Measuring Effectiveness of Supervisory Organizations.

Researcher:	Erik Koornneef, MA, MSc, CPHQ and PhD Candidate
Affiliation:	Institute of Health Policy and Management (iBMG), Erasmus University, Rotterdam, the Netherlands
Website:	https://sites.google.com/site/erikkoornneef/home
Contact details:	ekoornneef@gmail.com

Presented at:	20th Conference of the European Partnership for Supervisory Organizations in Health Services and Social Care (EPSO), Helsinki, Finland
Date:	Wednesday 30th September 2015

'The surprising truth is that when regulators do manage to focus their attention on thorny, persistent and specific problems, and when they devise interventions that work, we often applaud such work as if it were not expected' (Sparrow, 2000, p. 9).

1. Introduction

One of the central tenets within the study of public service delivery is the idea that it should deliver the greatest benefit to the maximum amount of people. Measuring these benefits and the performance of public services has taken up an increasingly prominent role in debates about the planning, management and delivery of public services, in particular where it applies to the role of supervisory or regulatory bodies[1]. In many countries, there has been a gradual transformation from centralized 'governments' to decentralized 'governance' over the last two decades[2]. This is often described as a movement from 'rowing' (whereby governments provide and distribute) to 'steering' (a situation whereby governments regulate)[3].

Regulatory or supervisory agencies around the world aim to provide oversight over the quality and performance of public services and provide assurances to the public through a range of regulatory interventions[4]. The public increasingly demands that the regulators and supervisor ensure that public services are of a high quality and deliver positive results. As a consequence, the effectiveness of the public sector has come under increased scrutiny.

In the healthcare sector in particular, regulatory systems have been established to not only ensure compliance with legislation and standards to protect individuals and communities from harm but also to improve the quality of services[5]. One of the main arguments for the introduction of healthcare regulation has been concerns in relation to the quality and safety of healthcare. For example, a study into healthcare experiences in the US found that 55% of a randomly selected sample of almost 7000 adults received care as clinically recommended[6]. This paper will explore some of these challenges and possible solutions within the context of the regulation of healthcare service provision.

Walshe and Shortell[7] make a distinction between regulation that was developed as a consequence of market failure or in response to changing social needs. The first type of regulation can be described as economic regulation whereas the second type of regulation can be classified as social regulation. Social regulation is also used to achieve wider social goals — equity, diversity, or social solidarity— and to hold powerful corporate, professional, or social interests to account[8]. In recent years, there has been an increased focus on whether the regulatory activities actually result in the achievement of these social goals[9]. This paper will review the current evidence regarding the effectiveness of supervisory organizations in achieving its regulatory goals.

In the final part of the paper we will describe alternative ways to measuring effectiveness of supervisory or regulatory organizations. Throughout this paper the term healthcare regulation is used to describe the collective function by an entity (regulator) to act in the interest of the public in order to achieve regulatory objectives.

2. The role of regulatory / supervisory organizations in healthcare

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"[10]. At its core regulation can be described as the attempt by governments to steer or direct events, activities and behavior.[3] Put differently regulation seeks to change behavior in order to produce desired outcomes[11].

The objectives of regulation can be generic, varied and range from protecting citizens (in particular those groups that may be viewed as 'vulnerable') to exercising control over regulated activities or organizations and improving the quality of public service delivery. Regulations are often designed to address failures or problems that arise from the market or government failure.

Various researchers have attempted to describe the main objectives of regulation in the healthcare context. Probably the most often cited classification stems from Leatherman and Sutherland[12] who distinguished three functional objectives of institutional healthcare regulation:

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

Within healthcare the focus of the regulator or the supervisor organization can be on the healthcare service providers, professionals who work in the healthcare sector or the actual healthcare industry or market. Within these three fields, three distinct types of regulatory activity or intervention can be distinguished [13]:

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

One of the main challenges within the regulation and supervision of healthcare services is the complex nature of healthcare service provision, characterized by its heterogeneity of services delivered, multiplicity of actors and lack of a set of agreed, unified, specific and measurable objectives[2]. Studies into the determinants of health outcomes have shown that the provision of health care services in itself 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[14]. Of these 5 years, it has been estimated that curative services contribute about 3.5 and clinical preventive services about 1.5 years. The greatest share of this gain from health care can be attributed to diagnosis and treatment of coronary heart disease, which contributes 1 to 2 of these additional years of life.

In many countries, institutional healthcare regulators have been give broad and generic remit and deal with a large number of heterogeneous organizations. As a result, a regulator's approach often consists of a complex set of regulatory interventions[4] with high levels of variance in context (i.e. the setting), contents (i.e. the characteristics of the intervention) and the application (i.e. the process through which the intervention is delivered). In order to evaluate to what extent regulatory or supervisory organizations achieve their objectives, a dichotomous categorization of approaches is often used. 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. However, in practice regulators or supervisors often use a mixture of the two approaches[15].

Another way of describing regulatory or supervisory approaches is by taking stock of the strategic needs of the regulated industry or service. Ayers and Braithwaite[16] 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. An extension of this line of thinking is the concept of risk-based regulation which is an approach characterized by a commitment to applying proportionality to the risks posed by the activities of an organization[17].

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 and supervisory organizations have increasingly adopted a risk-based and responsive approach[18]. However, 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[19].

In summary, there is a dearth of evidence in relation to how different regulatory and supervisory approaches work in practice[20] and what, if any, effect regulatory and supervisory activities have on the quality and safety of health care provision. The next section reviews the empirical evidence that currently exists.

3. Achieving regulatory objectives – Effectiveness

Effectiveness can be defined as 'the degree to which the objectives of a program, care, services, or system are achieved'.[21]

Although effectiveness studies have been carried out for some regulatory interventions, in particular accreditation [22 23] and clinical practice guidelines [24 25], researchers have noted a dearth of empirical evidence of the effects of regulatory interventions on the quality of health and social services.[20 18] As a recent RAND Europe review of the regulatory mechanisms of six countries stated: "The overall evidence of the effectiveness of regulatory strategies towards ensuring care quality and safety at system level is scarce".[26] A Cochrane review regarding the effects of regulatory inspections on the quality of care and compliance with standards[27] only found two studies for inclusion in their review, highlighting the lack of high-quality controlled evaluations of the effectiveness of regulatory inspection systems.

Despite the growing body of knowledge regarding the key challenges, to date limited research has been conducted into how healthcare regulation works in practice and, more importantly, what impact it has made[4]. 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, based on observational studies and has found associative rather than causal links between regulation and quality improvement[12].

The effects of one specific regulatory approach, accreditation, has been the focus of an increasing number of studies across the world. Most studies have found little empirical evidence whether accreditation is an effective strategy for improving performance in healthcare. 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 [28]. However, other researchers found that JCI accredited hospitals performed better than their non-accredited peers on several clinical performance measures[29]. A randomised controlled trials in South Africa[30] found no significant effect on performance of of accredited hospitals compared to the control group. Overall, the evidence for accreditation improving patient safety and quality is mixed but there is evidence emerging that accreditation has a positive impact on organizational performance.[23]

Similarly, growing evidence exists indicating that Clinical Practice Guidelines can, at times, have positive effects on the quality of clinical care[31]. Clinical Practice Guidelines are often used to support clinicians in using best avaliable 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[9]. Since the positive effects are widely acknowledged, health care regulatory authorities have regularly endorsed and mandated the development and implementation of guidelines.

Despite some encouraging evidence from these studies a number of important questions remain. First and foremost, why have regulatory approaches not been more successful in achieving the regulatory objectives? And, secondly, what can be done to understand the regulatory processes better? In this section we look at the reasons behind the relative lack of success and in the next section we take a look at how the regulatory and supervisory process can be understood better.

There are a number of explanations for this lack of empirical evidence as to why regulators and supervisors have not been more successful. First of all, regulatory or supervisory organizations often are not able to show that their supervisory processes are reliable, accurate and trustworthy. This is one area of potential concern for regulatory or supervisory organizations. For example, a study undertaken in the Netherlands[32] found that of 615 ratings from inspectors working for the Dutch Health Care Inspectorate, 53% were found to be unreliable, following an analysis by two independent observers. The researchers found that in 52% the inspectors had given the service provider a higher rating than what, on the basis of the descriptions of the evidence, could have been expected (false positives). Only 1% of the ratings were false negatives. A recent evaluation of the Care Quality Commission (CQC) in England[33] reported a low predictive value of the risk rating of 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[34]. It is clear that a lack of reliable supervisory activities significantly hinders the supervisory organization's ability to achieve its objectives. Similarly, a Norwegian research study of inspection reports issued by the healthcare supervisory 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[35].

Another challenge is that, as discussed, one of the main objectives of institutional healthcare regulation is to provide assurances of the quality of healthcare provision. However, quality as a construct is quite difficult to define and even more challenging to measure. One of the most frequently quoted definitions of healthcare quality stems from a seminal report by the US Institute of Medicine[36] who defined quality as: ' the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'. Quality of healthcare is multi-dimensional and a consensus appears to be emerging within national governments - USA, Australia, Canada, England, New Zealand - and international organisations - OECD, World Health Organization - that quality involves a small number of domains[37]. The US Institute of Medicine[36] (2001) identified six dimensions through which the overall concept of quality is expressed: Safety, effectiveness, patient-centeredness, timeliness, efficiency and equity.
Other international umbrella organisations, such as the WHO and the OECD have taken an active leadership role in defining and measuring quality of healthcare, through research, indicators development, performance measurements and conceptual frameworks. Notwithstanding this, the lack of evidence relating to healthcare quality creates additional measurement challenges for a supervisory or regulatory authority.

Thirdly, in common with economic regulators, regulatory agencies in the social field experience 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)[38]; at times regulated organizations may find ways to avoid compliance (regulatory escape)[39] or they may capture influence over the regulator (regulatory capture)[4]. 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 the benefits of these policies[13].

Furthermore, considering the complexity of the health care systems overall, including the diverse political and cultural contexts within which regulatory mechanisms operate, it can be a challenge to analyze information and ascertain a causal or even a associative relationship between the regulatory or supervisory system and the quality of care provided.[26] As discussed before, regulation in healthcare does not revolve around one organization and a regulator or supervisor may not always have the authority over a particular area resulting in difficulties when attaining objectives. In other words, the regulator or supervisor may not always be the author of their own destiny as there will always be confounding factors influence performance.

Finally, members of the general public often have particular expectations of the role and responsibility of regulatory or supervisory organizations. A survey found that the majority of the public in the Netherlands assigned a higher degree of responsibility for the quality of care to the regulator rather than the care providers[19]. Ensuring that the regulatory meets and exceeds the expectations of the public plays an important role in creating the right foundation for effective regulation. Healthcare regulators have moved from a command-and- control approach and a coercive, adversarial to a cooperative and persuasive relationship. However, in some settings this pendulum has swung back again with a regulator reclaiming lost ground and emphasizing a more stringent regulatory process with a renewed zeal for hard edge regulation with an emphasis on detection through inspections and sanctions[5].

These key challenges do not just apply to healthcare regulatory or supervisory organizations but the entire healthcare field which is characterized by fragmentation, complexity, ungovernability and interdependencies[40]. Therefore, any evaluation should take into account the premise that regulation or supervision aims to change behavior in order to produce the desired outcomes[11].

However, to date, the small number of evaluations into the effectiveness of healthcare regulation and supervision have focused on the processes, outputs and outcomes and not on the actual behaviors they are attempting to change. For example, the effectiveness of the UK regulatory healthcare authority has been reviewed a number of times in the last decade by looking at the governance of the regulatory organizations and the impact on performance. [20 41 33] A large international review of healthcare regulation and supervision concluded that little research has been conducted so far on assessing the role and functions of regulatory bodies.[18]

Similarly in the Netherlands the Health Council[42] has attempted to review the effectiveness of its regulatory system. One of the main conclusions was that evidence-based regulation or supervision us still in its infancy. Research conducted In Canada found that the introduction of a new inspection and certification process led to significant quality improvements in long-term care facilities in Quebec, Canada[43]. Undoubtedly these studies have helped to contribute to a better understanding of the effects of healthcare regulation and supervision.

However, what these evaluations have failed to create is a research model that does not just look at the general effects of regulation and supervision, such as the relationship between regulatory status and a health outcome such as mortality[44] but a model that studies how the regulatory system has an effect on the compliance behaviors of healthcare providers[45].

In conclusion, in order to determine the effectiveness of a regulatory intervention, one must first understand the determinants of compliant behavior. However, very few empirical studies in healthcare have looked at why some organizations or individuals display compliant behaviors and others do not[40]. Central to regulatory theory is the ability of regulators to ensure compliance with regulatory requirements such as standards, directives, rules, etc. [46]. 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 determinants of compliance. In the next section of this paper I will explore some insights into the determinants of compliance.

4. Alternative models

As noted above, despite decades of attention and investment in regulating and supervising healthcare services across the world relatively little is known about the types and success of regulatory approaches employed by regulatory agencies. A number of researchers have attempted to describe the relationship between regulatory approaches and outcomes by developing and using theoretical frameworks[7]. Recently the Organisation for Economic Cooperation and Development (OECD) established a framework to assist countries in systematically evaluating the design and implementation of regulatory policy, against the achievement of strategic regulatory objectives[1]. This framework sets out seven core principles for effective regulation. In this section we will describe

Healthcare regulation and supervision can probably be best understood as a series of complex interventions that are introduced into complex, fragmented and diverse healthcare field. Viewing healthcare regulation this way has implications for the choice of research methods and for the conceptual framework that can underpin the research studies in this field. As a series of complex interventions, regulatory approaches are critically influenced by the contexts into which they are introduced and by the processes of implementation in those contexts.[15] This means that the types of research methods used to understand and evaluate regulatory approaches must be able to shed light on how context and implementation interact in particular organizations. The need for a theory-driven approach has been advocated in order to gain a better understanding of the complexities and regulatory approaches. In this section we will review three models in particular, a model based on behavioral sciences; a model based procedural justice theory and an approach promoting the idea of establishing a comprehensive framework of performance indicators.

The role of behavioral science

Increasingly governmental agencies utilize and apply the learning from behavioral sciences.[1] For example, recently the World Bank[47] published a report on the important role of knowing how to influence the way people make decisions in the healthcare context.

Influenced by behavioral economists, such as Daniel Kahneman and Amos Tversky[48] and Richard Thaler and [49] Cass Sunstein[50], decision makers, politicians and regulatory authorities have increasingly investigated the role of psychological, cognitive, emotional and social factors on decision-making. Behavioral approaches recognize that humans are not entirely rational and frequently misjudge decisions because of their inherent biases and rules of thumb for making sense of information. For example, in a recent field experiment in the UK, researchers[51] found that including social norms and public goods messages in standard tax payment reminder letters considerably enhanced tax compliance. The move towards this new approach is also influencing regulatory authorities, as regulators are now increasingly applying behavioral science in their regulatory approach[50]. The World Bank[47] recently dedicated an entire report on the benefits of understanding the psychological, social, and cultural influences on decision making and human behavior and its impact on development outcomes. In relation to healthcare professionals' compliance with regulatory requirements, the World Bank[47] report commented on the "know-do" gap. Healthcare workers do not systematically use the knowledge that they already posses and "increasing spending on training will not improve quality, and it is time to focus on ways to get doctors to put into practice what they already know."

The application of behavioral economics and psychology in relation to healthcare professional's compliance with regulatory requirements has not yet been applied in a healthcare setting. Remarkably, other laboratory studies have pointed out that even subtle cues of being observed influences altruistic behavior[52], in particular in areas such as charitable giving[53 54], pro social behavior[55], voter turnout[56] and recycling [53].

The role of procedural justice

The traditional viewpoint regarding the determinants of compliance behavior has concentrated on instrumental motivations: people obey rules and laws because there are penalties and incentives. The logic behind this model is that individuals comply because they fear the consequences of being found in breach of regulatory requirements. The classic reference for this rational choice framework is Gary Becker[57], who proposed that, when given a choice, people evaluate their options and choose the option that promises the best outcomes. From this viewpoint, regulatees are motivated by self-interest and seek to maximise their gains and minimise their losses[58]. In the regulatory context, the regulatory authority views the regulatee as an 'amoral calculator', only concerned about their self-interest[59]. As a result, regulatory authorities with this instrumental viewpoint frequently use instruments such as inspections, sanctions and penalties. However, instrumental mechanisms have, at best, a small impact on compliance behavior. [60 61 51]

This traditional viewpoint regarding the determinants of compliance behavior concentrates on instrumental motivations: people obey rules and laws because there are penalties and incentives. In the regulatory context, the regulatory authority views the regulatee as an 'amoral calculator', only concerned about their self-interest[59]. As a result, regulatory authorities with this instrumental viewpoint frequently use instruments such as inspections, sanctions and penalties. However, instrumental mechanisms have, at best, a small impact on compliance behavior [62 63 51]. An alternative viewpoint looks at the role of people's social motivations in terms of the perceived legitimacy and fairness of the regulatory process.

In his seminal work on compliance and regulation in the 1980s, Tom R. Tyler found that when people perceived to have been treated fairly by authorities, they are more likely to comply with requirements, because there is a relational bond[62]. This is also known as procedural justice, the perceived fairness of the procedures involved in decision making and the perceived treatment one receives from the decision-maker [64]. The procedural justice-based approach is in stark contrast with the traditional viewpoint and approach that links cooperation and compliance to instrumental judgements of distributive fairness, fairness that is associated with outcomes decisions and distribution of resources [65]. In many areas of life, such as tax compliance, the courts system and policing, research indicates that perceptions of procedural fairness exert more influence on tax payers', litigants' and defendants' overall view of the authorities (such as the taxation officials, court and police) than their perceptions of distributive fairness. [65] Furthermore, several studies demonstrate that when people who are being regulated believe the regulator's process was fair they become more likely to comply with the regulator's instructions and follow the law and requirements.[63] For example, Kagan, Thornton and Gunningham studied why regulatees comply and cooperate with the regulators over a nine-year period. The researchers found that regulatees are motivated by fear of detection and punishment, as well as a fear of public humiliation and an internalized sense of duty or obligation to conform[66].

The role of performance indicators

A third approach to looking at new ways to evaluate effectiveness is by establishing a system of performance measurement, using performance indicators. As noted before, the OECD is working with its member countries to ensure the impact of regulation is measured in a standardized way using agreed performance indicators[1]. In the healthcare context, several countries have attempted to use performance indicators for regulatory and supervisory purposes[67]. Considering that effectiveness is the degree to which the objectives of the regulatory interventions are achieved, these objectives could be set and agreed a priori in the form of performance indicators.[26]

The establishment and reporting of performance indicators leads to greater transparency and creates accountability for regulatory and supervisory organizations. Performance monitoring of the healthcare system is increasingly used in many countries such as the Netherlands, Australia, United States and England as its potential is recognized as an important regulatory tool to improve quality[68 40]. At international level, the OECD's Health Care Quality Indicator (HCQI) Project is an international effort aimed at developing a common set of indicators for monitoring the quality of health care delivered across countries.[67] However, this type of performance monitoring is not specifically designed to measure the impact of regulatory or supervisory interventions. In comparison, in the field of hospital accreditation, attempts are made to develop and validate performance indicators that can be used to analyze and compare the costs and benefits of accreditation programs[69].

Summary

The number of evaluation studies that have reviewed the impact of regulatory interventions is not only small as previously described, the theoretical model is often too simplistic as it assumes a direct cause and effect relationship between regulatory interventions and health outcomes or healthcare improvement and does not sufficiently take into confounding factors that play an important role in a complex environment such as healthcare. The three models described above provide alternative models to analyse and review the effectivness of supervision and regulation. In the next section, I will describe a study currently being conducted in the United Arab Emirates. This study focuses on the potential roles of procedural justice and behavioral sciences in analyzing and reviewing the effects of regulatory and supervisory interventions.

5. Eyes, hands and compliance: A natural field experiment in the United Arab Emirates

This study aims to contribute to a better understanding of healthcare regulation by taking an in-depth look at a specific regulatory intervention aimed at improving healthcare quality and patient safety. The study examines the roles of procedural justice and behavioral cues on the levels of compliance with hand hygiene instructions amongst medical and nursing staff in a large hospital in the United Arab Emirates (UAE). Central to regulatory theory is the ability of regulators or supervisors to ensure compliance with regulatory requirements[46]. Since the extent to which different actors within the wider healthcare system comply with the regulatory requirements is assumed to impact on the quality and safety of healthcare, it is important to conduct further research into the determinants of compliance.

The traditional viewpoint regarding the determinants of compliance behavior has concentrated on instrumental motivations: people obey rules and laws because there are penalties and incentives. The logic behind this model is that individuals comply because they fear the consequences of being found in breach of regulatory requirements. The classic reference for this rational choice framework is Gary Becker[57], who proposed that, when given a choice, people evaluate their options and choose the option that promises the best outcomes. From this viewpoint, regulatees are motivated by self-interest and seek to maximize their gains and minimize their losses[58]. In the regulatory context, the regulatory authority views the regulatee as an 'amoral calculator', only concerned about their self-interest[59]. As a result, regulatory authorities with this instrumental viewpoint frequently use instruments such as inspections, sanctions and penalties. However, instrumental mechanisms have, at best, a small impact on compliance behavior. [60 61 51] In this study, the focus will be on the factors that influence and determine healthcare professionals' compliance with the regulatory requirements for hand hygiene.

The specific focus of this research study is on factors that can influence healthcare professionals' compliance with the regulatory requirements for hand hygiene. We will do this by looking at two variables: (1) the role of participant's perceptions in terms of the perceived legitimacy and fairness of the regulatory process and (2) the influence of subtle behavioral cues based on insights from behavioral economics.

To review the effects of participant's perceptions we will look at the participants' social motivations in terms of their perceptions regarding the legitimacy and fairness of the regulatory process. When people perceived to have been treated fairly by authorities, we anticipate they will be more likely to comply with requirements, because there is a relational bond. This is also known as procedural justice, the perceived fairness of the procedures involved in decision making and the perceived treatment one receives from the decision-maker. In order to review the effects of the second independent variable, we will investigate subtle behavioral cues of being observed by displaying a picture of human eyes in the area where the research is carried. 'Watching eyes' experiments have been tested in a variety of different settings and areas. Studies have found that people followed 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 behavior.

One of the biggest patient safety challenges in healthcare is the prevention and control of healthcare associated infections[70]. Healthcare associated infections are infections that people acquire while they are receiving treatment for medical conditions in a health care setting. At present, it is estimated that approximately 80,000 people in the USA and 37,000 in the European Union die each year as a result of healthcare associated infections[71 72]. Furthermore, it is estimated that the costs of healthcare associated infections in hospital in the USA ranged from 28.4 to 33.8 billion USD[73].

Adequate hand hygiene by healthcare professionals is considered one of the most effective measures to reduce healthcare associated infections since organisms that cause nosocomial infections are most commonly transmitted by the hands of healthcare professionals[74]. It is estimated that adequate hand hygiene can prevent between 15 and 30% healthcare associated infections [49]. Hand hygiene is a general term for removing microorganisms with a disinfecting agent such as alcohol or soap and water. Up until the Centers for Disease Control and Prevention (CDC)[75] and the World Health Organization (WHO)[76] published their guidelines with recommended hand hygiene practices in 2002 and 2009 respectively, there was a great variation in the way hand hygiene compliance was measured. As the international authority responsible for setting standards and providing leadership on global health matters, the WHO introduced a global campaign in 2009 (Save Lives: Clean Your Hands) that aims to reduce the number of healthcare associated infection by improving hand hygiene practices amongst healthcare workers. The largest international healthcare quality standards setting and accrediting body, the Joint Commission International (JCI) also endorsed the WHO campaign. In order to become accredited by JCI the healthcare facility has to demonstrate that it measures hand hygiene compliance in a standardized manner and results show that the organization meets its own targets.

Despite the well-recognized importance of adequate hand hygiene, studies across the globe have shown that healthcare professionals compliance rates are often very low, on average less than 50%[77], sometimes as low as 30-40%. [74 78 79] A systematic review found that only 25% of the studies reviewed reported a compliance rate higher than 50% [80].

In terms of improving hand hygiene practice, some studies have reported the positive effects of interventions such as repeated countrywide campaigns [79], education, feedback, installation of sinks and alcohol based solutions and organizational changes [81] and team-directed strategies [49]. Compliance is also associated with knowledge and awareness of healthcare professionals, as well as work and system constraints, such as the accessibility of hand hygiene agents [82]. To date, these hand-hygiene interventions have largely concentrated on improving compliance through education, training, reminders and feedback [24]. A recent systematic review found only three studies with positive results in relation to the effectiveness and sustainability of hand hygiene interventions that actually changed the behavior of health care professionals [83], all three interventions focused on an educational and awareness raising campaigns.

The first part of this study will focus on the role of people's social motivations in terms of the perceived legitimacy and fairness of the regulatory process. Regulatory or supervisory authorities with an instrumental viewpoint frequently use instruments such as inspections, sanctions and penalties. However, instrumental mechanisms have, at best, a small impact on compliance behavior [62 63 51]. In his seminal work on compliance and regulation in the 1980s, Tom R. Tyler found that when people perceived to have been treated fairly by authorities, they are more likely to comply with requirements, because there is a relational bond[62]. This is also known as procedural justice, the perceived fairness of the procedures involved in decision making and the perceived treatment one receives from the decision-maker [64]. The procedural justice-based approach is in stark contrast with the traditional viewpoint and approach that links cooperation and compliance to instrumental judgments of distributive fairness, fairness that is associated with outcomes decisions and distribution of resources [65]. In many areas of life, such as tax compliance, the courts system and policing, research indicates that perceptions of procedural fairness exert more influence on tax payers', litigants' and defendants' overall view of the authorities (such as the taxation officials, court and police) than their perceptions of distributive fairness. [65] Furthermore, several studies demonstrate that when people who are being regulated believe the regulator's process was fair they become more likely to comply with the regulator's instructions and follow the law and requirements. [63]

The second part of this study reviews the potential role of behavioral science. Influenced by behavioral economists, such as Daniel Kahneman and Amos Tversky[48] and Richard Thaler and [49] Cass Sunstein[50], decision makers, politicians and regulatory authorities have increasingly investigated the role of psychological, cognitive, emotional and social factors on decision-making. Behavioral approaches recognize that humans are not entirely rational and frequently misjudge decisions because of their inherent biases and rules of thumb for making sense of information. For example, in a recent field experiment in the UK, researchers[51] found that including social norms and public goods messages in standard tax payment reminder letters considerably enhanced tax compliance. The move towards this new approach towards regulation is also influencing regulatory authorities, as regulators are now increasingly applying behavioral science in their regulatory approach [50]. The World Bank[47] recently dedicated an entire report on the benefits of understanding the psychological, social, and cultural influences on decision making and human behavior and its impact on development outcomes. In relation to healthcare professionals' compliance with regulatory requirements, the World Bank[47] report commented on the "know-do" gap. Healthcare workers do not systematically use the knowledge that they already posses and "increasing spending on training will not improve quality, and it is time to focus on ways to get doctors to put into practice what they already know."

Therefore, the second area that our study will focus on is the application of behavioral economics and psychology in relation to healthcare professional's compliance with regulatory requirements. This has not yet been applied in a healthcare setting and this study, through a public good experiment, aims to highlight the important role of certain interventions based on the theories emanating from the field of behavioral economics. In particular, we will investigate whether perceiving subtle facial cues might influence one's behavior. [85] [86] Remarkably, other laboratory studies have pointed out that even subtle cues of being observed influences altruistic behavior[52], in particular in areas such as charitable giving[53] [54], pro social behavior[55], voter turnout[56] and recycling [53].

The effects of both variables will be reviewed against the professional's observed hand hygiene compliance in terms of technique and duration. This study will use an adapted version of the World Health Organization's Hand Hygiene (WHO) Observation tool[76] and the Center for Diseases Control and Prevention (CDC) Hand Hygiene Guidelines.[75] The WHO describes observation of hand hygiene as the 'gold standard' of measuring hand hygiene compliance. According to the regulatory requirements established by the WHO, a person's performance is deemed to be compliant with the recommended total duration if the entire hand washing task lasts more than 40 seconds[78] with the actual hand washing. Other authorities such as the Association for Professionals in Infection Control and Epidemiology (APIC) recommend that each healthcare professional spend between 15-20 seconds vigorously rubbing their hands. Many researchers have commented on the importance of appropriate hand hygiene techniques[49] [78], i.e. in accordance with recommended regulatory requirements. One of the main concerns from a patient safety perspective is that not all surfaces of the hands are covered during the hand wash task because of poor technique or use of insufficient amounts of solution that may leave contaminated surfaces. However, the majority of studies have focused on opportunities for hand hygiene [87] [88] [89] rather than the technique. A literature review of 41 studies focused on measuring hand washing performance, found that less than a quarter of the studies evaluated hand washing technique, presumably because frequency was much easier to document [90]. In 1985 Larson and Lusk[91] concluded that the way hands are washed is equally important as when hands are washed. Relevant regulatory actors such as the WHO[78], CDC[75], Joint Commission[92] and APIC[93] all concur that the hand hygiene technique is crucially important.

Many authorities such as the WHO, CDC and JCI have developed hand hygiene promotion posters to explain the main steps that need to be followed when washing hands. In addition, an observation form and instructions for how to measure compliance often accompany the posters. However, observers are required to observe and report the number of times the observed person (nurse, doctor, etc.) performed the correct action as a percentage of the total number of opportunities, rather than observing the adequacy of the technique.

In summary, in this research the observers will determine the hand hygiene technique compliance of each participant, i.e. whether they perform the correct technique and comply with the recommended duration. The focus will be on factors that can influence healthcare professionals' compliance with the regulatory requirements for hand hygiene. We will do this by looking at two variables: (1) the role of participant's perceptions in terms of the perceived legitimacy and fairness of the regulatory process and (2) the influence of subtle behavioral cues based on insights from behavioral economics.

To review the effects of participant's perceptions we will look at the participants' social motivations in terms of their perceptions regarding the legitimacy and fairness of the regulatory process. When people perceived to have been treated fairly by authorities, we anticipate they will be more likely to comply with requirements, because there is a relational bond. This is also known as procedural justice, the perceived fairness of the procedures involved in decision making and the perceived treatment one receives from the decision-maker. In order to review the effects of the second independent variable, we will investigate subtle behavioral cues of being observed by displaying a picture of human eyes in the area where the research is carried. 'Watching eyes' experiments have been tested in a variety of different settings and areas. Studies have found that people followed 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 behavior.

Participants will be asked to take part in a study where they are asked to perform a short clinical task (dressing a patient's wound) during which they are observed by a trained research assistant. It is expected that each participant will wash his or her hands before and after the wound dressing. Once in front of the hand washbasin, the hand washing duration and technique of each participant will be observed by a trained observer. The data from all parts of the study will be analyzed and synthesized to establish whether a relation exists between behavioral 'nudges'/subtle cues and hand hygiene compliance and/or a relationship between attitudes towards regulatory requirements and hand hygiene compliance.

6. Conclusions

As noted in this paper, one fundamental challenge in designing and implementing regulatory approaches within healthcare is the limited evidence of the actual effects that these interventions have on the quality of healthcare services. Given the widely reported negative effects of regulation, including regulatory capture, burden, creep and escape, it is now time to take an in-depth look at the effects of regulation.

This paper presented a new framework for the qualitative and quantitative measurement of regulation. It is worth noting that extensive research has recently been carried out by researchers such as Kieran Walshe in the UK, Paul Robben in the Netherlands, Sheila Leatherman and Kim Sutherland in the UK and John and Jeffrey Braithwaite and others in Australia, investigating the characteristics of effective regulatory strategies or approaches. These and other studies have made a significant contribution to the body of knowledge on the effects of regulation on the quality of healthcare services and at the same time these studies also confirmed the need for further research into the impact of healthcare regulation.

In conclusion, currently limited evidence exists what effect regulation and supervision have on the quality of healthcare. Equally important, there is limited evidence of how and why regulatory and supervisory approaches would achieve the desired outcomes. An evaluation model based on a straightforward cause and effect model may not be the most appropriate manner by which to measure the impact of a series of diverse regulatory and supervisory actions and interactions within a complex and fragmented healthcare environment. This paper reviewed three alternative ways of evaluating the effects of regulatory and supervisory requirements in healthcare: behavioral strategies (“nudging”), strategies based on procedural justice and the establishment of a comprehensive framework of performance indicators that measure the effects of regulation and supervision.

Finally, this paper described a forthcoming study that aims to expand the current knowledge and understanding of the regulatory and supervisory interventions by analyzing specific factors that influence compliance. The study examines the roles of procedural justice and behavioral cues on the levels of compliance with hand hygiene instructions amongst medical and nursing staff in a large hospital in the United Arab Emirates (UAE). The hypotheses of this research are (1) “nudging” or using subtle behavioral cues will have a significant effect on compliance and (2) professionals who consider that the behavior of the regulatory and supervisory organizations is fair and just, display a significant higher level of compliance than professionals who do not view the regulatory organization is fair and just.

References

1. OECD. *The Governance of Regulators*. OECD Publishing; 2014. doi:10.1787/9789264209015-en.

2. Helderman J-K, Bevan G, France G. The rise of the regulatory state in health care: a comparative analysis of the Netherlands, England and Italy. 2012. doi:10.1017/S1744133111000326.

3. Braithwaite J, Coglianese C, Levi-Faur D. Can regulation and governance make a difference? *Regul Gov*. 2007;1(1):1-7. doi:10.1111/j.1748-5991.2007.00006.x.

4. Walshe K and AB. *Designing Regulation - a Review*.; 2007.

5. Scrivens E. The future of regulation and governance. *J R Soc Promot Health*. 2007;127(2):72-77. doi:10.1177/1466424007075455.

6. McGlynn EA, Asch S, Adams J, et al. Quality of health care delivered to adults in the United States. *N Engl J Med*. 2003;348(26):2635-2645. Available at: http://www.ncbi.nlm.nih.gov/pubmed/14606462.

7. Walshe K, Shortell SM. Social regulation of healthcare organizations in the United States: developing a framework for evaluation. *Heal Serv Manag Res*. 2004;17(May):79-99.

8. Walshe K. Education and debate The rise of regulation in the NHS. 2002;324(April).

9. Koornneef E, Robben P, Hajat C, Ali A. The development, implementation and evaluation of clinical practice guidelines in Gulf Cooperation Council (GCC) countries: a systematic review of literature. *J Eval Clin Pract*. 2015:n/a-n/a. doi:10.1111/jep.12337.

10. Selznick P. Focusing organisational research on regulation. In: Noll RG, ed. *Regulatory Policy and the Social Sciences*. Berkeley : University of California Press; 1985:3638.

11. Coglianese C. *Measuring Regulatory Performance: Evaluating the Impact of Regulation and Regulatory Policy*. Paris; 2012. Available at: http://www.oecd.org/gov/regulatory-policy/1_coglianese web.pdf.

12. Sutherland K, Leatherman S. Regulation and quality improvement A review of the evidence. *Heal Found*. 2006;(October).

13. Braithwaite J, Healy J, Dwan K. *The Governance of Health Safety and Quality. A Discussion Paper*.; 2005.

14. Bunker JP. The role of medical care in contributing to health improvements within societies. *Int J Epidemiol*. 2001;30(6):1260-3. Available at: http://www.ncbi.nlm.nih.gov/pubmed/11821323.

15. Walshe K. Understanding what works--and why--in quality improvement: the need for theory-driven evaluation. *Int J Qual Health Care*. 2007;19(2):57-9. doi:10.1093/intqhc/mzm004.

16. Ayers, I., Braithwaite J. *Responsive Regulation: Transcending the Deregulation Debate*. Oxford University Press; 1994. doi:0195093763.

17. Adil M. Risk-based regulatory system and its effective use in health and social care. *J R Soc Promot Health*. 2008;128(4):196-201New referen. doi:10.1177/1466424008092234.

18. Ngo D, Breejen E den, Putters K, Bal R. *Supervising the Quality of Care in Changing Healthcare Systems. An International Comparison*. Rotterdam; 2008. Available at: http://epso-web.eu/mediapool/72/723588/data/Supervising_the_quality_of_health_care_doc.pdf.

19. Bouwman R, Bomhoff M, de Jong JD, Robben P, Friele R. The public's voice about healthcare quality regulation policies. A population-based survey. *BMC Health Serv Res*. 2015;15(1):325. doi:10.1186/s12913-015-0992-z.

20. Benson L a., Boyd A, Walshe K. Learning from regulatory interventions in healthcare. *Clin Gov An Int J*. 2006;11(3):213-224. doi:10.1108/14777270610683146.

21. Arah O a, Klazinga NS, Delnoij DMJ, ten Asbroek a H a, Custers T. Conceptual frameworks for health systems performance: a quest for effectiveness, quality, and improvement. *Int J Qual Health Care*. 2003;15(5):377-98. Available at: http://www.ncbi.nlm.nih.gov/pubmed/14527982.

22. Braithwaite J, Westbrook J, Johnston B, et al. Strengthening organizational performance through accreditation research - a framework for twelve interrelated studies: the ACCREDIT project study protocol. *BMC Res Notes*. 2011;4(1):390. doi:10.1186/1756-0500-4-390.

23. Braithwaite J, Greenfield D, Westbrook J, et al. Health service accreditation as a predictor of clinical and organisational performance: a blinded, random, stratified study. *Qual Saf Health Care*. 2010;19(1):14-21. doi:10.1136/qshc.2009.033928.

24. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet*. 2003;262((9391)):225-230.

25. Cabana MD, Rand CS, Powe NR, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA*. 1999;282(15):1458-1465. doi:10.1001/jama.282.15.1458.

26. Schweppenstedde D, Hinrichs S, Ogbu U, et al. *Regulating Quality and Safety of Health and Social Care International Experiences*. London, UK; 2014.

27. Flodgren G, Pomey M-P, Taber S a, Eccles MP. Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes. In: Eccles MP, ed. *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd; 2011:CD008992. doi:10.1002/14651858.CD008992.pub2.

28. Barker KN, Flynn E a, Pepper G a, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Arch Intern Med*. 2002;162(16):1897-903. Available at: http://www.ncbi.nlm.nih.gov/pubmed/12196090.

29. Schmaltz SP, Williams SC, Chassin MR, Loeb JM, Wachter RM. Hospital performance trends on national quality measures and the association with Joint Commission accreditation. *J Hosp Med*. 2011;6(8):454-61. doi:10.1002/jhm.905.

30. Salmon J, Heavens J, Lombard C, Tavrow P. The impact of accreditation on the quality of hospital care: KwaZulu-Natal province Republic of South Africa. 2003. Available at: http://www.popline.org/node/276015. Accessed September 1, 2014.

31. Grimshaw JM, Russell IT. Achieving health gain through clinical guidelines II: Ensuring guidelines change medical practice. *Qual Saf Heal Care*. 1994;3(1):45-52. doi:10.1136/qshc.3.1.45.

32. Tuijn SM, van den Bergh H, Robben PBM, Janssens FJG. De relatie tussen normen en oordelen in het toezicht op de gezondheidszorg. *TSG*. 2009;87(6):264-271. doi:10.1007/BF03082265.

33. Walshe K, Phipps D. *Developing a Strategic Framework to Guide the Care Quality Commission's Programme of Evaluation*. Manchester; 2013. Available at: http://webcache.googleusercontent.com/search?q=cache:KFM96LY9G-cJ:www.cqc.org.uk/sites/default/files/documents/cm_011404_item_5_report-regulatory-framework-finalv1.doc+&cd=5&hl=en&ct=clnk&gl=ae.

34. Boyd A, Addicott R, Robertson R, Ross S, Walshe K. *Measuring Quality through Inspection: The Validity and Reliability of Inspector Assessments of Acute Hospitals in England*.; 2014. Available at: http://www.kingsfund.org.uk/events/european-health-policy-group-autumn-2014-meeting.

35. Hovlid E, Høifødt H, Smedbråten B, Braut GS. A retrospective review of how nonconformities are expressed and finalized in external inspections of health-care facilities. *BMC Health Serv Res*. 2015;15(1):405. doi:10.1186/s12913-015-1068-9.

36. Institute of Medicine C on Q of HC in A. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington DC: National Academy Press; 2000. Available at: http://www.nap.edu/read/10027/chapter/1#ii.

37. Mattke S, Epstein AM, Leatherman S. The OECD Health Care Quality Indicators Project: history and background. *Int J Qual Health Care*. 2006;18 Suppl 1(September):1-4. doi:10.1093/intqhc/mzl019.

38. Sparrow M. *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance*. Washington DC: Brookings Institution Press; 2000.

39. Walshe K. The rise of regulation in the NHS. *Bmj*. 2002;324(7343):967-970. doi:10.1136/bmj.324.7343.967.

40. Healy J. *Improving Health Care Safety and Quality: Reluctant Regulators*. Ashgate; 2011.

41. Walshe K, Harvey G, Skelcher C, Jas P. Could do better? Knowledge, learning and performance improvement in public services. 2009;(May). Available at: http://digital.library.adelaide.edu.au/dspace/handle/2440/80854. Accessed September 1, 2014.

42. Health Council of The Netherlands. *Towards Evidence Based Supervision. Research into the Effects of Supervision by the Dutch Health Care Inspectorate*. The Hague; 2011.

43. Bravo G, Dubois M-F, Demers L, et al. Does regulating private long-term care facilities lead to better care? A study from Quebec, Canada. *Int J Qual Heal Care*. 2014;26(3):330-336. doi:10.1093/intqhc/mzu032.

44. Bravo G, Dubois M-F, De Wals P, Hébert R, Messier L. Relationship between regulatory status, quality of care, and three-year mortality in Canadian residential care facilities: a longitudinal study. *Health Serv Res*. 2002;37(5):1181-96. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1464030&tool=pmcentrez&rendertype=abstract.

45. Oude Wesselink S. Towards evidence-based government supervision in healthcare. 2015. Available at: http://www.oudewesselink.net/proefschrift/.

46. Tyler T, Mentovich A, Satyavada S. What motivates adherence to medical recommendations? The procedural justice approach to gaining deference in the medical arena. *Regul Gov*. 2013;(September). doi:10.1111/rego.12043.

47. World Bank. *World Development Report 2015: Mind, Society, and Behavior*. Washington DC: The World Bank; 2014. doi:10.1596/978-1-4648-0342-0.

48. Kahneman D, Tversky A. Prospect Theory: An Analysis of Decision under Risk. *Econometrica*. 1979;47(2):263-292. Available at: http://www.jstor.org/stable/1914185?seq=1#page_scan_tab_contents.

49. Huis A, van Achterberg T, de Bruin M, Grol R, Schoonhoven L, Hulscher M. A systematic review of hand hygiene improvement strategies: a behavioural approach. *Implement Sci*. 2012;7(1):92. doi:10.1186/1748-5908-7-92.

50. Lunn P. *Regulatory Policy and Behavioural Economics*. Paris: OECD Publishing; 2014. doi:10.1787/9789264207851-en.

51. Hallsworth M, List J, Metcalfe R, Vlaev I. *The Behavioralist As Tax Collector: Using Natural Field Experiments to Enhance Tax Compliance*. Cambridge, MA; 2014. doi:10.3386/w20007.

52. Haley KJ, Fessler DMT. Nobody's watching? Subtle cues affect generosity an anonymous economic game. *Evol Hum Behav*. 2005;26(3):245-256. doi:10.1016/j.evolhumbehav.2005.01.002.

53. Ekström M. Do watching eyes affect charitable giving? Evidence from a field experiment. *Exp Econ*. 2012;15(3):530-546. doi:10.1007/s10683-011-9312-6.

54. Fathi M, Bateson M, Nettle D. Effects of watching eyes and norm cues on charitable giving in a surreptitious behavioral experiment. *Evol Psychol*. 2014;12(5):878-887. Available at: http://europepmc.org/abstract/med/25331033.

55. Powell KL, Roberts G, Nettle D. Eye Images Increase Charitable Donations: Evidence From an Opportunistic Field Experiment in a Supermarket. *Ethology*. 2012;118(11):1096-1101. doi:10.1111/eth.12011.

56. Panagopoulos C. Watchful eyes: Implicit observability cues and voting. *Evol Hum Behav*. 2014;35(4):279-284. doi:10.1016/j.evolhumbehav.2014.02.008.

57. Becker GS. Crime and punishment: An economic approach. *J Polit Econ*. 1968.

58. May PJ. Compliance Motivations: Affirmative and Negative Bases. *Law Soc Rev*. 2004;38(1):41-68. doi:10.1111/j.0023-9216.2004.03801002.x.

59. Walshe K. *Regulating Healthcare: A Prescription for Improvement*. McGraw-Hill Education (UK); 2003.

60. Gunningham N, Kagan RA. Regulation and Business Behavior. *Law Policy*. 2005;27(2):213-218. doi:10.1111/j.1467-9930.2005.00197.x.

61. Tyler TR. Why people cooperate with organizations: An identity-based perspective. *Res Organ Behav*. 2012;21:201-246. Available at: http://search.proquest.com/docview/619397590?accountid=14496.

62. Tyler TR. *Why People Obey the Law*. Princeton University Press; 2006.

63. Paternoster R. The deterrent effect of the perceived certainty and severity of punishment: A review of the evidence and issues. *Justice Q*. 1987;4(2):173-217. doi:10.1080/07418828700089271.

64. Murphy K, Tyler TR, Curtis A. Nurturing regulatory compliance: Is procedural justice effective when people question the legitimacy of the law? *Regul Gov*. 2009;3(1):1-26. doi:10.1111/j.1748-5991.2009.01043.x.

65. Sunshine J, Tyler TR. The Role of Procedural Justice and Legitimacy in Shaping Public Support for Policing The Role of Procedural Justice and Legitimacy in Shaping Public Support for Policing. *Law Soc Rev*. 2003;37(3):513-548.

66. Gunningham NA, Thornton D, Kagan RA. Motivating Management: Corporate Compliance in Environmental Protection. *Law Policy*. 2005;27(2):289-316. doi:10.1111/j.1467-9930.2005.00201.x.

67. Arah O a, Westert GP, Hurst J, Klazinga NS. A conceptual framework for the OECD Health Care Quality Indicators Project. *Int J Qual Heal Care*. 2006;18 Suppl 1(September):5-13. doi:10.1093/intqhc/mzl024.

68. Smith PC, Anell A, Busse R, et al. Leadership and governance in seven developed health systems. *Health Policy (New York)*. 2012;106(1):37-49. doi:10.1016/j.healthpol.2011.12.009.

69. Mumford V, Greenfield D, Hogden A, et al. Development and application of an indicator assessment tool for measuring health services accreditation programs. *BMC Res Notes*. 2015;8(1):363. doi:10.1186/s13104-015-1330-6.

70. Stelfox HT. The “To Err is Human” report and the patient safety literature. *Qual Saf Heal Care*. 2006;15(3):174-178. Available at: http://qualitysafety.bmj.com/lookup/doi/10.1136/qshc.2006.017947.

71. Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz a J. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess (Summ)*. 2001;2001(43):i-x, 1-668. Available at: http://www.ncbi.nlm.nih.gov/pubmed/24423049.

72. World Health Organization (Who). Report on the Burden of Endemic Health Care-Associated Infection Worldwide. *WHO Libr Cat Data*. 2011:40. doi:http://whqlibdoc.who.int/publications/2011/9789241501507_eng.pdf.

73. Pfoh E, Dy S, Engineer C. Interventions To Improve Hand Hygiene Compliance: Brief Update Review. In: *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices.* Rockville, MD: Agency for Healthcare Research and Quality (US); 2013:67-72. Available at: http://www.ncbi.nlm.nih.gov/books/NBK133371/.

74. Pittet D, Allegranzi B, Sax H, et al. Evidence-based model for hand transmission during patient care and the role of improved practices. *Lancet Infect Dis*. 2006;6(10):641-652. doi:10.1016/S1473-3099(06)70600-4.

75. Boyce JM, Pittet D. *Guideline for Hand Hygiene in Health-Care Settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Society for Healthcare Epidemiology of America/Association for Prof*.; 2002. doi:10.1086/503164.

76. World Health Organization (Who). *Hand Hygiene Technical Reference Manual*.; 2009. Available at: http://apps.who.int/iris/bitstream/10665/44196/1/9789241598606_eng.pdf?ua=1.

77. Pittet D. Improving adherence to hand hygiene practice: A multidisciplinary approach. *Emerg Infect Dis*. 2001;7(2):234-240. doi:10.3201/eid0702.010217.

78. WHO. *WHO Guidelines on Hand Hygiene in Health Care First Global Patient Safety Challenge Clean Care Is Safer Care*.; 2009. Available at: http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf.

79. Costers M, Viseur N, Catry B, Simon a. Four multifaceted countrywide campaigns to promote hand hygiene in Belgian hospitals between 2005 and 2011: Impact on compliance to hand hygiene. *Eurosurveillance*. 2012;17(18):1-6.

80. Erasmus V, Daha TJ, Brug H, et al. Systematic review of studies on compliance with hand hygiene guidelines in hospital care. *Infect Control Hosp Epidemiol*. 2010;31(3):283-294. doi:10.1086/650451.

81. Gasink LB, Lautenbach E. Prevention and Treatment of Health Care-Acquired Infections. *Med Clin North Am*. 2008;92(2):295-313. doi:10.1016/j.mcna.2007.10.002.

82. Sax H, Allegranzi B, Uçkay I, Larson E, Boyce J, Pittet D. "My five moments for hand hygiene": a user-centred design approach to understand, train, monitor and report hand hygiene. *J Hosp Infect*. 2007;67(1):9-21. doi:10.1016/j.jhin.2007.06.004.

83. Edwards R, Charani E, Sevdalis N, et al. Optimisation of infection prevention and control in acute health care by use of behaviour change: A systematic review. *Lancet Infect Dis*. 2012;12(4):318-329. doi:10.1016/S1473-3099(11)70283-3.

84. May PJ. Regulatory Implementation : Examining Barriers from Regulatory Processes Regulatory Implementation : Examining Barriers from Regulatory Processes. 2004;(March).

85. Bateson M, Nettle D, Roberts G. Cues of being watched enhance cooperation in a real-world setting. *Biol Lett*. 2006;2(3):412-414. doi:10.1098/rsbl.2006.0509.

86. Bateson M, Callow L, Holmes JR, Redmond Roche ML, Nettle D. Do images of "watching eyes" induce behaviour that is more pro-social or more normative? A field experiment on littering. *PLoS One*. 2013;8(12):1-9. doi:10.1371/journal.pone.0082055.

87. Allegranzi B, Gayet-Ageron A, Damani N, et al. Global implementation of WHO's multimodal strategy for improvement of hand hygiene: A quasi-experimental study. *Lancet Infect Dis*. 2013;13(10):843-851. doi:10.1016/S1473-3099(13)70163-4.

88. Gould D. 30th anniversary commentary on Larson E. & Lusk E. (1985) evaluating handwashing technique. Journal of Advanced Nursing 10, 547-552. *J Adv Nurs*. 2006;53(1):51-52. doi:10.1111/j.1365-2648.2006.03668.x.

89. Abd Elaziz KM, Bakr IM. Assessment of knowledge, attitude and practice of hand washing among health care workers in Ain Shams university hospitals in Cairo. *J Prev Med Hyg*. 2009;50(1):19-25.

90. Gould DJ, Chudleigh J, Drey NS, Moralejo D. Measuring handwashing performance in health service audits and research studies. *J Hosp Infect*. 2007;66(2):109-115. doi:10.1016/j.jhin.2007.02.009.

91. Larson E, Lusk E. Evaluating handwashing technique. 1985. *J Adv Nurs*. 2006;53(1). doi:10.1111/j.1365-2648.2006.03666.x.

92. Joint Commission International. Measuring Hand Hygiene Adherence: Overcoming the Challenges. 2009:204. Available at: http://www.jointcommission.org/assets/1/18/hh_monograph.pdf.

93. Larson EL. APIC guideline for handwashing and hand antisepsis in health care settings. *Am J Infect Control*. 1995;23(4):251-269. doi:10.1016/0196-6553(95)90070-5.