Improving compliance with healthcare regulatory requirements in the United Arab Emirates

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Improving Compliance With Healthcare Regulatory Requirements In The United Arab Emirates

Verbetering van het naleven van regelgeving
door de gezondheidszorg
in de Verenigde Arabische Emiraten

Thesis

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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.

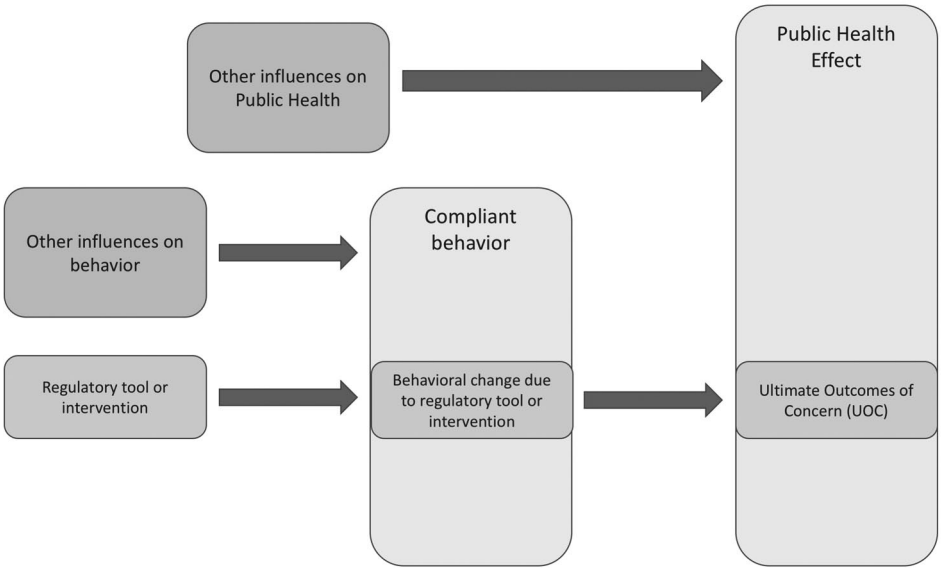
The Organisation for Economic Cooperation and Development (OECD) has designed a generic regulatory framework or effect chain to evaluate whether the regulatory methods and interventions have the desired effect and achieve the regulatory objectives[29]. As a recent report from the OECD points out, in 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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2

Health system reform in the Emirate of Abu Dhabi, United Arab Emirates

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2.1 Abstract

The desire to achieve the best outcomes in the provision of healthcare has driven health system reforms in many countries across the globe, including the Emirate of Abu Dhabi, United Arab Emirates.

As a young state (the United Arab Emirates was founded as an independent state in 1971) with a diverse (with 78% expatriates) and young population (40.23% of the national Emirati population is under 15 years of age), the government of the Emirate of Abu Dhabi has embarked on a journey to reform their healthcare system. This reform focuses on the redesign, financing, regulation and provision of healthcare with the aim of delivering accessible, affordable and high quality health care.

We will describe and review the health system reform in Abu Dhabi to date: its background, history and characteristics. The review looks at whether the main components of the reform (mandatory health insurance; enhanced competition and a centralized regulatory system) have had the desired effects in terms of improving quality, enhancing access and ensuring affordability.

Looking towards the future for the health system in Abu Dhabi we conclude that it is too early to tell whether the reform programme is having the desired effects in terms of achieving its goals of quality, access and affordability.

2.2 Introduction

Since the beginning of the foundation of the United Arab Emirates (UAE) as an independent, sovereign state in 1971, the late founder and President of the UAE, His Highness Sheikh Zayed bin Sultan Al Nahyan, consistently expressed his vision of access to high quality health-care for the entire community. Over the past four decades, realizing this vision has been one of the key drivers of reform in the provision of healthcare.

The United Arab Emirates (UAE) is a Federal union of 7 distinct State-Emirates. The Emirate of Abu Dhabi acts as the political capital for the Federation and, together with Dubai, the two Emirates account for more than two thirds of non-oil Gross Domestic Products (GDP) of the UAE[1].

The Emirate of Abu Dhabi is rich in national resources and over 2.2 million of barrels of oil are produced annually in the Emirate of Abu Dhabi, of which over 90% is exported and half of the GDP of the Emirate of Abu Dhabi relates to oil[1]. One of the main objectives of the government of Abu Dhabi is to reduce its reliance on the oil exports by promoting diversification and targeting growth areas such as tourism, healthcare, telecommunications and aviation[2]. Abu Dhabi is the second largest federal state, population wise, within the United Arab Emirates, with an estimated total population of around 2.4 million in 2011[3]. The population is multi-cultural, diverse and young: 22% of the population is Emirati, of whom two thirds are under the age of 30, 2.2% are over 65 years of age and only 8.8% of the labour force is Emirati. The majority of the expatriate population is male (70%) and almost half of expatriates are under the age of 30[1].

This vision for healthcare in the Emirate of Abu Dhabi has been outlined by the Executive Council's (the executive authority or council of Ministers) Policy Agenda 2007-2008 and Economic Vision 2030 for Abu Dhabi[2,4]. These strategies have played a key role in focusing on the strengthening of a secure and stable society and a dynamic open economy based on pillars such as education, healthcare, enhanced privatization, sustainable development within a transparent regulatory environment. The main aims are to establish a sustainable economic development in Abu Dhabi and ensuring a balanced social and regional economic development approach that brings benefits to all.
In this introduction, we will describe the main characteristics of the health system reform in the Emirate of Abu Dhabi since 2007, when a major reorganization took place of the health system.

Since 2007, healthcare regulation in the Emirate of Abu Dhabi has been the responsibility of one central, statutory agency, the Health Authority – Abu Dhabi (HAAD). HAAD reports

directly to the Executive Council (the executive authority of the Emirate of Abu Dhabi) and sets regulatory requirements for healthcare providers, professionals and payers (insurance companies), operates a mandatory licensing system, monitors compliance with requirements and takes action to enforce compliance. In addition, HAAD plays a central role in health promotion campaigns and public health programs and strategic planning[5]. Since its establishment HAAD has set out to the achievement of affordable, quality healthcare that is accessible to all[6].

Note: The term health system reform is used in this article rather than healthcare reform since the definition of health systems is broader and encompasses the resources, actors and institutions related to the financing, regulation and provision of all activities whose primary purpose is to promote, restore or maintain health[7].

The population in the Emirate of Abu Dhabi has a number of interesting characteristics. The birth and death rates have declined rapidly over the last two decades. However, there is a marked difference between the death rates of the national and expatriate populations: the death rate for the Emirati (national) population was 2.2 per 1,000 in 2011, compared to 3.8 in 1985 for the nationals. In comparison, the death rate for the expatriate population was 1.0 in 2011 and 1.8 in 1985[3]. At the same time the birth rate amongst nationals has decreased from 46.9 per 1,000 in 1985 to 33.7 in 2011. During the same period, the birth rate amongst the expatriate community decreased from 29.1 in 1985 to 8.7 in 2011. The high rates of male expatriates (77% of all expatriates are male) and a young expatriate population (99.4% of the expatriate population is below the age of 65) are the most likely causes for these differences[3].

Across the United Arab Emirates the infant mortality rate has dropped significantly from 15 to 7 per 1,000 births between 1990 and 2009[3]. In 2010, life expectancy at birth for Abu Dhabi Emirate was 74.9 years for males and 77.0 years for females[1]. Across all age groups, nationals accounted for 34% of all deaths. Nationals accounted for 59% of all the deaths above the age of 65. However, of all deaths of young adults (20 – 39 years) 14.4% were nationals[3]. The leading causes of death are diseases of the circulatory system, cancer and deaths due to road traffic injuries.

The Emirate has relative high rates of chronic diseases related to life style including obesity, diabetes and cardiovascular diseases[5]. Over the last three decades the prevalence of diabetes has increased fivefold from around 5% to almost 25% of the national Emirati population in Abu Dhabi[8]. According to preliminary analysis by the Health Authority Abu Dhabi, 21% of Emirati nationals are diabetics compared to 18% of expatriates[3]. In addition, cardiovascular diseases accounted for over a quarter of deaths in 2011, with obesity rates high for both the

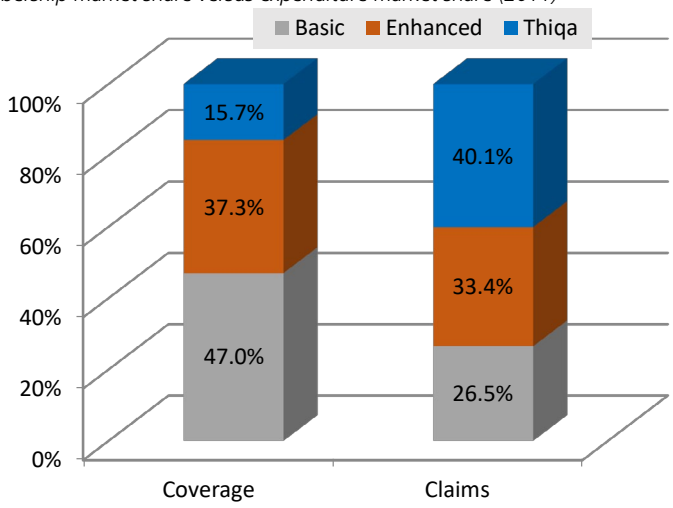
national as well as the expatriate population (national: 33% for males and 38% for females; expatriates: 17% for males and 32% for females)[3]. One recent study of a sample of over 500 Emirati women reported a prevalence of obesity (defined by body mass index > or = 30) of 35% with many women (28%) reporting having a chronic disease (including obesity, diabetes, cardiovascular disease, respiratory disease)[9].

By Emirati law employers are required to provide for health insurance coverage for its employees and their families. Residence status is generally contingent on being employed. Hence, there are very few retired or unemployed expatriates[10]. There are three insurance schemes in operation in the Emirate of Abu Dhabi: Thiqa cover, which is available only for Emirati nationals; Basic cover, mainly for unskilled labourers and lower paid employees and Enhanced cover, mainly for higher skilled expatriate workers. There are over 400,000 people insured through Thiqa; over 1.3 million insured with the Basic product and over 1 million policy holders with the Enhanced cover[3].

The Thiqa and Basic schemes are provided by the National Health Insurance Company, Daman, a Abu Dhabi government owned entity that has a strategic partnership with Munich Re, a large German health insurance company. The Enhanced scheme is provided by 35 licensed insurers, including Daman. Individual members of the different schemes have to make co-payments, which differs per insurance company and relates mainly to payments for pharmaceutics, optical and dental services.

As Figure 1 below shows, there are noticeable differences in the utilization of healthcare between different groups as reflected in the percentage of claims per health scheme: 15.7% of insured individuals hold a Thiqa card, compared to 47% who have Basic insurance. However, as a percentage of the amount claimed, Thiqa card holders represent 40.1% of the market, whereas Basic insurance card holders represent 26.5%. The higher utilization rate of Thiqa members can be explained by the differences between the expatriate and national, Emirati population. The expatriate population tends to be younger, predominantly male and more transient. In contrast, a higher percentage of the national population has is over the age of 65 and there is a higher birth rate amongst the national population. Lifestyle characteristics may also play an important role with a high prevalence of diabetes amongst national. A recent study found that in one of the largest hospitals in Abu Dhabi, nationals accounted for 72.2% of all diabetes related inpatient encounters[8]. Finally, the lower number claims per member per year for workers on the basic insurance (average of 3 claims per year, as compared to 14 claims per year for Thiqa members) may also be due to the fact that the level of co-payment is higher for the Basic insurance product[3].

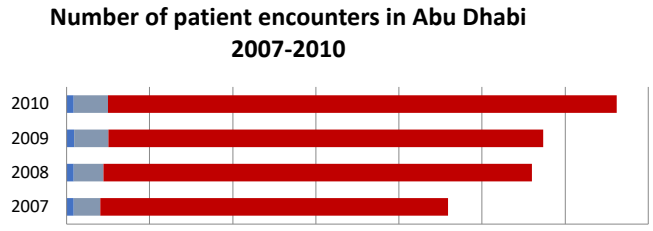
Figure 1 Membership market share versus expenditure market share (2011)



There has been a noticeable growth in the provision of healthcare services in the United Arab Emirates over the last decade. According to recent statistics, in 2010 the total number of patient encounters had grown by 17.5% compared to 2009, whereas the growth rate in 2009 was 2.5% and in 2008 22%[3]. It is difficult to explain the dip in the growth rate between 2008 and 2009, however at the same time the Abu Dhabi economy contracted by 24%[1], mainly due to the global economic recession.

As Figure 2 below illustrates, the absolute growth for Outpatient Care between 2007 and 2010 was 46.4% (12.2 million encounters in 2010, compared to 8.4 million in 2007). During the same period the absolute growth for Emergency Care was 28.2% and for Inpatient Care only 0.4%.

Figure 2 Number of patient encounters in Abu Dhabi, 2007 - 2010



	2007	2008	2009	2010
Inpatient discharges	173,331	174,587	177,428	174,099
Emergency	637,630	712,598	829,533	817,624
Outpatient	8,367,065	10,314,318	10,461,119	12,246,071

A further analysis of the encounters over the same time period[1,3,5,6] indicates that, when expressed in relative terms, the growth has been less evident (see also Table 1 below). Whilst there has been a particular growth in outpatient encounters (an increase of 26.1% in just 4 years), the relative growth in ED encounters was small and there was even a decrease in the discharge rates for inpatients over those 4 years.

Table 1 Number of patient encounters in Abu Dhabi per 1,000 population, 2007-2010

Number of patient episodes in Abu Dhabi, per 1,000 population					
Year	2007	2008	2009	2010	Difference 2007-10
Discharge rate per 1,000 population	102.21	95.58	92.61	88.48	-13.43%
ED encounters per 1,000 population	376.01	390.11	432.97	415.53	10.51%
Outpatient encounters per 1,000 population	4,934.03	5,646.50	5,460.15	6,223.68	26.14%

Healthcare in Abu Dhabi is provided by over 22,000 licensed healthcare professionals who work in over 1,200 facilities, ranging from pharmacies, clinics, and rehabilitation centres to acute hospitals. In total there are almost 5,000 physicians, almost 1,000 dentists, over 8,000 nurses and 5,000 allied health professionals[3].

In terms of provision of healthcare, the establishment of a new state-owned company in charge of the management and contracting of healthcare services was established by law in 2007, with governmental support. This company, SEHA (Arabic for Health), provides inpatient and outpatient services and over 66% of all hospital beds are provided by or on behalf of SEHA (see Table 2 below). Prior to being established as a Government supported, private company, the facilities in the SEHA group were managed by the General Authority for Health Services, GAHS. SEHA manages its own existing facilities and has contracted the management of a number of large hospitals with international healthcare groups, such as John Hopkins Medicine and the Cleveland Clinic. The overall market share for SEHA is 56% for inpatients and 31% for outpatients. The remainder is provided by over 1,000 private healthcare facilities.

Table 2 Provision of health services in the Emirate of Abu Dhabi

Provision of health services in the Emirate of Abu Dhabi: SEHA and non-SEHA						
	2009			2010		
	SEHA	Non-SEHA	Total	SEHA	Non-SEHA	Total
No. healthcare facilities	118 (11%)	959 (89%)	1,077	145 (12%)	1,066 (88%)	1,211
No. encounters	4,428,075 (39%)	7,042,013 (61%)	11,470,089	4,654,264 (34%)	8,890,793 (66%)	13,545,057
No. inpatient beds	2,439 (67%)	1,182 (33%)	3,621	2,369 (66%)	1,210 (34%)	3,579

In the next section we will review the health system reform program in Abu Dhabi.

2.3 Discussion: Health System Reform in the Emirate of Abu Dhabi

The provision of high quality, affordable and sustainable healthcare that citizens can freely access remains a dream for many politicians, providers, payers, policy and decision makers. In many countries, the gap between dream and reality has led stakeholders such as patient lobby groups, political parties, researchers, providers, insurers and policy makers to advocate for structural and lasting reform to address the multitude of persisting quality problems and financial concerns.

In the previous section we described some of the main characteristics of the health system in Abu Dhabi, in terms of population, payer and provider. We will now review the current situation in Abu Dhabi by looking at whether the different elements of the reform have had the desired effect in terms of achieving the projected outcomes: improving quality, expanding access and ensuring affordability[6,11]. Before we look at the three main elements of the reform in Abu Dhabi (mandatory health insurance, enhanced competition and a centralized regulatory system) we will briefly describe the international research into health system reform.

Even though international organizations such as the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD) have carried out many comparative reviews, the evidence of the impact of health system reforms remains inconclusive as healthcare costs continue to grow, disparities remain and health outcomes do not improve significantly. The WHO, following an extensive review of the available evidence[12], concluded that here is little evidence concerning the effectiveness of many reform policies. On behalf of the OECD Docteur and Oxley[13] conducted a similar review six years later and drew as similar conclusion [page 8]: 'choices about further reform are hampered by the insufficiency of information about the impact of the (numerous) reforms'.

More recently the Australian Government mandated a Commission to review the health system and produce recommendations for reform. The Commission found that health systems are notoriously resistant to reform in a large part because of the competing objectives of access, quality and affordability[14]. Inherent to the process of reforming healthcare is that the goals cannot always be aligned and often compete with each other. For example, the objective of delivering of high quality healthcare can be expensive and therefore clash with the objective of delivering affordable healthcare.

More evidence has been found at an individual country level. In relation to England for example, the King's Fund reviewed the reform period under Labour government and concluded that considerable progress had been made. Particularly improvements had been made in reducing waiting times for treatment, reductions in rates of health care associated infections, improvements in areas of clinical priority such as cancer and cardiac care and progress in reducing rates of cigarette smoking[15].

Pollitt[16] concluded that one of the biggest assumptions is that there has been some well thought through and well-designed plan behind reform. However, reform is often the result of many compromises and systematic evidence is relatively sparse. The challenge is whether and how to attribute indicators of population health or specific outcomes to health service interventions.

Although Abu Dhabi's health system reform is relatively young, after 5-6 years it is time to take stock and briefly analysing whether the three main characteristics of the reform have resulted in the desired outcomes.

Health insurance

As described earlier, the introduction of the mandatory health insurance system for all workers is a key characteristic of the reform program. All employers are obliged to enrol and fund insurance for all eligible expatriate employees. The insurance requirements and the pricing are set by the regulatory authority.

In terms of access to health care, according to the regulatory authority, over 95% of the population is enrolled in one of three health insurance plans. However, this high level of enrolment has not led to an even distribution in terms of the utilization of healthcare. As noted in the Introduction, members of the Basic insurance access healthcare less frequently and have a higher level of co-payment. This could be an indication for underutilization and lower access for this particular group. However, it has to be considered that the age and sex distribution of this group is different. Furthermore, expats often leave the country when they become severely ill, which would lead to lower utilization numbers when compared to

the national population. Therefore the lower utilization in the Basic plan will require more attention and further analysis in the future. In addition, Emirati patients continue to use healthcare services outside of the United Arab Emirates. A Medical Board approved almost 3,000 patients to avail of treatment abroad in 2010, an increase of 13% when compared to 2009[17].

Limited information is available regarding the affordability of healthcare. At a macro level, the most recent figures indicate that across the United Arab Emirates, 2.7% of GDP was spent on healthcare in 2009[18]. The two largest insurance products, the Basic product and Thiqa scheme, are underwritten by the Abu Dhabi Government and limited data is available in relation to the overall costs to the Government. However, what is noticeable is a substantial increase in the number of payer submissions (claims) and the costs per insurance plan. Table 3 indicates the growth in payer submissions (claims), per insurance product, the overall growth is 42.1%, with the biggest growth (87.0%) in the Daman Basic product[3,5,6].

Table 3 Health insurance in Abu Dhabi (2009-2011)

Payer claims and market share per insurance product, 2009-2011							
	2009		2010		2011		Growth
	Claims	Market share	Claims	Market share	Claims	Market share	2009-2011
Basic product (Daman)	2,132,354	20.1%	2,932,545	22.5%	3,987,477	26.5%	87.0%
Thiqa product (Daman)	4,475,578	42.3%	5,920,296	45.4%	6,029,795	40.1%	34.7%
Enhanced product	3,981,416	37.6%	4,200,514	32.2%	5,025,707	33.4%	26.2%
Total	**10,589,348**	**100.0%**	**13,053,355**	**100.0%**	**15,042,979**	**100.0%**	**42.1%**

At the same time, the average cost per claim is substantially lower for the Basic product, as shown in Table 4 below.

Table 4 Cost of average health insurance claim (2011)

Cost of average insurance claim, 2011 (in AED)		
	Inpatient	Outpatients
Basic product (Daman)	8,792	152
Thiqa product (Daman)	12,727	362
Enhanced product	9,344	343

Recent research of the health insurance in Abu Dhabi[19] has indicated that being covered by health insurance actually lowers per capita household's health care spending to the extent that those benefiting from the introduction of mandatory health insurance experience a statistically significant increase in household's disposable income. In comparison, in other Emirates, the original situation pre-2007 has remained with many low skill-low paid expatriates who are either not insured at all or who are faced with out-of-pocket payments.

It is difficult to ascertain what impact the introduction of a mandatory health insurance system has made on the quality of healthcare provision. The regulatory authority has also begun to implement a comprehensive pay for quality program. The first steps of establishing an eClaims system, introducing a competitive market of insurance companies for the Enhanced product and a standardized new basic price list have been taken already. However, further evidence is required to review the effects of health insurance regulation on quality.

Enhanced Competition

Another important feature of the health system in Abu Dhabi has been enhanced competition through an increased privatization and the commissioning of large healthcare service contract to internationally recognised and well-established institutions such as the Cleveland Clinic and John Hopkins Hospital. With the establishment of the Abu Dhabi Health Services Company (SEHA) in early 2007, a mechanism was created to commission the delivery of critical care to external companies and with this create a quasi-market. SEHA manages the performance of contracted providers by monitoring a set of agreed key performance indicators. This model includes financial penalties when the performance falls below the expected targets.

As described above, the private sector has expanded significantly and between 2009 and 2010 the total number of healthcare facilities grew by 12.4%, with almost 90% of these facilities run by private companies[5]. It remains to be seen whether these changes have contributed to an improvement in the quality of care provided as limited information is available on the quality of healthcare services.

The increase in number of facilities does not necessarily mean an improvement in terms of access to care. As we have noted above, the utilization rates differ starkly between different population groups. Also, worth noting is the increase in Emirati nationals travelling abroad for treatment, despite the increase in the number and range of healthcare facilities. In 2012 the regulatory authority for healthcare, HAAD, launched a Capacity Master plan to ensure improved planning to address quality and access issues and stricter regulate the supply of healthcare services, in particular in areas where there appears to be oversupply (for example general/family medicine and dentistry) and undersupply (for example intensive care, psychiatry and emergency medicine)[3].

In terms of affordability of care, to date no concrete evidence exists to suggest that the affordability of care has changed since the introduction of competition between providers.

Centralized regulatory system

The final characteristic of the health system reform in Abu Dhabi is the establishment of a centralized regulatory system, with one agency (Health Authority Abu Dhabi) responsible for the regulation of healthcare professionals, healthcare providers and healthcare insurance companies.

With the establishment of a regulatory authority, the government of Abu Dhabi created a mechanism to control costs and, indirectly, affordability, through a reimbursement mechanism. The regulatory authority sets the level of reimbursement for all the different activities performed by healthcare providers. Since concrete evidence is not readily available, it still unclear what the effects have been on the affordability of care.

The introduction of the mandatory insurance system has led to an improved situation where virtually all residents are covered by insurance and therefore can access the basic healthcare that they require. The enforcement by the regulatory has indirectly contributed to improving access to care by all residents as heavy penalties are imposed on non-compliant employers [5]. Again the exact impact that this part of the reform has had remains unclear as further evidence is required.

In terms of quality, the regulatory authority is currently developing a quality rating system for all hospitals in Abu Dhabi, to provide relevant and trustworthy information about the quality of care. The Health Authority Abu Dhabi aims to create transparency and accountability in the healthcare industry by providing information about the quality of care to all stakeholders. As a first step the Health Authority Abu Dhabi introduced a rating system for pharmaceutical Facilities in 2011, with a view of expanding this to all healthcare facilities in 2012.

2.4 Conclusion: Reform in Abu Dhabi - what's next?

Although in many countries stakeholders often hold different views on the most effective mechanism to implement reform, there appears to be a consensus on what the overall aims should be: affordable, high quality healthcare that citizens can freely access. The goals set by the Abu Dhabi government reflect the priorities of health system reform in other countries: ensure the provision of high quality, affordable and sustainable healthcare that can be accessed by the community.

To date research on the effects of the healthcare reform on the access, affordability and quality of healthcare in Abu Dhabi has been scarce.

Despite this lack of evidence, a number of tentative conclusions can be drawn. In terms of the first goal: improving access to healthcare, great strides have been made as over 95% of the population (expatriates and nationals) are now members of a healthcare insurance scheme. However, the utilisation rates differ strongly between policy holders. Policy holders in the lower income groups underutilise the healthcare services and this discrepancy raises questions in relation to the achievement of an equitable distribution according to health needs

Even though the WHO estimated that the UAE's expenditure on healthcare is relatively low (2.7% of GDP) compared to other countries, the Government of Abu Dhabi has made the sustainability of healthcare funding a key governmental priority[4]. However, no research has been conducted on the affordability of care from an individual insurance card holder and it remains to be seen what the impact of the health system reform has been as it is too early to tell whether they have had the desired effects on the affordability of care.

Finally, the regulatory authority has begun to measure the effects of the reform on the quality of healthcare have been measured in a number of different ways. For example, in 2010 the Health Authority Abu Dhabi contracted an external agency to conduct a comprehensive patient satisfaction survey. Over 34,000 people were interviewed and the study reported an overall satisfaction rating of 83% for outpatients and 86% for inpatients across all 37 facilities participating[5].

In conclusion, many challenges in terms of access, affordability and quality remain to be addressed in the Emirate of Abu Dhabi. The first steps have been taken under the leadership of the Health Authority Abu Dhabi but in order to effect sustainable, long-term change, the reform needs to continue in its efforts to ensure high quality, reliable excellence in healthcare. Creating transparency by publicly reporting on the performance and quality of healthcare is one of the major initiatives currently under way in Abu Dhabi. As part of their ongoing efforts to measure the impact of healthcare reform, the Health Authority Abu Dhabi has also established an ambitious research initiative to examine the relationship between regulatory approaches and compliance with regulatory requirements. Ayers and Braithwaite[20] originally 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 organizations. The hypothesis behind this research study is that responsive regulatory interventions increase the likelihood of compliance with regulatory requirements, which in turn leads to better quality outcomes[21].

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3

Progress and outcomes of health systems reform in the United Arab Emirates: a systematic review

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3.1 Abstract

Background

The United Arab Emirates (UAE) government aspires to build a world class health system to improve the quality of healthcare and the health outcomes for its population. To achieve this it has implemented extensive health system reforms in the past ten years. The nature, extent and success of these reforms has not recently been comprehensively reviewed. In this paper we review the progress and outcomes of health systems reform in the UAE.

Methods

We searched relevant databases and other sources to identify published and unpublished studies and other data available between 01 January 2002 and 31 March 2016. Eligible studies were appraised and data were descriptively and narratively synthesized.

Results

Seventeen studies were included covering the following themes: the UAE health system, population health, the burden of disease, healthcare financing, healthcare workforce and the impact of reforms. Few, if any, studies prospectively set out to define and measure outcomes. A central part of the reforms has been the introduction of mandatory private health insurance, the development of the private sector and the separation of planning and regulatory responsibilities from provider functions. The review confirmed the commitment of the UAE to build a world class health system but amongst researchers and commentators' opinion is divided on whether the reforms have been successful although patient satisfaction with services appears high and there are some positive indications including increasing coverage of hospital accreditation. The UAE has a rapidly growing population with a unique age and sex distribution, there have been notable successes in improving child and maternal mortality and extending life expectancy but there are high levels of chronic diseases. The relevance of the reforms for public health and their impact on the determinants of chronic diseases have been questioned.

Conclusions

From the existing research literature, it is not possible to conclude whether UAE health system reforms are working. We recommend that research should continue in this area but that research questions should be more clearly defined, focusing whenever possible on outcomes rather than processes.

3.2 Background

The United Arab Emirates (UAE) is a young nation, established in 1971 as a federation of seven Emirates: Abu Dhabi, Dubai, Ajman, Umm Al Quwain, Sharjah, Fujairah and Ras Al Khaimah (Figure 1). This newness has allowed its leaders to deliberately plan for the development of UAE society in order to strengthen national unity, promote continuous economic growth and personal health and wellbeing[1].

Figure 1 Map of United Arab Emirates showing the seven Emirates

As recently as the late 1960s, in the UAE, it was reported that only half of new-born babies survived and one in three mothers died during childbirth[2]. Almost fifty years later many health outcomes are on par or even better than those seen in developed countries. The maternal mortality ratio (MMR) is now 8 per 100,000 live births (in contrast to an MMR of 14 in the USA) and the infant mortality rate is 5.6 per 1,000 live births (5.8 in the USA)[3]. Healthcare in the UAE has benefited from rapid economic growth and there has been a significant increase in the number of healthcare facilities and healthcare professionals and in levels of service use. For example, between 2011 and 2015 healthcare spending in the UAE grew by 10% to US$ 11 billion[4].

In 2014, the Vice President and Prime Minister of the UAE, His Highness Sheikh Mohammed bin Rashid Al Maktoum, launched an ambitious set of plans with the overall goal of making the UAE one of the best countries in the world by 2021, the 50th anniversary of its foundation. The *UAE National Agenda 2021* consists of a comprehensive set of key performance

indicators (KPI) with specific targets and clear pathways for achieving those targets[5]. For example, in 2016, the UAE Government announced the appointment of a Minister of Happiness whose task it is to ensure that the UAE is ranked among the top five countries in the world according to the World Happiness Report[6].

The improvement of the health of its citizens and the performance of the healthcare system form one of seven headings of the UAE national strategy. The KPIs include population health targets, such as increasing life expectancy and reducing tobacco consumption, as well as more structural and organizational targets, such as the regulatory requirement for all healthcare facilities to be externally accredited[5]. Overall, the UAE aims to be ranked amongst the top 20 countries in the world, according to the Legatum Prosperity Indicator. In 2015 the UAE was ranked 34th globally, an improvement from 37th place in 2014[7].

Given its starting point, it is remarkable what has been achieved in the UAE in the last four decades. However since the early 2000s the UAE has been involved with an ambitious program of health system reforms to further improve health and health services and to address cost and quality challenges. These reforms have focused on the introduction of private health insurance and encouraging the growth of private health provision against a back-drop of rapid population growth and a rising prevalence of chronic disease and chronic disease risk factors including obesity, low levels of physical activity and diabetes[8].

The purpose of this paper is to describe the main healthcare challenges and public health issues in the UAE and review the progress and outcomes of health systems reform. This will be achieved by reviewing secondary data from peer-reviewed journal publications and reports of government agencies and related health organizations. Even though the term *health system reform* is regularly used, it is rarely defined in any operational way[9]. In this paper we have defined health system reform as "sustained, purposeful change to improve the efficiency, equity and effectiveness of the health care sector"[10].

3.3 Methods

Data for this review were obtained by means of a systematic search of the published literature using defined keywords, conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[11]. MEDLINE (accessed by PubMed), EMBASE and PsycINFO electronic databases were searched covering the period from 2002 to April 2016 using a combination of the following MESH terms, free-text words, and entry terms: UAE; United Arab Emirates; Dubai; Abu Dhabi; healthcare quality, access and evaluation; healthcare reform, health system reform, health sector reform.

In addition, reference lists of published studies were searched manually for relevant articles. To minimize publication bias and improve the usefulness of our review we also conducted a thorough analysis of existing, publicly available "grey" literature by means of personal contact with senior officers at health authorities, government agencies and health sector organizations and a review of publications and reports from health policy centres, the healthcare business sector and key international sources. These sources included the World Health Organization (WHO) and its regional office for the Eastern Mediterranean (EMRO), the Organisation for Economic Co-operation and Development (OECD), the World Bank, and local sources such as the Health Authority Abu Dhabi (HAAD), Dubai Health Authority (DHA), Ministry of Health and the Federal Competitiveness and Statistics Authority.

Finally, a small number of other sources were reviewed from local "think tanks" and consultancy and research firms. These included Ernst and Young, Colliers International, The Economist Intelligence Unit, US-UAE Business Council, Joint Commission International and Sheikh Saud bin Saqr Al Qasimi Foundation for Policy Research.

Eligible studies were those that focused on the UAE health system. Excluded studies were those that focused on healthcare in the wider region, studies that were published before 2002, articles that were not available in English and duplicate studies or those that formed part of a larger study. Two reviewers (EK, IB) independently screened the titles and abstracts of identified studies and duplicates were removed. Studies considered eligible for full text screening were retrieved for full review. The reviewers independently assessed the papers for eligibility and quality, and then met to resolve any disagreements regarding eligibility and/or quality. The key features of the studies were summarized using a data extraction form that recorded first author name, year, study design, setting, theme and key findings. A descriptive and narrative synthesis of the studies was carried out.

3.4 Results

We screened 353 published articles and 17 met our inclusion criteria (Figure 2). Of these, three related to Dubai, eight to Abu Dhabi and six were UAE-wide and all were published after 2010. There were four cross-sectional studies, six policy reviews, three data reviews, two case studies and two literature reviews. From a careful reading of the selected papers it was possible to classify the content into six categories or themes. The six themes are: the UAE health system, population health, the burden of disease, healthcare financing, healthcare infrastructure and workforce and the impact of reforms (Table 1). The findings are summarized under these headings in the following sections. For the sake of clarity, while acknowledging the possible inferior quality, we have included the grey literature, appropriately referenced, it in our summary along with the published literature.

Figure 2 Flow diagram of the search and selection process

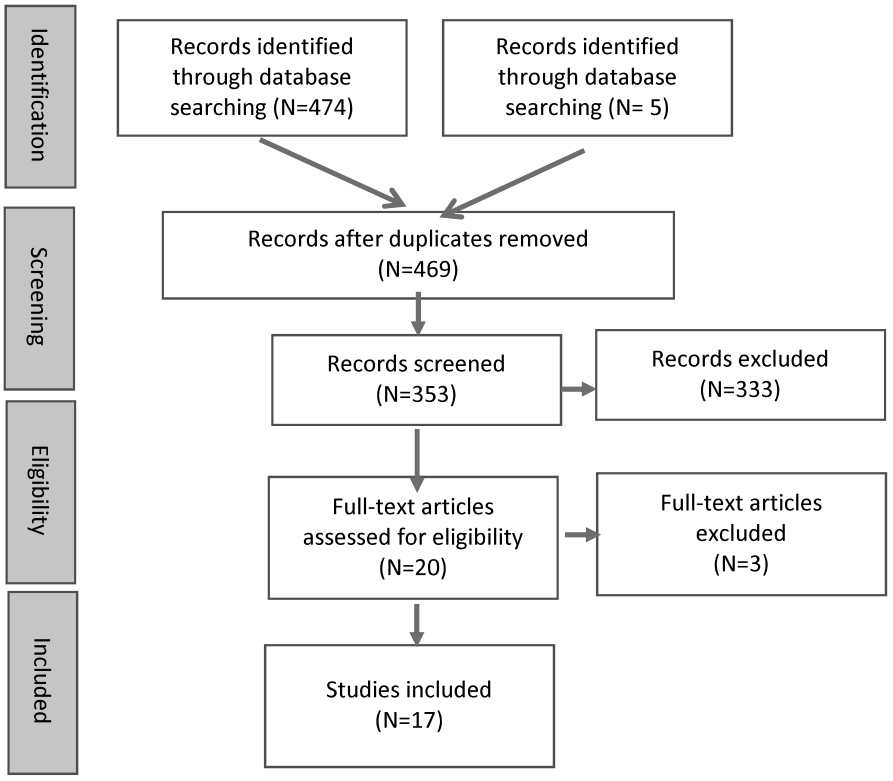


Table 1 Summary of study characteristics included in the literature search

First author, Year	Study Design / Method	Focus	Topics	Key Findings
Al Maskari, 2010[12]	Retrospective cohort study	Dubai	Healthcare Financing	Average costs (without complications): 1,605 USD, with complications 5,645 USD
			Burden of disease (diabetes)	61% of all diabetes patients in the cohort reported to have suffered poor health during the past month
Al Zaabi, 2014[13]	Retrospective cohort study	Abu Dhabi	Healthcare Financing	Asthma treatment in the UAE costs around 200 USD per capita
			Burden of disease (asthma)	Crude prevalence of asthma is 4.8%, much lower than expected

Table 1 (continued)

First author, Year	Study Design / Method	Focus	Topics	Key Findings
Blair, 2012[14]	Data review	UAE	Burden of disease	Substantial population growth
			Population Health	Data quality needs to be improved
Blair, 2012[15]	Healthcare policy review	UAE	UAE Health System	Review of UAE healthcare system 2000-2010
			Population Health	Dramatic population growth, young population
			Burden of disease	Main causes of death: road injury, health and cerebrovascular diseases
			Healthcare Financing	Expenditure has grown from 1.7 billion USD in 2000 to 9.5 billion USD in 2011
			Healthcare infrastructure and workforce	Largely expat clinical workforce (>85%)
			Impact of reforms	Satisfaction appears high but citizens still opt for treatment abroad
Al Hosani, 2014[16]	Healthcare policy review	UAE	Burden of disease	National neonatal screening program
Brownie, 2015[17]	Regulatory policy review	UAE	Healthcare infrastructure and workforce	Brief historical overview of regulation and licensing in the UAE
			UAE Health System	Move towards central, consistent regulation and licensure
Hajat, 2012[18]	Retrospective cohort study	Abu Dhabi	Burden of disease	This population-wide cardiovascular screening program demonstrated a high cardiovascular burden for our small sample in Abu Dhabi
Hajat, 2012[19]	Healthcare policy review	Abu Dhabi	Burden of disease	Largely unhealthy lifestyle - lack of physical activity, poor diets & tobacco consumption
			Population Health	Weqaya - a program aimed at improving population health (cardiovascular)
			Healthcare Financing	Diabetes may cost up to $1.1 billion per year in Abu Dhabi
			UAE Health System	Weqaya program - screened 94% of national population
Hamidi, 2014[20]	Focused literature review	Abu Dhabi	Healthcare Financing	In Abu Dhabi there has been a significant growth in demand for healthcare since 2007
			UAE Health System	Strategies are in place designed to slow the rise in spending
Hamidi, 2015[21]	Data review	Abu Dhabi	UAE Health System	The health care model has not fully matured yet and needs to focus on creating a sustainable model that is affordable and provides high quality, safe care

Table 1 (continued)

First author, Year	Study Design / Method	Focus	Topics	Key Findings
Hamidi, 2015[22]	Data analysis	Dubai	UAE Health System	Changes required to move from curative to preventive care and from inpatient to day care, outpatient and home-based care
			Healthcare infrastructure and workforce	Cost containment for pharmaceuticals
			Healthcare Financing	Strengthen long-term care
Koornneef, 2012[8]	Healthcare policy review	Abu Dhabi	Impact of reforms	Limited information available, some evidence of improved access and patient satisfaction
			UAE Health System	Three key characteristics: centralized regulatory system, mandatory insurance and competition
Loney, 2013[23]	Literature search	UAE	Population Health	UAE has significantly invested resources into population-based control measures
			Burden of disease	Top four priorities: cardio, injury, cancer, respiratory diseases
Mosaad, 2014[24]	Healthcare policy review	UAE	UAE Health System	Risk factors: ageing population, population growth, health risk factors
			Healthcare infrastructure and workforce	Lack of clinical staff, hospital beds and referral network
			Impact of reforms	Progress is "underway" in the UAE with a focus on quality, screening and competition. However, the focus is not on prevention
Osenenko et al., 2015[25]	Retrospective cohort study	UAE	Population Health	Greater understanding of the factors leading to high adherence to guidelines would be useful
			Impact of reforms	Compared to international benchmarks, the patients in Dubai received similar quality outcomes
Sharif, 2011[26]	Case study	Dubai	UAE Health System	Review of the necessary changes in the healthcare system in Dubai to accommodate population growth and burden of disease
Vetter, 2012[27]	Case study	Abu Dhabi	Healthcare Financing	Strong regulatory focus on cost containment
			UAE Health System	Many changes since 2006, in particular introduction of mandatory insurance and the establishment of a regulator

The UAE health system

Ten of the included papers discussed the UAE health system. Improving the quality of healthcare as well as the actual health outcomes for its citizens has been a key strategic goal of the UAE government since its formation in 1971. Dubai and Abu Dhabi have their own health authorities for licensing, regulation and quality assurance. The Federal Ministry of Health (MOH) fulfils these functions in the other five emirates. In addition, the MOH carries out certain high-level functions for all Emirates[17]. In both Dubai and Abu Dhabi around 70% of outpatient visits are made to private healthcare facilities while for inpatient activity in private facilities the proportion is 40% in Abu Dhabi and 60% in Dubai[28,29]. In the remaining five Emirates, the Ministry of Health is both the regulator as well as the main provider of most healthcare services. According to the most recent data, in 2014, there were 36 government and 79 private hospitals in the UAE, an increase of 25% since 2009[30].

In 2006 the government of Abu Dhabi embarked on a significant health system reform program with a clear focus on the redesign of the healthcare financing and regulatory system[8]. The regulatory function (the responsibility of Health Authority Abu Dhabi) was separated from service provision (the responsibility of the Abu Dhabi health service company, SEHA). Also, the new system required all persons to have private health insurance and provides a centralized platform for automated claims processing and an improved level of accountability and transparency because of market regulation[27]. One study reported large differences in healthcare utilization rates between UAE nationals who, on average, used outpatient clinical services once per month compared to expatriates where usage rates were 3-4 times less[31].

In 2014, Dubai also began to introduce mandatory health insurance, with about one third of its residents currently estimated to be insured[32]. A recent review of the Dubai health system concluded that more effort should be made to move from curative to preventive services[22]. The same review also found that the current system of care encouraged excessive hospital utilization and recommended a reorientation towards outpatient, home based and day surgery services.

It has been reported that the rest of the UAE will follow soon with the introduction of mandatory private health insurance but a final date has not been set[33]. The MOH is considering introducing health insurance but has not yet done so. In the northern Emirates, the private sector is less well developed than in Dubai and Abu Dhabi and the quality and cost of services varies between these two Emirates and the remainder of the country[31].

Five of the studies examined the UAE health regulatory system with one highlighting the trend towards regulatory fragmentation as a serious challenge to the future of healthcare in the UAE[32]. A further study reported the lack of regulatory control and a lack of competition

between insurance companies as the two main obstacles to achieving greater cost efficiency in the healthcare market[20]. Researchers who evaluated the regulatory system for healthcare professionals concluded that the UAE had made significant progress in developing and implementing best regulatory practice[17]. Other research on the regulation of healthcare services in Abu Dhabi concluded that several challenges remained to be addressed, in particular with respect to quality improvement[32]. Interestingly, Abu Dhabi's healthcare regulator itself, HAAD, concluded in 2013 that "the current model of care in Abu Dhabi does not adequately support self-care or prevention and screening programs and diagnostic services are not integrated into care plans. Also, patients have undirected access to services and specialty care which leads to inappropriate use and, in turn, over-supply of services"[29].

Population health

Five studies addressed this topic. The UAE population can be characterized as young and fast growing. The UAE population pyramid is remarkable in term its youthfulness and the high proportion of male expatriates[14]. Overall, the median age is 30 but amongst UAE nationals, who only account for approximately 11% of the population, 79% are aged less than 35[3,30]. Expatriates are typically of working age but despite this the majority are aged 35 or less. Population growth rate has also been remarkable. In 1950 the population was 70,000, in 1968 it was 180,000 but this has now grown to 9.16 million[34,35]. Over the last 10 years the population has more than doubled, mainly due to large net in-migration of expatriates. Since the population of nationals is small, the contribution of the birth rate amongst nationals to overall population growth is also small. For example, between 2010 and 2014, the UAE population grew by over one million. However, during this four-year period, the national population increase by only 126,609 (births minus deaths). In other words, population growth amongst nationals contributed only 11.7% of total population growth. By comparison, natural growth amongst expatriates contributed 19% of total population growth and net in-migration contributed the remaining 70%.

The great majority of the expatriate population in the UAE are male, young and originally from Asian countries. For example, it is estimated that approximately 2.6 million Indian nationals reside in the UAE[36]. The total fertility rate (average number of children that would be born to a woman over her lifetime) decreased from 4.4 in 1990 to 2.4 in 2010[23]. During the same period, the average life expectancy improved from 72 years to 77 years[37]. The unique characteristics of the UAE population should play a major role in the development and implementation of health strategies and policies. Clearly child and maternal health services, youth services, health promotion and preventative services and occupational health services should be priorities[31]. A recurring theme from the studies that we reviewed is the need to improve health data collection and reporting[14,31]. For example, birth and death data are reported but not by nationality, making it difficult to determine what, if any, specific, targeted strategies are required.

In summary, the demographic transition in the UAE is one characterized by declining birth and death rates which with high net in-migration has resulted in significant population growth[24]. There has been a second health transition in the UAE in recent decades, an epidemiological transition, characterized by a decline in communicable diseases and a rise in non-communicable or chronic diseases, such as heart disease, diabetes and cancer[24]. This is described in the following section.

The burden of disease

Eight studies discussed UAE mortality, morbidity and risk factors. As mentioned earlier, the UAE Government has set itself a number of challenging targets through its Vision 2021 strategy[5]. Of particular relevance are the targets to reduce the number of deaths (per 100,000 population) from cardiovascular disease from 297 to 158. Other targets relate to a reduction in the number of adults with diabetes (from 19% to 16%), a reduction of obesity amongst children (from 13% to 12%) and an increase in the healthy life expectancy (from 67 years to 73 years). Since its independence in 1971, the UAE has made significant progress with increased life expectancy and lower maternal and infant mortality rates[19]. However, despite these achievements, the UAE faces a number of challenges including rising rates of non-communicable diseases such as diabetes, cardiovascular diseases and cancer[23].

The UAE has made progress with the control and prevention of communicable diseases, through a strong focus on immunization, surveillance, mandatory reporting and effective treatment[23]. The mandatory screening of all expatriate workers linked to the visa application and renewal process has also had an effect[38]. The national neonatal screening program for new born babies has been successful with an increased uptake from 50% in 1998 to 95% in 2010 resulting in early detection, treatment and follow up[16]. The WHO currently estimates that world-wide around 67% of all deaths are now attributable to non-communicable diseases, with the leading causes of death reported as cardiovascular diseases, injury and cancer[39]. This is also the situation in UAE, where mortality from non-communicable diseases (NCDs) among those aged 60 years or younger is amongst the highest in the world. The leading causes of premature deaths in the UAE are road injury, cardiovascular disease and respiratory illnesses[31]. In the studies that we reviewed, authors identified the determinants of this health loss as unhealthy lifestyles (physical inactivity, high caloric intake) and a lack of health system focus on prevention, chronic disease management, early stage interventions and inadequate treatment options for NCDs and their complications. As solutions, these authors proposed further research, the establishment of reliable surveillance and monitoring programs and improved training and education for healthcare professionals[12,16,23].

We found five studies that described interventions to address the UAE burden of NCDs. One such intervention is the Abu Dhabi Weqaya program that aims to screen adults for

cardiovascular disease risk factors followed by targeted follow up, treatment and secondary prevention[18]. Weqaya has confirmed a high prevalence of cardiovascular disease risk factors amongst the adult population. Following the successful implementation of screening in a small, high-risk population using newly agreed UAE screening guidelines other researchers have recommended a national diabetes screening program[40]. In the review we found a number of studies that reviewed the direct and indirect economic burden of selected diseases, including asthma and diabetes[12,13]. The economic burden of asthma was estimated at US$ 29 million in Abu Dhabi and US$ 24 million in Dubai, an annual per capita cost of around US$ 200, about half the cost compared to European or North American benchmarks.

One of the most cited articles in the review assessed the direct medical costs of diabetes care, the annual cost of diabetes without complications was US$ 1605, similar to the costs in most western countries but the treatment costs of diabetes mellitus with complications was up to 9.4 times higher[12]. The authors of these papers that reviewed the economic costs of high burden diseases typically recommended improvements in management including nationwide early screening and rapid implementation of best-practice clinical guidelines as a means to improve outcomes while controlling costs.

Healthcare financing

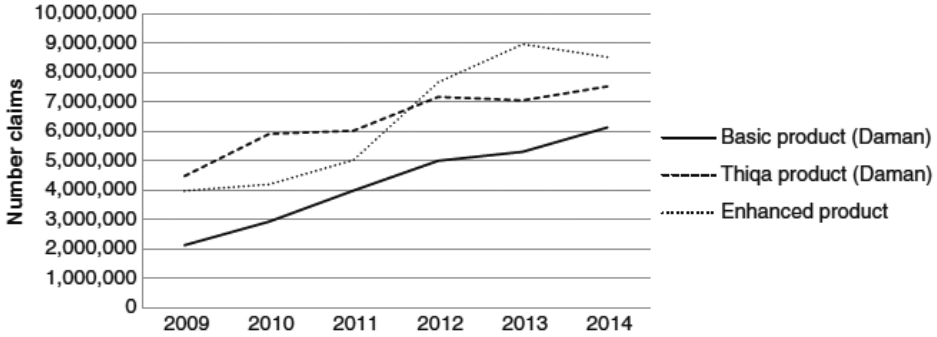
Seven studies discussed healthcare financing. Recently published WHO data indicates that in the UAE over the last 12 years, total expenditure on health as percentage of gross domestic product (GDP) has increased by over 36% (from 2.2% of GDP in 2000 to 3.0% in 2012)[3].

In absolute terms, the UAE's GDP rose from US $ 104.3 billion in 2000 to US$ 372.3 billion 2012, meaning that health spending grew from US$ 2.3 billion to US$ 11.2 billion. More recent reports show a further increase to US$ 13.6 billion in 2014 with an expected budget of US$ 25.7 billion by 2024[41].

In Abu Dhabi, mandatory health insurance for all nationals and expatriates has been the major driver of its healthcare reform since 2006[21]. There are three different insurance schemes: two for expatriates (Basic and Enhanced) and one for UAE nationals (Thiqa). In 2011 there were 15.3 million insurance claims with an average cost per claim of $105 giving a total insurance bill of US$ 1.6 billion. This had grown to over 22 million claims and US$ 2.9 billion by 2014[29].

Even though there has been a steady rise in the number of claims (Figure 3) as well as the overall cost, some researchers have argued that this is appropriate because universal health insurance cover and transparent, standardized payment rules and regulation allow for better control of cost, ensure that health needs are met and offer patients the freedom to choose provider[8,27].

Figure 3 Health insurance claims by type of insurance scheme, Abu Dhabi, 2009- 2014



However, other researchers have concluded that increasing claims and costs signal the need for further changes to ensure long-term financial sustainability[21]. The WHO and other sources estimate that the UAE government spent almost a quarter of its total healthcare expenditure in 2010 to send its citizens abroad for medical care[27,39].

Dubai Health Authority for example sponsored 2,717 patients in 2014 for treatment abroad, an increase of almost 2,000 in 10 years[28] (Table 2). While in 2013, Health Authority Abu Dhabi sponsored over 1,400 patients[29]. There are also other referral sources for UAE nationals who wish to be sent abroad for medical treatment, including the Ministry of Health, Ministry of Defence, Abu Dhabi National Oil Company (ADNOC) and other large companies[8].

Table 2 Funding of International Patient Care by Dubai Health Authority
Source: Dubai Health Authority's Annual Reports[42].

Year	No. UAE Patients who received medical treatment outside UAE	Average cost per patient (US$)	Total cost (US$)
2004	808	40,436	32,672,262
2005	679	54,768	37,187,738
2006	863	57,221	49,381,471
2007	946	51,499	48,717,711
2008	850	75,204	63,923,706
2009	1073	59,128	63,444,414
2010	975	68,392	66,682,561
2011	1428	57,766	82,489,373
2012	1819	50,681	92,189,101
2013	2010	46,921	94,311,172
2014	2717	44,142	119,932,970

At the same time, the UAE is working to attract medical tourists to its healthcare facilities, in particular its highly specialized hospitals. For example in 2012, Dubai attracted over 500,000 medical tourists, a figure that is expected to grow annually by 10-15%[43].

In the UAE the level of out-of-pocket (OOP) healthcare expenses is relatively low in comparison to other countries in the region and the rest of the world. At 20% the OOP is just above the OECD average of 17% indicating a reasonable level of financial protection[44].

A number of studies have commented on the low levels (ranging from 4-15%) of generic prescribing and the high use of branded pharmaceuticals with the inevitable implications for increasing costs[45,46]. In the UAE, data on health care spending is not yet available in a standardized format. The claims based data for Abu Dhabi shown in Table 2 contains only the reimbursement cost not the actual cost. Denials, co-payments and sole payments are not included. Also cost estimates typically exclude capital expenditure, funding provided through other government institutions such as the Ministry of Defence and ADNOC and cash payments.

Table 3 gives a breakdown and estimate of the healthcare expenditure in the UAE based on our findings from this review[22,42].

Table 3 UAE total healthcare expenditure (Billion US$), by Emirate, 2014

	Healthcare Expenditure (Billion US$)
Abu Dhabi	4
Dubai	3.5
Northern Emirates	2.5
International Patient Care	3.6
Total	13.6

Healthcare infrastructure and workforce

Five studies addressed this topic. Hospital bed and physician and nurse numbers have increased in the past decade generally keeping pace with the growth of the population (Table 4). The total number of hospital beds has more than doubled and there has almost been a five-fold increase in the number of nurses and physicians[30]. A number of case studies have reviewed the current demand and supply and made recommendations for future configuration and capacity. Few of these studies reported that additional increases in hospital beds and staff numbers were justified[26,31,41].

However, the Health Authority Abu Dhabi estimated that a further 4,800 physicians and 13,000 nurses would be required for Abu Dhabi alone to meet the projected 2022 demand[29]. The goal for the UAE is to bring the level of nurses and physicians to a world class level, which means that the number of nurses need to be almost doubled and the number of physicians needs to increase by 20%[5].

Table 4 UAE healthcare infrastructure, by category, Government and private, 2005-2014

	2005	2010	2014
Government*			
Hospitals	26	34	36
Beds	4,273	7,029	7,493
Physicians	2,105	5,031	6,504
Nurses	6,132	10,875	16,547
Private			
Hospitals	37	58	79
Beds	1,546	2,556	4,164
Physicians	1,143	7,866	10,165
Nurses	1,866	10,611	16,882
Total			
Hospitals	63	92	115
Beds	5,819	9,585	11,657
Physicians	3,248	12,897	16,669
Nurses	7,998	21,486	33,429

** Includes Ministry of Health, Ministry of Interior, Ministry of Defence, Abu Dhabi Health Authority, Dubai Health Authority and ADNOC*

Despite these reported shortfalls in capacity and resources, the authors were unable to find any studies that analysed the potential effects of the reported lack of manpower and hospital beds. On the contrary, a number of studies, as well as a report from the Abu Dhabi regulatory authority described potential oversupply in certain areas[29,31]. Another challenge is the high rate of turnover of clinical staff, with one report estimating that around 15% of physicians and 13% of nurses left their positions in the UAE in 2012 alone[47].

The impact of reforms: quality

Only three of the studies focused on the impact of health system reforms. Although a number of researchers have commented that it is too early to say whether the UAE health system reforms that have been in place over the past 10 years have achieved the desired outcomes, there is evidence of a positive trend[8,31]. A recent study in a large hospital in Abu Dhabi found a decrease in reported clinically significant adverse events in one department (paediatrics) over a four year period[48]. This decrease coincided with the reform of its residency training program, leading to the researcher's conclusion that "it is quite likely that our residents are providing better patient care". In Abu Dhabi, a study into perceptions and attitudes towards medical research amongst focus group participants noted that the UAE has one of the best healthcare systems in the region[49].

The UAE has also witnessed a significant growth in *Joint Commission International* (JCI) accreditation[50]. JCI accreditation has become increasingly important in the UAE, where a

growing number of providers have achieved JCI accreditation[51] (Table 5). It is estimated that currently 47% of healthcare facilities are accredited and the UAE government's ambition is to achieve 100% accreditation by 2021[5]. In our review we found few studies that reported quality and outcomes of care. However, in one study in Dubai that reviewed the quality of care for diabetic patients, using a standardized assessment, the researchers found a number of differences when compared to the US benchmark and recommended a nationwide benchmarking program[25]. Another study found that while a private hospital maintained its performance following JCI accreditation, accreditation did not contribute to an overall, sustained improvement[52]. Finally, in our review, we found that studies that examined patient satisfaction generally reported consistently high levels compared to other countries[8,31].

Table 5 Joint Commission International accredited facilities, UAE, 2007-2015
Source: Joint Commission International

Year	No of healthcare facilities with JCI accreditation
2007	14
2008	18
2009	33
2010	42
2011	49
2012	55
2013	82
2014	102
2015	116

3.5 Discussion

This review has highlighted the ambition and commitment of the UAE to build a world class health system and has catalogued the major reforms that have been implemented in the past decade to achieve this. The paucity and limited scope of the studies means that it is not possible to conclude whether the reforms are working although patient satisfaction with services appears high and there are some isolated examples of quality improvement.

The UAE health system is not a single system, rather there are several systems and of these the three main systems are operated by the health authorities of Abu Dhabi and Dubai and the Ministry of Health (MOH). These systems have expanded in the past ten years in line with the growth of the population and increases in national income and have been subjected to major reforms aimed at improving public health and quality while keeping costs at sustainable levels, thereby achieving a world class health service.

The main elements of the reforms have been a move to mandatory private health insurance for all citizens and expatriates, the development of the private sector to deliver services and the separation of planning and regulatory responsibilities from provider functions. These reforms have moved at different speeds, being most complete in Abu Dhabi, in the development phase in Dubai and just commencing in the MOH. This patchy implementation has highlighted variations in access, affordability and quality across the Emirates. Amongst researchers and commentators opinion is divided on whether the reforms have been successful. Few, if any, studies have prospectively set out to define and measure outcomes and while some researchers have expressed optimism others have been more critical. The relevance of the reforms for public health and their impact on the determinants of chronic diseases have been questioned with some researchers citing market failure and oversupply.

The UAE has a rapidly growing population with a unique age and sex distribution. There is an unusually high proportion of young people and expatriates of working age, small numbers of older persons and rapid year on year growth due to high net in-migration. It might be expected that the unique characteristics of the population would be a major factor to be considered when planning and implementing health services but there is little published research to support this. While child and maternal health services are well developed, there is little published evidence of needs analysis in the areas of youth services, health promotion, preventative services and occupational health services. Also health data is not collected and reported in a way that allows the health needs of these population sub-groups to be defined.

The UAE has passed through the epidemiological transition with impressive reductions in health loss from infections and neonatal and nutritional disorders but an increasing burden of non-communicable disease (NCD) notably cardiovascular disease (CVD), diabetes and road injury. The lifestyle risk factors for these diseases (obesity, low physical activity) are at high levels. From our review there is evidence of high level commitment to addressing these issues. The Abu Dhabi *Weqaya* program set out to identify and manage individual CVD risk factors but after the initial report describing the program and presenting baseline data there have been no updates on outcomes, effectiveness or recommendations to extend the program to the whole UAE adult population. There is good evidence for the considerable cost burden that NCDs place on health budgets and bench-marking has shown that the situation in the UAE is comparable to that in other high income countries. However there is also evidence that in the management of NCDs international best practice is not always followed.

Total expenditure on health has increased both in absolute terms and as a percentage of national income. As in all health systems these increases can be explained on the basis of population growth, aging of the population, advances in technology and price inflation. In

the UAE, the increases may also be justified if there was previously unmet need that is now being met.

In our review we found researchers who suspected over-use, waste and fraud and who questioned whether the increases in activity and cost were sustainable or whether further reforms were required. In the review, a recurring theme was the need to economize on drug costs by encouraging greater use of generic products. In our review we were surprised that, given the excellence of the UAE health system, substantial numbers of patients are funded to have medical treatment abroad at substantial cost. This is all the more noteworthy because the UAE health system is highly successful at attracting incoming medical tourists. The reasons for this curious state of affairs was not explored in depth but if the UAE's ambition to have a world class health system is fully achieved then funding patients to receive routine treatment abroad would seem to be improvident. In the review we found discussion of the percentage of total health expenditure that is contributed by out-of-pocket (OOP) expenses, a widely used metric to indicate financial security. In the UAE, the OOP percentage is comparable to that seen in other countries with well-developed progressive health systems. This might appear surprising given the high levels of disposable income enjoyed by many UAE citizens and expatriates. However, once again our review highlighted the need to improve the quality of data collection and reporting and to make allowance for the fact that the UAE population is very heterogeneous

In this review, we found that a normative approach was typically adopted to plan and predict future capacity both for hospital bed numbers and numbers of doctors, nurses and other healthcare staff. The norms or benchmarks that are used are those from North America and Europe. It is not clear if there is shortage or oversupply or what, if any, are the consequences of this. What is clear from published evidence is the high staff turnover and poor retention rates.

From our review, it is not possible to say if the UAE health systems reforms are working. Some researchers have concluded that it is too early to expect to see any effect but mostly the research in this area has not focused specifically on this question. We found isolated reports of initiatives that have improved quality. UAE national policy is that all hospitals should be JCI accredited and good progress is being made towards this target. Again, there are a few reports of the beneficial effects of accreditation but this is an area that is poorly researched. We found isolated examples of where services or programs had been audited against international best practice benchmarks with mixed findings. Where researchers commented on patient satisfaction with services this was usually high.

Despite the increased focus on healthcare reforms in many countries, it remains a concept lacking a clear definition[9]. According to one definition, health system reform can be described as a "significant purposive effort to improve the performance of the health care system"[53].

With respect to the impact of reforms, several authors have cautioned against simplistic, cause-and-effect logic because of the complexities involved in overseeing and providing healthcare with multiple, demanding stakeholders, competing political priorities and high expectations[54,55]. However, despite this caution, over the last three decades, global institutions such as the World Health Organization and the World Bank have stimulated national government to reform their health systems, with notable results[56]. For example, governments of developing countries, such as Brazil, Russia, India, China and South Africa have committed themselves to radical reform programs with the goal of achieving universal health coverage and China in particular has made significant progress in ensuring that its population has access to healthcare[53,57]. Similarly, the Affordable Care Act in the US has resulted in an impressive decrease in the percentage of uninsured adults[58]. Specifically to the Middle East and North Africa region, researchers have commented on the increased focus on building or reforming health insurance systems as a popular method of reform[59].

This is the most complete summary, to date, of the evidence available on the progress and outcomes of health systems reform in the United Arab Emirates. Our study is not without limitations. We found a limited number of studies that addressed UAE health system reform and of those that did most lacked robust methodology and failed to focus on the outcomes of reform. Although our search strategy was broad and included both published and unpublished sources to minimize publication bias it is possible that papers meeting our inclusion criteria were missed and therefore, not included in the review. Nevertheless, the review provides a stock-take or baseline from which future researchers can plan and develop their research questions. We have identified some important gaps in knowledge that may inform future research.

3.6 Conclusion

The UAE government is committed to build a world class health system to improve the quality of healthcare health outcomes for its population. To achieve this, it has implemented extensive health system reforms in the past 10 years including the introduction of mandatory private health insurance, the development of the private sector and the separation of planning and regulatory responsibilities from provider functions.

From the existing research literature, it is not possible to conclude whether the reforms are working although there are some positive indications including high patient satisfaction, increasing coverage of JCI accreditation and isolated examples of quality improvement. We recommend that research should continue in this area but that research questions should be more clearly defined focusing whenever possible on outcomes rather than processes. In addition, there is need for better quality data collection and reporting to allow the health needs and outcomes of specific population sub-groups to be defined. Finally, there is scope to align services and program more closely with international best practice and to benchmark UAE performance with that of similar highly developed, progressive health systems from around the world.

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4

The development, implementation and evaluation of Clinical Practice Guidelines in Gulf Cooperation Council (GCC) Countries

This Chapter is published as:

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4.1 Abstract

Objective: Our aim was to examine and describe the current situation in Gulf Cooperation Council (GCC) member countries regarding the development, implementation and evaluation of clinical practice guidelines. The objectives were to describe from where the studies originated, what the clinical focus was of each study and examine the methodology and the status of each study (i.e. development, dissemination, implementation and evaluation).

Methods: Review of literature – two stages: Stage 1: screening through an abstract review, followed by independent adjudicator. Stage 2: detailed assessment and classification.

Results: Considering the widespread acceptance that CPG's are useful and effective tools for quality improvement in healthcare, it is worth noting that relatively few studies have been conducted in the GCC region that examine CPG. Furthermore, the reviewers found that the quality of the research methods used could be improved. However, the majority of the studies that were conducted evaluated the effects of guidelines and focused on the 'lifestyle diseases', in particular diabetes and cardiovascular diseases. It is also worth noting that there has been a steady increase in the number of publications over the 10 years period.

Conclusions: More attention needs to be given to developing, disseminating, implementing and evaluating CPG's in the GCC region in order to improve the quality and safety of health care.

4.2 Introduction

Concerns about patient safety, an increased focus on high quality, rising consumer expectations and increased healthcare costs have all highlighted the need to regulate and improve the quality of healthcare services. 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[1]. In order to abate or control risks and provide assurances to the society, different regulatory interventions have been introduced to both *deter* particular non-desirable actions and behaviours and *encourage* compliance with desired actions and behaviours. Both forms of regulation (deterrence and compliance) are used extensively in healthcare regulation[2].

Despite the best intentions of regulatory authorities, there still is a dearth of empirical evidence of the overall effectiveness of regulatory interventions on the quality of health care[3–5].

However, studies into the effectiveness of regulatory interventions have found moderate, positive results on the quality and safety of healthcare in relation to two regulatory interventions in particular: accreditation[6] and evidence based best practice guidelines such as Clinical Practice Guidelines[7–9]. The focus of this study is on one of these interventions in particular: This study will provide an overview of the availability, use and effects of guidelines in the Gulf Cooperation Council (GCC) region. This study forms part of a broader investigation into the relationship between regulatory approaches and compliance with regulatory requirements for healthcare organizations and professionals[10].

In clinical practice, clinicians are encouraged to implement and adhere to evidence-based clinical practice guidelines (CPGs), as these are regarded as important tools for quality improvement and patient safety. Clinical practice guidelines are used to translate, adopt and implement best evidence into everyday clinical practice[11].
The Institute of Medicine[12] defines clinical practice guidelines as "*statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options*".

The aim of developing clinical guidelines is to produce explicit recommendations that are both scientifically valid and helpful in clinical practice[13]. Implementation can be described as 'a planned process and systematic introduction of innovations or changes of proven value; the aim being that these are given a structural place in professional practice, in the functioning of organizations or in the health care structure[9]. Finally, the evaluation of guidelines considers whether the recommendations in the guideline and pathway are adhered to, whether practices have changed and whether the intended health outcomes have improved[14].

There is evidence that the use of standardized practice is associated with improvements in the quality and safety of care[15–17], as well as cost savings[18]. Since the positive effects are widely acknowledged, healthcare regulatory authorities have regularly endorsed and mandated the development and implementation of guidelines[4]. The effectiveness of clinical practice guidelines in terms of improvement in the quality of care and patient outcomes has been well documented[7,9] which has led to a proliferation of guidelines, often as part of a regulatory intervention.

This study analyses the current situation in one of the fastest changing regions in the world: The Gulf region in the Arabian Peninsula. Six countries in the Gulf region (the United Arab Emirates, the Kingdom of Bahrain, the Kingdom of Saudi Arabia, the Sultanate of Oman, the State of Qatar and the State of Kuwait) that shared a common language, religion and history in the Gulf region established a cooperative agreement in 1981, the Gulf Cooperation Council (GCC). The GCC countries collaborate on a variety of areas, including economic development, foreign policy and also healthcare. The GCC Council of Health Ministers is comprised of health ministers from each of the seven member states and convenes biannually. The total, combined population of the six GCC countries was 45 million in 2011, with astonishing population growth rates of up to 850% in the last 3 decades in Qatar and 780% in the United Arab Emirates[19], mainly due to the increase of expatriate worker. During the same period, GCC countries witnessed a rise in life expectancy (for example life expectancy in the United Arab Emirates improved from 69 years in 1980 to 77 years in 2011) and significant improvements in under-five mortality, achieving reductions ranging from 70% to an impressive 91% lower mortality in Oman. Another notable characteristic is the large number of expatriates: nationals are a minority in all GCC countries, except Oman and Saudi Arabia[20].

4.3 Methods

The aims of this review were to investigate the stages of development, implementation and evaluation of clinical practice guidelines in the countries of the GCC region and to present the latest available information, per GCC country and clinical specialty.

Screening

A systematic literature review was conducted in Medline and PubMed databases and Cochrane Library on clinical practice guidelines in the GCC region. Searches included studies published between 2000 and 2013, in the English language. Two reviewers (EK and AA) independently screened the titles and abstracts and selected potentially relevant articles that met the inclusion criteria. Any differences between the two reviewers were referred to a third researcher (CA) for resolution.

The following search strategy was deployed:

#1 Clinical practice guideline OR clinical guidelines OR evidence-based guidelines
#2 Develop* OR availab* OR implement* OR adopt* OR adher* OR compliance OR disseminat* OR evaluat* OR promulgat* OR effect* OR impact
#3 Gulf Cooperation Countries OR GCC OR United Arab Emirates OR UAE OR Oman OR Sultanate of Oman OR Qatar OR Saudi Arabia OR Kingdom of Saudi ArabiaOR Kuwait OR Bahrain OR Kingdom of Bahrain
#4 (#1 AND #2 AND #3)

Data extraction and assessment

Once the articles had been screened and selected for inclusion, the studies were assessed utilizing a standardized template and information on the following was recorded by two researchers (EK and AA):

- Country (countries) where research was carried out
- Disease / condition
- Type of study and research methodology
- Stage of maturity (development, implementation, evaluation)
- Date when study was conducted and publication date

Any discrepancies or disagreements were resolved through discussions, involving the entire research team.

4.4 Results

Selection of publications

The final search was conducted on 2 October 2013 and resulted in 229 articles. Two reviewers independently reviewed the titles and abstract and key words to determine eligibility. Any disputes were referred to a third researcher. This resulted in the selection of 73 papers for further analysis and assessment. Among these 73 articles identified, 58 were selected following the detailed assessment of the studies. Out of these 58 articles, 24 (40.4%) were published by journals from the GCC Region, primarily from Saudi Arabia (32.78% of all articles).

Country or countries of origin

The majority of the publications originated from Saudi Arabia (27), followed by the United Arab Emirates (8), Kuwait (7), Oman (4), Bahrain (3) and Qatar (1). In addition, 2 articles covered the entire Gulf Cooperation Council (GCC) Region and a further six covered the

entire Middle East and North Africa Region (MENA Region). However, the overwhelming majority of articles refer to and compare their findings with international Clinical Practice Guidelines (50 out of 58 articles).

Topic of study: Disease or Condition

Table 1 below indicates what type of disease or condition the articles focused on. Unsurprisingly, the majority of articles (30 out of 58 articles) dealt with the common lifestyle associated diseases in the GCC region (i.e. cardiovascular, diabetes, hypertension and cancer). However, quite a range of topics were studied, including pandemic influenza, smoking cessation, etc.

Table 1 Publications by topic

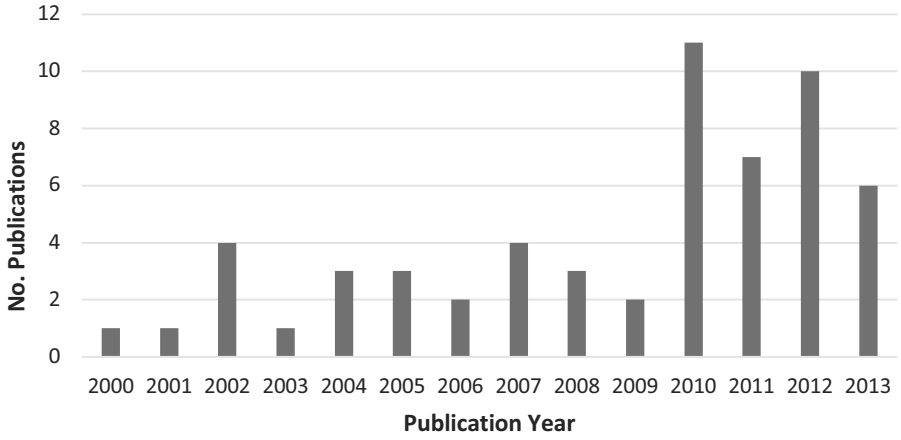
	n (%)
Diabetes	14 (24.1%)
Other	12 (20.7%)
Asthma	7 (12.1%)
Cancer	6 (10.3%)
Infectious diseases	5 (8.6%)
Hypertension	4 (6.9%)
Communicable diseases	3 (5.2%)
Community Acquired Pneumonia	3 (5.2%)
Cardiovascular disease	2 (3.4%)
N/A	2 (3.4%)

Two articles did not deal with a specific topic, one article[21] dealt with the attitudes and self-reported behaviours of healthcare professionals toward clinical practice guidelines in a hospital in Saudi Arabia and the second article[22] described a brief background on clinical practice guidelines in Saudi Arabia.

Publication date

There has been a steady increase in the number of articles published over the last 15 years, as shown Figure 1 below, with a marked increase since 2010. Over 60% of all articles were published in the last 4 years.

Figure 1 Publications by year



Stages and study design

A small number of publications simply reproduce the guidelines in an article format, for example the Osteoporosis Guidelines in Saudi Arabia[23] and GCC Guidelines for Community-Acquired Pneumonia[24] and a larger number describe the entire process for developing guidelines. In total, 20 articles describe the development of a guideline, most often based on a literature review and expert consultation. However, only one study[25] utilises the AGREE Instrument to evaluate the quality of the CPG. A number of articles also make reference to guidelines developed by regional GCC working groups, such as the GCC Community-Acquired Pneumonia Working Group[26–28] and the MENA Region–National Comprehensive Cancer Network Breast Cancer Guidelines[29].

In total 7 publications focused solely on the implementation process and systematic introduction of the guidelines into practice, mainly using surveys as methodology, for example the implementation of Asthma Guidelines in Oman[30].

In terms of publication productivity, it is difficult to infer anything from this number of articles, since there have been very few comparative studies. However, it appears to be lower than what could be expected, considering the population size. A study[31] into the quantity and quality of biomedical publications between 2001-2005 found that the 12 countries selected from the Arab world (including the GCC region) producing significantly fewer biomedical publications of lower quality than other Middle Eastern countries (Turkey, Israel and Iran). Other studies have found similar results[32,33].

Finally, the majority of the publications (31 out of 58) described findings from evaluating the adherence to guidelines or the effects of the implementation of guidelines. The research

methodology to evaluate adherence and effects included cross sectional studies, case series, retrospective reviews of medical records and in one study, a randomised controlled trial[34]. These evaluation studies are important as they attempt to discover whether practices have changed and whether the intended outcomes have been achieved.

A closer review of these evaluation studies indicate that out of the 31 studies, 25 concentrated solely on evaluating the adherence to the processes, for example the self-reported adherence of primary care physicians in Bahrain to the WHO-recommended guidelines for the management of acute diarrhoea[35]. Two studies focused solely on the effects of the guidelines[36,37] and a further six remaining studies focused on both the adherence to guidelines as well as the effects, for example, one study from the UAE looked at the physician's adherence to diabetes guidelines and its effects on the health outcomes of patients[38]. Most of these studies used evaluation studies used methods such as chart reviews of patient files and reviews of medical records, such as[26,39,40], and a smaller number used prospective cross-sectional reviews through observation, for example[35,41,42] or surveys for healthcare professionals[43] and patients[44]. A number of studies used a combination of methods, for example medical records reviews and physician surveys[45].

The reviewers looked in particular at the methodological quality of the 31 studies that evaluated the adherence to and effects of Clinical Practice Guidelines. This part of the review focused on three criteria in particular: whether a standardized and validated evaluation tool with clear requirements based on an established Clinical Practice Guideline was used; whether the evaluation reflected existing international and national guidelines and whether the appropriate study design was used and clearly described. Table 3 summarizes the findings.

Table 3 Methodological quality of evaluation studies

Review Criteria		Percentage
1	Standardized/validated evaluation tool was used reflecting CPG requirements	54.8%
2	Study refers to existing international and national guidelines	80.6%
3	Appropriate study design was used and clearly described, i.e. cross-sectional studies, intervention studies (RCT), cohort studies, reviews)	67.7%

In terms of the strength of the evidence (see Table 4 below), a high proportion of evaluation studies that looked at the effects of guidelines on patient outcomes showed strong positive results. Whereas only a small proportion of the studies that reviewed healthcare professional's adherence showed strong levels of adherence with guidelines.

Table 4 Summary of the findings of evaluation studies

	Strong/significant results	Moderate results	Poor results
Adherence	32.3%	19.4%	48.4%
Patient outcomes	75.0%	12.5%	12.5%

4.5 Discussion

The main finding that emerged from this research is that the development, implementation and evaluation of Clinical Practice Guidelines is still in its infancy in the GCC Region. The relatively small number of studies that were found, screened and reviewed concentrated on evaluating the effects of particular guidelines and described the development and implementation process. The majority of articles originated from Saudi Arabia and the studies focused on the lifestyle diseases most prevalent in the region.

Quantity: Publication productivity

The underlying premise of this study is that the publication of articles on the development, dissemination, implementation and evaluation of Clinical Practice Guidelines is an indicator or proxy for the current situation in the GCC region in terms of evidence-based healthcare practice.

It is essential that Clinical Practice Guidelines are adapted to the complex social, cultural and economic situation in a region in order for the guidelines to have optimal effect[46]. However, the total number of articles found, screened and selected, 58 in total, is relatively small, considering the combined population of the entire GCC region. Other researchers, such as[24,47], also found a scarcity of studies into the development, dissemination and evaluation of Clinical Practice Guidelines from the Gulf Region. It is worth noting that according to the SJR-SCImago Journal & Country Rank[48], the six counties are ranked as follows in term of the number of citeable documents in the subject area of Medicine: Saudi Arabia (41st in the world), Kuwait (60), United Arab Emirates (62), Oman (77), Qatar (82) and Bahrain (92). In comparison, countries such as the US have seen a proliferation of guidelines with over 700 guidelines accepted by its national guideline authority, the National Guideline Clearinghouse, in 2008 alone[12].

Apart from a few initiatives such as the MENA – NCCN Breast Cancer Guidelines network, there appears to be a shortage of professional associations and regulatory authorities involved in guidelines development, review and adoption. It is worth pointing out that out of 98 member organizations of the Guidelines International Network (G-I-N) only 2 hail from the GCC Region[49]. In comparison, in many countries the efforts to standardize healthcare and improve quality and patient safety agencies have resulted in the establishment of national repositories of guidelines, such as the National Institute for Health and Care Excellence (NICE) in England that has published over 100 pathways and almost 200 guidelines to date[50]. In the US the National Clearinghouse has published almost 3,000 guidelines and internationally, the Guidelines International Network's database currently lists almost 4,000 Clinical Practice Guidelines[12]. This proliferation has resulted in an increased number of guidelines in place in healthcare providers.

Quality: Implementation and Adherence

Considering the widespread evidence of the positive effects of the implementation of Clinical Practice Guidelines on the process and outcome of healthcare, it is encouraging that recently there has been a significant increase in the number of publications coming from the GCC Region, in particular since 2010.

It has been estimated that around 70% of the population of the GCC Region is overweight and around one third of the population obese[19]. Therefore, it is important to note that the majority of the publications address the clinical needs associated with the so-called 'life style diseases' in the region (diabetes, hypertension, etc.).

Whilst it is encouraging that a significant number of research publications attempted to review and evaluate the effects and adherence to guidelines, there is room for improvement of the methodological quality of these studies. Only a small majority of the evaluation studies (54.8%) used a standardized and validated evaluation tool with clear requirements based on an established Clinical Practice Guideline and around one third of the evaluation studies used an appropriated research method.

In addition, the actual published results have been mixed. In Qatar, for example, adherence to diabetes guidelines was classified as intermediate, with an overall adherence rating of 68.1%[51]. Compliance with paediatric asthma guidelines in a large emergency department in Saudi Arabia was considered to be poor, with only 3 out of 8 recommendations applied consistently[40]. Adherence to community-acquired pneumonia guidelines in Oman was the subject of another study[26], which found very poor adherence to local guidelines. Similarly, a study in Kuwait[52] found the adherence to antibiotic prescribing guidelines was low, with only 30.4% of prescriptions fully adhering to the guidelines. In terms of hypertension management in one region in Saudi Arabia[53], the study concluded that most physicians did not adhere to the guidelines and lack the necessary knowledge. A study in the United Arab Emirates[43] found that whilst physicians have favourable attitudes towards smoking cessation counselling guidelines, their actual practice fell below recommendations. However, in another study from Saudi Arabia[21], both the physician's attitude towards the guidelines as well as the self-reported adherence was high, which was attributed to the credibility and respectability of the source of the guidelines.

These findings in relation to a weak adherence to guidelines by healthcare professionals confirms the mixed findings from other studies[7,51] and can be explained by the fact that the development of Clinical Practice Guidelines often does not meet the required standards set by international and national organizations such as the US Institute of Medicine or UK based National Institute for Clinical Excellence (NICE).

In addition, many evaluation studies reviewed adherence and outcomes against non-specific best practice requirement, such as medical nutritional treatment based on recommendations from the American Diabetes Association[34], rather than Clinical Practice Guidelines developed regionally or locally. Other explanations for the lack of adherence include lack of education and training[53], absence of clear implementation strategies[17,18], poor access to the evidence[12] and lack of awareness and familiarity amongst healthcare professionals[54]. Interestingly, the lack of perceived credibility of the guidelines was also cited as an explanation for poor adherence to the guidelines[21,40].

In terms of the effects on patient outcomes, it should also be noted that the studies that evaluated the effects of guidelines on health outcomes showed a largely positive, strong impact. Out of the 8 studies that looked at the effects of the adherence with the guidelines on patient outcomes, five reported significant positive results[38,41,55–57]. It is worth noting however, that only a small number (8 out of 58) evaluated effects on patient outcomes.

In terms of research methodology used, there is still a lot of room for improvement. Only one study[34] [34] used a Randomised Control Trial (RCT) and a large number of studies simply described the process for developing a guideline. Furthermore, the research methodology used was often descriptive and seldom were the guidelines appraised for their quality. This finding is consistent with other recent reviews of international guidelines, which found that the quality scores against the AGREE appraisal instrument were moderate to weak[25,58].

4.6 Conclusion

The overall goal of the research was to review how countries in the GCC region have developed, implemented and evaluated clinical practice guidelines. The GCC region has seen unprecedented economic and demographic growth, as well as social and cultural change. As a consequence, the prevalence of lifestyle diseases such as diabetes and cardiovascular diseases is widespread[51]. It is therefore encouraging that many of the Clinical Practice Guidelines developed and implemented in the GCC Region focus on these diseases in particular.

As described above, the relatively small number of research articles published in the GCC Region over the 13-year period raises concerns about the likelihood to successfully address any evidence gap and attain better quality outcomes. This is a particular concern to the GCC region since the healthcare sector relies on the experience and expertise of healthcare professional from a wide variety of different backgrounds. In addition, whilst some evaluation studies were methodologically robust, many studies focused on generic practice

requirements rather than evaluating the effects of and adherence to specific, relevant Clinical Practice Guidelines. A more rigorous approach to the development and evaluation of Clinical Practice Guidelines needs to be established to address these methodological weaknesses.

Despite all this, a number of positive signs may indicate that there is a gradual change occurring, as evidenced by the recent increase in number of studies, as well as an emphasis on evaluating the effectiveness and a focus on lifestyle diseases.

Further in-depth research exploring the reasons behind non-adherence to Clinical Practice Guidelines is needed as this will enable regulators, healthcare providers and healthcare professionals to apply the required clinical practice in a consistent manner, resulting in better outcomes for patients. In particular, further research need to look at the application of regulatory mechanisms using a procedural justice approach towards regulatory requirements that support the argument that when health care authorities use fair procedures rather than sanctions, health care professionals are more likely to overcome barriers to achieving adherence to guidelines[59].

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5

A cross-sectional study into medical students' perceptions of healthcare regulation and self-reported compliance.
A study conducted in the City of Al Ain, United Arab Emirates, 2016

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5.1 Abstract

Background:

Although healthcare regulation is commonplace, there is limited evidence of its impact. Making sure that healthcare professionals comply with the regulatory requirements is a prerequisite to achieving effective regulation. Therefore, investigating factors that influence compliance may provide better insights into how regulators can be more effective. This study aimed to find out if medical students' perceptions of regulation in the United Arab Emirates are associated with self-reported regulatory compliance.

Methods:

In the cross-sectional study, we administered a structured questionnaire to students of medicine with different statements concerning their perceptions of healthcare regulation and self-reported compliance. The statements included statement regarding the legitimacy, fairness and regulatory performance, as well as the risk to getting caught and being punished. The association between perceptions and self-reported compliance was analysed using multiple regression models.

Results:

One hundred and six Year 3 and 4 pre-clinical medicine students (56.4% response rate) completed the survey. Almost 40% of the students rated their level of awareness and understanding of regulation as Good or Very Good., despite their lack of direct contact with the regulatory authorities (less than 10% reported monthly or more frequent contact). Self-reported compliance was high with almost 85% of the students either agreeing or strongly agreeing with the four compliance statements (mean score 4.1 out of 5). The findings suggest that positive perceptions of the regulator's performance (β 0.27; 95% CI 0.13 – 0.41), fairness of the regulatory processes (β 0.25; 95% CI 0.11 – 0.38) and its legitimacy (β 0.23; 95% CI 0.05 – 0.41), are stronger associated with compliance than the perceived risks of getting caught and being punished (β 0.10; 95% CI -0.04 – 0.23).

Conclusions:

To improve compliant behaviour, healthcare regulators should pay more attention to their own perceived performance, as well as the perceived fairness and legitimacy of their regulatory processes rather than focusing on more traditional methods of deterrence, such as perceived risk of getting caught and being published.

5.2 Background

One of the central tenets within the study of public service delivery is the notion that public services should deliver the greatest benefit to the maximum number of people[1]. Regulation plays an important role in this as it aims to oversee the quality and performance of services[2]. In the healthcare context, regulation consists of mandatory requirements, such as standards, laws or directives and tends to focus on basic safety elements to protect public health[3] and improve quality of care[4]. The assumption is that a positive effect will be realized if these regulatory requirements are complied with in full[4].

However, researchers have reported a lack of empirical evidence regarding the effects of regulatory interventions on the level of compliance as well as the actual quality of healthcare and patient outcomes[5,4,6]. A study undertaken by the RAND Cooperation into the regulatory mechanisms of six countries concluded that the overall evidence of the effectiveness of regulatory strategies towards ensuring care quality and safety at system level is still scarce[7]. One of the biggest challenges in this context is the healthcare professionals' lack of compliance with requirements which contributes to a poor quality of care and put patients at risk[8]. Even a simple requirements such as appropriate hand hygiene is known to be one of the most effective ways of improving patient safety[9] and it is widely endorsed by regulators as a mandatory requirement[10]. Despite these efforts, actual compliant behaviour is lower than the recommended guidelines, around 40%[11].

Regulation involves rules that must be followed but in the healthcare context very few empirical have looked at why some organizations or individuals display compliant behaviour and others do not[6,4]. This study will take a closer look at the reasons why some people comply with regulatory requirements and others do not by focusing on the role of perceptions of procedural justice and deterrence.

The traditional viewpoint of compliance with regulation has primarily concentrated on deterrence: people are thought to obey rules and laws because there are penalties and incentives[2]. From this point of view, people are "amoral calculators", interested and motivated by their self-interest. This view supports the notion of a regulatory approached characterized by the strict application of formal enforcement mechanisms[12]. However, studies across different settings have found that deterrence with penalties and rewards has a small influence on people's compliance behaviour[13] and sometimes even the opposite effect[14].

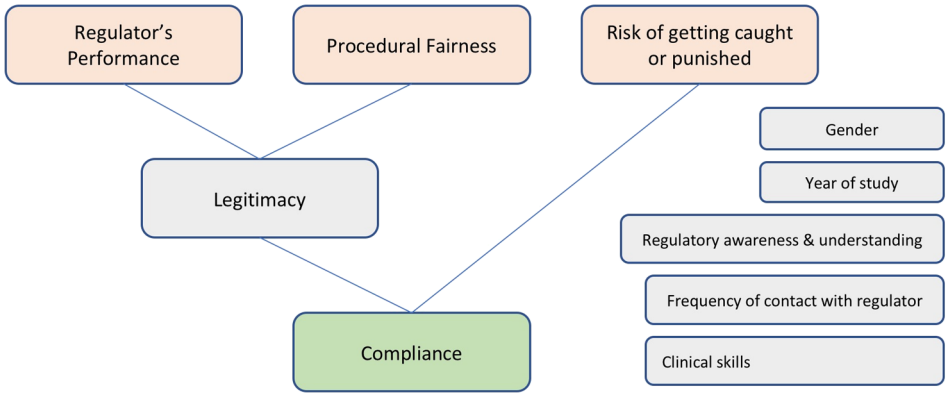
In contrast, several studies have found that a regulatory process that is procedurally fair is an important motivating factor for compliance in different areas, such as residential homebuilders' compliance with regulations[15], business firms' compliance with environmental protection

regulation[16], taxpayers' compliance with taxation rules[17] and even patients' adherence to doctors' medical recommendations[18]. As Healy[6] puts it "the evidence is that most people and most organizations respond well to a respectful and supportive approach".

In his seminal work on compliance and regulation in the 1980s, Tom R. Tyler studied people's self-reported compliance with the law. In the so-called Chicago study, Tyler[19] looked at what factors shape compliance and what make people obey laws and regulatory requirements. One of his main findings was that when people are treated fairly by authorities, they are more likely to comply with requirements, because there is a relational bond. This is also known as the procedural justice model which leads to legitimacy, the belief that rules and regulations should be obeyed by virtue of who made the decision or how the decision was made[20]. The perceived fairness of the procedures and processes involved in regulatory decision making, as well as the perceived treatment one receives, are known to be important factors influencing compliance[17]. There is growing empirical evidence that this regulatory approach focused on cooperation has a stronger impact than the more traditional, deterrence based approach[21]. This emphasis on legitimacy also influenced Ayers and Braithwaite[22] to propose the theory of 'responsive regulation' that focuses on regulation based on trust and asserts that regulator should be flexible and decide to utilize a range of regulatory measures and strategies depending on what is required. These regulatory measures and strategies can range from persuasion all the way to legal penalties.

The Figure below (based on Sunshine and Tyler's original model[23]) explains the predictive model for compliance in a conceptual manner. We propose two antecedent conditions of legitimacy: the regulator's performance and the perceived procedural fairness[24]. Legitimacy itself, together with the perceived risk of getting caught and punished are considered to be the strongest antecedents to the self-reported compliance.

Figure 1 Conceptual model



The study took place in one of the main medical and health sciences university of the United Arab Emirates (UAE). The UAE is a federal union of seven states (Emirates), established in 1971. The country has seen a huge economic and population growth, from an estimate of 287,000 inhabitants in 1971 to around 9.1 million population in 2017.[25] The UAE consists of a large portion of expatriates workers (around 88.5%) and a small number of UAE Nationals (around 11.5%)[26,27]. In terms of healthcare regulation, the UAE is quite fragmented[28] and the two largest emirates, Dubai and Abu Dhabi, have their own regulatory authorities that are responsible to provide oversight and control over the facilities and professionals in their respective jurisdictions.

At a Federal level the Ministry of Health is responsible for regulating the activities of the remaining facilities and professionals[29]. The UAE has a relatively well performing healthcare systems in the region, for example, Legatum Prosperity group ranked the UAE 28th out of 149 countries[30] and it has made significant progress in establishing major academic and research institutions[31].

The hypothesis of this study is that a more favourable perception of regulation in terms of legitimacy is associated with higher levels of self-reported compliance with regulatory requirements in the healthcare context. The objective of this study was to explore and investigate medical students' perceptions of the healthcare regulatory environment. This was carried out by assessing the perceptions of medical students across a range of legitimacy related constructs such as procedural fairness, performance, risk and empowerment and the self-reported levels of compliance.

5.3 Methods

Study design

To test the association between legitimacy and other factors and self-reported compliance, a cross-sectional survey was designed to elicit the views and perceptions of the participants. All students in the medical school were invited to participate in the study. The research proposal received approval from the relevant Research and Ethics Committee in January 2016 and the study was carried out over a two-day period in April 2016.

The survey instrument focused on the general views and perception of regulation in healthcare rather than specific personal experiences. The survey instrument was developed in consultation with the university's Faculty of Medicine and it was prepared after a thorough review of the medical literature, identifying distinct items that have been used in other studies[17,18,32,33] to measure the relevant dependent and independent variables.

Study population

The country's relevant educational authority has accredited the university to provide the medical education program[34]. The faculty offered a six-year Doctor of Medicine, M.D. Program to UAE Nationals. The medical faculty ranked amongst the best medical schools in the GCC region and the university took in around 100 new medical students annually in 2016/2017. At the time of this study the university served as the primary source of medical education for citizens of the UAE[35]. The first two years of the six-year curriculum included a clinical foundation module that provided students with basic knowledge of the principles underlying clinical practice. Even though medical education in the UAE has received national accreditation, the undergraduate program has been characterized as being too focused on classroom based education, rather than hands on training[36]

As part of the university's first year curriculum for medical students, the university offered a short, general orientation into the health care service provision in the UAE, including the regulatory role and function of the relevant authorities. Despite this it was assumed that students had a limited experience and understanding of the regulatory context and the survey briefly described the role of the regulatory authorities in healthcare, with a clear short description of the main regulatory functions.

Data Collection

All third, fourth, fifth and sixth year medical students (333 students in total) received an invitation by email from the Assistant Dean of the Medical Faculty to participate in the research study. However, the students were required to visit the Research Lab in person, as the research study formed part of a wider study into regulatory compliance. This meant that final year students (fifth and sixth year, 145 students) were unable to take part as they were enrolled in residency programs in various hospitals and clinics across the UAE. The total (third and fourth year) student population was therefore 188. Upon registration, each participant received a unique identifier and each student was asked to complete the Consent form. Once consent was granted, the participants were brought to a classroom by a Research Assistant where the students could complete the survey.

Study variables

The survey consisted of two sections – the first section dealt with measuring the students' views and opinions regarding regulation as well as their self-reported compliance and the second section asked general, background questions about the students' experience as well as their self-reported compliance rating. In the first section students were asked to indicate their level of agreement on a five-point Likert scale with eighteen statements. The scales ranged from one (Strongly Disagree) to five (Strongly Agree). The survey items assess the medical students' appraisal of the healthcare regulatory authority in the UAE across the main

facets of legitimacy: perceived risk of detection, performance and empowerment of regulatory authority and fairness. The survey also contained numerous questions about students' self-reported awareness and understanding of regulatory requirements.

In our study the dependent variable, compliance with regulatory requirements, is measured by the medical students' self-reported compliance. The independent variables, related to the students' perceptions, are measured using statements describing statements relating to legitimacy, fairness, risk (the perceived likelihood of being caught and punished for not complying with the regulatory requirements) and the regulatory authority's performance or empowerment (views regarding the authority and power of the regulatory authorities).

In addition to this, the students' prior knowledge, understanding and experiences with regulatory authorities was measured. In this study, we explored medical students' perceptions of four independent variables (perceptions of the regulator's legitimacy, fairness, performance and estimates of risks) and one dependent variable (self-reported compliance). The different statements (see Appendix I) were derived from other studies into the relationship between legitimacy and compliance in the fields of compliance with taxation, justice and policing[24,23,17].

Compliance

Four questions were devised to assess the dependent variable, self-reported compliance (Cronbach's Alpha: .393). These items included statements such as "My friends and family would describe me as somebody who complies with rules and regulations", "I try very hard to follow relevant guidelines and requirements from regulatory authorities" and "In general, I tend to comply with what is expected of me by regulatory authorities".

Legitimacy

Legitimacy is defined as the property of an authority or institution that leads people to feel that authority or institution is entitled to be deferred to and obeyed[32]. Put simply, legitimacy is the perception that one "ought to obey" another. The independent variable related to the theory that people are more inclined and willing to follow rules and regulations if they believe these are legitimate, i.e. the regulations are desirable, proper and appropriate in line with societal norms, values and beliefs[37].

This study measured legitimacy as the perceived obligation to obey and trust in regulatory authorities, with five items (Cronbach's Alpha: .475), such as "You should accept the decisions made by the regulatory authority, even if you think they are wrong" and "The laws and regulation issued by the regulator are consistent (in line with) the views of residents in the UAE".

Fairness

The survey instrument contained four items relating to the fairness of the decision-making and treatment (Cronbach's Alpha: .799) such as "The regulatory authorities in the healthcare field make their decisions based on facts, not opinions" and "Regulatory requirements are applied to all people consistently". The two key dimensions of procedural fairness judgments are fairness of decision making (voice, neutrality) and fairness of interpersonal treatment (trust, respect)[19].

Performance and Empowerment

The students' perceptions of the performance of the regulatory agencies was measured by asking how effective they perceive regulatory authority is and the effects of the regulatory actions. Two items (Cronbach's Alpha: .635) were included: "Regulations such as standards, directives and policies are needed because they have a strong, positive impact on the quality of care delivery" and "In my opinion, the regulatory authorities are effective in improving the quality of health care delivery". The students were also asked to what extent they agreed that the regulatory authority should be autonomous and have power to make decisions: "The regulatory authority should have the power to decide which regulatory requirements are the most important".

Risk of getting caught or punished

The survey included two items (Cronbach's Alpha: .303) that looked at the students' perceptions regarding the likelihood of being caught and punished for not complying with regulatory requirements, including "It is likely that you get caught and penalized if you break any rule or regulation".

Statistical analysis

The students' responses were coded and the data was analysed using SPSS (v22, IBM Inc.) software.

In order to analyse the relationship between the independent and dependent variables, the scores were calculated for each item by allocating a weight between 1-5, with a weight of 1 for "Strongly Disagree" and 5 for "Strongly Agree". The scores for each item were added up and divided by the total number of completed items. Missing data were excluded from the calculation. In total 106 surveys were completed and each survey included 23 items (see Appendix 1). Seven surveys were incomplete with no more than one item not filled in. The average score for each variable was calculated by adding up the average score for the relevant items and then dividing this score by the number of items for the variable.

In order to test what factors influenced self-reported compliance, we performed an ordinary least squares regression analysis using the indexes of legitimacy, risk, performance evalua-

tion, procedural fairness, awareness and understanding, as well as the frequency of contact, self-assessed clinical skills evaluation and demographic variables. From the regression model's beta and 95% confidence intervals were derived. *P*-values of <0.05 were considered to be significant.

5.4 Results

A total of 106 students agreed to participate in the study (response rate 56.4%, 106/188), 83 participants were female (78.3%) and 23 were male (27.1%), see Table 1 below. All participants were UAE nationals, 23% male and 77% female.

Table 1 Participation rates amongst male and female students

Year	Male		Female	
	No. Participated	Response Rate	No. Participated	Response Rate
3	18	75%	37	47%
4	5	25%	46	70%
Total	**23**	**52%**	**83**	**58%**

In terms of the frequency of contact with the regulatory authority, a high percentage of students (62.3%) had never dealt directly with a regulatory authority, whilst 27.4% had infrequently dealings with the regulators, see Table 2 below.

Table 2 Frequency of contact with the regulatory authorities (n=106)

	Never	Infrequent	Monthly	Weekly	Daily
In the past 12 months, how often you have been in direct contact with regulatory authorities such as HAAD, DHA or the UAE Ministry of Health?	62.3%	27.4%	8.5%	1.9%	0.0%

The respondents were also asked a number of background questions. Overall, the majority of students rated their own clinical skills and competencies as "good" (55.7%) or "very good" (9.4%), see Table 3 below. Furthermore, over 60% of respondents indicated that they had an average or above average understanding and awareness of the regulatory requirements.

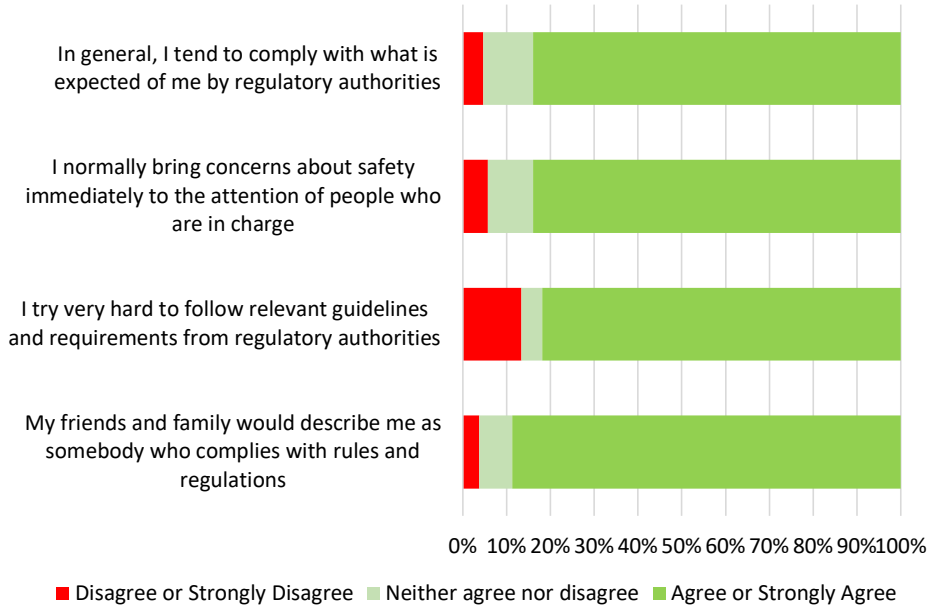
Table 3 Clinical skills and awareness/understanding of regulatory requirements (n=106)

	Very Good	Good	Average	Poor	Very Poor
Overall, how would you rate your awareness and understanding of the current regulatory requirements in the UAE?	8.5%	31.1%	21.7%	17.9%	20.8%
I would rate my own clinical skills and competencies as…..	9.4%	55.7%	26.4%	6.6%	1.9%

The highest mean on the four independent variables was the performance and empowerment of the regulatory authority: 4.1 out of 5. The legitimacy variable had the lowest mean score, 3.3, followed by perceived fairness (mean: 3.8) and the perceived likelihood of being caught and penalized for breaking a rule or regulation (mean: 3.8). In order to measure the dependent variable, self-reported compliance with regulatory requirements had a mean score of 4.1 out of 5.

An average of almost 85% of all respondents either agreed or strongly agreed with the four compliance statements, see Figure 2 below.

Figure 2 Self-reported compliance amongst medical students in the UAE (n=106)



Finally, this analysis enables us to estimate the strength of the relationship between each independent variable and the dependent variable. The results of our analysis are shown in Table 4 below.

The strongest relationship was between legitimacy and compliance (β 0.23; 95% CI 0.05 – 0.41), fairness and compliance (β 0.25; 95% CI 0.11 – 0.38) and regulatory performance and compliance (β 0.27; 95% CI 0.13 – 0.41)

Table 4 Examining variables associated with self-reported compliance

	β	95% Confidence Interval
Legitimacy	0.23*	0.05 – 0.41
Fairness	0.25**	0.11 – 0.38
Performance & Empowerment	0.27**	0.13 – 0.41
Risk	0.10	-0.04 – 0.23
Contact with regulator	0.09	-0.05 – 0.23
Regulatory awareness and understanding	0.04	-0.04 – 0.12
Clinical skills and competencies rating	-0.05	-0.18 – 0.07

** p <.05*
***p < .001*

5.5 Discussion

Considering that one of the core objectives of regulation is to oversee or control activities that are socially valued[38], it is important to find out more about how the people who are the subject to the regulatory requirement perceive the regulations. As noted, there is growing empirical evidence that a positive perception of the regulatory authorities' fairness, performance and legitimacy increases the likelihood of compliance in fields such as law and order and taxation[24]. This procedural justice model of compliance has remained almost entirely based on research evidence from the United States[39] and has only been used in a small number of areas[40]. Using the extensive body of evidence[19], this is the first ever study conducted exploring the relationship between the perceptions of regulation and self-reported compliance amongst medical students.

We would like to make three general observations about the results before we look at the extent to which deterrence and procedural justice have an influence on compliance with regulatory requirements.

First of all, in terms of the UAE's regulatory context, researchers[28] have commented on the consequences of a fragmented regulatory system leading to confusion and complicated rules governing each Emirate. However, over 60% of all respondents rated their awareness and understanding of current regulatory requirement as average or above average. This is even more remarkable considering the high number of students (more than 90%) that had limited or no contact with the regulatory authorities.

It is also noteworthy that the majority of medical students rated their own clinical skills and competencies highly (more than 66% of students rating their skills and competencies as very

good or good, see also Figure 1), considering that other studies observed that in the UAE "undergraduate medical education continues to be comprised of long hours in the classroom and frequent written examinations, but limited hands-on training"[36]. Other studies have found similarly high self-reported skills rating[41,42], with a negative relationship between years of experience and self-assessment ratings of clinical skills and competencies. One possible explanation could be that the lack of experience has impacted the overestimation of their own skills and competencies as well as the compliance levels.

Finally, another interesting observation is the participants' high average compliance score. For example, almost 90% either agreed or strongly agreed with the statement "My friends and family would describe me as somebody who complies with rules and regulations". In contrast, several researchers have found suboptimal levels of compliance in similar settings in the UAE such as adverse drug reporting[43], over the counter sales of antibiotics[44] and adherence to diabetes medication[45]. Since these are self-reported ratings, it may not necessarily translate into actual compliant behaviour.

These three observation are interesting from al regulator's point of view, as it indicates the high level of support for healthcare regulation, as well as high scores on self-reported competencies and compliance. A team of researchers who evaluated the regulatory system for healthcare professionals concluded that the UAE had made significant progress in developing and implementing best regulatory practice[27]. Our study supports this view insofar that medical students had a largely positive view of the performance of the regulatory authorities in the UAE, with almost 86% of all students agreeing with the statement that regulatory authorities in the UAE are effective in improving the quality of health care delivery. A recent study exploring UAE medical students' perceptions of international accreditation for medical education found a similarly high level of support[34] for this particular type of regulatory intervention.

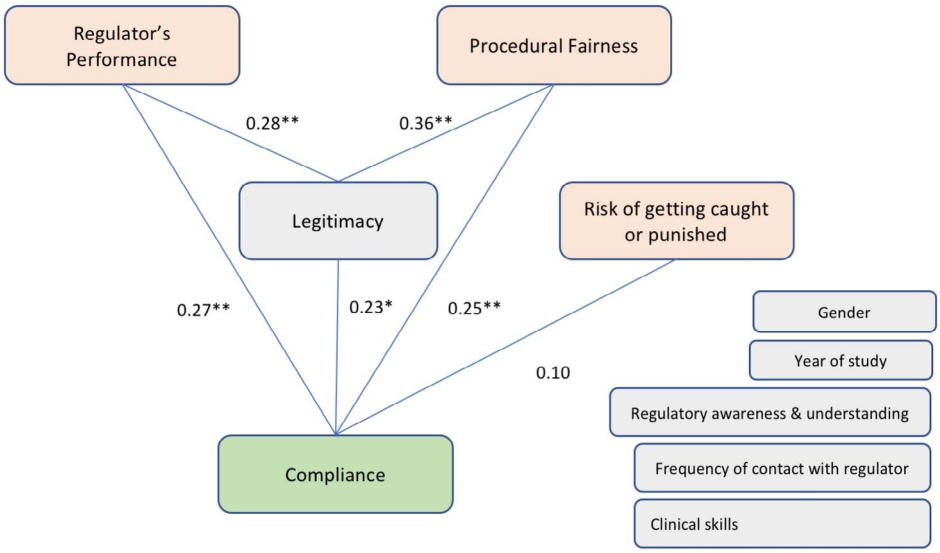
In terms of the factors influencing compliance, the results described in the previous section support our hypothesis that procedural justice related variables have a stronger effect on compliance than deterrence as measured by the perceived likelihood of getting caught and being penalized.

As Figure 3 below indicates, both regulatory performance and fairness are also associated with legitimacy, a finding similar to other studies[32,46,17]. The other variables, such as gender, clinical skills, regulatory awareness and understanding, etc. do not have a significant association with the compliance ratings and there are no discernible trends between these variables and the self-reported compliance.

Similar to other studies[23], procedural fairness was the primary driver of perceptions of legitimacy (beta=0.36). The perceived likelihood to get caught or be punished (beta=0.10) does

not have a significant association with compliance rates. These findings are consistent with studies in other fields, such as policing[47] and law.[17]

Figure 3 Our findings, using the conceptual model



In terms of measuring this relationship in a healthcare context, our research has found similar results as two other studies. The first study[18] found strong support for the argument that when healthcare authorities use fair procedures, patients are more likely to accept their recommendations. The second study[33,48] concluded that the satisfaction of nursing home owners is more strongly associated with the fairness of the inspection process than the actual favourableness of the regulatory outcomes.

Obviously, it should be noted that the largely positive attitudes towards regulation as well as the high levels of self-reported compliance may not necessarily be sustained over time and result in positive behaviours and attitudes of physicians in the future. It is encouraging to note the positive attitude and intention to comply amongst current students. Other researchers[49] have found that healthcare professionals' intention to comply appears to have a reasonably strong relationship with actual compliance. In terms of medical education, more attention could be given to ensuring that medical students are empowered to comply with regulatory requirements and meet the healthcare needs of the society.

Limitations of study

The overall response rate was reasonably high (56.4%) and a number of students who had intended to participate contacted the medical school beforehand to explain that they were unable to attend in person due to other commitments. The response rate may have been

higher if an additional, online survey option had also been made available to the students. The medical school is the primary source of medical education in the UAE[35] and each year around 80-100 students graduate from this particular school and only around 130 students apply for residency programs in the UAE every year[34]. Therefore it could be argued that participants are reasonably representative of the slightly larger population of medical students. The sample did not differ from the total Year 3 and 4 population in terms of gender (sample: 78% female vs. 77% female for the total population).

The study assessed the self-reported rather than the observed compliance levels. However, self-reported compliance in the healthcare field is not always associated with actual compliance[50]. In other words, a high level of self-reported compliance may not translate into a high level of actual, observed compliance making it difficult to draw any major conclusions from surveys based on self-reported compliance levels.

Another limitation of this study is the lack of students' exposure to regulatory authorities, over 60% indicated that they never had any contact with the regulatory organizations. Since the students were only in their third and fourth year we would not have expected them to be overly engaged with the regulatory authorities as their professional licensing process would only commence after graduation. At the same time, students did indicate a high level of awareness and understanding of the regulatory requirements, perhaps as a result of their pre-clinical, practice based training, involving learning courses focused on real life examples.

Since the medical students were relatively unfamiliar with the regulatory requirements, they may have tended to provide responses which they deemed to be socially desirable. The high, self-assessed scores on awareness, clinical skills and compliance may be an indication of a high level of social desirability[51]. Other studies in the UAE with similar self-assessment methods found equally high rating in terms of competency[42]. These high scores may indicate that the medical students responded in a socially desirable way and some of the study results should be interpreted with caution.

Finally, the medical students had limited clinical experience and exposure to regulations or regulatory authorities. This may have resulted in a overestimation of the importance and impact of regulation.

5.6 Conclusion

Regulation based on trust and fairness is often more effective than more traditional, rational choice approach[33], with a focus on deterrence. This study aimed to contribute to the growing

body of knowledge[5,52] into the role of procedural justice and its effects in healthcare. As we have seen in this study, negative motivations arising from a fear of the consequences of violating regulatory requirements is not as strong a factor when it comes to influencing compliance compared to positive or affirmative motivations such as creating a sense of trust in the regulatory authority's work and the obligation to comply[53].

Considering that a lack of compliance with regulations may have serious and sometimes catastrophic consequences, policy makers, educators, regulators, providers and researchers need to be aware of these factors influencing compliance. Similar to studies in other fields, such as policing, our findings support for the hypothesis that people's law-related behaviour is strongly shaped by their judgments about the legitimacy, fairness and performance of the regulatory agency[54], a proposition that was initially viewed as counterintuitive but has received widespread confirmation, initially from psychologists and more recently from a broad range of social scientists.

Based on these insights we postulate that regulatory agencies should spend further efforts in enhancing their legitimacy as it has a strong association with (self-reported) compliance behaviours. The regulatory authorities in the UAE have the opportunity to change the perceptions of their workforce and more can be done to raise awareness and improve the understanding of the role and function of the regulator. A suggested way forward is for the regulatory agencies to conduct a regular self-assessment, at least once per year, with an opportunity feedback for all participants in order to make the necessary changes and improve compliance.

Even though there is relatively limited empirical evidence which regulatory approaches work best[55], this research may assist regulatory agencies to expand their regulatory toolkit[56] and experiment with alternative ways of setting direction, monitoring compliance and enforcement. To truly measure the effects of a regulatory approach based on the procedural justice model, healthcare researchers should make use of randomized control trails to find out whether this has a meaningful impacts on perceptions and compliance. A small number of researchers[57,58] have attempted to conduct trials in other regulatory contexts, such as policing and law. Regulatory agencies should attempt to present themselves as trustworthy and reliable actors in the healthcare field by ensuring that their directive approach is accessible and understandable, their monitoring is logical, transparent and fair, and their enforcement role is easily understood and based on evidence.

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6

Is there a difference between self-perceived performance and observed performance in an Objective Structured Clinical Examination (OSCE)?

An exploratory study among medical students in the United Arab Emirates

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6.1 Abstract

Competency-based education and training has become a key component of healthcare systems across the globe. Ensuring that healthcare professionals are able to assess their own competencies is critical for continued professional development and the delivery of high-quality care.

The aim of this study was to assess how medical students perceive their performance on an objective structured clinical examination. Using a cross-sectional study design, a sample of Emirati third and fourth year (preclinical) medical students (N=106; 56.4% response rate) was recruited from the United Arab Emirates University in Al Ain, United Arab Emirates. Medical students completed a short non-invasive clinical task (i.e. measuring and recording blood pressure and performing hand hygiene) followed by a structured survey to self-assess their performance and skills. Trained assessors used a clinical skills observation checklist tool to score each student's performance.

According to the observed performance, 27.36% of medical students performed the objective structured clinical task adequately. In contrast, 69.52% rated their own performance as adequate. Furthermore, only 8.43% of medical students rated their own clinical skills as below average. This study did not find evidence that medical students can accurately assess their own clinical skills and performance.

In order to support the delivery of high-quality healthcare, it is important that medical students develop their ability to accurately assess their own clinical skills and performance early in their medical careers. Teaching and appraising self-reflection is an important component of any undergraduate or postgraduate medical degree program.

6.2 Introduction

Medical education plays an important role in maintaining and improving the quality of a country's healthcare system[1]. Many competencies are defined for medical students that must be acquired before graduation, such as clinical knowledge and expertise, professional integrity, empathy, communicative skills, and conceptual thinking[2,3]. To achieve these desired competencies, future doctors need to be able to accurately self-assess and appraise their multiple skills, also in addition to recognizing their limitations[3].

In this paper, we assumed that a competency involves multiple skills. Healthcare providers and educators are moving towards competency-based education and assessment skills, and the lack of self-assessment skills from healthcare professionals can act as a barrier for self-paced learning[4]. Self-assessment has multiple definitions in the literature and the term has also been used to describe self-reflection or self-evaluation. Andrade and Du (page 160) define each of these concepts independently, and in this paper we used their self-assessment definition as the "process of formative assessment during which students reflect on and evaluate the quality of their work and their learning, judge the degree to which they reflect explicitly stated goals or criteria, identify strengths and weaknesses in their work and revise accordingly"[5]. Studies have found that physicians often assess themselves as being more competent than they actually are[6]. Therefore, introducing self-assessment for medical students may assist them to accurately assess their own skills and competencies in the future. Accurate self-assessment of personal and professional capabilities are now seen as essential for success[7] as healthcare professionals and essential for delivery of high quality care.

The Objective Structured Clinical Examination (OSCE) is a comprehensive evaluation tool that has been used to assess the competencies of medical students in the majority of medical schools worldwide[8]. The OSCE assesses clinical skills, counselling, and communication-based competencies through direct observation[8]. The OSCE has been widely used over the past two decades and can be defined as a "timed examination in which medical students interact with a series of simulated patients in stations"[8]. The OSCE comprises several clinical stations, usually 10-12, where the student performs tasks including history-taking, physical examinations, counselling or patient management, and clinical procedures. The student is required to complete the task within a set time limit and according to well-defined criteria for each specific clinical skill. These clinical tasks are normally assessed by trained assessors from the medical faculty[8,9].

This study took place in the United Arab Emirates (UAE), an independent federation, consisting of seven Emirates with a total population of approximately 9.1 million people, in 2016[10]. It is a relatively young, high-income country, established in 1971[11] with a strong government-led

desire to build a world-class healthcare system to improve the health of its population[12]. The World Health Organization described the Eastern Mediterranean Region, where the UAE is located, as a region facing major challenges regarding the healthcare workforce. Specifically, the UAE faces major challenges related to the shortage of UAE national healthcare workers, a high reliance on expatriate staff, limited health professionals' production capacity, and a high turnover of expatriate healthcare workers[13]. In this context, the present study focuses on one of these challenges: the capacity deficit to educate and train an adequate number of appropriately educated and trained UAE nationals' healthcare professionals.

The main objective of the study was to explore the differences between self-assessment and trained-assessors OSCE score. Our hypothesis was that a medical student who rates their clinical skills and competencies as adequate would also achieve a higher observed OSCE overall score.

6.3 Methods

Study design

A cross-sectional study was used to investigate the relationship between self-perceived performance from medical students and trained-assessor rated OSCE performance. The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Statement was used to structure this paper[14].

Setting

The study was conducted at the clinical skills simulation centre of the College of Medicine and Health Sciences of the United Arab Emirates University, the largest public university in the UAE. Data collection occurred over two consecutive days in April 2016. This study was approved by the institution's Social Sciences Research Ethics Committee (ERS_2015_3212).

Participants

Medical students from the Doctor of Medicine (M.D.) six-year program at the College of Medicine and Health Sciences were the study population. Pre-clinical students (third and fourth year) were invited to participate in the survey and to perform a specific non-invasive clinical task (measure blood pressure).

Variables

The study variables were overall OSCE score, student self-assessed performance, and self-reported clinical skills. These two last variables were measured by statements in the survey, ranked by a Likert scale ranging from one to five. The variable self-assessed performance was

defined through the survey sentence "Overall, I think that I performed the OSCE to the best of my abilities" measured by the Likert scale as strongly disagree (1), disagree (2), neither (3), agree (4) and strongly agree (5). The variable self-reported clinical skills was defined through the sentence "I would rate my own clinical skills and competence as" categorized into (1) poor, (2) fair, (3) average, (4) good and (5) very good.

The dependent variable overall OSCE score was created by summing the scores of the clinical skills observation tool that was completed by the observers. The trained observers were faculty and staff from the College of Medicine. They were considered eligible to assess the clinical task of collecting blood pressure by their qualifications, and they were professionally trained on how to evaluate the quality of hand hygiene practice, having successfully completed a two hour long online hand hygiene course from Hand Hygiene Australia and through a bespoke two-hour face-to-face practical course prepared by the authors.

Data sources/measurements

To accomplish our research objective, we used a cross-sectional survey and a clinical observation tool to collect the data. The survey was designed specifically for this study and the designing process took into consideration a review of other papers and surveys[15–18]. The survey formed part of a larger study exploring medical student's perceptions of healthcare regulation[19] and included questions regarding the two above mentioned variables (self-perceived performance and self-reported clinical skills).

The clinical skills observation tool was designed in consideration of other observation tools used to assess OSCE, for example, the OSCEstop[20]. This observation tool included data collection on four major parts: preparation, including introducing self to the patient, hand hygiene including the WHO hand hygiene standards (before and after the clinical task), and blood pressure measurement (clinical task performed at OSCE). These four parts were assessed by observers using a Likert scale ranging from one to three (one – performed adequately, two – attempted, but performed inadequately and three – not attempted).

Eligible medical students received an email invitation to participate in the research study one week before the study took place. Students were informed and asked to perform a clinical task and to complete the survey. Students who were willing to participate booked a slot or '*walked in*' at the clinical skills simulation centre during the two days of the data collection. Upon arrival, the students received a brief description of the study and consent process, and they were requested to read and sign a consent form. A research assistant explained the study as follows: the participant was asked to perform a short non-invasive clinical task – measuring and recording a person's blood pressure – and complete the survey afterwards. Students were randomly assigned to one of the four available clinical skills simulation rooms.

One of the observers played the role of the "standardized patient", and the other one pretended to be completing a Sudoku book, but observed the student performing the OSCE and completed the clinical skills observation tool. Usually the OSCE is a circuit of stations, but as this OSCE was designed specifically for this study, it comprised only one station with one clinical task. At the end of the task, the participant was asked to complete the survey and earned a Certificate of Attendance. All students had received the same training on performing the clinical task and were aware of the key steps involved in completing the task correctly and in accordance with the UAE health regulations.

Bias

To minimize potential bias in our study, the observers were not known to the students, they were always of the same gender as the participants and they were trained and experienced in observing students' OSCE performance. In addition, each participant was randomly assigned to the clinical room where the OSCE was carried out. The layout of the clinical observation rooms was identical. Students were unaware (blinded) to the covert assessor role of the research assistant who pretended to complete the Sudoku book whilst they performed their clinical task. This method of blinding was used to minimize any possible Hawthorne effect (i.e. observer effect that causes reactivity in which an individual modifies their behaviour in response to awareness of being observed).

Study sample size

All undergraduate medical students from the third and fourth year (N=188) were invited to participate in the study. From the 188 students, 106 participated in our study (56.38% response rate).

Quantitative variables/Statistical methods

Descriptive statistical techniques were used to describe the dependent variable (trained assessor rated overall OSCE score) and the two independent ones under analysis: self-perceived performance and self-reported clinical skills. A t-test was used to test the difference between genders and the dependent variable. An ANOVA was used to determine the difference between the categories of the independent variables and the OSCE overall score. All the tests were performed using α=5%.

6.4 Results

Participants

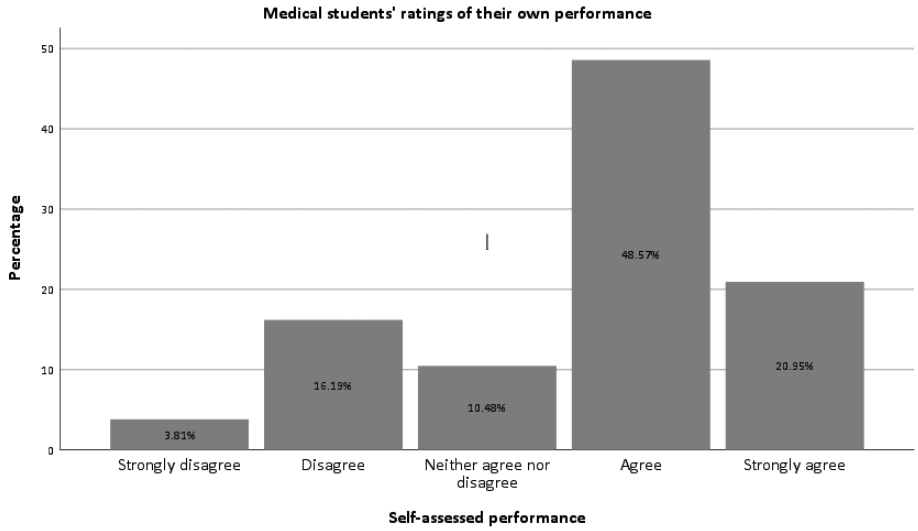
A total of 106 medical students participated in our study representing 31.80% of all undergraduate medical students in the university. All university students from the College of

Medicine and Health Sciences at the United Arab Emirates University are UAE nationals, and 77.40% were female. The proportion of male/female in the study sample is similar to the gender distribution of the medical student population in the college.

Main results

When asked if they performed the OSCE to the best of their abilities, the majority (69.52%) of students answered agree or strongly agree, while nearly a third (30.48%) of students self-assessed their performance as neutral (neither) or negative (disagree or strongly disagree) (Figure 1).

Figure 1 Medical students self-perceived performance after OSCE.



Half of the students (55.66%) self-reported their clinical skills as 'good' and only 8.49% considered their clinical skills below average (Figure 2). None of the students rated their clinical skills and competencies as 'poor'.

The observed score shows that the OSCE overall score was performed 'adequately' by 27.36% of students, while 72.64% were rated as 'attempted, but performed inadequately'. None of the students did not attempted. The mean (±SD) of the trained-assessor observed OSCE overall score was 1.7±0.0, minimum of 1.0 and maximum of 2.6. The mean (±SD) of the trained-assessor observed OSCE score for females was 1.7±0.0 and for males was 1.6±0.0 (Figure 3). This difference was not statistically significant (p=0.794).

Figure 2 Medical students self-reported clinical skills

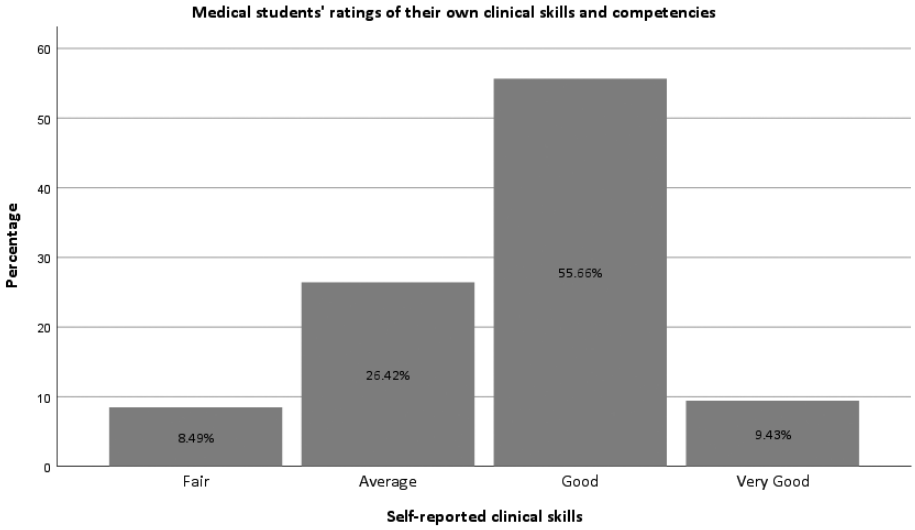
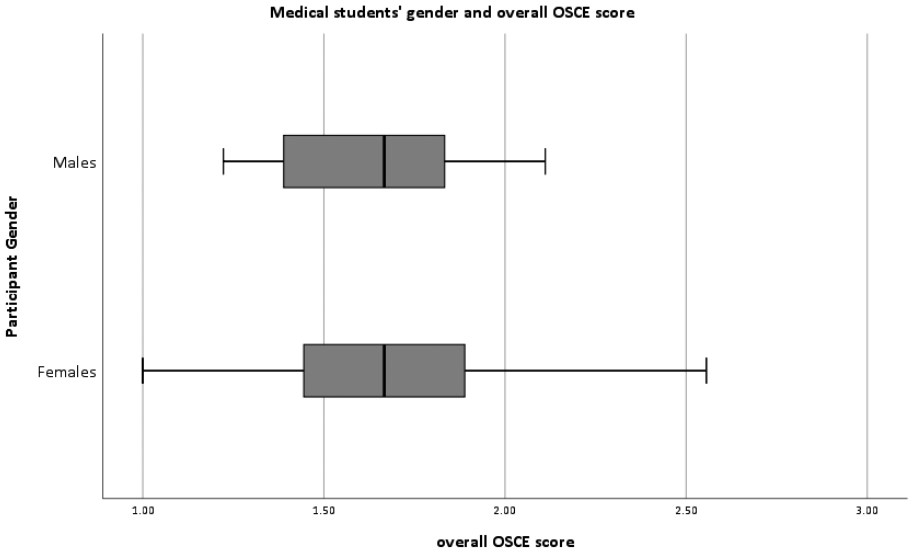
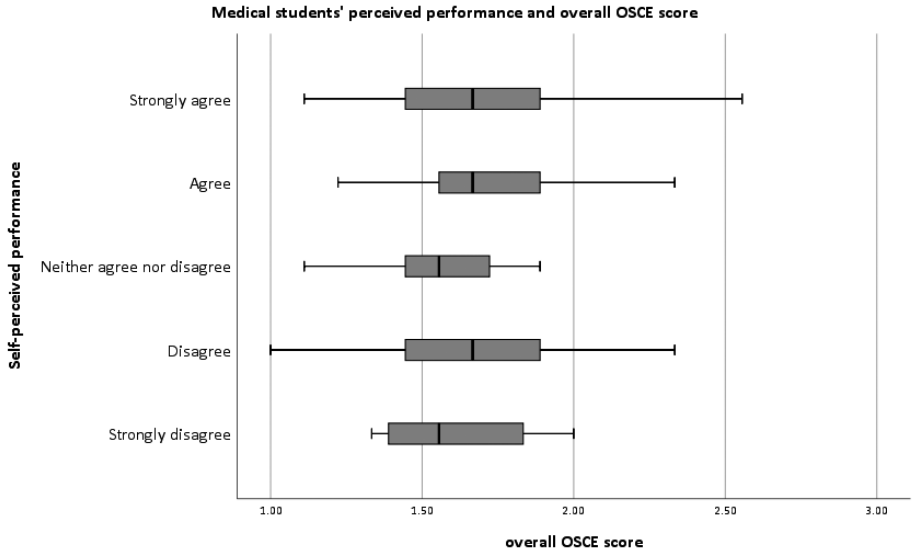


Figure 3 OSCE overall score per gender



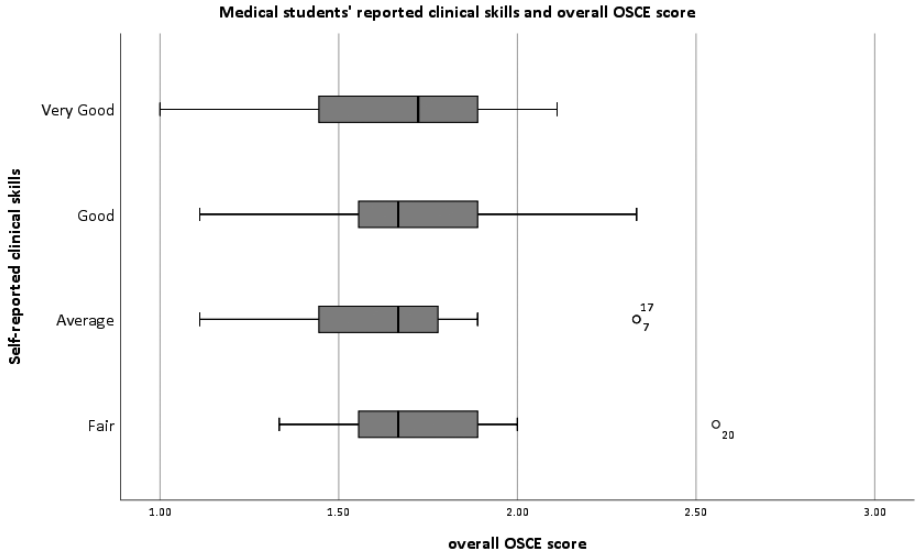
The students that 'strongly disagreed' and the students that 'neither agreed nor disagreed' to performing the OSCE at their best had a mean OSCE overall score of 1.6±0.1 and 1.6±0.0, respectively (Figure 4). The students that 'strongly agreed', 'agreed' and 'disagreed' revealed same mean OSCE overall score with a decimal difference amongst them. ANOVA was calculated to assess the difference between the students' perceived performance categories and there were no statistically significant differences (p=0.763).

Figure 4 OSCE overall score and medical students self-perceived performance.



The students that reported their clinical skills as 'fair' showed the highest mean (±SD) OSCE overall score (1.8±0.1). While the students who reported their clinical skills to be 'good' or 'very good' presented mean (±SD) overall OSCE score of 1.7±0.0 and 1.7±0.1, respectively. There was no statistical significance between how students reported their clinical skills and OSCE overall score (p=0.6). The intragroup variance between gender, self-perceived performance and self-reported clinical skills is not statistically significant (p=0.492).

Figure 5 OSCE overall score and medical students self-reported clinical skills



The intragroup variance between gender, self-perceived performance and self-reported clinical skills is not statistically significant (p=0.492).

6.5 Discussion

Key results

The key result is that this study did not find evidence to support the hypothesis that medical students in the pre-clinical phase can accurately self-assess their own skills, competencies and performance. In other words, the lack of a statistically significance between the mean of overall OSCE score the two self-rated variables may indicate that medical students in the pre-clinical phase have not yet developed the necessary self-reflection skills to accurately appraise their own performance compared to their assessed performance. There was no difference between the gender of the medical students regarding self-assessment and trained-assessor observed overall OSCE score. These findings were similar to Andrade and Du's study that explored the attitudes toward and beliefs about self-assessment in undergraduate teacher education students in the United States and did not find differences in the responses of male and female students[5].

Limitations

The undergraduate preclinical medical students that participated in the present study represented nearly a third (31.80%) of the total medical students at the United Arab Emirates University. One of the limitations of this study is that it represents a convenient sample from one of six medical universities in the UAE, and includes only third and fourth-year preclinical medical students.

Interpretation

Only one-quarter of preclinical medical students performed the OSCE adequately. However, the majority of the students reported a positive self-assessment when asked if they performed the OSCE to their best ability. In Oman, a similar study compared the difference between the student's self-assessment and the trained-assessor OSCE score in 60 medical students and the results show that the students consistently overestimated their performance in four of the 12 items while underestimating their performance in the remaining eight items[21].

Almost 70% of participants self-reported their clinical skills as good or very good and that they had completed the OSCE to the best of their ability. This is in stark contrast with the actual trained-assessed OSCE appraisal which found that only 27% of students performed the OSCE task adequately. Other studies have found similar discrepancies. In a systematic review including 20 studies on the accuracy of physician self-assessment compared with observed

assessments, the results showed that physicians did not accurately self-assess themselves in the majority of the studies[6]. In addition, the systematic review reported only weak or no associations were found between self-rated assessment and external observed assessments[6]. The inaccuracy of self-assessment is also reported in medical students as being frequent and across several specialities or levels in the graduating program[3,4,22].

The timing of assessment has been shown to play a role in student self-reflection. A study examining the self-rated competencies of 168 medical students pre- and post-OSCE showed that students decreased their self-rating after the family medicine objective examination, but not significantly for family medicine specific skills[4]. A study of 244 medical students for the specialization in general practice revealed that the method of self-assessment was experienced and perceived as useful, but only 57% of the sample opted for self-assessment combined with individual feedback on their strengths and weaknesses[3]. Self-assessment is a complex process of internalization and self-regulation[5], and many medical students may not have developed the necessary cognitive skills and reflective practices during their medical undergraduate degrees to provide a realistic self-appraisal. Therefore, providing sufficient time for students to develop their self-reflection skills is an important component of any undergraduate or postgraduate medical degree programme.

Some authors have questioned the reliability of self-assessment[4,6,23]. It has been reported by medical students that if the subjective self-rating is to be used as a formal aspect of the medical education program, then it should be complemented with formative feedback from the supervisors[3]. As such, several researchers advise the development of all-inclusive continuing professional education programs including portfolios, documenting practice-based learning and improvement activities, and creating less general and more detailed learning objectives[3,6]. In this case, it is important to include direct observation in clinical training which has also been a standard in medical education as it is linked to students self-confidence in their final year[23]. For future studies including medical students, we would suggest including a third way of measuring clinical competencies: peer review, this would ensure a triangulated measurement: self, peer and external assessments[24].

6.6 Conclusion

The self-assessment of medical students is not related to trained-assessed OSCE score in this study. To achieve good practices in future healthcare professionals, specifically physicians, it is important to understand the discrepancies between the medical student's self-perception and their actual observed performance. Further research is required to provide a deeper understanding of the factors related to the discrepancy between student self-assessment

and trained-assessed performance. Such detailed information would allow educators to create better learning environments with more effective self-assessment strategies. This paper contributes to the understanding of the current production of Emirati medical students in the UAE, to achieve the UAE Vision 2021 and to the 2030 agenda of the Sustainable Development Goals and Universal Health Coverage.

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7

Surveillance cues do not enhance altruistic behaviour among anonymous strangers in the field

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7.1 Abstract

The degree of altruistic behaviour among strangers is an evolutionary puzzle. A prominent explanation is the evolutionary legacy hypothesis according to which an evolved reciprocity-based psychology affects behaviour even when reciprocity is impossible, i.e., altruistic behaviour in such instances is maladaptive. Empirical support for this explanation comes from laboratory experiments showing that surveillance cues, e.g., photographs of watching eyes, increase altruistic behaviour.

A competing interpretation for this evidence, however, is that the cues signal the experimenter's expectations and participants, aware of being monitored, intentionally behave more altruistically to boost their reputation. Here we report the first results from a field experiment on the topic in which participants are unaware they are being monitored and reciprocity is precluded. The experiment investigates the impact of surveillance cues on a textbook example of altruistic behaviour – hand hygiene *prior* to treating a 'patient'. We find no evidence surveillance cues affect hand hygiene, despite using different measures of hand-hygiene quality and cues that have been previously shown to be effective. We argue that surveillance cues may have an effect only when participants have reasons to believe they are actually monitored. Thus they cannot support claims altruistic behaviour between strangers is maladaptive.

7.2 Introduction

The degree of altruistic behaviour among strangers in modern societies is a major evolutionary puzzle[1,2]. A prominent explanation is the 'evolutionary legacy hypothesis.' It posits that the human brain evolved in ancestral conditions that differed radically from those in modern environments[3,4]. Although nowadays many encounters are with anonymous strangers, for much of our evolutionary past, humans interacted repeatedly in small social groups where one's reputation was constantly at stake, leading to the evolution of cognitive mechanisms to automatically identify reputation-building opportunities[5,6,7]. According to the evolutionary legacy hypothesis, individuals may behave altruistically in anonymous one-shot interactions due to an uncontrolled, automatic reaction aimed to bolster one's good reputation in anticipation of positive reciprocity, even when such opportunities do not exist; i.e., the observed altruistic behaviour between anonymous strangers is maladaptive[8,9].

Empirical support for this hypothesis comes from laboratory experiments showing that reputation-related surveillance cues such as displaying photographs of watching eyes promote altruistic behaviour, i.e., actions which benefit another individual at a personal cost[10,11,12]. Since the cues do not affect one's reputation, participants are anonymous to each other and direct reciprocity is precluded by design, the effect has been attributed to the automatic activation of one's reciprocity-based psychology[8,9]. A problem with this interpretation, however, is that participants are not anonymous to the experimenter who may be observing their choices or can easily infer them from their earnings. A competing interpretation therefore is that the increase in altruism is due to an 'experimenter effect'[13,14,15]: surveillance cues signal the experimenter's expectations to participants who intentionally react to the stimulus in a way they believe would boost their reputation with him/her. In other words, even though direct reciprocity between participants is precluded, indirect reciprocity concerns may still play a role. In line with this interpretation, survey evidence shows the effect on altruistic behaviour is mediated by participants' expectation of reward by "a third party who was monitoring them"[16].

One way to eliminate the possibility of an experimenter effect is to conduct field experiments such that individuals are unaware they are participating in a study. In order to provide clear evidence that altruistic behaviour is maladaptive, however, certain conditions need to be satisfied such that alternative explanations are ruled out. In particular, it is critical that all encounters in the experiment are anonymous, one-shot and reciprocity of any kind is precluded. It is also desirable that exposure to the cues is brief as habituation with the false stimulus may attenuate the effect through intentional brain processes[7,12]. If surveillance cues are found to increase altruistic behaviour in such circumstances this would support the hypothesis that altruistic behaviour between anonymous strangers is maladaptive. If surveillance cues have no effect, it would suggest that previous findings may have been due to

an *intentional* decision taken to bolster one's reputation with the experimenter. Here, we present the first evidence from such a field experiment.

We take advantage of a unique opportunity to study altruistic behaviour in a setup which meets all the aforementioned requirements. This distinguishes our experiment from previous field studies in which surveillance cues were displayed in *public* spaces over an *extended* period of time[17–25]. As we explain in the last section of our paper, these studies were designed to address different research questions. As such, the positive effect of surveillance cues on altruistic behaviour in these studies suggests a potentially useful, low-cost, policy intervention, but it cannot support the claim that altruistic behaviour among strangers is maladaptive as many of the aforementioned conditions are not satisfied and indirect reciprocity opportunities exist.

In our experiment we investigate how two distinct surveillance cues impact the quality of hand hygiene by medical students before treating a 'patient.' Hand hygiene (HH) is a general term used to describe the process of removing microorganisms with a disinfectant agent such as alcohol, or soap and water[26]. Appropriate HH among healthcare workers is considered by some to be the most effective measure to prevent healthcare-associated infections[27], which are associated with 50,000 and 99,000 deaths each year in Europe and the USA, respectively[28], and annual hospital costs between $28.4 to $33.8 billion USD[26]. It is estimated that a one-percent improvement in the quality of hand hygiene could save approximately $40,000 USD per year in a 200-bed hospital for a single type of infection[29]. That is, *how* one washes his or her hands is critical. Accordingly, compliance with HH guidelines has been identified by the World Health Organization (WHO) as a first priority in health-care facilities[28].

Appropriate HH *prior* to treating a patient is a textbook example of altruistic behaviour. According to WHO's guidelines, when contact with a patient is not invasive – as is the case in our experiment – a healthcare provider must follow a specific technique to thoroughly wash his/her hands both before and after contact, for 40 to 60 seconds each time (when contact is invasive, the duration should be between 120 to 300 seconds)[28]. HH prior to treating a patient is not only costly, taking time and effort, but also it does not benefit the healthcare provider directly, only the patient whose chances of a healthcare associated infection are estimated to decrease between 15 and 30%[30]. Both the cost to the practitioner[31] and the lack of individual benefits[32] from HH prior to treating a patient have been cited as prime reasons for why compliance with WHO's guidelines is low. In support of the idea that HH prior to treating a patient constitutes an altruistic act is the evidence that compliance with HH guidelines is substantially higher *after* contract with the patient[31,33]. In the concluding section, we present results from a survey showing that concerns for the welfare of the patient indeed appear to be the primary reason for washing hands prior to treating a patient in our experiment.

7.3 The experiment

The experiment was conducted in a large university, which is well-regarded locally for its medical program: the United Arab Emirates University (UAE). Participants were advanced undergraduate students in the Doctor of Medicine (MD) program who had completed training modules in the basic principles of clinical practice, including infection prevention and HH in accordance with WHO guidelines. For the experiment, we took advantage of a unique opportunity offered by the program for students to *privately* practice their clinical skills – a *Practice* Objective Structured Clinical Examination (POSCE). The *official* OSCE is a critical part of all MD programs aimed to formally evaluate one's clinical competence. Medical students in the OSCE are observed and evaluated by faculty members as they go through a series of stations, interviewing, examining and treating different standardized patients who present some type of medical problem. The POSCE was identical to the OSCE, with two crucial differences: (*i*) faculty members were not present to observe or evaluate the competence of the students, and (*ii*) participants remained anonymous throughout the process. Students were fully aware that the purpose of the exercise was for them to practice their skills without being judged or evaluated.

A note outside the 'patient's room' informed students that their main task was to take the blood pressure of a standardized patient. Medical students are aware that, whenever they are having physical contact with a standardized patient, there is a real risk of contaminating him/her. Participants therefore know that best clinical practice requires they wash their hands carefully immediately prior to measuring the standardized patient's blood pressure, following the WHO's HH guidelines. At the same time, participants are not monitored and, like with the OSCE, each practice slot lasts ten minutes – this is signified by automated bells in the corridors, which were meant to reinforce the fact that the POSCE was not monitored. During this time, they had to briefly interview the standardized patient, wash their hands, measure blood pressure, wash their hands again, and provide feedback to the patient. Given their limited experience with the blood measurement instruments, participants had an incentive to take advantage of this one-off opportunity and spend most of their time practicing measuring blood pressure as it is likely to be relevant in the official OSCE. Therefore, there is a non-trivial cost for participants from properly washing their hands, but incurring the cost benefits the standardized patient. It should be noted that students could not benefit patients by expediting HH as each POSCE slot lasted *exactly* ten minutes, i.e., they could leave neither earlier nor later.

The experimental treatments varied the surveillance cues which were displayed, approximately at eye-level, above a wash basin (see Fig.1) and underneath the standard HH poster by WHO explaining in detail appropriate HH. Due to the HH guidelines and the limited

time of the session, exposure to the surveillance cue was necessarily brief (<60 seconds). Participants were randomly assigned to treatments/cues. The *Baseline* condition, like previous studies, consists of a non-reputation-related image – the picture of a tree. In the *Eyes* treatment, a pair of stern-looking male eyes was displayed. This particular image was chosen as it has been previously associated with a large positive effect on HH, i.e., a 122% increase relative to a baseline condition when the cue was placed in a public space over an extended time period[25]. This was important as it was uncertain ex ante how large a sample we could hope to attract. Ultimately, the turnout was substantial and higher than we had expected: 114 students out of an eligible student population of 330. With this sample size, our tests have sufficient power to detect treatment differences substantially smaller than those in King et al.[25] Note that in order to be exposed to the treatment manipulation, participants had to go to the wash basin to wash their hands. Some participants in our sample had to be prompted to do so by the standardized patient. Our results are unaffected if we exclude these participants from the analysis.

Figure 1 Picture of the wash basin in the private examination room featuring the watching eyes

The *Camera* treatment is the first of its kind in the literature. In this treatment, the picture of a CCTV camera was placed over the wash basin. Such CCTV cameras are omnipresent in the country of our study, although none was available in the examination room. If people have developed cognitive mechanisms to *automatically* identify reputation-building opportunities through millennia, and this is the cause for the changes in altruistic behaviour when reputation-related cues are presented, then we would expect to observe an effect in the Eyes

but not in the Camera treatment [8]. A difference in HH between our Camera and Baseline conditions could be interpreted as evidence participants are concerned about actually being watched.

Apart from informing students they would need to measure blood pressure, the briefing note outside the room explained that the only people inside the room will be two simulated patients that will take turns being the 'patient'. (Rooms were spacious: approx. 25 square meters or 270 square feet). This is standard practice as a person should not have his/her blood pressure measured repeatedly. The simulated patients (RAs) were trained to appear indifferent to the actions of the medical students. At any given point, one RA waited for his/her blood pressure to be measured, and the other –seated at a faraway corner of the room – waited for his turn, while filling out a Sudoku book. In actuality, this individual was covertly monitoring the student's HH practice. All RAs had been professionally trained on how to evaluate the quality of one's HH. Crucially, the simulated patients were selected such that they were completely unknown to the students (with one exception).

Like in previous studies, direct reciprocity is prevented by design: not only were standardized patients in a passive role, but they were also trained to appear bored and indifferent to the POSCE. To preclude indirect reciprocity, encounters had to be anonymous such that reputational concerns could not affect altruistic behaviour. For this reason, students and simulated patients were explicitly instructed not to share their identities. As both 'patients' would remain in the room at the end of the session to receive the next medical student, while the practicing student would leave, it was clear to participants that encounters were one-shot and that there would be no opportunities for the 'patients' to reciprocate, either directly or indirectly. Further, to ensure observers were blind to our treatment manipulation, the RA who acted as the patient changed the poster before the next participant entered the room so that the observer was not aware which poster was displayed at any point in time.

7.4 Results

Our measure of altruistic behaviour is the quality of hand hygiene prior to treating the patient. As mentioned, how a medical practitioner washes his/her hands is of critical importance for minimizing the risk of an infection. The survey evidence presented in the concluding section suggests that participants were well aware of this. In order to evaluate the quality of hand hygiene amongst participants, we use three distinct measures from the WHO guidelines about HH. First, we consider the time spent washing hands. Second, we study the quality of hand coverage, i.e., the extent to which a participant washed all surfaces of his/her hands. Third, we consider compliance with a rule prescribing participants use a tissue to switch off

the tap, after finishing washing their hands. For simplicity and brevity, we present the means of these variables in the figures below.

Fig. 2 shows that, across treatments, participants on average washed their hands for slightly more than 20 seconds. While this may be more than the time spent by many adults washing their hands, it falls considerably short of the minimum recommended duration stated by WHO (40 seconds). This implies that there are good conditions for our treatments to increase the quality of hand hygiene and, in this instance in particular, the time spent washing. However, we find no statistically significant differences across treatments (Eyes vs. Baseline: *P*=0.69, *N*=71; Camera vs. Baseline: *P*=0.64, *N*=79; Mann-Whitney Test, two-tailed).

Figure 2 Average time spent washing hands across treatments (with 95-percent confidence intervals)

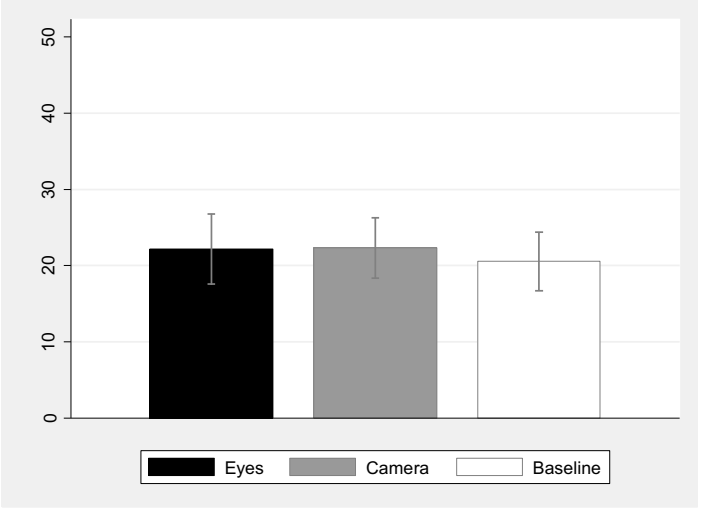


Fig. 3 presents the average quality of hand coverage across treatments. As mentioned, the RAs were professionally trained to evaluate the extent to which participants followed the WHO guidelines and, in this instance, covered adequately all hand surfaces. Performance was coded as 0 if the participant did not attempt to cover multiple surfaces (e.g., did a simple rub of the palms against each other), as 1 if the participant covered multiple but not all surfaces (e.g., did not wash thumbs), and 2 if the participant covered all surfaces.

As can be seen in Fig. 3, average coverage is very similar in Eyes and Baseline, and statistically indistinguishable (*P*=0.99, *N*=71; Mann-Whitney Test, two-tailed). Although the quality of coverage is slightly higher in the Camera treatment, the difference with Baseline is statistically insignificant (*P*=0.18, *N*=79; Mann-Whitney Test, two-tailed).

Figure 3 Average quality of hand coverage across treatments (with 95-percent confidence intervals)

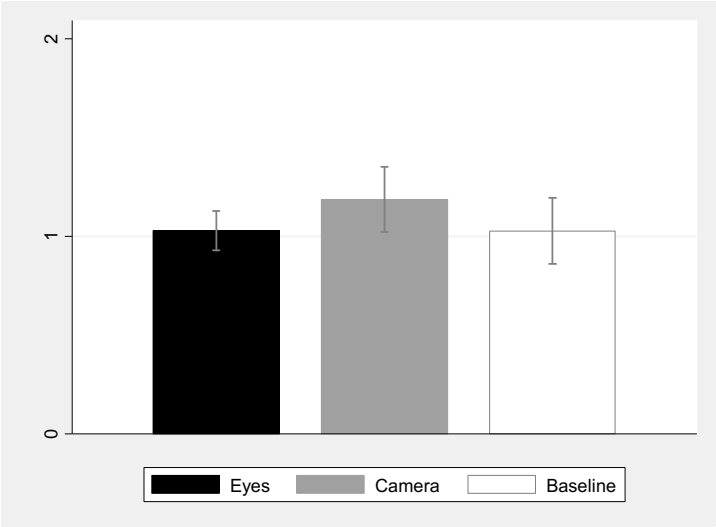
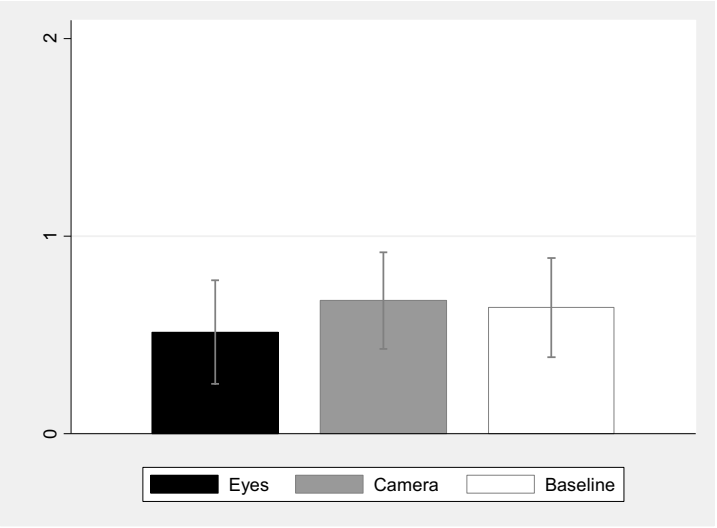


Fig. 4 presents the extent to which participants across treatments turned off the tap after washing their hands using a paper towel. This is critical in HH because a lot of bacteria can be found on the water tap. Participants have therefore been trained that not using a towel reduces considerably the efficacy of HH at combating disease transmission. Performance was coded as 0 if the participant did not use a paper towel at all, as 1 if the participant used a paper towel but improperly (e.g., used paper towel but also touched tap with bare hands), and 2 if the participant used properly a paper towel. Average compliance with this rule is lower in Eyes than in Baseline, although the difference is again statistically insignificant (*P*=0.39, *N*=71; Mann-Whitney Test, two-tailed). Compliance is similar in Camera and Baseline and statistically insignificant (*P*=0.90, *N*=79; Mann-Whitney Test, two-tailed). Neither the fraction of participants using a paper towel properly differs significantly across treatments (Eyes: 17.1%, Camera: 20.9%, Baseline: 16.7%; Eyes vs. Baseline: *P*=1.00, *N*=71; Camera vs. Baseline: *P*=0.78, *N*=79; Fisher Exact Test, two-tailed) nor the fraction of participants not using a towel at all (Eyes: 65.7%, Camera: 53.5%, Baseline: 52.7%; Eyes vs. Baseline: *P*=0.37, *N*=71; Camera vs. Baseline: *P*=1.00, *N*=79; Fisher Exact Test, two-tailed).

Figure 4 Average compliance with turning-off-tap-with-paper-towel rule across treatments (with 95-percent confidence intervals)



7.5 Discussion

Our paper presents the first empirical test of the impact of surveillance cues on the altruistic behaviour of anonymous strangers when reciprocity is precluded and participants are unaware they are being studied. These conditions are critical to obtain clear support for the evolutionary legacy hypothesis – a prominent explanation for altruistic behaviour between strangers – according to which costly altruistic behaviour in anonymous encounters is an anomaly, owning to our ancestral past and the development of automated, involuntary mechanisms for boosting one's good reputation. Despite using cues that have been successfully used previously in the literature, we find no evidence surveillance cues increase the degree of altruistic behaviour in our experiment. That is, our findings do not support the hypothesis that altruistic behaviour among strangers is maladaptive.

One concern with all studies reporting null results is that this is due to the statistical tests being underpowered. This is clearly not the case in our experiment. Not only do we find no evidence across three distinct measures that the picture of eyes has a significant impact on altruistic behaviour in our experiment, but the effect itself is sometimes zero (Fig. 3) or negative (Fig. 4). By comparison, the effect of posting a picture of a camera over a wash basin – which as we argued could not be considered as supportive of the evolutionary legacy hypothesis – is also always insignificant and small in size, but at least it is always positive. Therefore, the overall lack of a significant effect cannot be attributed to insufficient statistical power.

Another concern may be that the lack of a positive effect is due to the fact that our experiment investigates the impact of surveillance cues on the quality of hand hygiene (intensive margin) but not on the decision to wash hands (extensive margin). Indeed, early evidence from dictator game experiments – in which an individual is assigned an amount of money and must decide how much of it to share with a passive recipient – suggested that surveillance cues may have a greater impact on the likelihood a 'dictator' shares a positive amount (extensive margin) than on the actual amount they share (intensive margin); combining margins the effect was often zero[11]. A recent meta-analysis of laboratory studies however contradicts these earlier results, finding no differential effect of cues on the extensive and the intensive margin[34]. Further, some field studies find the opposite result, i.e., that the impact of the cues is stronger on the intensive margin[19] or that a positive effect on charitable donations is obtained even when there are no differences in the proportion of donors responding to the cues[13]. Therefore, there exist neither clear empirical evidence nor theoretical reasons to expect the automatic activation of the reciprocity-based psychology will operate differently on the decisions on the extensive and intensive margins.

Although our design precludes both direct and indirect reciprocity by ensuring encounters are one-shot and all individuals involved (both participants and standardized patients) are unknown and anonymous to each other, we cannot rule out the possibility that, despite our efforts to avoid this, the presence of the standardized patients may have activated participants' reciprocity-based psychology already in the Baseline treatment, making it difficult to identify a treatment effect. However, it is worth emphasizing that similar concerns apply in laboratory environments. In fact, they are arguably greater: not only there are several participants in the lab *at the same time* – some of whom subjects may know personally – but their decisions are recorded by a computer and possibly observed by the experimenter. Even if this is not the case, participants – who often partake repeatedly in lab experiments – should anticipate that their final payment will ultimately reveal the extent of their altruistic behaviour to the experimenter. If the reason for not observing a surveillance-cue effect in our experiment is the activation of the reciprocity-based psychology already in the Baseline condition, then it follows that the lab evidence on "watching eyes" cannot provide clear support either that altruistic behaviour among strangers is maladaptive.

It should also be noted that behaviour across measures in our experiment falls considerably short of that described in the WHO guidelines. If participants were concerned about their reputation, one might have expected higher compliance with the guidelines than observed.

An altogether different concern with our study could be that hand hygiene prior to treating a patient is in fact *not* an altruistic act as we claimed. Although similar claims are common in the medical literature[31,33], one might wonder whether hand hygiene is regarded as altruistic,

i.e., as conferring a benefit to the patient, in our particular context by medical students such those participating in our experiment. To address this concern, we administered a survey to 100 medical students with the same level of training and background as those who participated in our experiment. Respondents were presented with a vignette designed to mimic the situation and incentives in our experiment, and asked whether they would wash their hands prior to treating the patient or not, and the reasons for their decisions. The survey also included a question to evaluate our claim that the quality of hand-hygiene matters when it comes to reducing infection by asking participants whether they agree that washing hands for longer reduces the risk of infection for the patient.

Of the survey respondents who stated they would wash their hands prior to taking the blood pressure, 96.6% agreed with the statement that they would do so to avoid doing harm to the patient. We can reject the hypothesis that respondents neither agree nor disagree with the statement in favor of the alternative hypothesis that they agree with it ($P<0.01$, $N=87$, Wilcoxon signed rank, two tailed). This supports our interpretation of hand hygiene prior to treating a patient as being an altruistic act as it is driven by a concern for the welfare of the patient. Participants were also more likely to agree with this reason for hand washing than with any of the other reasons ($P<0.01$ for all pairwise comparisons, $N=87$, Wilcoxon signed rank, two tailed) indicating that the desire to do no harm to the patient is the main concern driving hand hygiene prior to contact with the patient.

Perhaps unsurprisingly, we find that other concerns also appear to play a role, implying that hand hygiene prior to treatment is not driven exclusively by altruistic concerns for everyone. This, however, does not invalidate our analysis which only requires that altruistic motives are an important determinant of behaviour in our experiment. We can also reject the hypothesis that respondents neither agree nor disagree with this statement in favor of the alternative hypothesis that they agree with it ($P<0.01$, $N=93$, Wilcoxon signed rank, two tailed).

At first pass, our findings appear to contradict those in previous field studies finding a strong positive effect of surveillance cues on altruistic behaviour in natural environments[17–25]. Such interpretation of our findings however would be wrong. A critical difference between these studies and ours, stemming from the different research aims, is that the cues in these studies were placed in public spaces such as university cafeterias[17,18], public car parks[20], super markets[13,21] or hospital entrances[25], over an extended period of time. This implies that real reputational concerns were at play.

For example, participants in all these studies could self-select into several treatments, more than once, suggesting that individuals may be aware of the treatment manipulations and thus suspect they are being monitored. Similarly, since the manipulations occurred in places

frequented by the participants, many of the encounters were likely to be neither anonymous nor one-shot, implying that reciprocity is not precluded by design. For these reasons, these studies suggest a potentially useful, low-cost, policy intervention (as was intended by the authors) but the evidence cannot inform the debate of whether altruistic behaviour between strangers is maladaptive.

Taken together, the field evidence suggests that surveillance cues may be effective in promoting altruistic behaviour in circumstances in which there are *real* opportunities to build a good reputation. In these instances, the cues may serve as a signal of what the expected behaviour is and that behaviour is monitored. In line with this is the finding that the surveillance-cue effect appears to be strongest when peer effects are modest[13,18], possibly due to the increased difficulty of monitoring behaviour in large groups. Additional studies can help explore the underlying mechanism through which surveillance cues operate. Our findings indicate that surveillance-cues effects should not readily be interpreted as evidence that altruistic behaviour between strangers is maladaptive.

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8

Discussion

8.1 Overview

This final chapter discusses the main findings and limitations of this study and the implications for research policy and practice, followed by the overall conclusions.

This study focused on what methods healthcare regulatory agencies can deploy in order to achieve their objectives. Research into the effectiveness of healthcare regulation can be challenging due to the complex nature of healthcare provision, as well as the interconnected relationships between regulatory methods, the targeted behaviours and the ultimate outcomes of concern. The aim of this research was to explore the role and effects of healthcare regulation by investigating the factors that influence compliant behaviour. The central question guiding this research was:

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

The research objectives are:

1. Review the role and impact of health system reform in the United Arab Emirates (UAE) with a specific focus on Abu Dhabi;
2. Review the current availability, use and effects of a healthcare regulatory intervention (Clinical Practice Guidelines) in the Gulf region;
3. Examine the explanatory powers of several independent variables (instrumental and social motivations, as well as self-reported compliance) on compliance-related behaviours;
4. Test whether a simple behavioural cue can be effectively deployed as a regulatory method to improve compliance.

This study consisted of a systematic review of the overall context of the health system reform in the UAE and the Emirate of Abu Dhabi as well as a review of one particular regulatory method and its application in the local environment. We conducted a survey into how people who are required to comply with healthcare regulation perceive these requirements and what can be done to improve their compliance. Finally, we evaluated regulatory compliance by conducting a field experiment to measure how future healthcare professionals respond to behavioural cues.

This research study took place in the UAE, a fast developing country with relatively new healthcare system. The systematic reviews focused on first two research objectives and charted the progress and outcomes of health system reform in Abu Dhabi and the UAE, as well as the role and impact of one particular regulatory method throughout the Gulf Region, over the last decades.

The setting of the research was the UAE's oldest and best established medical school, ranked amongst the best medical schools in the Gulf Region. The medical school is the primary source of medical education for UAE nationals[1] and as such it plays an important role in the UAE healthcare system. For example, it has been estimated that only around 13% of all physicians licensed in Abu Dhabi are Emirati (around 1,200 in total)[2], many of whom graduates from the medical school involved in our study.

8.2 Research findings

This research used a mixture of methodologies to answer the research question and address each research objective. Our research study used the so-called effect chain[3] as the conceptual model in combination with the regulatory toolkit taxonomy designed by Freiberg[4], to present and explore our empirical findings

We conducted systematic literature reviews to provide an insight into the local context of health system reform in Abu Dhabi, the UAE and the wider Gulf region, with a focus on healthcare regulation. We started with a review of the recent health system reform in the Emirate of Abu Dhabi, following the introduction of a mandatory healthcare insurance system and the establishment of a regulatory authority in 2006[5]. In this review, we evaluated whether the health system reform program (including the establishment of a centralized regulatory system in Abu Dhabi) had achieved the desired effects. The study found that the new mandatory health insurance system had led to an improved situation where virtually all residents had access to the required care. However, we found no clear evidence that the introduction of a centralized regulatory system had made much impact on the quality and affordability of healthcare in Abu Dhabi (Chapter 2). Research studies conducted subsequently reached similar conclusions regarding inappropriate overutilization[6] of healthcare services, lack of information about the quality of care[7] and concerns about the long term financial sustainability[8].

As part of this phase, the research expanded into an evaluation of the entire UAE healthcare system. We conducted a systematic review, based on the AGREE tool[9], to evaluate the nature, extent and impact of the healthcare system reform since the early 2000s. The UAE, as a relatively new federation of seven independent Emirates, has made substantial progress since its establishment, with an ambitious set of plans to create one of the best countries in the world before the country celebrates its 50th anniversary in 2021[10]. The review did not find enough substantial evidence to conclude that the health system reform program, including the regulatory reform, had achieved its objectives and resulted in the desired improvements. Our study identified a number of areas that needed improvement[11], such as the lack of

regulatory integration[7], poor data collection and reporting[12] and the increased prevalence of lifestyle related diseases, such as diabetes and cardiovascular diseases[13] (Chapter 3).

In order to address the second research objective, we examined and reviewed the role and impact of one regulatory tool, Clinical Practice Guidelines (CPGs), in the wider Gulf region. By conducting another systematic literature review, our research study analysed the development, implementation and evaluation of Clinical Practice Guidelines over a 13-year period. We concluded[14] that, in the wider Gulf region, there had been a lack of proliferation and implementation of evidence based clinical guidelines, raising concerns about the ability of different healthcare systems to address the growing public health concerns regarding non communicable diseases[15] (Chapter 4). Our study did not find robust evidence of widespread proliferation of CPGs or evidence that the implementation of this regulatory tool had resulted in quality improvements. A small number of published research studies (8 studies, out of a total of 58) had evaluated the effectiveness of the introduction of CPG as an intervention. Out of these effectiveness studies, 5 reported positive results. However, for many of these studies CPGs formed part of a series of interventions, such as the introduction of specialized clinics and awareness raising activities, making it difficult to draw any conclusions about the role and effects of CPG as a regulatory instrument.

There are several regional and local characteristics that play an important role in this research. First, the healthcare system in the UAE, and the rest of the Gulf region, is relatively young compared to other, developed countries and regions. Up until the late 1960s and early 1970s, most of the Gulf region was relatively underdeveloped in terms of healthcare provision and infrastructure. In terms of medical education for example, the UAE only opened its first medical school in the mid 1980s[16]. It is worth bearing in mind that the Gulf society has changed dramatically over the last 40 – 50 years, with huge demographic and societal changes accompanied by strong economic growth[17].

Whereas some countries such as the United Kingdom, France, Germany and The Netherlands have had some type of healthcare regulation in place since the mid-19th century[18,19], many countries in the Gulf region established their regulatory system more recently, towards the end of the 20th century. The healthcare regulatory infrastructure in the UAE was controlled at a federal level until 2006 when, at an Emirate level, Dubai and Abu Dhabi established their own regulatory systems, resulting in a more complex healthcare infrastructure[20]. Taking this into consideration, our systematic reviews summarized the progress made in a relatively short period of time as well as identifying a number of areas for further improvement.

In addition to the challenge of building capacity within the healthcare system over a short period of time, there are indications that the region also encounters capability challenges, such

as a lack of awareness around mandatory adverse event reporting[21], a limited contribution to medical research[22] and a lack of technical efficiency of its hospitals[23]. This local context with a relatively new healthcare system with a number of capacity as well as capability gaps, creates a challenging environment for the effective provision of oversight.

Our research also looked at factors influencing compliance (self-reported and observed). In this part of the study[24], medical students were asked for their opinions and perception of healthcare regulations as well as their levels of compliance with regulatory requirements. Our findings supported the hypothesis that an individual's compliance level is shaped by their perceptions of the legitimacy, fairness and performance of the regulatory agency. At the same time, our cross-sectional study found that deterrence factors, such as the perceived likelihood of getting caught, had no effect on the reported compliance levels (Chapter 5).

Our follow up study[25] (Chapter 6) found a discrepancy between self-reported and observed performance: Nearly 70% of participants reported that they had performed the clinical task to the best of their abilities. However, from our observations, we found that the majority of the medical students (more than 75%) did not adequately perform the clinical tasks during the clinical skills simulation. We concluded that the self-assessed performance of medical students is not related to their observed compliance and therefore may be an unreliable predictor of observed compliance. Other studies found similar discrepancies between self assessed and observed performance.[26,27] One study, involving nursing staff in Kuwait, found a self-reported compliance of 90% with hand hygiene requirements and an observed compliance of 33%.[28] It is worth noting that actual, observed hand hygiene compliance scores amongst healthcare professionals are frequently below 40%[29] and our participants' ability to rate their own performance may have actually been accurate, considering that the expected observed compliance level is below 40%.

The final part of our study included a natural field experiment (Chapter 7), involving medical students who were faced with a task to demonstrate their clinical skills (hand hygiene performed before and after blood pressure measurement). Compliance with regulatory requirements was measured by observing clinical practice. Compliance with hand hygiene requirements was chosen as it can be viewed as an example of altruistic behaviour since the action does not benefit the actor directly or immediately. The evolutionary legacy hypothesis postulates that actors may display complaint (altruistic) behaviour if it is viewed as a reputation building opportunity. Our study did not find evidence that exposure to visual behavioural cues resulted in improved compliance[30] and concluded that further research needs to be conducted into the potential benefits of such methods.

8.3 Methodological considerations

To ensure scientific rigor we used several research models, in accordance with the study design outlined in Chapter 1. This section describes the most relevant aspects of the research methodologies deployed in our study and discusses the potential impact on the findings.

Design of studies evaluating the health care systems in Abu Dhabi and UAE

We reviewed the progress of the healthcare system in Abu Dhabi and the UAE between 2002 and 2016 (Chapters 2 and 3). These reviews were based on an extensive search and evaluation of the available evidence.

We faced a number of methodological challenges conducting this research. First of all, it was difficult to draw firm conclusions due to the overall lack of high-quality research evidence into the impact of health system reform in Abu Dhabi and the UAE. We conducted two studies, five years apart, in order to investigate whether improvements in the health system research had been made between our first study in 2011/2012 and the second study in 2015/2016. To improve the usefulness of our reviews we conducted a thorough analysis of 'grey' literature, including reports issued by local government agencies, international bodies, such as the World Health Organization (WHO). We also used the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) guidelines for the second systematic review to ensure that we conducted a thorough and comprehensive search of all available literature. A final challenge concerned the lack of uniformity when it comes to complex interventions aimed at improving healthcare quality.[31] We addressed this by including a large number of different search terms and by conducting the second review. However, the paucity and limited scope of the studies means that it is difficult to draw any major conclusions as to whether the reform programs in Abu Dhabi and the UAE have achieved the desired impact.

Design of a study to evaluate the development, implementation and impact of Clinical Practice Guidelines

A number of international studies have found a moderate, positive effect of CPGs on the quality and safety of health care independent of geographical location.[32,33] We therefore conducted another systematic review to investigate the development, implementation and evaluation of one particular healthcare regulatory instrument, Clinical Practice Guidelines (CPGs), in the wider Gulf region (Chapter 4). Many healthcare regulatory agencies have attempted to steer and direct the behaviour of healthcare professionals by developing and disseminating CPGs[34] and our research examined the availability, use and effects of these regulatory instruments in the Gulf region.

The first challenges related to the relevancy and paucity of the research: research evidence can rapidly become outdated as more and more research is published[35]. To address this, we only included recent literature (between 2000 and 2013) and confined our search to one geographical area (GCC). We also designed and followed a comprehensive search strategy, including two different screening stages, in order to ensure that all relevant studies were included in the review.

Perhaps a bigger limitation is that many systematic reviews are unable to draw clear conclusions due to the a lack of scientifically sound primary research studies.[36] For example, a Cochrane review on the effectiveness of one widely implemented regulatory method, external inspection, found only two high quality, controlled evaluations that met the researchers' review criteria.[37,38] We had a similar findings in our review: research studies lacked robust methodology. For example, we only came across one randomized control trial, the remaining studies were largely descriptive, making it harder to draw clear conclusions.

Design of a cross sectional survey to ascertain the perceptions of medical students

We designed a cross-sectional survey to elicit the views and perceptions of the medical students (Chapter 5) in order to assess the relationship between factors such as perceived legitimacy, fairness and regulatory performance and self-reported compliance. Over 100 medical students took part (response rate 56.4%) and completed the survey. Considering the 56.4% response rate, there may have been a selection bias with some students opting out. However, the participants did not differ from the total population on variables such as gender, nationality and age.

Perhaps a more important limitation is the potential social desirability bias that can occur when participants do not answer based on their own beliefs or experiences, but rather by what they think is socially appropriate or expected from them. We undertook a number of steps to remedy this. Participants were informed that their responses would be kept confidential and their participation would not affect their grades. Secondly the participants completed the survey in a neutral environment with no interaction with fellow students, researchers or university staff.

Cross-sectional survey data rarely point directly at a causal relationship, since there are often many variables of interest that obscure the relationship between the variables.[39] In our study, variables such as age, sex, frequency of contact with regulator, etc. were included to address such concerns and the findings indicated that these contextual factors had limited effect on the self-reported compliance behaviours.

The survey measured self-reported compliance and it could be argued that self-reported compliance is not necessarily linked to actual compliant behaviour.[40] We therefore conducted a separate analysis to investigate this further (Chapter 6).

Design of a natural field experiment to test the effects of a simple and subtle behavioural cue

We conducted a field experiment to find out whether surveillance cues have an impact on the altruistic behaviour among anonymous strangers. This type of research methodology has rarely (if ever) been used in the field of healthcare regulation and several researchers have recommended the use of experimental designs to investigate the impact of regulatory methods[31,38]. Influenced by the so-called effect change model[3], we tested whether the intended behaviour (hand hygiene) can be affected by different behavioural cues. Students involved in this study volunteered to participate, signed a consent form and were randomly assigned to one of four examination rooms. In addition to this, the practice slot and room was randomly assigned into one of three treatments. This experimental study design is the most scientifically rigorous available to establish a causal relationship between two variables, in this case behavioural cues and observed compliant behaviour.

One potential methodological concern was the potential changes in participant's behaviour due to their awareness of being observed (observer or Hawthorne effect). This concern was particularly relevant because the study took place in the same university where the medical students received their clinical training. Although we cannot completely rule out this potential bias, it is worth emphasizing four points. First, participants were randomly assigned to different private examination rooms located in an isolated wing of the university that students normally do not access. Participants were then asked to perform a relatively simple clinical practice task and observers were not known to the participants. In order to further minimize potential bias, the observers were trained and experienced in observing students' performance and used a standardized observation checklist. Furthermore, one of the research assistants covertly monitored the participant's behaviour by acting bored pretending to complete a Sudoku book. Finally, if participant had been concerned about their reputation, their compliance score would have been higher than observed. As noted, the actual observed compliance behaviour fell considerably short of the WHO guidelines.

The second methodological concern was the statistical significance of the sample size. Since our study was the first to explore the impact of surveillance cues on compliance behaviour in a natural field setting, we had no benchmark for the potential sizes of the different treatment groups. To remedy this, we based our statistical calculations on other numerous studies, including the WHO estimates of hand hygiene compliance (40%)[41], as well as a similar experiment[42].

Even though this study can be classified as a natural field experiment, the replicability of these findings to a real life setting might be challenging[43]. Having conducted this study in a well-controlled environment with only two "bystanders" provides the methodological assurances of the validity of our findings. However, it has been argued that the effects of a subtle behavioural cue may actually be stronger in a real life environment as people are more sensitive to social consequences of one's actions in public spaces such as bus stops and super markets[44]. Replicating this study in a real life setting certainly has merits even though our study showed no evidence behavioural cues improve regulatory compliance.

8.4 Implications for healthcare regulatory research, policy and practice

In this study we reviewed the potential impact of three regulatory tools in particular: guidelines, behavioural cues and perceptions. This section discusses the implications of this research study, in terms of further research and future policy and practice.

Implications for further research

This study contributes to the research into healthcare regulation in two important ways. First of all, there are several research implications within the geographical context and secondly the study also identified areas for improvement in the broader context of the study into healthcare regulation.

Firstly, this research study has provided new insights into the role of healthcare regulatory methods in a rapidly developing region. Further research is required to study the role and impact of regulatory methods. The unique healthcare regulatory context in the UAE provides a number of opportunities for further research. As the healthcare system in the UAE is evolving, it may be an opportune time to conduct interrupted time series or even randomized controlled trials, in order to measure the effects of various regulatory methods. For example, a recent interrupted time series analysis study in a UAE hospital[45] reviewed the impact of accreditation and found that improvement achieved from accreditation was maintained during the three year accreditation cycle. Healthcare regulatory agencies in the UAE have introduced new regulatory initiatives in recent times, such as mandatory health insurance, electronic medical records and health information exchanges[46]. As these interventions are being implemented, regulatory agencies and research institutions should conduct effectiveness studies using research methods such as randomized controlled trials, longitudinal studies and field experiments.

Secondly, a taxonomy of regulatory methods can help to focus the research activities and allow regulatory agencies to concentrate on day-to-day activities that can influence compliance behaviour. At the same time, regulatory agencies need to support further research into the relationship between the behaviour and the ultimate outcomes of concern. Whilst further research using the effect chain would help to create a better understanding of the impact of regulation, it should not become a goal in itself. Several researchers have argued that, in practice causality might be impossible to prove[47] due to the complexity of the 'phenomena' being studied and the data limitations[18].

Our study found an association between perceptions of legitimacy and fairness and reported compliance. Using experimental research designs can help researchers to conduct simple, cost effective, observational studies into compliant behaviours that investigate what part of the regulation works, for whom and in what circumstances[48]. The paucity of high-quality research evidence into the effectiveness of healthcare regulation[38] can be addressed by breaking down the regulatory processes and its methods into smaller chunks that allow a regulatory authority to examine which parts work and which do not[49].

Future research on the optimal utilization of regulatory methods should concentrate on continuing using low-cost research studies using a mixture of different methodologies, including natural field experiments and surveys, as well as population based surveys to measure the views and perceptions of the general public[50,51].

Implications for policy and practice

This research study presents a number of findings which have implications for policy and practice. First, regulatory agencies need to take into consideration how regulated organizations and their staff perceive characteristics such as fairness, performance and legitimacy when performing their regulatory functions. The future physicians who participated in our study are more likely to display compliant behaviour when they perceive the regulatory agency as being fair, competent and legitimate. These findings provide further evidence in support of the responsive regulation paradigm as postulated by Ayres and Braithwaite[52]. The responsive regulation theory argues that better regulatory outcomes can be achieved if the regulatory agency is responsive to the needs of the regulated persons and organizations. Considering the costs of regulation and impact of non-compliance, combined with the lack of evidence for a deterrence approach, policy makers and regulatory agencies should focus more on creating a regulatory environment that reflects the principles of responsive regulation.

A taxonomy of regulatory methods will help regulatory agencies and researchers to gain more granular insights into the role and impact of a variety of methods. Regulatory agencies need to concentrate their research activities on the intended overall impact of the regulatory

activities, broken down into smaller steps or processes[47]. Each process within the effect chain should have its own, measurable goals and regulatory methods. This way the regulatory authority can direct its energy and efforts towards methods that are within their locus of control, helping the regulatory authority to show its added value[53]. For example, in our study, we were able to show that simple behavioural cues did not have a significant impact on compliant behaviours.

Regulatory agencies need to be flexible and explore, adapt, design and implement the most appropriate regulatory methods at their disposal to target relevant compliant behaviours that will ultimately lead to better outcomes. Even though many regulatory agencies have a wide arsenal of regulatory methods available to them, there is limited evidence how, when and if these methods achieve the desired effects in a healthcare setting. A taxonomy of relevant methods may help in identifying the most suitable method in order to achieve the regulatory objectives. In his seminal book about regulation, The Regulatory Craft, Malcolm Sparrow articulated this regulatory strategy as follows: "*Pick an important problem. Fix it. Tell everyone*"[47].

Implications for local policy

Despite its many achievements, the UAE health system remains fragmented and in need of further reform[54]. The UAE Government has acknowledged this and set out a clear vision for the future with the ultimate goal to create a world-class health system[55].

To address the fragmentation of the UAE health system, the UAE should consider establishing a single, independent statutory healthcare regulatory authority dedicated to overseeing the performance of the overall health system, building on the best international practice available. Our research evidence points towards a need to collect more reliable data on healthcare outcomes and benchmark the performance globally[56]. Compared to other health systems with a more mature health care system, the UAE appears to be on the right track with its focus on market reforms through privatization, rates setting and public-private partnerships[2]. In the first instance, the UAE healthcare regulatory agencies could review their existing regulatory methods at their disposal and formulate new ways of implementation. For example, the healthcare professional licensing system in the UAE is now harmonised across the entire country[57] and this harmonised system could provide a useful platform for further cooperation between the regulatory authorities.

As a rapidly growing and developing country, the UAE could build on the combined experience and knowledge from regulatory agencies from other countries. The OECD has developed a monitoring framework and effect chain to measure regulatory progress[3] and at a national level the UAE could utilize this framework as well as subsequent versions and

iterations[58,59] to conduct periodic reviews. In addition, the UAE is in an ideal position to learn from and put in practice the most relevant, up to date evidence when it comes to effective regulatory methods.

8.5 Conclusion

This research looked at how healthcare regulators can best utilize regulatory methods in order to improve compliance. To answer the research question, we identified a suitable taxonomy and a broader effect chain framework that we could use. Predicting whether and how healthcare providers and professionals will respond to different regulatory methods and comply with regulatory requirements is a fundamental prerequisite to improve regulatory compliance. We used the taxonomy proposed by Freiberg[4] as a tool to identify and select regulatory methods.

In our study we reviewed the potential use and impact of three such regulatory methods: Legal (Clinical Practice Guidelines), Structural (behavioural nudges) and Informational (perceptions).

Our systematic review of CPGs in Gulf countries over a 13-year period found a small number of studies that had evaluated an impact on outcomes. A number of these studies had found positive effects, but it was unclear how the actual CPG compliance had contributed to this because CPG compliance formed part of a larger intervention, often including activities such as awareness raising, clinic redesign and training. Our overall conclusion is that CPGs have potential as a regulatory tool and regulatory authorities should consider using CPGs as tools to improve patient outcomes.

Changing the choice architecture by introducing behavioural nudges did not lead to a significant change in compliant behaviour. In our study we conducted a field experiment and found no difference in compliance behaviours between participants exposed to different behavioural cues. However, this regulatory method is relatively inexpensive to implement and in a different environment with an extended exposure it may help to improve compliance.

Our survey measured the perceived fairness, legitimacy, risk of getting caught or punished and performance of the regulatory agency and its relationship with self-reported compliance. We concluded that regulation based on trust and fairness is more likely to be effective than regulation with a focus on deterrence. Our research findings may help regulatory agencies to concentrate their efforts on building trust by ensuring that its regulatory processes are fair and transparent. It should be noted that in a follow up study we could not find a relationship

between the self-reported compliance and observed compliance. However, recent evidence also suggests that inspectors judgements and observations are not as reliable as often assumed[60] . Regulatory agencies need to realize that a complex and multidimensional reality cannot be measured by one tool alone and it is often a multitude or hybrid of tools that will give an accurate reflection of compliance.[61]

As noted in the introductory Chapter, the so-called effect chain assumes that an increase in compliance leads to improvements in the healthcare performance.[62] Our research looked at the first part of the effect chain: the relationship between particular regulatory methods and compliant behaviour. This research found limited evidence of this relationship, but it can be used as an impetus for regulators to introduce new and innovative regulatory methods that can improve compliance and deliver positive results.

In response to the paucity of evidence regarding the effectiveness of healthcare regulation, combined with the growing concerns over quality and safety of care (i.e. do nothing is not an option), regulatory agencies have a bigger chance to make an impact if they regularly reviewed the regulatory methods at their disposal and design a regulatory approach accordingly. By starting to acknowledge and address the limitations of their endeavours, regulatory agencies can establish a productive effect chain.

Finally, it may also guide and inspire future researchers, practitioners and policy makers to develop, test and implement new and innovative regulatory methods that will improve compliance and support the overall achievement of regulatory objectives. Well executed research projects, no matter how small, will help to build legitimacy and ultimately trust in the healthcare system. In turn, this legitimacy and trust will have an impact on compliance levels and ultimately lead to the achievement of regulatory goals.

8.6 References

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Summary

Healthcare systems face numerous challenges such as rising consumer expectations, increasing costs and patient safety concerns. Governments establish regulatory systems in an attempt to steer or direct events, activities and behaviours in order to improve the quality of care, provide assurance that minimum standards are achieved and ensure accountability. Regulation covers a wide range of interventions and seeks to change behaviour in order to produce desired outcomes. The objectives of regulation are varied and range from protecting citizens, regulating social problems, exercising control over regulated activities or organizations and improving the overall quality of public service delivery. Healthcare regulatory agencies aim to provide oversight over the quality, safety, access and price of healthcare services using a wide range of regulatory methods.

Despite the important role of a well-functioning healthcare regulatory system, limited research has been conducted into how regulation works in practice and what impact it makes. 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. Our study was carried out in the United Arab Emirates (UAE), a federation of states (Emirates) in the Persian Gulf region. We use a mixture of methodologies (systematic reviews, a survey and a field experiment) to answer the following research question:

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

Predicting whether and how healthcare providers and professionals will respond to different regulatory methods and comply with regulatory requirements is a fundamental prerequisite to improve regulatory effectiveness. Healthcare regulatory agencies are often given a broad and rather 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 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).

This research looked at how healthcare regulators can best utilize regulatory methods in order to improve compliance. To answer the research question, we firstly identified a suitable taxonomy and a broader framework that we could use and develop further. This taxonomy, developed by Arie Freiberg, can help regulators 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, with its gradual escalation from persuasion to punishment, is not a suitable way to deal with all regulatory challenges.

In this research we have focused on the recent changes to the healthcare regulatory context in the UAE. This local context, with a relatively new healthcare system, creates a challenging environment for healthcare regulators.

From our systematic reviews, we conclude that the new mandatory health insurance system in Abu Dhabi has led to an improved situation where virtually all residents have access to the required care. However, we find no clear evidence that the introduction of a centralized regulatory system has made a similar positive impact on the quality and affordability of healthcare. We conducted a second systematic review to evaluate the nature, extent and impact of healthcare system reform since the early 2000s. This second review does not find enough substantial evidence to conclude that the health system reform program, including the regulatory reform, has yet to fully achieve its stated objectives.

In our study, we review the potential use and impact of three regulatory methods: legal (Clinical Practice Guidelines, CPGs), structural (behavioural nudges) and informational (perceptions of healthcare professionals).

Our systematic review of CPGs in Gulf countries over a 13-year period yields a small number of studies that have evaluated the impact of CPGs on health outcomes. A number of these studies describe positive effects but it is unclear how actual CPG compliance contributes to this because CPG compliance formed part of a number of interventions, such as awareness raising, service redesign and training. We conclude that regulatory authorities should consider using CPGs as tools to improve patient outcomes.

Changing the choice architecture by introducing behavioural nudges does not lead to a significant change in compliance behaviours. Using a field experiment, we find no difference in compliance behaviours between participants exposed to different behavioural cues. However, this regulatory method is relatively inexpensive to implement and in a different environment with extended exposure, may help to improve compliance.

In our survey involving medical students in the UAE we measure different self-reported factors related to compliance. These factors include perceived fairness, legitimacy, the risk of getting caught or punished and performance of the regulatory agency. We conclude that regulation based on trust and fairness is more likely to be effective than regulation with a focus on deterrence. Our findings support the hypothesis that an individual's compliance level is shaped by their perceptions of the legitimacy, fairness and performance of the regula-

tory agency. At the same time, our cross-sectional study finds that deterrence factors, such as the perceived likelihood of getting caught, has no effect on the reported compliance levels.

A number of important findings emerge for policymakers and researchers. In terms of the geographical context, this research study provides a unique perspective on healthcare regulatory methods in a rapidly developing region. Our research shows a scarcity of research, not just in Abu Dhabi, but also in the UAE and the wider Gulf region and further research is required to study the role and impact of regulatory methods. An evidence-based taxonomy of regulatory methods can help to focus research activities and allow regulatory agencies to concentrate on methods that have been proven to improve compliance behaviour.

Healthcare regulatory agencies should take into consideration how the regulated organization and their staff perceive the regulatory agency when it comes to fairness, performance and legitimacy. Considering the costs of regulation, the potentially negative consequences of non-compliance and the lack of evidence for a deterrence approach, policymakers and regulatory agencies should focus their energy on creating legitimate and transparent processes to support policies and regulation.

Regulatory agencies need to be flexible and explore, adapt, design and implement regulatory methods that improve compliance level. Even though many regulatory agencies have a wide arsenal of regulatory methods available to them, there is limited evidence on how, when and if these methods achieve the desired effects in the healthcare setting. A taxonomy of relevant methods may help in identifying the most suitable approach in order to achieve the regulatory objectives. In his seminal book about regulation, The Regulatory Craft, Malcolm Sparrow articulated this regulatory strategy as follows: "*Pick an important problem. Fix it. Tell everyone*"

Samenvatting

De gezondheidszorg staat voor tal van uitdagingen: hoge verwachtingen van patiënten en zorgverleners, toenemende kosten en zorgen over de veiligheid van de patiënt. De overheid zet systemen op in een poging om activiteiten en gedrag van zorgverleners aan te sturen en te regelen en zodoende de kwaliteit van zorg te verbeteren, zekerheid te bieden dat minimum normen worden bereikt en verantwoordelijkheid voor kwaliteit en veiligheid te waarborgen.

Toezicht bestrijkt een breed scala aan interventies en probeert gedrag te veranderen om gewenste resultaten te bereiken. De doelstellingen van regelgeving zijn uiteenlopend en variëren van het beschermen van burgers, het reguleren van sociale problemen, uitoefenen van controle over gereguleerde activiteiten of organisaties tot het verbeteren van de algemene kwaliteit van de openbare dienstverlening. Toezichthoudende instanties in de gezondheidszorg streven ernaar toezicht te houden op de kwaliteit, veiligheid, toegankelijkheid en prijs van de gezondheidszorg met behulp van diverse methoden.

Ondanks de belangrijke rol van een goed functionerend toezicht in de gezondheidszorg, is er beperkt onderzoek verricht naar de manier waarop toezicht in de praktijk werkt en welke impact dit heeft. Deze studie heeft als doel bij te dragen aan een beter begrip van toezicht op de gezondheidszorg door onderzoek naar drie verschillende methoden die worden gebruikt om het gedrag en de prestaties te beïnvloeden. Onze studie is uitgevoerd in de Verenigde Arabische Emiraten (VAE), een federatie van staten (Emiraten) in de Perzische Golf. We gebruiken een mix van onderzoeksmethoden (systematische reviews, een enquête en een veldexperiment) om de volgende onderzoeksvraag te beantwoorden:

Hoe kunnen toezichthouders toezichtsmethoden gebruiken om naleving van de regelgeving door de gezondheidszorg te verbeteren?

Het voorspellen of en hoe zorgaanbieders en professionals zullen reageren op verschillende methodes en voldoen aan wettelijke eisen, is een fundamentele voorwaarde om de effectiviteit van het toezicht te verbeteren. Toezichthouders in de gezondheidszorg hebben vaak een brede en nogal generieke taak om toezicht te houden op tal van heterogene organisaties, markten en professionals. Als gevolg hiervan bestaat de benadering van een toezichthouder vaak uit een mix van verschillende instrumenten die verschillen qua context (de setting), inhoud (de kenmerken van de interventie) en toepassing (de gebruikte methoden en het proces waarmee de interventie wordt geleverd).

In dit onderzoek is onderzocht hoe toezichthouders op de gezondheidszorg het beste hun methoden en instrumenten kunnen gebruiken om de naleving te verbeteren. Om de

onderzoeksvraag te beantwoorden, hebben we eerst een geschikte taxonomie en een breder raamwerk geïdentificeerd en verder ontwikkeld. Deze taxonomie, ontwikkeld door Arie Freiberg, kan toezichthouders helpen om zich te concentreren op factoren die van invloed zijn op de naleving en de naleving bevorderen. De toolkit van Freiberg is een niet-hiërarchische taxonomie van methoden, gebaseerd op het uitgangspunt dat "responsive regulation", met de geleidelijke escalatie van overtuiging naar sancties, geen geschikte manier is om alle uitdagingen aan te pakken.

In dit onderzoek hebben we ons gericht op de recente wijzigingen in de gezondheidszorg in de Verenigde Arabische Emiraten. Deze lokale context, met een relatief nieuw zorgstelsel creëert een uitdagende omgeving voor toezichthouders. Uit onze systematische reviews blijkt dat de nieuwe, verplichte ziektekostenverzekering in Abu Dhabi heeft geleid tot verbetering: vrijwel alle inwoners hebben nu toegang tot de vereiste zorg gebruiken. We vinden echter geen duidelijk bewijs dat de introductie van een gecentraliseerd systeem van toezichthouden een vergelijkbare positieve impact had op de kwaliteit en betaalbaarheid van de gezondheidszorg. We hebben daarom een tweede systematisch onderzoek uitgevoerd om de aard, omvang en impact van de hervorming van het zorgstelsel vanaf het jaar 2000 verder te evalueren. Dit onderzoek vindt niet genoeg substantieel bewijs om te concluderen dat het hervormingsprogramma voor de gezondheidszorg, inclusief de hervorming van het toezicht, zijn doelen al heeft bereikt.

In onze studie hebben we de potentiële toepassing en impact van drie toezichtsmethoden onderzocht: wetgevend toezicht (Clinical Practice Guidelines, CPGs), structureel toezicht (behavioural nudges) en informatieve toezicht (percepties van professionals).

Onze systematische review van CPG's in de Golfstaten gedurende een periode van 13 jaar levert een klein aantal studies op die de impact van CPG's op gezondheidsresultaten hebben geëvalueerd. Een aantal van deze onderzoeken heeft positieve effecten gevonden. Het is onduidelijk hoe de naleving van CPG's aan het effect heeft bijgedragen. De naleving van de CPG's maakt deel uit van een bredere interventie, zoals training van patiënten, hervorming van het zorgstelsel en de opleiding van zorgverleners. We concluderen dat toezichthouders moeten overwegen om CPG's te gebruiken als hulpmiddel om de patiëntresultaten te verbeteren.

Het veranderen van de keuzearchitectuur, door de introductie van nieuwe signalen die het nalevingsgedrag kunnen beïnvloeden, leidt niet tot een significante verandering in nalevingsgedrag. In een veldexperiment vinden we geen verschil in het gedrag tussen deelnemers die werden blootgesteld aan verschillende signalen. Deze toezichtsmethode kan op een relatief goedkope manier worden ingevoerd en heeft in een andere omgeving met een langere blootstelling mogelijk wel een positief effect op de naleving.

In ons onderzoek onder medische studenten in de VAE zijn verschillende factoren gemeten in relatie tot de zelfgerapporteerde naleving. De factoren zijn: rechtvaardigheid, legitimiteit, het risico om gepakt of gestraft te worden en de prestaties van de toezichthouder. We concluderen dat toezicht gebaseerd op vertrouwen en eerlijkheid effectiever is dan toezicht met een focus op afschrikking. Onze bevindingen ondersteunen de hypothese dat het nalevingsniveau wordt bepaald door de perceptie van legitimiteit, rechtvaardigheid en prestaties van de toezichthouder. Tegelijkertijd blijkt uit onze cross-sectionele studie dat afschrikwekkende factoren, zoals de kans om gepakt te worden, geen effect heeft op de gerapporteerde nalevingsniveaus.

Uit het onderzoek volgen aanbevelingen voor beleidsmakers en onderzoekers. Wat de geografische context betreft biedt dit onderzoek een uniek perspectief op toezichtsmethoden voor de gezondheidszorg in een zich snel ontwikkelende regio. Ons onderzoek toont een gebrek aan soortgelijk onderzoek. Er is meer onderzoek nodig in Abu Dhabi, maar ook in de VAE en de bredere Golfregio om de rol en impact van methoden van toezichthouden te bestuderen. Een empirisch onderbouwde taxonomie van methoden kan helpen met het focussen van onderzoeksactiviteiten en stelt toezichthouders in staat zich te concentreren op effectieve methoden om naleving te bevorderen.

Toezichthouders in de gezondheidszorg moeten rekening houden met de beoordeling van de toezichthouder door de ondertoezichtstaande organisatie en hun personeel. Het gaat hierbij om rechtvaardigheid, prestaties en legitimiteit van de toezichthouder. Gezien de kosten van toezicht, de mogelijk negatieve gevolgen van het niet-naleven van regelgeving en het gebrek aan bewijs voor toezicht gebaseerd op afschrikking, moeten beleidsmakers en toezichthouders hun energie richten op het creëren van transparante en legitieme procedures in beleid en toezicht.

Toezichthouders moeten flexibel zijn en hun methoden onderzoeken, aanpassen, ontwerpen en implementeren om het nalevingsgedrag te bevorderen. Hoewel veel toezichthouders over een breed arsenaal aan methoden beschikken, is er beperkt bewijs hoe, wanneer en waarom deze methoden de gewenste effecten in de gezondheidszorg bereiken. Een taxonomie van relevante methoden kan helpen bij het identificeren van de meest geschikte aanpak om de doelstellingen van toezicht te bereiken. In zijn baanbrekend boek over toezicht, The Regulatory Craft, verwoordde Malcolm Sparrow deze strategie als volgt: "*Pick an important problem. Fix it. Tell everyone*"

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Everyone has their own, personal and unique PhD journey and mine started in the spring of 1996 when Professor Juliaan Van Acker offered me a PhD scholarship at the Radboud University, Nijmegen, The Netherlands. I complete this journey almost a quarter of a century later. Better late than never. Thank you, Juliaan, for putting me on this journey.

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Portfolio

Overview	
PhD Period	2011 – 2019
University	Erasmus University, The Netherlands
Department	Erasmus School of Health Policy & Management
Research Interests	• Quality improvement in healthcare • Healthcare policy and management • Effective regulation in healthcare
Supervisors (Erasmus University)	• Professor Dr. Paul Robben, Erasmus School of Health Policy & Management, Erasmus University Rotterdam, The Netherlands • Sandra Oude Wesselink, PhD, Public Health Department, Erasmus MC, Erasmus University Rotterdam, The Netherlands
Collaborators (UAE University)	• Dr. Iain Blair, Director, Institute of Public Health, College of Medicine and Health Sciences, UAE University, UAE • Dr. Marilia Silva Paulo, Institute of Public Health, College of Medicine and Health Sciences, UAE University, UAE • Dr. Ahmed Deemas Alsuwaidi, Associate Professor and Assistant Dean for Student Affairs, UAE University, UAE
Collaborator (New York University, Abu Dhabi)	• Professor Nikos Nikiforakis, Professor of Economics, NYU Abu Dhabi, • Aurelie Dariel, Research Associate, NYU Abu Dhabi
Collaborators (Mohammed Bin Rashid University Dubai)	• Dr. Tom Loney, Associate Professor of Public Health and Epidemiology, College of Medicine, Mohammed Bin Rashid University, Dubai • Prof. Dr. Amir Sharif, Vice Chancellor, College of Medicine, Mohammed Bin Rashid University, Dubai

Courses	**Year**
Social & Behavioural Research, Collaborative Institutional Training Initiative (CITI Program), New York University Abu Dhabi, UAE	2015
Certified Professional in Healthcare Quality (CPHQ) National Association for Healthcare Quality (NAHQ), USA	2012

PhD Training 2009 – 2010 **(Royal College of Surgeons, Trinity College Dublin, Ireland)**	
Course	Year
Population and Individual Health	2009
Health Systems and Policy	2009
Evidence Synthesis and Clinical Trials	2010
Applying Research Methods	2009
Statistics	2010
Health Economics and Econometrics	2010
Health Information	2010

Conference Presentations		
Conference – Title	Conference	Year
Artificial Intelligence and Healthcare Regulation	Artelligence Forum, Dubai, UAE	2018
Wink – The Nudge Conference, The Netherlands	Wink – The Nudge Conference, The Netherlands	2017
Healthcare Reform in Abu Dhabi	Netherlands Economic Mission to the United Arab Emirates	2017
Ensuring Quality: Harmonizing and Optimizing Inspection Approach in Healthcare Regulation	Dubai Healthcare Regulation Conference, UAE	2016
Measuring the effectiveness of supervisory organisations	20th EPSO Conference Helsinki, Finland	2015
Eyes, hands and compliance. A natural field experiment	New York University Abu Dhabi, Department of Economics, UAE	2015
Measuring the effects of regulation on the quality of health services: Developing a conceptual framework for evaluation	ECPR Third Biennial Conference, Regulation in the Age of Crisis, UCD, Dublin, Ireland	2010

Selected list of publications

Koornneef, E., Loney, T., Alsuwaidi, A. and Paulo, M. (2018) Does self-perceived performance correlate with observed performance in an Objective Structured Clinical Examination (OSCE)? An exploratory study among medical students in the United Arab Emirates, *MedEdPublish*, 7, (3), 42, https://doi.org/10.15694/mep.2018.0000180.1

Koornneef, E., Oude Wesselink, S. and Robben, P. (2018), A cross-sectional study into medical students' perceptions of healthcare regulation and self-reported compliance: a study conducted in the City of Al Ain, United Arab Emirates, 2016, *BMC Medical Education*, 18, (1), 305-320

Koornneef, E., Dariel, A., Elbarazi, I., Alsuwaidi, A., Robben, P. and Nikiforakis, N. (2018), Surveillance cues do not enhance altruistic behaviour among anonymous strangers in the field, *PloS One*, 13, (8), https://doi.org/10.1371/journal.pone.0197959

Koornneef, E., Blair, I. and Robben, P. (2017), Progress and outcomes of health systems reform in the United Arab Emirates: a systematic review, *BMC Health Services Research*, 17, 1

Koornneef, E. (2015), Measuring effectiveness of supervisory organizations, Presentation at the 20th Conference of the European Partnership for Supervisory Organizations in Health Services and Social Care (EPSO), Helsinki, Finland. http://www.epsonet.eu/helsinki-2015.html

Koornneef, E., Robben, P., Hajat, C. and Ali, A. (2015), The development, implementation and evaluation of clinical practice guidelines in Gulf Cooperation Council (GCC) Countries: A systematic review of literature, *Journal of Evaluation in Clinical Practice*, doi: 10.1111/jep.12337

Koornneef, E., Robben, P., Seiari Al, M.B. and Siksek Al, Z. (2012), Health system reform the Emirate of Abu Dhabi, United Arab Emirates, *Health Policy*, 108, 2

Koornneef, E. (2010), Effects of regulatory interventions on the quality and safety of health-care, *Proceedings of the third European Consortium for Political Research Conference*

About the author

Erik Koornneef (De Lier, the Netherlands, 1973) studied Educational Sciences at the Radboud University Nijmegen and received his Masters' Degree in 1996. That same year Erik emigrated to Ireland where he had a successful and distinguished career within the public sector spanning almost 15 years.

Erik worked in a variety of senior healthcare positions in Ireland where he carried out regulatory functions such as the development of national standards for health and social care and monitoring the quality of health care. Whilst working in Ireland he successfully completed a Masters' Degree in Health Services Management from Trinity College Dublin in 2006. He also served on two Council of Europe Healthcare Committees in Strasbourg, France, between 2007 and 2010.

In the summer of 2010 Erik moved to the UAE to head up the audit department for the healthcare regulatory authority in Abu Dhabi, UAE. His career to date in the Middle East region has included senior leadership roles for the regulatory authority in Abu Dhabi as well as the UAE's Ministry of Presidential Affairs. He joined IBM Watson as a Senior Director in 2016 where he established its international government and policy work, with a particular focus on healthcare improvement Middle East region. Erik is currently the Vice President for Policy and Compliance at the Abu Dhabi Health Information Exchange (Malaffi).

Erik is driven by a passion to improve healthcare quality and patient outcomes by establishing robust, evidence based and effective healthcare regulatory systems. He has conducted extensive research into regulatory methods which can be used by healthcare regulatory authorities. This dissertation is the result of his research carried out from 2011 until 2019.

Erik lives in Abu Dhabi with his wife Sally and their three children: Joshua, Niels and Lotte.

Erik Koornneef
Abu Dhabi, UAE

Propositions to accompany the PhD thesis

Improving compliance with healthcare regulatory requirements in the United Arab Emirates

By Erik Koornneef

1. Healthcare regulatory agencies should spend more resources to explore and experiment with a variety of regulatory methods (This PhD Thesis).
2. For a rapidly developing country such as the UAE, it is imperative that it regularly reviews and benchmarks its healthcare performance and takes action to improve its performance (This PhD Thesis).
3. A positive perception of the healthcare regulatory agencies' fairness, legitimacy and performance increases the likelihood of compliant behaviour (This PhD Thesis).
4. Medical universities need to investigate how medical students can acquire the necessary reflective skills to accurately assess their own clinical performance (This PhD Thesis).
5. Surveillance cues, such as watching eyes, may be effective in promoting compliant behaviour in situations where there are real opportunities to build and enhance a good reputation (This PhD Thesis).
6. Innovative methods using Artificial Intelligence (AI) can help to improve the quality of healthcare by providing accurate, real-time and comprehensive insights into the performance of providers and professionals (Griffiths and Leaver, 2018).
7. A reliable way to make people believe in falsehoods is frequent repetition, because familiarity is not easily distinguished from truth. Authoritarian institutions and marketers have always known this fact (Kahneman, 2011).
8. Online access to medical records by patients has the potential to improve the quality of patient-centred care and patient satisfaction (Mold et al, 2015).
9. More prospective validation should be conducted into tasks that machines could perform to help clinicians or predict clinical outcomes that would be useful for health systems (Topol, 2019).
10. In order to achieve better healthcare outcomes, healthcare policies should focus on changing the strongest determinants of health, in particular behavioural patterns and social circumstances, rather than changing the actual healthcare delivery (McGinnis, Williams-Russo and Knickman, 2003).
11. Governments should "regulate the regulators" by obliging healthcare regulatory agencies to ringfence a certain amount of their annual budget to research and development.

About this study

Healthcare is one of the most challenging, resource intensive and complex areas of public sector reform. Many countries have established healthcare regulatory systems to provide assurance that standards are complied with and to improve the quality of care. This research focused on the healthcare system in the United Arab Emirates (UAE), a young, modern state with an ambitious healthcare reform program.

This study takes an in-depth look at three different methods used to regulate the conduct and performance of healthcare professionals and organizations. Using a variety of methodologies, this research offers practical insights and recommendations for policy makers, regulators and researchers.

About the author

Erik Koornneef is a global healthcare executive with international management experience in growing healthcare economies.

Erik has held several senior roles in the healthcare industry, including the Health and Information Quality Authority of Ireland, the Abu Dhabi Department of Health, the UAE Ministry of Presidential Affairs (Medical Office) and IBM Watson Health.

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