door-to-needle time', gathered via national quality indicator system	Reading care plans, interviews with community nurses and clients during inspections.
Interpretation	Percentage of patient treated within 1 h for each hospital is assesses in collaboration between regulator and national society of neurologists, to help put data into context	Clients' current needs and wishes should be reflected in the care plans.
Intervention	Public reporting of individual hospital outcomes and dialogue between inspector and hospital board in case of deviant outcome	Communication to the sector that the regulator will monitor care plans during inspections. Dialogue between inspector and provider on quality of care plans assessed during inspections. Enforcement measures when quality is assessed as substandard.

Value Driven Regulation also builds on aspects of 'reflexive regulation'. As in reflexive regulation, Value Driven Regulation is characterized by learning of all stakeholders, including the regulatory agency itself, by applying a continuous reflection on options for improvement, especially when knowledge is lacking or routines are taken for granted (Rutz, 2017). Value Driven Regulation moreover builds on the concept of 'experimentalist governance'. Governance processes may be considered experimentalist when "they systematically provoke doubt about their own assumptions and practices; treat all solutions as incomplete and corrigible; and produce an ongoing, reciprocal readjustment of ends and means through comparison of different approaches to advancing common general aims." (Sabel and Zeitlin, 2011). Although this can be the case in Value Driven Regulation, it does not have to be. There are values which do not call for systematically provoked doubt, for example the value that one can only practice dentistry after completing the educational curriculum for dentistry.

Value Driven Regulation positions the regulator to question the assumption that the standards it oversees adequately reflect societal value. It keeps regulators alert that compliance is a means to an end, not a goal in itself. But it does not call for a devaluation of the concept of standards. Standards remain crucial for high quality care and the regulation thereof, as essential element of the 'Issue', although the way standards are formulated may range from fixed to open and everything in between.

Value Driven Regulation creates options for the regulator to add value in situations where there is dissent or uncertainty regarding the societal value, the standards or the addressees. Take, for instance, the case of 'integrated care'. This notion refers to care provided to a person by multiple providers e.g., a vulnerable older person living at home who receives care from her general practitioner, community nurse, physiotherapist, pharmacist, and internal medical specialist at the hospital. Classic regulatory regimes are aimed at each individual provider. But although each may comply to their own quality standards, this does not always lead to overall quality of care. And although some of such integrated care processes, e.g. for diabetes, have standards that can be used as a starting point for regulation, for many situations, e.g. multimorbidity or vulnerablility, standards are lacking. The problem for regulators is often that they only have a mandate to regulate individual healthcare providers or professionals, not networks, and when there are no clear standards available, regulation becomes even more of a challenge. The Dutch Health and Youth Care Inspectorate, like many similar regulators around the world, aims to develop a regulatory policy that can positively impact the quality of integrated care for these groups of patients nonetheless. In many Dutch regions, networks exist of health and care providers aimed at aligning and improving integrated care. Value Driven Regulation would encourage the regulator to engage with such a network and assess to what extent the participants agree on the societal value their collaboration is aiming at, the behavior they expect from each other ('standard') and who can be addressed to help achieve the network's aims ('addressee'). The regulator should realize it cannot answer these questions itself but can question the answers participants give. It could, for example, question why there is no user engagement in the network ('are the right addressees involved'). The regulator can encourage a dialogue between participants on these issues and the 'shadow of hierarchy' (Héritier and Eckert, 2008) due to its regulatory relationship with some participants, will help make such a dialogue less non-committal. Once consensus has been reached, the regulator can shift to the 4-I's model to monitor and influence the quality of the integrated care. But, depending on the 'maturity' of the network collaboration, it could also encourage the network itself to gather intelligence on their actions, interpret this data together and develop interventions to improve their efforts towards creating societal value. In that case, the regulator can take a step back and switch from outcome-oriented regulation to process-oriented regulation (Gilad, 2010).

5. Role of inspections

External inspections are just one of a wide range of tools a regulator can apply to address an Issue, gather Intelligence and Influence regulatee behaviour. In an earlier study, Hovlid et al., referring to Walshe, defined external inspections as "a system, process or arrangement in which some dimensions or characteristics of a healthcare provider organisation and its activities are assessed or analysed against a framework of ideas, knowledge, or measures derived or developed outside that organisation." (Hovlid et al., 2017) An inspection is always focused on one specific regulatee. The inspection can be performed from the regulator's office, e.g. a 'desk inspection' based on data, but is most often a face-to-face encounter between an inspector and a regulatee. Inspections can help (re)define the Issue in situations where either the societal value, standards and/or addressee are ambiguous or contested. In Hovlid et al.'s (2022) case-study 10 there was disagreement about the relevance of a guideline for the assessment of psychiatric patients. Societal value (assessment of patients is important) and addressee (hospital leaders and clinicians) were uncontested, but the standard (guideline) was. This disagreement can be interpreted in two ways: 'the regulatee is not compliant to the standard', or 'the standard might not fit the context of the regulatee'. The first interpretation will lead to the regulator using its influence to enhance compliance, for example through interventions within the pyramid of 'responsive regulation' (Ayres and Braithwaite, 1992). The 'standard' in this case remains unaltered. The effect of these regulatory interventions will be determined by the increase in regulatee compliance or in practitioners gaming the system, and probably a combination of both. The second interpretation will lead to a reassessment of the standard. Development of new standards, or a shared understanding of how to interpret an existing standard, could be a measure of an effective regulatory intervention in these cases. In both situations an external inspection could be the intervention of choice, but the measure of effect of these inspections would be quite different.

6. Establishing the impact of inspections

From the perspective of Value Driven Regulation, 'improved clinical care after inspection' would be just one of many possible measures to determine the effect of inspections. The measure of impact depends on what issue the regulator aims to influence with its inspections. Although

improved clinical care is arguably always the end goal, in many cases this will be hard to establish. As Hovlid et al. (2022) point out, contextual structures supporting accountability and engaging staff in improvement work are essential facilitators in achieving visibly improved clinical outcomes. If these essential facilitators are not present, regulators can still have positive impact on healthcare quality, by redefining the Issue it wants to influence, in this case defining the standard as 'developing these facilitators' instead of e.g. 'administration of antibiotics within 1 h'. When the facilitators are in place, the regulator can again redefine its Issue to focus on clinical outcomes, or it can focus on making sure the healthcare provider does.

Hovlid et al. (2022) suspect that the "mixed findings in the research literature regarding the effects of inspections reflect that inspections are complex interventions used in varying contexts, and that the underlying mechanisms of change are poorly understood." We agree and would add that in our experience regulators often poorly define the Issue prior to engaging in a regulatory activity. When it is not clear to the regulator what concrete interpretation of a societal value they are striving for, and when there is insufficient reflexivity to adapt how they gather and interpret intelligence and design interventions to best attain this societal value, it will be hard to impossible to have a positive impact, let alone demonstrate this in research. The concept of Value Driven Regulation can help regulators remain relevant by ensuring that its policy and practice remains firmly focused on creating societal value. For researchers, it can help understand how regulation and its specific interventions impact quality of care. Future research into the impact of regulation in general, and external inspection as regulatory intervention, can build on and further improve the concept of Value Driven Regulation. These could include evaluations of specific regulatory programs, or research into the how the model can be implemented in practice. Further research could also focus on the ways in which different regulatory agencies interact concerning complex problems in relation to vulnerable groups who often experience multiple problems (i.e. concerning quality of care, housing, financial debt, etc.). Moreover, research could be focused on procedures through which contested societal values can be translated into regulatory objects, taking different perspectives into account. Whereas we have already learned quite a bit on how regulation can impact on societal values—and the Hovlid et al. paper again adds to this—there is still much work to do.

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