Measuring the effects of regulation on the quality of health services: Developing a conceptual framework for evaluation.

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Abstract

In its attempts to assure citizens of the quality and safety of healthcare, governments have responded by introducing and maintaining healthcare regulation for three areas: healthcare professionals, healthcare markets and institutions providing healthcare services. This paper takes a closer look at the objectives of institutional regulation of healthcare services by describing and reviewing the main theoretical and empirical evidence.

Regulation covers a wide range of interventions and can be viewed as an attempt by governments to direct events, activities and behaviours through directive measures (standards, targets, guidelines, etc), surveillance or assessment of the levels of compliance (through audits, inspections, etc.), and enforcing compliance (through sanctions, penalties and rewards). The objectives of healthcare regulation are generic and range from protecting citizens to improving quality of public service delivery. Regulation aims to both deter particular actions and behaviours and encourage compliance with desired actions and behaviours.

Based on the review of the available evidence, this study proposes a conceptual framework to describe and analyse three components of healthcare regulation:

- Regulatory approaches deployed by the regulator;
- Interaction between regulator and the regulated;
- Outputs and outcomes of healthcare regulation

The paper concludes that a number of assumptions are prevalent in the literature and practice of healthcare regulation that require further exploration:

- The design of a regulatory system is an articulation of a clear and coherent vision and can be viewed as the result of a rational decision making process;
- There is a justifiable trust in the reliability and validity of the regulatory approaches;
- The objectives of regulatory approaches can be clearly articulated, agreed and amenable to measurement.

The paper calls for further reflection on what works within the institutional healthcare regulation and to explore why particular actions, behaviours, activities and roles work better in what context. The paper proposes a new conceptual framework which can be used to explore the assumptions underpinning the regulation of healthcare services.
‘The surprising truth is that when regulators do manage to focus their attention on thorny, persistent and specific problems, and when they devise interventions that work, we often applaud such work as if it were not expected’ (Sparrow, 2000, p. 9).

1. Introduction

One of the central concepts within the study of public service delivery is the notion that it should deliver the greatest benefit to the maximum amount of people. Measuring these benefits and the actual performance of public services has taken up an increasingly prominent role in debates and discussions on the planning, management and delivery of services in Ireland and abroad (OECD, 2006, 2008). One important element in these debates and discussions has been the role and function of governments.

Over the last two decades the notion of a small government with a separation between the delivery or administration of public services and strategic oversight and policy development role has gained influence across the world. The term New Public Management is frequently used to describe this political vision of the government’s role moving away from directly providing public services to a more strategic oversight role. The often used analogy to describe this process is that governments should primarily ‘steer’, rather than ‘row’ (Lewis et al, 2006). Historically this process of New Public Management has exercised a big influence on the traditional government controlled and delivered public services, such as transport, telecommunication, broadcasting and energy. More recently, many governments have targeted other sectors, such as healthcare, social services and education. However, with the introduction and implementation of a vision of New Public Management new challenges have emerged as ‘steering’ can often be as challenging as ‘rowing’. The challenges that governments often are confronted with relate to finding the most effective mechanisms that can be employed in order to achieve the greatest benefit to a maximum amount of people. This paper will explore some of these challenges within the context of healthcare regulation.

In addition to an increased focus on the performance from within governments and the public services, changing societal values, along with rising expectations have also had implications for public services. The public increasingly demands results and the productivity of the public sector has come under increased scrutiny.

One of the ways in which various governments around the world have provided oversight over the quality and performance of public services and assurances to the public has been through a range of regulatory interventions (Walshe and Boyd, 2007). Regulations often exist because governments aim to abate or control a (real or perceived) risk to society through regulation (Sparrow, 2000). In the healthcare sector, governments have established regulatory systems to not only control compliance with legislation and standards to protect individuals and communities from harm but also to improve the quality of services (Scrivens, 2007). Walshe and Shortell (2004) make a distinction between regulation that was developed as a consequence of market failure or in response to changing social needs. The first type of regulation can be described as economic regulation whereas the second type of regulation can be classified as social regulation. Social regulation is also used to achieve wider social goals — equity, diversity, or social solidarity— and to hold powerful corporate, professional, or social interests to account (Walshe, 2002).

One of the main arguments for the introduction of healthcare regulation has been concerns in relation to the quality and safety of healthcare. For example, a study into healthcare experiences in the US found that 55% of a randomly selected sample of almost 7000 adults received care as clinically recommended (McGlynn et al, 2003). It is important to stress that the linkages between the two regulatory responses are often underdeveloped and poorly understood.
Barrientos (2004) commented on the lack of research into the linkages between the different (social and economic) regulatory domains. As Levi-Faur and Jordana (2004) put it ‘the incremental transfer of regulatory knowledge and institutions from economic to social spheres is encouraging to the extent that regulatory institutions have some clear advantages over ministries, and that the mere fact of reform opens new possibilities for effective governance. Yet it is also a cause for concern, since social regulation is advancing slower than economic regulation’.

This study focuses in particular on the objectives of social regulation in the context of healthcare service provision, the objectives and the approaches used by regulators to achieve these objectives. Throughout this paper the term healthcare regulation is used to describe the collective function by an entity (regulator) to act in the interest of the public in order to achieve regulatory objectives.

2. Healthcare regulation

Regulation covers a wide range of interventions and has been defined as “sustained and focused control exercised by a public agency over activities which are valued by a community” (Selznick, 1985). At its core regulation can be described as the attempt by governments to steer or direct events, activities and behaviours (Leatherman and Sutherland, 2006; Braithwaite, Coglianese and Levi-Faur 2008).

Regulatory objectives

The objectives of regulation can be generic, varied and range from protecting citizens (in particular those groups that may be viewed as ‘vulnerable’) to exercising control over regulated activities or organizations and improving the quality of public service delivery. Regulations are often designed to address failures or problems that arise from the market or government failure. As Dixon (2005, 2) puts it ‘Regulation is needed because organizations by themselves may not deliver the objectives required by commissioners or consumers’.

Various researchers have attempted to describe the main objectives of regulation in the healthcare context. Probably the most often cited classification stems from Leatherman and Sutherland (2006) who distinguished three functional objectives of institutional regulation (see also Table 1 below):

- to improve performance and quality
- to provide assurance that minimally acceptable standards are achieved
- to provide accountability both for levels of performance and value for money

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<th>Hood et al, 1999</th>
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<td>Shaping behaviours</td>
<td>Improve performance and quality</td>
<td>Improving performance</td>
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<td>Arm’s length separation between target organisation and overseeing organisation</td>
<td>Provide accountability both for levels of performance and value for money</td>
<td>Making regulated organisations more accountable</td>
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<td>Formal authority or mandate of overseer to scrutinise and influence the target organisation</td>
<td>Provide assurance that minimally acceptable standards are achieved</td>
<td>Providing information</td>
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Table 1 – Objectives of healthcare regulation
Regulatory interventions

Within the areas of health and social care, regulatory interventions can be classified as targeting health and social care markets, professionals and providers:

- Institutional healthcare regulation focuses on organizations that provide healthcare;
- Professional regulation deals with the competence of clinicians’ performance of clinical practice, mechanism for professional regulation include registration, credentialing and certification;
- Market regulation in healthcare aims to address market imperfections, through managing competition, supply management and public accountability (Leatherman and Sutherland, 2006).

Within the institutional regulation of health service providers, three distinct types of regulatory activity or intervention in healthcare have been described by researchers such as Braithwaite, Healy and Dwan (2005) and Macleod and McSherry (2006):

- Directive measures (standards, targets, indicators, guidelines, etc),
- Surveillance or assessment of the levels of performance (through audits, inspections, investigations, etc.), and
- Enforcing compliance through advice, formal sanctions, penalties and also through rewards.

Figure 1 below summarises the research on the taxonomy of regulatory interventions as they apply to the providers of healthcare.

![Figure 1 – Taxonomy of Regulatory interventions (adopted from Sutherland and Leatherman, 2006)](image)

Regulatory approaches

The term regulatory approach (or style or regime) has been used to describe the manner in which regulators go about to achieve their objectives, using actions, displaying behaviours, undertaking activities and performing roles. Traditionally regulators have concentrated their efforts on prescribing the rules and standards and subsequently determining the compliance. However, increasingly regulators are beginning to study the manner by which regulators can achieve their objectives. A classification of regulatory approaches does not currently exist (May, 2007). Although the terms regulatory interventions and regulatory approaches are often used interchangeably in this paper the term approach is used to describe the manner in which regulators attempt to achieve their regulatory objectives. Whereas the interventions consist of specific actions or activities, the term approach encompasses the overall cumulative effect of the behaviours, actions and activities by the regulator.
Reflecting best available evidence on what approaches work best and influenced by national public policies, such as regulatory reform strategies, healthcare regulators have adopted different approaches (May, 2010), including:

- Prescriptive approach whereby the regulator prescribes regulated organisations what to do and how to do it;
- System-or process based approach which assert that the objectives of regulation can be achieved through appropriate systems for monitoring key processes by regulated organisations;
- Performance or outcome based approach which focuses on whether the desired level of quality has been attained. Examples of this in the area of public health include setting specific targets for food companies to reduce the sugar or fat content of their products (Sugarman and Sandman, 2008).

At the same time, other researchers (Walshe and Shortell, 2004) have used a dichotomous categorization of approaches by describing regulators as either deterrence regulators who view the regulated organisations as ‘amoral actors’ out to get what they can or compliance regulators, who view the regulated organisations is fundamentally good and well-intentioned. In practice regulators often use a mixture of the two approaches.

Another way of describing regulatory approaches is by taking stock of the strategic needs of the regulated industry or service. Ayers and Braithwaite (1992) developed a theoretical model of ‘responsive regulation’ asserting that regulatory interventions are more likely to succeed if they are responsive to the culture, context and conduct of the regulated organisations. An extension of this line of thinking is the concept of risk-based regulation which an approach characterised by a commitment to applying proportionality to the risks posed by the activities of an organisation (Adil, 2008).

However, there has been a notable absence of research into regulatory approaches in the context of healthcare regulation and, in general a relative dearth of evidence in relation to how these different regulatory approaches work in practice (Coglianese, Nash and Olmstead, 2004; May, 2010). In the English healthcare regulatory context, the unintended negative consequences of a particular regulatory approach has been highlighted by researchers such as Gwyn Bevan (2008) who reviewed a number of healthcare quality scandals in England in the 1990s and concluded that the regulatory approach taken appears to have been based on two acts of faith: a belief in the feasibility of regulating the quality of care in large, complex organisations and the belief in compliance based regulatory approach, using self-assessment and random checks.

Bal et al (2008) reviewed current trends amongst healthcare regulators in Europe in the context of each country’s level of state control and intervention. One of their main findings was that increasingly governments use market mechanisms to regulate healthcare providers. The research study also found that increasingly regulators are using risk-based approaches to regulation. Within this context the authors note that regulators increasingly provide better transparency and accountability for their work. A final change noted by the researchers was that whilst that individual organizational responsibility for the quality and safety of care has become more decentralized, from a political perspective many governments have tried to tighten their grip on the quality of care by empowering centralized authorities to regulate the quality of healthcare service provision.

The literature suggests that some regulatory approaches are more effective in achieving the regulatory objectives than others (Braithwaite et al, 1994). However, little is known why this is the case and what can be done to achieve a more effective regulatory system.
3. Achieving regulatory objectives: Quality in healthcare

As discussed, one of the main objectives of institutional healthcare regulation is to provide assurances of the quality of healthcare provision. The quality of healthcare service provision, and public service provision in general, is of key concern to many people, including users and providers of services, as well as funders and policy makers. However, quality as a construct is quite difficult to define and even more challenging to measure.

One of the most frequently quoted definitions of healthcare quality stems from a seminal report by the US Institute of Medicine (US Institute of Medicine, Crossing the Quality Chasm, 1990) who define quality as: ‘the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge’. Quality often only becomes visible or noticeable when it is absent and poor quality care generates unnecessary costs through the underuse, overuse and misuse of interventions and services.

Quality of healthcare is multi-dimensional and a consensus appears to be emerging within national governments (US, Australia, Canada, England, New Zealand) and international organisations (OECD, World Health Organization [WHO]) that quality involves a small number of domains (McLoughlin and Leatherman, 2003). In the US, the President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998) described a high performance health system as a system that achieves four goals: safety, patient centredness, effective care and a seamless, coordinated service. The US Institute of Medicine (2001) identified six dimensions through which the overall concept of quality is expressed: Safety, effectiveness, patient-centredness, timeliness, efficiency and equity. Other international umbrella organisations, such as the WHO and the OECD have taken an active leadership role in defining and measuring quality of healthcare, through research, indicators development, performance measurements and conceptual frameworks. The reasons for the increased interest includes rising costs, adverse events, market failures, evidence of poor quality, lack of accountability and inequalities between and within national health systems.

As noted before, one of the core objectives of regulation is to improve the quality of healthcare service provision. The idea behind this is that regulation is one of a number of interventions or mechanisms that can be used to achieve a quality service. In the European context, researchers (Spencer and Walshe, 2009) found that in eighteen of twenty four European countries surveyed had a statutory legal requirement for healthcare organisations to establish and maintain a quality improvement strategy.

However, despite the growing body of general regulatory theory, to date, limited research has been conducted into how healthcare regulation works in practice and, more importantly, what impact it has made (Walshe and Shortell, 2004; Leatherman and Sutherland, 2006; Walshe and Boyd, 2007).

The following is a short overview of the research carried out over the last two decades and its key findings:

- Almost fifteen years ago, the US Department of Health and Human Services commissioned a group of researchers to conduct a study into the effects of regulation on quality of care (Phillips, et al, 1995). Their research showed that States with extensive regulatory systems had positive effects on the quality of care, quality of life and safety of nursing homes, when compared to States with limited regulatory systems. Effects of regulatory systems measured by this research included lower use of inappropriate prescriptions, greater availability of devices that support residents to function more independently and higher percentage of safety features by extensive regulatory systems.
In the US, researchers compared medication errors between hospitals accredited by the Joint Commission on Accreditation of Healthcare Organisations and non accredited hospitals and found no statistically significant differences (Barker, et al, 2002).

In South Africa researchers (Salmon et al, 2003) conducted a randomised control trial of hospital accreditation amongst twenty randomly selected public hospitals. After two years, in comparison with the control group, the intervention group of hospitals showed little or no effect on the performance against eight indicators of quality.

Again in the US, researchers (Miller, 2005) found no statistically significant association between the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation scores and the Agency for Healthcare Research and Quality’s indicators.

In England, Bevan (2008) reported that a serious outbreak of Clostridium difficile in a NHS Trust hospital had not been detected by the healthcare regulator through its system of validation.

In the UK, the Health Foundation conducted a five-year research study looking at interventions (including regulatory interventions) aimed at improving quality in healthcare. One of the key conclusions of this research has been that the research evidence of the impact of regulatory interventions on quality of healthcare is sparse, based on observational studies and has found associative rather than causal links between regulation and quality improvement (Leatherman and Sutherland, 2006).

The Commission for Health Improvement (CHI) in England commissioned an evaluation of its clinical review process in 2006, one of the main conclusions of the study was that internationally, there have been few empirical studies analysing the work of health care regulators and their impact on the organisations they regulate (Benson, et al, 2006).

At a European level, as Sparreboom (2009) notes, the goal of evaluating the effectiveness of regulation is becoming more common amongst European healthcare regulators. His research on the usage of effectiveness evaluations amongst healthcare regulators in Europe highlighted that although all regulatory organisations interviewed were interested in conducting effectiveness research, few had actually conducted studies that looked at the effects of regulatory interventions.

The effects of one specific regulatory approach, accreditation, has been the focus of an increasing number of studies across the world. Most studies have found little empirical evidence whether accreditation is an effective strategy for improving performance in healthcare. A feasibility study commissioned by the Belgian Government (de Walque et al, 2008) concluded that despite the resources invested in hospital accreditation, research result have not found any evidence of the effectiveness of accreditation. In recognition of the challenges in measuring the effects of an intervention such as accreditation numerous national accreditation bodies, such as the Australian Council on Healthcare Standards, have investigated the relationship between accreditation and performance (Greenfield and Braithwaite, 2009).

The findings from these studies raise a number of important questions. First and foremost, what are the reasons for this lack of impact? Why have regulatory approaches not been more successful in achieving the regulatory objectives? And, secondly, what needs to be done to understand the regulatory processes better? Before I introduce a new conceptual framework which can be used to analyse and review the regulatory processes, I will take a look at the main challenges associated with the regulation of healthcare.
4 Challenges of healthcare regulation

Although the concept of regulation has been widely supported and has gained increased attention, a number of key challenges to the achievement of effective regulation have emerged. These include:

- Regulatory capture - from the perspective of the public choice theory, regulated organisations can be viewed as rational actors who will choose their actions on the basis of an evaluation of the potential consequences of their actions (Becker, 1968). At times, regulated organisations may therefore attempt to achieve the policy outcomes they prefer, in other words, they capture influence over the regulatory body (Walshe and Boyd, 2007);
- Regulatory escape – over time regulated organizations will try and avoid adherence to the regulations (Walshe, 2001; Alexius, 2005). Regulated organisations will attempt to negotiate with regulators if the regulatory requirements are challenging. If regulators are unable to gain societal and political support for its enforcement actions, the regulator becomes trapped because without the political support it can not resolve the dilemma (Parker, 2006). The dilemma is particularly visible in the context of financial regulation where some financial institutions are considered ‘too big to fail’;
- Regulatory burden caused by overly prescriptive and complex regulations – numerous researchers (May, 2007; Scrivens, 2006) have commented on the potentially burdensome and restrictive nature of, in particular, prescriptive regulations;
- Regulatory creep – a recent report from the UK Better Regulation Commission (2006) commented on the notion that often more regulatory interventions are introduced to address perceived hazards and risks. In Ireland a significant increase in the number of regulatory agencies has also been reported (Scott, 2008; Purcell, 2008);
- Regulatory obsolescence – unnecessary rules are slow to disappear and new rules to address new risks are slow in coming (Sparrow, 2000);
- Goal displacement – service providers may divert attention to the requirements of the regulator (Boyne, 2003);
- Costs of regulation – Hood et al (1998) commented that where the social distance is greatest between regulator and regulated organisation, regulatory behaviour is the most formal and regulation most costly. In the UK, the Prime Minister’s Office of Public Services Reform (2003) estimated that in 2002/2003, the total cost of funding all regulators with an inspection function, including the healthcare regulator, was approximately £550m. In the US, one researcher (Conover, 2004) estimated that total costs of healthcare at $169 billion. Recent comparative research in Ireland conducted by the Economist Intelligence Unit on behalf of the Department of an Taoiseach (2009) compared review the economic regulatory environment in Ireland. Using the same formula to compare the costs of healthcare regulation in Ireland shows that, in Ireland, the cost of healthcare regulation (in this case institutional regulation) was €3.26 per head of the population per year (see Table 2 below).

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<th>Country</th>
<th>Ireland</th>
<th>Netherlands</th>
<th>England</th>
<th>Norway</th>
<th>Scotland</th>
<th>Northern Ireland</th>
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<tr>
<td>Regulator Income, €m</td>
<td>15.00</td>
<td>39.20</td>
<td>200.00</td>
<td>21.28</td>
<td>20.00</td>
<td>7.00</td>
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<tr>
<td>Regulator Income per head of population, €</td>
<td>3.26</td>
<td>2.45</td>
<td>3.92</td>
<td>4.55</td>
<td>4.00</td>
<td>3.89</td>
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Table 2 Healthcare institutional regulation, income ratios, 2008. (Figures based on annual reports of the main regulatory agency responsible for the institutional regulation of healthcare services, excluding mental health)
These challenges are obviously not specific to healthcare regulation. One of the primary concerns within the institutional regulation of healthcare services is the complex nature of healthcare service provision, characterised by its heterogeneity of services delivered, multiplicity of actors and lack of a set of agreed, unified, specific and measurable objectives. Studies into the determinants of health outcomes have shown that the provision of health care services has a limited but not negligible role as a determinant of health. Approximately five years of the 30-year increase in life expectancy achieved this century can be attributed to improved medical care (Bunker et al., 1994). Of these 5 years, it has been estimated that curative services contribute about 3.5 and clinical preventive services about 1.5 years. The greatest share of this gain from health care can be attributed to diagnosis and treatment of coronary heart disease, which contributes 1 to 2 of these additional years of life.

In many countries, institutional healthcare regulators have been give broad and generic remit and deal with a large number of heterogeneous organisations. At the same time, regulatory approaches or regimes often consists of a complex set of regulatory interventions (Walshe, 2007) with high levels of variance in context (i.e. the setting), contents (i.e. the characteristics of the intervention) and the application (i.e. the process through which the intervention is delivered).

Measuring effects of any interventions in the context of healthcare is incredibly complex. A recent study undertaken in the Netherlands (Tuijn et al, 2009) found that of 615 ratings from inspectors working for the Dutch Health Care Inspectorate, 53% were found to be unreliable, following an analysis by two independent observers. The researchers found that in 52% the inspectors had given the service provider a higher rating than what, on the basis of the descriptions of the evidence, could have been expected (false positives). Only 1% of the ratings were false negatives. Furthermore, the more difficult question is determining exactly what contribution the regulatory interventions made to the outcome. This is also known as the attribution problem (Mayne, 2001). When studies have found a relationship between a regulatory approach and an output or outcome, the causal and explanatory power has been limited. Since regulatory approaches are almost always applied to all regulated organisations simultaneously and regulatory interventions are complex and heterogeneous, it is often not feasible to use experimental methods or randomized control trials.

Attempts have been made to resolve these dilemmas and address the challenges, through initiatives initiated from central government, with catchy titles such as Better Regulation, reducing red tape, regulatory reform, Regulatory Impact Assessments, etc.. However, many of these policy initiatives are insufficiently grounded in evidence and often based on naïve and overly optimistic view of the benefits of these policies (Bevan, 2008).

As Braithwaite, Healy and Dwan (2005) put it: ‘Regulatory activities fail when they ignore the subleties of organizational behaviour... when naïve, universal assumptions are made that the mechanics of change are simple’.

At the same time, researchers have responded to these challenges by proposing new theoretical concepts for healthcare regulation. For example, Aryes and Braithwaite (1992) argued for more “responsive” regulation, i.e. the use of interventions which are responsive to the context, conduct and culture of those being regulated. Others, such as Sparrow (2000), called for regulatory craftsmanship, proportionate and responsive to the problem at hand.

Healthcare regulators have also responded by moving from a command-and- control approach to market-based incentives and by moving from a coercive, adversarial to a cooperative and persuasive relationship. However, in some settings this pendulum has swung back again with a regulator reclaiming lost ground and emphasizing a more stringent regulatory process with a renewed zeal for hard edge regulation with an emphasis on detection through inspections and sanctions (Scrivens, 2007; Bevan, 2008).
5. Conceptual framework

Three decades ago, Covell (1980) commented on the methodological difficulties of measuring and evaluating the effects of institutional regulation and the quality of care. Despite decades of investment in regulating healthcare services across the world still relatively little is known about the types and success of regulatory approaches employed by regulatory agencies. A number of researchers have attempted to describe the relationship between regulatory approaches and outcomes by developing and using theoretical frameworks (Walshe and Shortell, 2004; Phillips, et al, 1995).

A consensus appears to have emerged from this research (e.g. Walshe and Boyd, 2007; Chuang and Inder, 2009) which argues that healthcare regulation is best understood as a series of complex interventions that are introduced into complex and diverse ‘social worlds.’ Viewing healthcare regulation in this way has implications for the choice of research methods and for the conceptual framework that can underpin the research studies in this field. As a series of complex interventions, regulatory approaches are critically influenced by the contexts into which they are introduced and by the processes of implementation in those contexts (Øvretveit 2004; Walshe 2007): This means that the types of research methods used to understand and evaluate regulatory approaches must be able to shed light on how context and implementation interact in particular organisations. The need for a theory-driven approach has been advocated in order to gain a better understanding of the complexities and regulatory approaches (Walshe, 2007).

Similar methodological and theoretical challenges have emerged in other fields of social regulation. For example, research into the effects of regulatory approaches on the quality of schools has been grappling with similar challenges. In the Netherlands, Ehren, Leeuw and Scheerens (2005) analysed the assumptions concerning the regulatory approach taken by the school inspectorate, using a programme theory. As noted before, regulatory approaches are made up of actions, behaviours, activities and roles by the regulator.

The regulatory approach reflects and consists of a number of underlying assumptions. Together these assumptions form the so-called programme theory behind a regulatory approach (Walshe and Boyd, 2007). These assumptions are often implicit statements, such as ‘The inspectorate will respond to concerns in a prompt manner, proportionate to the identified risks’. This statement can be translated into the following assumption: ‘If the inspectorate is responsive to patient safety concerns, then the risks to patient safety are controlled and minimised’. Another example of a statement could be ‘Managers will use performance information to make better decisions’, which can be translated into ‘If the inspectorate reports their findings publicly, then managers will be able to make better decisions and consequently the quality of healthcare will be improved’. A final statement can be that ‘Compliance with standards equals high quality care’. As an assumption this could be worded as follows: ‘If an organisation demonstrates a high level of compliance with standards, then that organisation provides a high quality service’.

The chain of assumptions can be used to gain a better understanding of the effects of regulation (Walshe and Boyd, 2007; Walshe et al, 2009). The programme theory can help to predict the effectiveness of regulation by describing and evaluating how healthcare regulators should act, the effects these approaches should have and how these effects should be realised (Ehren et al, 2005).
In relation to the overall study into institutional healthcare regulation, a number of overarching assumptions are often made, including:

- The design of a regulatory system is an articulation of a clear and coherent vision and can be viewed as the result of a rational decision making process. The extent to which regulators actually purposefully design their regulatory approach, by reviewing all possible options and select an approach on the basis of evidence gathered, has been questioned by researchers such as Walshe and Boyd (2007). More often than not the design is a result of a process of decision making that can be described as ‘muddling through’;
- There is a justifiable trust in the reliability and validity of the regulatory approaches. As noted before recent research from the Dutch Healthcare Inspectorate (Tuijn et al, 2009) has raised questions in relation to the validity of judgments by inspectors. Regulators are obviously not immune to ‘gaming’ but it is often assumed that regulators are unbiased actors whose reports are always reliable;
- The objectives of regulatory approaches can be clearly articulated, agreed and are amenable to measurement. It is often implied that the objectives of regulatory approaches can be clearly defined. However, objectives are often poorly defined (i.e. too generic), with a focus on process indicators and a lack of agreement between different stakeholders. For example, within a regulatory system of accreditation, stakeholders rarely agreed on the intended outcomes (De Walque, 2008) and a single, agreed definition of the processes (in other words the regulatory approach) is also often lacking (Spencer and Walshe, 2007). Pollitt et al (2008) came to a similar conclusion when they looked at a directive regulatory intervention, the development of performance indicators, and conclude that the types of indicators vary greatly in healthcare.

Figure 1 below describes a new conceptual framework for the measurement of the healthcare institutional regulatory process. In this model the dependent variables are the outcomes for service users, as measured by indicators such as, for example, healthcare associated infections or , and the outputs as measured through compliance behaviours. The independent variables are the approach taken by the regulator and the profile of the regulated organisation.

![Diagram](image)

Note: Organisational profile can be defined as the characteristics of the provider itself, such as the perceived probability of sanctions when non-compliant or perceived reasonableness of directive measures. Compliance behaviour is defined as the rate of compliance with national regulatory standards or rules.
The key questions within this conceptual framework are:

1. **What is the relationship between regulatory approaches and patient outcomes?** Are some approaches more successful than others? An exploration into the assumptions that the behaviours, actions and activities of the regulator influence the outcome for service users. Do performance-based regulatory approaches have a bigger effect on the outcomes than more prescriptive, command and control approaches? For example, the notion of a performance based regulatory approach could mean that regulators take measures to reward healthcare services for a reduction in healthcare associated infections. Another example in the public health arena includes adopting specific regulatory measures for curtailing the production of food or beverages with a high sugar content (Sugarman and Sandman, 2008).

2. **What is the relationship between regulatory approaches and compliance behaviours?** Braithwaite et al (1994) looked at the regulatory encounter in the context of nursing home regulation and found that the inspection style used by inspectors does not have a direct effect on compliance behaviour of the nursing home managers. However, adapting the regulatory approach to reflect the motivational posture of the nursing home manager did explain the change in compliance. In this case changing the regulatory strategy from coercion to cooperation helped the resisting managers in achieving a higher level of compliance. The next question looks at the regulatory encounter and the relationship between regulator and regulatee.

3. **How do regulated organisations view the approach taken by the regulator and how does the regulatory agency view their own approach?** Different factors play a role within the interaction between the regulator and regulated organisations. These factors include consistency of the regulatory approach, perceived legitimacy and fairness and level of trust in regulator. Braithwaite et al (1994) measured the way in which regulated organisations and the regulator perceived the regulatory encounter and found that the regulator’s message may be lost due to the regulated organisation’s misinterpretation of the interaction. For example, the regulator may approach the regulated organisation in a cooperative and persuasive way and the regulated organisations interpreted this interaction as a sign that further intervention was needed.

4. **What is the relationship between the organisational profile of the regulated organisation and their compliance behaviours?** The motivation to comply with regulatory requirements can be affected by the type or profile of an organisation. For example, May (2004) argued that compliance can be motivated by social pressures, a sense of duty or the fear of detection and resulting sanctions. Other studies have looked at the compliance with regulation from an individual perspective. For example Elffers, van der Heijden and Hezemans (2003), looked at self-reported individual non-compliance with different legislative requirements and found that the perceived benefits of non-compliance are a major factor in promoting rule transgression.

5. **What is the relationship between compliance with regulation and patient outcomes?** Braithwaite, Greenfield et al. (2010) found a significant positive correlation between compliance with accreditation standards and organisational culture and leadership. However, they were unable to demonstrate a correlation between compliance and clinical performance (an outcome measure). Similarly, a Canadian longitudinal study did not demonstrate a correlation between regulatory compliance and the length of survival of nursing home residents (Bravo et al, 2002).
6. Conclusion

The conceptual framework provides the theoretical background that can be used as a platform to conduct further research and analyse and review empirical evidence.

One fundamental challenge in designing and implementing regulatory approaches within healthcare is the limited evidence of the actual effects that these interventions have on the quality of healthcare services. Given the widely reported negative effects of regulation, including regulatory capture, burden, creep and escape, it is now time to take an in-depth look at the effects of regulation. This paper presented a new framework for the qualitative and quantitative measurement of regulation. It is worth noting that research has recently been carried out by researchers such as Kieran Walshe in the UK, Paul Robben in the Netherlands, Sheila Leatherman and Kim Sutherland in the UK and John Braithwaite and others in Australia, investigating the characteristics of effective regulatory strategies or approaches. These and other studies have made a significant contribution to the body of knowledge on the effects of regulation on the quality of healthcare services, these studies also confirmed the need for further research into the impact of healthcare regulation.

In conclusion, currently limited evidence exists what effect regulation has on the quality of healthcare. Equally important, there is limited evidence of how and why regulatory approaches would achieve the desired outcomes. This study proposes a new conceptual framework which can be used to explore the assumptions behind the regulation of healthcare services.

In order to gain a better understanding of the role and impact of a regulatory regime on the quality of healthcare services further research is required. This research should analyse the way regulatory interventions impact on the quality of service delivery and, in turn, on the outcomes for customers of the services.
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