Introduction

1.1 Background

For many governments healthcare is perhaps the most challenging, resource intensive and complex areas of public service to manage, control and oversee. Despite huge expenditure and ever increasing amounts of investment healthcare systems are bereft with challenges: rising consumer expectations, ageing populations, global public health security threats, poor access to essential services, overtreatment and patient safety concerns, to name but a few[1].

One way by which governments around the world attempt to protect society from harm, provide assurances to the public and improve the quality of health services has been through the design and implementation of a range of regulatory interventions[2]. Governments have established healthcare regulatory systems to not only assure compliance with legislation and standards to protect individuals and communities from harm but also to improve the quality of services[3].

It is perhaps surprising that there appears to be a lack of scientific evidence that healthcare regulation achieves the desired results. Researchers have argued that the main challenge is not regulation or oversight per se, but the manner in which regulatory methods are implemented which has resulted in this lack of evidence[4].

The notion that governments and their agencies need to strengthen its control and oversight over the quality and performance of healthcare is a relatively new concept[5]. In many countries, the role of the medical profession in overseeing its own performance has remained a powerful and strong oversight method but in many cases there has been a shift towards a more independent, centralized, external of accountability and a also mixture of both forms[6]. As Healy[7] points out: "*a regulatory revolution is underway in the twenty-first century as governments around the world to strengthen the regulation of professionals and organizations in order to ensure better and safer health care*". A number of influential patient safety reports, such as a report from the US Institute of Medicine[8] which highlighted preventable deaths from adverse events and a RAND report[9] which found that, on average, only 54% of American patients receive the recommended care, contributed to this shift from oversight based on professional autonomy to the establishment of independent regulatory agencies.

This study was carried out in the United Arab Emirates (UAE), a federation of states (Emirates) in the Persian Gulf region (see Figure 1 below). Until 1971, when the UAE gained independence from the United Kingdom, the UAE was known as The Trucial States of the Persian Gulf Coast. Today the UAE consists of seven Emirates with an open economy with a high per capita GDP[10]. The broader geographical focus of this study is on the Gulf region. The focus of one Chapter (Chapter 4) is on the so-called Gulf Cooperation Council (GCC), a cooperative

organization founded by six member states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates) in 1981. The remaining Chapters focus on healthcare in the UAE, in particular its main Emirate, Abu Dhabi.

The UAE has changed dramatically since its establishment as an independent country in 1971. A census in late 1950s estimated that around 50,000 people were living in the area at that time[11]. The latest population estimates indicate that the population has grown to over 9 million[12]. Abu Dhabi and Dubai are the largest Emirates within the federation, with a total population of around 3 million each[13].

Figure 1 A map of the United Araba Emirates (source: World Health Organization[14])

The population of the UAE is relatively young: around 60% of the population is estimated to be below 34 years of age[15] and in Abu Dhabi only 1.8% of the population is over 60 years of age[16]. The vast majority of residents are expatriates (in 2016 around 82% of the population of Abu Dhabi were expatriates and 18% UAE nationals[13]). Furthermore, the majority of UAE residents are male (around 64% in Abu Dhabi, in 2016[16]) due to the reliance on

male expatriates who work in the construction and service industries. The rapid economic growth following the discovery of significant natural resources (oil and gas) in the 1950s and the subsequent exploration has had a major impact on the health of the population, due to a shift in behaviour and lifestyles from a semi-nomadic and active to an urbanised and sedentary lifestyle.[17] The lifestyle changes have led to a large and increasing burden of chronic disease, such as diabetes and cardiovascular diseases[18].

At the time of its foundation in 1971 the UAE had only 7 hospitals and 12 healthcare centres[19]. The most recent figures indicate that there are now 130 hospitals in the UAE[20] (see Table 1 below). At the same time the healthcare spending as a percentage of the overall GDP has remained the same since 2005, around 3.5%. A similar increase can be seen in the number of healthcare professionals working in the UAE. In 2010 there were around 4,800 licensed physicians working in Abu Dhabi, by 2016 this had increased to just under 9,000[13]. More importantly, the physician density grew from around 20 physicians per 10,000 head of population to 29.5. During the same time period in the US, the ratio had grown from 27.7 in 2010 to 29.7 in 2016[21].

Healthcare in the UAE is provided by a mixture of government and private providers. In the Emirate of Abu Dhabi healthcare is provided by almost 50,000 licensed healthcare professionals who work for over 2,400 private and public providers, ranging from pharmacies, clinics, rehabilitation centres to primary, secondary and tertiary hospitals[13]. Since 2001 Abu Dhabi has taken charge of its own healthcare system, with a mandatory health insurance for all residents and a focus on competition[22]. Abu Dhabi has its own healthcare regulatory authority[23] and, despite increased competition, the largest provider is a government owned network of health services, SEHA. The role of the regulatory authority for Abu Dhabi, the Department of Health (formerly known as the Health Authority Abu Dhabi), includes traditional regulatory roles such as setting standards and developing policies, monitoring compliance and enforcement, as well as a broader role in terms of defining the entire health strategy for the Abu Dhabi population, including a focus on health promotion and research. The healthcare regulatory context in Abu Dhabi differs from the other Emirates insofar that the service provision and regulatory roles are separated and divided over multiple agencies in Abu Dhabi. In Dubai and the rest of the Emirates, the regulator is also the main provider of healthcare services (see Table 1 below). The six other Emirates have established their own systems of governance, including a number of different regulators[22], primarily the Ministry of Health and Prevention (Federal level) and the Dubai Health Authority (Dubai). The Government of Dubai established a separate healthcare free zone in 2011 including it its own regulatory authority, the Dubai Healthcare City Authority[19].

Table 1 Healthcare regulators in the UAE
(source: UAE Federal Competitiveness and Statistics Authority[20])

Emirate	Population	Name regulator	Service provider	No. licensed hospitals	No. licensed physicians	No. licensed nurses
Abu Dhabi	3.1M	Department of Health	No	56	8983	21735
Dubai	3M	Dubai Health Authority	Yes	35	8614	16624
Dubai City		Dubai Health Care City Authority	No			
Northern Emirates	3M	Ministry of Health and Prevention	Yes	39	3827	7796

The UAE has embarked on an ambitious reform program, Vision 2021[24], with an overall aim to be ranked globally among the top 20 countries (in 2017 the UAE was ranked 39th on the Legatum Prosperity Index[25]). Vision 2021 also outlines the performance improvement targets for all aspects of health care: service provision, population health, public health and healthcare regulation. The current healthcare regulatory landscape in the UAE is quite fragmented with a number of different healthcare regulatory authorities responsible for their own area[26]. There have been calls for a more 'nuanced' regulatory approach to address this fragmentation[23] and create an environment that is more conducive to competition and private sector growth.

A number of educational, research and regulatory organizations in the UAE participated in this research, including the largest and highest ranked university in the UAE (UAE University), the Abu Dhabi healthcare regulatory authority and the Behavioural Economics Department within the New York University Abu Dhabi. Throughout the period of this PhD study (2010-2019), I combined these research activities with full time leadership roles with a number of healthcare regulators and oversight agencies in the UAE, including the Health Authority Abu Dhabi (now known as the Department of Health) and the Ministry of Presidential Affairs. This study aims to contribute to a better understanding of healthcare regulation by taking an in-depth look at three different regulatory methods used to regulate the conduct and performance of healthcare professionals and organizations in the Emirate of Abu Dhabi and the UAE.

In this Chapter I will delve into the role, objectives and methods of regulation in the healthcare sector, as well as describe its anticipated benefits and highlight some of its unintended consequences. At the end of the Chapter I will also outline the focus of this thesis and describe the methodology for the study.

1.2 Healthcare regulation

At its core regulation can be described as the attempt by governments to steer or direct events, activities and behaviour.[27] 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*"[28]. Put differently, regulation seeks to change behaviour in order to produce desired outcomes[29].

Regulatory objectives and activities

The objectives of regulation are varied and range from protecting citizens (particularly groups that may be viewed as 'vulnerable'), regulating social problems[30], exercising control over regulated activities or organizations and improving the quality of public service delivery[31]. Regulations are often designed to address failures or problems that arise from market or government failure[32]. Regulatory agencies aim to provide oversight over the quality of public services and provide assurances to the public using a range of regulatory interventions[33]. The public increasingly demands that the regulators ensure that public services deliver positive results and improve the quality of service. As a result, the effectiveness of the public sector, including the role of its regulatory agencies, has come under increased scrutiny[34].

The focus of healthcare regulatory agencies can be on the institutions provider healthcare (institutional), the professionals who work in the healthcare sector or the entire healthcare market[35]. Three functional objectives of institutional healthcare regulation can be distinguished[7,35]:

- Improve performance and quality
- Provide assurance that minimally acceptable standards are achieved
- Ensure accountability both for levels of performance and value for money

Healthcare regulatory systems have been established to achieve these objectives, using three types of regulatory activity[36]:

- 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 rewards.

Taxonomy of healthcare regulation

There is no generally accepted taxonomy of healthcare regulatory methods[37]. The absence of a coherent taxonomy of regulatory methods hinders research into the effectiveness as there

is a lack of common understanding and classification. The UK based Health Foundation, a non-profit think tank, was one of the first organizations to categorize healthcare regulation and listed 10 different interventions[35]. Healy[7] lists 33 different regulatory mechanism and rates their impact on quality an patient safety, without further explanation upon which these ratings are based. Before reviewing the effectiveness of healthcare regulation, it is important to clarify and categorize regulatory methods.

In many countries, healthcare regulators have been given a broad and generic remit to oversee numerous heterogeneous organizations, markets and professionals. As a result, a regulator's approach often consists of a mix of regulatory interventions[33] 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 methods used and the process through which the intervention is delivered).

A dichotomous categorization of regulatory approaches is often used when describing regulatory practice. In this categorization regulators are described as either deterrence regulators who view the regulated organizations as 'amoral actors' out to get what they can or compliance regulators, who view the regulated organizations as fundamentally good and well intentioned. In practice regulators often use a mixture of the two approaches[2,31]. Reflecting on this dichotomy, Ayres and Braithwaite[38] developed a theoretical hybrid 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 organizations and individuals. At its core, the responsive regulatory approach is based on trust between regulator and the regulated organization. This approach argues that the regulated party is intrinsically motivated by social responsibility and therefore regulatory approaches should be flexible and based on dialogue. Healthcare regulatory agencies have increasingly adopted such a risk-based and responsive approach[39]. At times this approach has been called into question as too soft and ineffective in preventing major failings and high-profile incidents such as the Mid Staffordshire NHS Foundation Trust scandal in the United Kingdom[40]. In order to achieve effective regulatory oversight, many regulatory agencies seek to find a balance between assurance and improvement. For example, recent research in the United Kingdom described the emergence of hybrid regulatory models being adopted by the UK healthcare regulatory agencies[31].

Utilizing multiple regulatory mechanisms that respond to the needs of the regulated environment, with often multiple interventions working at the same time, is a fundamental characteristic of 'responsive regulation'.[38] This responsive regulation model has received growing criticism as it does not assist in dealing with ambiguity in the regulatory context[41].

Even though it is argued that regulators should consider all potential tools and instruments at their disposal[42], the exact manner by which to implement this is less well understood.

The legal academic Professor Arie Freiberg from the Monash Law School in Melbourne, Australia has developed a taxonomy of regulatory methods.[37] This taxonomy can assist regulators in general to focus on day-to-day factors that influence compliance and produce regulatory outcomes. Freiberg's regulatory toolkit is a non-hierarchical taxonomy of regulatory methods, based on the premise that the responsive regulation model, its gradual escalation from persuasion to punishment is not suitable for all situations. Freiberg[37] lists six different modes of regulating: through economic tools; through contracts (or grants); through authorization; through structural means; through information; and through law.

Table 2 below is a summary of the six regulatory methods within the taxonomy developed by Freiberg, with a short description of each category and some examples relating to the healthcare regulatory system.

Table 2 Freiberg's taxonomy of six regulatory methods[37]

Regulatory Methods	Description	Examples in healthcare
Economic regulation	Taxes, prices, tenders and market regulation	Introducing competition into the healthcare system by the removal of barriers to market entry.
Transactional regulation	Contracts, grant and procurement contracts	Public procurement process established to contain costs and create greater efficiencies
Authorization as regulation	Accreditation, certification, registration and licensing	External inspections, accreditation and licensing
Structural regulation	Physical design, process design and choice architecture	Behavioural cues, visual reminders and structural design
Informational regulation	Using information to raise awareness, improving decision making and change attitudes, for example through ratings and indicators	Quality ratings, registries and performance indicators
Legal regulation	Laws, guidelines and rules	Standards, clinical practice guidelines

1.3 Healthcare Regulatory Methods

Effectiveness can be defined as 'the degree to which the objectives of a program, care, services, or system are achieved'[43]. In this section we will use Freiberg's taxonomy[37] to review the existing empirical evidence that describes the effects of healthcare regulation.

Economic Regulation

Governments may seek to create, oversee or influence markets by limiting or preventing access to a market or liberalization of a monopoly or duopoly. Other ways to influence a market can be by imposing taxes, charges or levies. The main reasons to deploy these method are to create efficiencies, improve access to healthcare and establish financial accountability[44]. For example, the recent expansion of health insurance coverage under the Affordable Care Act in the United States has resulted in a significant increase in insurance coverage and utilization[45,46]. Economic regulation has been criticized as a crude and largely ineffective mechanism in the healthcare sector[47], delivering negligible benefits[48]. When it comes to healthcare regulation the focus has often been on so-called social regulation[44] that aims to change the behaviour and performance of organizations and professionals, rather than economic regulation.

Transactional Regulation

Transactional regulation consists of oversight arrangement through contractual and purchasing agreements, as well as grants, between government agencies and third parties[37]. These regulatory arrangements may include stipulations and requirements for the third party, for example compliance with privacy requirements, minimum wages for staff or the contractual agreement may stipulate that the third party achieve quality accreditation. These terms and conditions can be applied to ensure efficiency gains through competition and create greater accountability. In healthcare regulation, transactional methods include rate setting[35]. There is some evidence that rate setting can be used as an effective mechanism to contain expenditure and constrain expenditure growth[35].

Authorization as Regulation

The effects of one specific form of authorization, accreditation, has been the focus of an increasing number of studies across the world[49]. Most studies have found limited empirical evidence in support of the widespread use of accreditation as an effective strategy for improving performance in healthcare[50]. In the US for example, researchers compared medication errors between hospitals accredited by the Joint Commission International (JCI) and non-accredited hospitals and found no statistically significant differences[51]. A randomized controlled trials in South Africa[52] found no significant effect on performance of accredited hospitals compared to the control group. However, in Denmark researchers found an associa-

tion between hospital accreditation status and 30-day mortality risk for in-patients, with fully accredited hospitals having lower mortality risk than partially accredited hospital[53]. Overall, the evidence for accreditation improving patient safety and quality is weak, with no convincing evidence that accreditation has an overall significant effects on the quality of care[54,55,56].

Another regulatory tool that uses an authorization mechanism is an external inspection system. Similar to accreditation, there is sparse knowledge of the effects of external inspections.[57] A Cochrane study that looked at the effectiveness of external inspection systems found a paucity of high-quality studies and no firm conclusions could be drawn[58]. In addition, numerous researchers have demonstrated a lack of reliability in the external inspection processes with noticeable variations in the inspection reports[59,60].

Other authorization tools, such as professional licensure, certification or registration have had a more noticeable impact on the quality of care provided[61]. For example, studies have found an association between a medical team with a higher proportion of registered or licensed nurses and lower mortality rates and improved patient outcomes[62]. Similarly, earlier involvement of licensed consultants are associated with better patient outcomes and lower levels of involvement, for example during weekends or holidays, have been associated with poorer patient outcomes[63]. However, professional licensure boards in different countries such as the US and UK have come under criticism for failing to protect the safety of patients[64]and improve the quality of care[65].

Structural Regulation

Structural regulation involves amending the design of the physical or technological environment with the aim of changing the behaviour of the regulated persons. The idea behind this regulatory method is to manipulate the environment or redesign the care processes in order to influence behaviour[37]. This is also often referred to as the choice architecture. There are examples of structural regulation in the public health field, including warning labels on cigarette packaging, water sanitation or hazardous waste disposal[37]. There is some evidence that choice architecture may have a positive effect on the targeted compliance behaviour, for example, presumed consent for organ donations[66] or active surveillance and isolation of infected patients to prevent transmission[67]. However, further research is required as this is a relatively new field of study in healthcare regulation.

Informational Regulation

Ensuring that patients and their families have access to reliable, timely and accurate information is an important healthcare regulatory objective as it empowers recipients to make an informed decision. Informational regulation can include requirements to fully disclose side effects of certain medical treatment, warning labels and the public release of performance results.

An effective way to improve quality and contain costs are patient registries that track and make available the outcomes various population groups[68]. A large study comparing 13 registries in 5 countries concluded that registries can improve patient outcomes at a lower costs[69]. In the Netherlands, the establishment and maintenance of a national colorectal cancer surgery registry resulted in a 29% decline in mortality and 20% decline in severe complications[70].

Another informational regulatory tool is to disclose and release information such as reports about the quality of care. Food or menu labelling, for example, can help to reduce overall calorie intake.[71] A large systematic review also concluded that the public release of performance data helps to stimulate change and improve quality.[72]

Finally, regulators can also use less prescriptive and directive tools and more persuasive tools[38], such as information campaigns and training. As Gunningham points out[73], one of the most powerful tools for any regulator is acquiring and expanding its credibility and legitimacy. Ayres and Braithwaite's concept of responsive regulation[38] can assist regulators in finding the right regulatory strategy with the highest likelihood of success[74]. For example, many patients do not adhere to medical recommendations, resulting in lower than expected patient outcomes.[75] However, when patients are more likely to accept a clinician's recommendation if patients perceive that the clinician is credible and uses fair procedures[76]. Applying this understanding in the regulatory context may also result in greater compliance with regulatory requirements.

Legal Regulation

Methods of legal regulation include laws, guidelines and rules. Growing evidence exists indicating that Clinical Practice Guidelines (CPGs) can, at times, have positive effects on the quality of clinical care[77]. Clinical Practice Guidelines are often used to support clinicians in using best available clinical evidence in their daily clinical practice. There is some evidence that by standardizing clinical practice improvements in the quality and safety of care can be made[78,79]. Since the positive effects are widely acknowledged, health care regulatory agencies have often mandated the development and implementation of guidelines[80].

Another form of applying regulatory requirements is through mandatory incident and adverse event reporting[81]. Several longitudinal[82] studies reviewing adverse event rates over a period of time found limited evidence that these mandatory systems resulted in a reduction in incidents or adverse events[83].

Finally, many healthcare regulators have attempted to steer the behaviours of organizations and professionals by setting standards describing and specifying the compliance require-

ments and expectations. Standards are considered an essential part of quality improvement[84], however, the evidence available is sparse and the link between standards and improvements in quality are primarily associative rather than causal[58].

In summary, many healthcare regulatory agencies have an arsenal of different regulatory methods at their disposal with limited insights into the effectiveness of each method and how the regulator can maximize the impact of the regulatory methods. This study takes an in-depth look at the potential benefits of three methods: Structural (behavioural cues), Legal (clinical practice guidelines) and Informational (Legitimacy).

1.4 Effectiveness of healthcare regulation: Measurement Challenges

To date limited research has been conducted into how healthcare regulation works in practice and, more importantly, what impact it has made[33]. One of the key conclusions of the empirical research has been that the research evidence of the impact of regulatory interventions on quality of healthcare is sparse[85], based on observational studies and research has found an associative rather than causal link between regulation and quality improvement.[35] As a recent RAND Europe review of the regulatory mechanisms of six countries concluded: "*The overall evidence of the effectiveness of regulatory strategies towards ensuring care quality and safety at system level is scarce*".[86]

There are several explanations for this lack of empirical evidence. First of all, regulatory agencies often are not always able to show evidence that their regulatory methods are reliable, accurate and trustworthy. For example, a study undertaken in the Netherlands[87,88] found that 53% of rating by inspectors working for the Dutch Health Care Inspectorate were unreliable. The researchers found that in 52% the inspectors had given the service provider a higher rating than what, based on the descriptions of the evidence, could have been expected (false positives). The remaining 1% were false negatives: the inspectors had given the service provider a lower rating than expected. A recent evaluation of the Care Quality Commission (CQC) in England[89] reported a low predictive value of the risk rating for healthcare facilities and the rate of compliance. In other words, there was no statistically significant relationship between the risk rating and the performance of the operator. Further research found significant variation in CQC assessments[59]. Similarly, a Norwegian research study of inspection reports issued by the healthcare regulatory organization found that none of the reports contained any reference to outcomes and in 47% of the inspection reports the observations did not explain or display how deficiencies might affect processes in the organization and often made no specific reference to the exact standard[57].

A second challenge is that the objectives of healthcare regulation can be poorly defined and not specific enough to be measured. For example, improving the quality of healthcare is one of the most common objectives for healthcare regulatory agencies. However, quality as a construct is difficult to define and even more challenging to measure[90]. Quality of healthcare is multi-dimensional and a consensus appears to be emerging within national governments - USA, Australia, Canada, England, New Zealand - and international organizations - OECD, World Health Organization - that quality involves a small number of domains[91]. The US Institute of Medicine[8] (2001) identified six dimensions through which the overall concept of quality is expressed: Safety, effectiveness, patient-centeredness, timeliness, efficiency and equity. Other international umbrella organizations, 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. Notwithstanding this, the lack of unified definition relating to healthcare quality, as well as other regulatory objectives, creates additional measurement challenges for a regulatory agency.

Thirdly, regulatory agencies often encounter numerous challenges relating to their relationship with the regulated organizations. For example, unnecessary rules are slow to disappear and new rules to address new risks are slow in coming (regulatory obsolescence)[32]; at times regulated organizations may find ways to avoid compliance (regulatory escape)[5] or they may capture influence over the regulator (regulatory capture)[33]. Attempts have been made to address these 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 initiatives are insufficiently grounded in evidence and often based on naïve and overly optimistic view of their benefits[36].

Furthermore, considering the complexity of the health care systems overall, including the diverse political and cultural contexts within which regulatory agencies operate, it can be a challenge to analyse information and ascertain causal or even associative relationships between the regulatory methods deployed and the quality of care provided.[86] Regulation in healthcare does not revolve around one organization and a regulator may not always have the authority over a particular area. The regulatory agency often has to consider the confounding factors that influence compliance. Scholars in the field of regulation, such as Braithwaite and Healy[36] and Gunningham and Grabosky[92] have advocated for the use of a mixture of regulatory strategies, making it even more challenging to ascertain relationships between a regulatory intervention and its expected outcomes.

Finally, citizens often have misperceptions and unrealistic expectations when it comes to the role, responsibility and influence of regulatory agencies. Public concerns often relate

to the direct costs of healthcare regulation[93] and the perceived outcomes[31]. Table 3 below offers an overview of the annual costs of institutional healthcare regulatory agencies in five countries showing that, for the selected countries, the average direct expenditure for healthcare institutional regulatory authorities varied between 4.38 and 7.68 USD per head of population. However, healthcare regulatory costs are only make up a really small part of the healthcare expenditure per head of population. For example, in Sweden, the total healthcare expenditure per capita in Sweden was 5,219 USD in 2014[94] of which less 0.15% (7.68 USD) was spent on healthcare regulation.

Table 3 Healthcare regulatory agencies comparison across five countries[31,95,96]

Country	Population	Healthcare Regulatory Authority	Staff (WTE, approx.)	Annual Regulatory Expenditure	Expenditure per head population
England	53M	Care Quality Commission (CQC)	2681	314M USD	5.92 USD
Ireland	4.8M	Health Information and Quality Authority (HIQA)	192	21M USD	4.38 USD
Netherlands	17 M	Dutch Healthcare Inspectorate (IGZ)	610	81M USD	4.76 USD
Scotland	5.3M	Healthcare Improvement Scotland (HIS)	329	32M USD	6.04 USD
Sweden	9.9M	Health and Social Care Inspectorate (IVO)	640	76M USD	7.68 USD

A survey in the Netherlands found that the majority of the public assigned a higher degree of responsibility for the quality of care to the regulator rather than the care providers[97]. A similar survey in Sydney, Australia, found that, when it comes to the public's view regarding the responsibility for healthcare quality, respondents allocated the highest scores to the regulatory agencies[98]. Ensuring that the regulatory meets and exceeds the expectations of the public plays an important role in creating the right foundation for effective regulation.

To date, the small number of evaluations into the effectiveness of healthcare regulation have mostly focused on the regulatory processes and, to a lesser extent, the outputs and outcomes. Evaluations have not yet focused on the actual behaviours that regulatory agencies are attempting to change. For example, the effectiveness of the UK regulatory healthcare authorities has been reviewed a number of times in the last decade by looking only at the governance of the regulatory agencies and the impact on performance.[99,100,89]

The effect chain

To create a better understanding of the achieving regulatory outcomes, we first need to understand the determinants of compliant behaviour. Only a small number of empirical studies have looked at why some healthcare organizations or individuals display compli-

ant behaviours and others do not[7]. The ability of regulatory agencies to ensure compliance with regulatory requirements such as standards, directives, rules, guidelines, etc. underpins the study into healthcare regulation.[76] Since the extent to which different actors within the wider healthcare system comply with regulatory requirements is assumed to impact on the quality and safety of healthcare, it is important to conduct further research into the exact determinants of compliance.

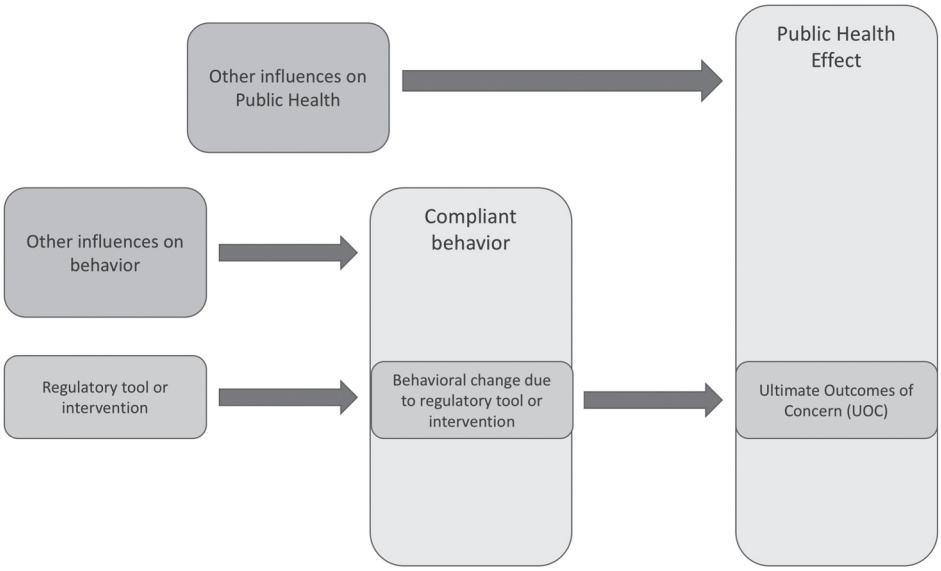
The Organisation for Economic Cooperation and Development (OECD) has designed a generic regulatory framework or effect chain to evaluate whether the regulatory methods and interventions have the desired effect and achieve the regulatory objectives[29]. As a recent report from the OECD points out, in order to be effective, healthcare regulators need to ensure that their institutional governance arrangements and regulatory instruments are evidence based and fit for purpose[101] The independent scientific healthcare advisory body in the Netherlands, the Health Council[102], started to conduct multidisciplinary research into the effectiveness of its regulatory system[103] around 10 years ago creating the impetus for the development of an effect chain framework currently used by the Dutch Healthcare Inspectorate[85], see Figures 2 and 3 below.

Figure 2 – Effect chain for healthcare regulation, adapted from OECD[29]

Studies into the determinants of health outcomes have found 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[104]. Of these 5 years, 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. The quality of health care is one of a number of determinants of health outcomes, as Figure 3 illustrates. Other determinants include genetic disposition, social circumstances, environmental factors and behavioural choices[105].

In addition to this, the relationship between the regulatory interventions and the behaviour of the organization or individuals is also quite complex and not yet well understood[106]. Even if compliance improves, it does not always lead to improved health outcomes, as Oude Wesselink et al[107] found when investigating the effects of diabetes guidelines compliance and health outcomes. Other studies have found similar results, with a lack of positive outcomes from regulatory interventions such as accreditation[54,93,106] and external inspection[58].

Figure 3 – Effect chain for healthcare regulation, adapted from OECD[29]



1.5 Research aim and objectives

This research study aims to contribute to a better understanding of the role and effect of regulation in healthcare, including providing new insights into the complexity and inter-relationships of factors influencing compliance of healthcare professionals.

The central question guiding this research is:

How can regulators utilize regulatory methods to improve healthcare regulatory compliance?

The research objectives are:

Research objectives:	Chapter(s)
Review the role and impact of health system reform in the United Arab Emirates with a specific focus on Abu Dhabi.	Chapters 2 and 3
Review the current availability, use and effects of a particular healthcare regulatory intervention (Clinical Practice Guidelines) in the Gulf region	Chapter 4
Examine the determinants of self- reported compliance by particularly looking at the social motivators of behaviour and the relationship between perceptions of procedural justice and legitimacy and compliance with regulatory requirements	Chapters 5 and 6
Test whether a simple behavioural cue can be effective in improving compliance with regulatory requirements.	Chapter 7

This research study investigates the relationship between regulatory methods and compliant behaviour, assuming that the compliant behaviour, in turn, will ultimately lead to improvements in the quality of care and better patient outcomes.

1.6 Study Design

The extent to which different actors, in particular clinicians, within the healthcare system comply with the regulatory requirements is assumed to have an impact on the quality and safety of healthcare (see Figures 2 & 3, the regulatory effect chain). Conducting research into the determinants of compliance is therefore important in order to gain better insights into what methods are effective in improving compliance.

In this study, we looked at how a number of regulatory methods – legal (Clinical Practice Guidelines, Chapter 4), informational (perceptions of legitimacy, Chapters 5 and 6) and structural methods (behavioural cues, Chapter 7), interact with regulatory compliance, using a number of different research methods. In addition, we also conducted systematic reviews of the existing evidence regarding the healthcare system reform in the UAE.

We selected these study designs for a number of reasons. Due to a lack of research in the fields of health policy, management and regulation in Abu Dhabi, the UAE and across the broader Gulf region[108], the research started with systematic reviews of the healthcare systems in Abu Dhabi and the UAE, as well as a review of the development, implementation and evaluation of one regulatory method (Clinical Practice Guidelines, CPGs) in the Gulf Region. We chose CPGs as the topic for our systematic review because of the growing evidence of the positive impact CPGs have on the quality and safety of healthcare.[80] Since most Gulf countries have only recently established healthcare regulatory authorities, it made sense to focus our initial research on a relatively well understood regulatory method.

Increasing the number of UAE nationals (Emiratis) in all medical professions forms an important part of the UAE's Vision 2021[109] and in our study we focused on this group. The study took place in the largest medical and health sciences university in the UAE. We conducted a survey with these medical students to measure their perceptions of healthcare regulation and their self-reported compliance levels.

We selected a natural field experiment as our third study design because we wanted to investigate a regulatory method that could be replicated in other settings. One of the challenges when comparing effectiveness of regulatory methods is that healthcare regulatory agencies are quite unique in terms of their functions, remit and instruments[39]. Conducting an

experiment in a controlled environment allowed us to generate research findings that could be applicable elsewhere.

Systematic Reviews – Abu Dhabi, UAE and the Gulf region

Our research started with an investigation into the health system reform with an initial, specific focus on the regulatory context in the Emirate of Abu Dhabi. This was followed by a more general review of the healthcare system in the entire UAE to review the progress against its strategic reform program, Vision 2021.[24] Finally, the research focused on the development, implementation and evaluation of a specific regulatory method, Clinical Practice Guidelines within the Gulf region.

Each systematic literature review was conducted using a variety of databases, such as Medline, PubMed and the Cochrane Library, as well as publicly available "grey" literature. A search strategy was prepared for each study using defined keywords and reviewers independently screened and selected potentially relevant articles that met the inclusion criteria. Once the articles were screened and selected for inclusion, the studies were assessed utilizing a standardized template and information.

Cross sectional study into the perceptions of healthcare regulation and self-reported compliance

The traditional viewpoint on the determinants of compliance behaviour has concentrated on instrumental motivations: people obey rules and laws because there are penalties and incentives. However, instrumental mechanisms have, at best, a small impact on compliance behaviour.[110,111,112] An alternative viewpoint looks at the role of people's social motivations in terms of the perceived legitimacy and fairness of the regulatory process[76]. The study focused on the factors that influence and determine healthcare professionals' compliance with specific regulatory requirements by investigating the relationship between participants' perceptions regarding the legitimacy and fairness of the regulatory process and the self-reported compliance.

Natural field experiment into the effects of subtle behavioural cues

Influenced by behavioural economists, such as Daniel Kahneman and Amos Tversky[113] and Richard Thaler[114] and Cass Sunstein[115], decision makers, politicians and researchers have increasingly investigated the role and impact of psychological, cognitive, emotional and social factors on decision-making. Behavioural approaches recognise that humans are not entirely rational and humans frequently misjudge decisions because of their inherent biases when making sense of information. The move towards this new approach is also influencing regulatory agencies[115]. In order to review the effects of behavioural cues, we conducted a field experiment to investigate the effects of cues of being observed by displaying a picture of

human eyes in the area where the research is carried out. 'Watching eyes' experiments have been tested in a variety of different settings and areas. Previous studies[116] have found that people complied with instructions or social norms better when eyes images were displayed, for example paying for coffee, clearing/sorting one's litter, preventing bicycle theft, charitable donations and other pro social behaviour.

1.7 Outline of this Thesis

This thesis consists of a series of studies that contribute to a small but growing body of scientific evidence related to the role and impact of regulatory methods in the healthcare sector. Chapters 2 and 3 serve as an introduction and contextualization of the main body of research which is presented in the subsequent Chapters.

Chapter 2 sets the scene in terms of the context of the healthcare reform in the Emirate of Abu Dhabi, as part of the UAE where this study took place and Chapter 3 presents a more in-depth progress report on the reform progress within the country as a whole.

The findings of the specific role and compliance effects of healthcare regulatory methods are described in Chapters 4, 5, 6 and 7. In Chapter 4 we describe the findings from a literature review focused on one of the more prevalent regulatory methods, Clinical Practice Guidelines. This study looks at the development, implementation and evaluation of this regulatory tool in the Gulf Region.

In Chapters 5 and 6 we present the findings of a cross-sectional survey measuring the perceptions of students in medicine in the UAE and its influence on their actual and self-reported compliance. Chapter 7 describes the results of a field experiment with medical students in a natural setting in a medical faculty in the UAE, exploring the impact of simple behavioural cues on levels of regulatory compliance.

In the final chapter of this thesis, Chapter 8, we discuss the methodology, limitations of the research, the interpretation of the main findings and it describes a potential way forward to improve compliance with healthcare regulation.

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