Evaluating the effect of external inspections of the Care Quality Commission of acute NHS hospitals in England

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Abstract

Background: External oversight institutions were introduced to the English National Health Service (NHS) in an attempt to encourage quality improvements and avoid failures of care. Despite the breadth of literature exploring the theoretical relationship between improvement of quality of care and external oversight, robust empirical evidence does not yet exist to support this premise. In this thesis, the effect and costs of the Care Quality Commission (CQC) external inspections of acute hospitals on quality of care are explored. The aim is to determine to what extent inspections are associated with changes in care quality, and if inspections are cost-effective.

Methods: Three pieces of empirical research are presented. First, existing literature on the effect of external oversight on hospital organisational performance and clinical outcomes was surveyed through an overview of reviews. Second, the effect of CQC inspections and their announcement on seven measures of care quality was estimated in three scenarios using an interrupted time-series design. Finally, the opportunity costs of CQC inspections were explored in a purposive sample of English acute NHS trusts.

Results: The overview of reviews showed that external oversight has mixed effects on organisational performance and clinical outcomes. However, the quality of the evidence was low to moderate. The interrupted time-series studies suggest CQC inspections were not associated with changes in the measures of care quality. Although some statistically significant changes were present, the size of the effect is unlikely to be clinically relevant. The opportunity cost for acute trusts of a CQC inspection was estimated to lie between £169,691 and £418,136.

Conclusions: CQC inspections are not associated with improvements in the quality of care provided in acute NHS hospitals.

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Acknowledgements

As anything related to this thesis, acknowledging all the potential contributions to its completion is complex. There is no linear cause-effect relationship; small stimulus might have had big effects and I am not even aware of its impact; and this system has history.

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Declaration

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References.

1 Introduction

1.1 Thesis rationale

When the National Health Service (NHS) was created in 1948, it was believed that the codes of ethics of the professions would suffice to continuously improve healthcare processes, manage efficiently resources, and coordinate efforts between the different parts of the system. Although the service relied on professionalism for more than 30 years, several events led to the incremental introduction of systems for quality improvement going beyond the traditional professional self-regulation that was predominant in the early years. This began with the findings of the Griffiths Report (1983) leading to the introduction of managers and managerialism, as ideology, in the early 1980s. It continued in the 1990s with the implementation of a quasi-market as a solution for the continuous financial pressures the NHS was suffering. In the 2000s, the findings of the Bristol Royal Infirmary Inquiry into the deaths of 29 babies undergoing cardiac surgery (Kennedy, 2001) led to the creation of regulatory institutions to ensure the public the service was safe and any irregularities would be investigated.

The Commission for Health Improvement (CHI) was the first institution and focused on assessing the clinical governance arrangements of acute NHS trusts through "Clinical Governance Reviews" (CGRs), that were later added to the "star ratings" (Bevan and Cornwell, 2006). The Commission for Healthcare Audit and Inspection (CHAI or the Healthcare Commission) replaced CHI in 2004. The likely reason for its abolition was the second attempt to develop provider competition and, therefore, encourage new entrants from the independent sector (Bevan, 2011). CHAI was a light-touch regulator of the whole health sector that produced the "annual health checks". These relied on self-assessments of performance and inspections were targeted to those at risk of breaching standards and a random 10% of not-at-risk trusts on an annual basis (Adil, 2008, Bevan, 2011). Both institutions were responsible for driving quality improvement, ensuring the delivery of minimum standards of care, and providing information on quality. CHI provided the "star ratings" used for "naming and shaming", whilst CHAI "annual health checks" aimed to inform patient choice in a quasi-market.

The Care Quality Commission was created in 2008 to bring together the regulation of mental, social, and health care into one institution (Care Quality Commission, 2010b). At first, it inherited the model of regulation of CHAI, but it changed the regime of inspection to oversee a broader range of providers. A series of internal problems and external criticism led to a change

of regime in 2013 (Care Quality Commission, 2013a). In parallel to the problems the CQC had internally, the lighter touch regulatory approach of CHAI was believed to have allowed Mid-Staffordshire NHS Foundation Trust to prioritise finances at the expense of clinical quality. The trust managed to reduce its deficit by cutting nursing staff while demanding waiting time targets were met, but care provided was poor and mortality rates higher than expected (Bevan, 2015). This is argued by Bevan (2011) to be the root cause of the Healthcare Commission failing to detect the problems underlying the developing scandal. This lead to the commissioning of an independent inquiry published in 2010 (i.e. the Francis Report) and a public inquiry published in 2013 (i.e. the Francis Inquiry). The first Francis Report found that care provided was below expected standards. Patients were not treated with dignity and respect, whilst there was a bullying culture that was not open to learning from previous mistakes (Francis, 2010). The second Francis Inquiry found that the regulatory system that was created to prevent failures of care had itself failed (Francis, 2013).

The events of Mid-Staffordshire offered a chance to increase the intensity of inspection-based regimens based on a belief that inspections and regulation are effective in preventing failures and improving quality, and therefore, more intense oversight would generate more sustainable improvement, higher quality, stronger leadership, improved safety, and fewer failures.

Two key uncertainties have not been addressed, empirically or theoretically, in any depth to support this increase in intensity, scale, and resources committed. First, it is not known whether a more resource-intensive regime of inspections provides advantages in terms of driving improvements over no inspection and the less resource-intensive regime of inspections that was previously used. Second, it is not known to what extent the characteristics and performance of trusts prior to inspection affect their performance post-inspection, which could guide the frequency and targeting of inspections.

1.2 Thesis aim and approach

This thesis aimed to evaluate, in terms of effects and costs, CQC inspections of NHS acute trusts in England. In the case of the effects, a carefully selected suite of measures of process of care and clinical outcomes was selected.[1] Potential confounders have been accounted for in this selection, and in the research design and methods used. In the case of the costs, a

[1] Falls with harm, Pressure ulcers, Summary Hospital Mortality Index, Accident and Emergency (A&E) waiting times, Referral to Treatment (RTT) waiting times, Patients' perception of care, and rate of staff leaving each NHS trust.

purposive sample of NHS trusts was selected to provide a broad estimate of the opportunity costs borne by NHS trusts.

Four research gaps were identified regarding the effect of external oversight regimes. Firstly, the mechanism explaining how they produce an effect. Secondly, why, how, and when hospitals respond to an upcoming inspection. Thirdly, which factors are associated with the size and direction of the effect of an inspection. Finally, what is the size of the effect and how previous performance influences the response to an inspection. The decision to estimate the effect of the change of regime using a quasi-experimental approach was based on the lack of robust assessments of the quantitative effect of these interventions in the English NHS and what was deemed achievable in the period available. Additionally, combining the effect and the information on cost would permit an estimate of cost-effectiveness, which is not available in the literature.

The ten chapters that comprise this thesis provide a mix of theoretical perspectives (i.e. economic, organisational, psychological and social theories), historical and empirical insights into potential factors that could explain the effect (or lack of effect) of CQC inspections of acute hospitals in the context of the NHS between 2012 and 2017.

1.2.1 Thesis structure

With the aim of exploring the question "what is the effect of the Care Quality Commission inspections of acute NHS trusts on measures of quality of care", Chapter 2 introduces the idea that a working approach to quality can be seen as rooted in (at least) four influential schools of thought. After outlining these, Chapter 3 examines their operationalisation into models of governance for quality and the emergence of the policy consensus that external regulation is a "good" and effective mechanism for promoting quality.

Chapter 4 set out to test the assumption that external regulation improves organisational performance and clinical outcomes by systematically reviewing the global literature on inspection-based regulation.

The UK context is in many ways unique, and the regulatory environment is certainly different to other healthcare systems. The policy levers available (i.e. incentives, commissioning arrangements, professional roles, regulation, public reporting of performance) are all different. The thesis examines the contribution of inspections in general, and in particular, the more-resource intensive regime implemented after the Francis inquiry, to changes in care quality. Additionally, the contribution of previous quality performance to the effect of inspections was

explored. Accordingly, chapter five outlines an approach to primary research and modelling these effects over time that minimises biases and increases the trustworthiness of the findings presented in chapters 6, 7 and 8.

Constant financial pressures in the NHS has made it increasingly important to provide evidence of the value for money of new interventions. Therefore, Chapter 9 introduces an estimation of the opportunity cost of CQC inspections in a purposive sample of acute NHS trusts in England.

Lastly, Chapter 10 synthesises the key findings of this thesis and places them within the broader historical, political and economic context of the NHS in England. Implications for policy, research and conclusions are also discussed.

2 Theoretical perspectives on quality and quality governance

> *Quality does not have to be defined. You understand it without definition, ahead of definition. Quality is a direct experience independent of and prior to intellectual abstractions (Pirsig, 1992).*

Although quality is intuitive (Harvey and Green, 1993) - suggesting that defining it should be easy - a consensus on its definition is elusive (Harvey and Green, 1993, Pfeffer and Coote, 1991). One of the challenges in defining quality lies in how to construct a single definition that remains meaningful and applicable to each individual context and purpose (Steffen, 1988). Once quality is defined, its presence can be assessed (Harvey and Green, 1993).

Definitions are useful because they allow for the mutual understanding of different cultures and knowledge-bound groups (Wierzbicka, 1996). However, the meaning attributed to these definitions is a social construction; therefore, their interpretation is not static, and any interaction with another agent or contextual changes can modify them (Blumer, 1986).

In the English NHS, the concept of care quality is an example of how definitions can evolve. In the early days of the NHS, quality was understood as universal access, equity, hierarchical organisational structures, and professionalism in its workforce. In the 1970s, quality became linked to performance measurement and in the 1980s to general managers, which signalled a shift away from quality as a natural by-product of professionalism (Webster, 2002, Klein, 2013) to one that necessitated assurance and governance.[2]

Governance of quality has changed in the same way definitions of quality have, with different perspectives devising various instruments for it. Governance has a broader meaning than regulation since it refers to the provision, distribution, and regulation of activities (Braithwaite et al., 2007). Therefore, governance of quality involves the instruments and mechanisms used by funders, usually governments, to steer behaviour and thus improve the quality of care delivered (Braithwaite et al., 2007, Bevan and Fasolo, 2013).

[2] In the early stages of this thesis, a documentary analysis and a historical review were performed to inform how the concept of quality had evolved in the NHS. The results of this analysis are available in the Appendix to Chapter 2, Table 2.1.

The aim of this chapter is to explore the measurement of and efforts to improve "quality" in the healthcare sector and describe solutions that draw on different theoretical perspectives to govern quality in the NHS. This is achieved, firstly, by presenting an overview of different conceptualisations of quality - both general and healthcare specific - and their relation to the definitions used in the NHS. Secondly, the views on governing quality from four perspectives (healthcare professional, management, economics, and law) are described, together with the limitations of each perspective and the unintended consequences of monitoring quality.

2.1 From generic to health-specific definitions of quality

Quality or *qualitas* was first used by Plato to describe "of what sort" or "to what extent" (Todd, 2006, Miller, 2014). Plato proposed that concepts of beauty, goodness, justice and quality are abstract: they do not exist in the physical world, and therefore, require no definition because they can be understood through experience (Dickie, 1997). Pfeffer and Coote (1991) term this approach the 'traditional view', with Garvin (1984) referring to this as the 'transcendent approach' to quality. Quality, from this perspective and in a modern context, is present in an excellent product or service that exceeds standards and has restricted accessibility (e.g. luxurious items) (Harvey and Green, 1993).

The shift from an abstract, undefinable concept to the concrete, definable features of production came with the methods of Henry Ford. Ford's approach to reducing waste and increasing productivity (Sheingold and Hahn, 2014, Cantiello et al., 2016, Zarbo and D'Angelo, 2006), linked production (as a process) with quality as an outcome. In the 1980s, this growing interest in providing quality products extended to service industries. Ideas such as 'conformation to specifications' (focusing on the manufacturing process), 'fitness for use' (focusing on fulfilling users' expectations), and 'total quality management' (reducing defective items or redundant processes) (Garvin, 1984) became ubiquitous in industrial discourse. Alongside these shifts in manufacturing processes came a transformation in the role of consumers, casting them as active social agents with the power to shape the delivery of goods and services, rather than merely passive recipients of products. This shift led to a consumerism movement, with users being afforded the opportunity to express their views about and shape the delivery of quality (Pfeffer and Coote, 1991, Harvey and Green, 1993).

Quality in manufacturing is associated with standardising production processes to make them efficient and reliable, satisfying consumers and maximising profits (Garvin, 1984). However, the service industry is different. Services have three features. First, they are intangible, meaning that setting precise standards of production is difficult. Second, they are heterogeneous due to inconsistencies in delivery. Third, services are inseparable because

production and consumption occur at the same time. Additionally, these consumers are highly involved and their input is key for the quality of the services (e.g. accuracy of a patient in describing his/her symptoms) (Parasuraman et al., 1985). This means that standardising processes is hardly achievable. Despite their limited application, there have been attempts to implement generic definitions in services such as healthcare (e.g. total quality management) (Walshe, 2009). The following section presents healthcare-specific definitions, which try to recognise that healthcare is both a service and a complex system.

2.1.1 Health-specific conceptualisations of quality

For the clinicians, managers and others who deliver healthcare, quality is both experienced existentially and also often defined formally within organisations; it is an outcome and also a process; it can be recognised and yet it is hard to influence through one's own agency. Quality in healthcare is an abstract and multifaceted concept in a service industry that is also "complex" and "adaptive" (Plsek and Greenhalgh, 2001).

Complex adaptive systems have multiple components that interact and connect with each other, continually adapting to the environment (The Health Foundation, 2010). The interrelatedness of systems means that individual components have to be studied in connection. Whilst the outcomes of system component interactions can be unpredictable, patterns of behaviour can emerge from repeated interactions (Plsek and Greenhalgh, 2001, Kannampallil et al., 2011). Complex adaptive systems are also capable of self-organising (The Health Foundation, 2010). Therefore, the quality of a healthcare provider depends on its interaction with the environment and is the result of the performance of several interconnected aspects of care and self-governing sub-systems.

One of the most influential models of quality was proposed by Avedis Donabedian (Donabedian, 1966), with a model that consists of three main elements (Donabedian (1966, 1978, 1980)):

- *Structure:* the physical environment where the medical care occurs, including material resources, human resources and organisational structure.

- *Process:* the medical visit itself, including the patient's attitude and reasons for seeking care, and the practitioner's decisions and actions in terms of diagnosing and deciding on the course of treatment.

- *Outcome:* the effect of care on a patient's health status, including measurable outcomes such as mortality, but also a patient's satisfaction and behaviour relating to his/her health (i.e., adherence to treatment).

In later work, Donabedian proposed a utilitarian perspective:

> *Quality of care is the kind of care which is expected to maximise an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts (Donabedian (1980) extracted from Evans et al. (2001)).*

Following the traditional concept-definition-measurement approach, the Institute of Medicine (IOM) generated a definition of quality that could guide the quality assurance efforts of Medicare (Institute of Medicine (US), 1990a, 1990b). Based on hundreds of, sometimes conflicting, definitions and components, the IOM chose those that were more relevant for improving service outcomes (Institute of Medicine (US), 1990a):

> *Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Lohr and Schroeder, 1990).*

Alongside the growth of managerial techniques for quality *improvement*, came an emphasis on measurement and monitoring (Brook et al., 2000, Campbell et al., 2000). Following these lines and as an extension of his previous work, Donabedian (2002) identified seven desirable features of high-quality care that could be measured: efficacy, effectiveness, efficiency (i.e. including clinical, production and distributional efficiency), optimality (i.e. optimum balance between cost and improvement to avoid waste), acceptability, legitimacy (i.e. fulfilment of social preferences), and equity. International organisations and countries have developed several frameworks as a way to clarify what aspects of care should be targeted and measured (Institute of Medicine (US), 2001a, Braithwaite et al., 2017b). Such frameworks tend towards specifying broad domains of quality relevant for the performance of a system in the long term, in a given context, and allowing for variation in how quality is measured over time (e.g. indicators within domains) (Institute of Medicine (US), 2001a, Stelfox and Straus, 2013).

The domains of quality identified by Donabedian (2002), the Institute of Medicine (US) (2001b), two international organisations (i.e. WHO and OECD), and two countries (i.e. Canada and Australia) with health systems similar to the UK (Braithwaite et al., 2017b) are summarised in Table 2.1.

Table 2.1 Summary of domains of quality of care

	IOM 2001	Donabedian 2002	WHO 2006	OECD 2006, 2015	Australia 2009, 2016	Canada 2012
Efficacy		✓				
Safety	✓	✓	✓	✓	✓	✓
Competence		✓				✓
Accessibility			✓	✓	✓	✓
Timeliness	✓					
Continuity					✓	✓
Acceptability		✓	✓			✓
Patient-centred	✓		✓	✓		
Responsiveness				✓	✓	
Effectiveness	✓	✓	✓	✓	✓	✓
Efficiency	✓	✓	✓	✓	✓	✓
Sustainability					✓	
Equity	✓	✓	✓	✓*	✓*	✓*
Appropriateness		✓			✓	✓
Legitimacy		✓				

IOM: Institute of Medicine. WHO: World Health Organisation. OECD: Organisation for Economic Co-operation and Development.
*Equity does not appear as a domain for assessing the health system performance, but it is included as a crosscutting aim of the health system.

This table illustrates the lack of clarity about what the components of quality of care are, and therefore, what to measure and improve. The most common domains identified are safety, effectiveness, efficiency, equity, patient-centeredness, and accessibility. Although there are commonalities in their names, the meaning of each domain varies between countries. For example, in Australia, effectiveness refers to care being appropriate for patients' needs and producing a desired outcome (National Health Performance Committee, 2009), whilst in Canada this is achieved separately in the domains of appropriateness and effectiveness (Canadian Institute for Health Information, 2012).

The indicators within each domain also differ. Canada uses the hospitalised hip fracture event rate as a proxy for safety (Statistics Canada, 2017), whilst Australia uses rates of healthcare-associated infections, unplanned hospital readmissions, and potentially preventable hospitalisations (Australian Institute of Health and Welfare, 2017). Whilst domains overlap, their operationalisation - and thus meaning and interpretation - differs.

Differing measures and indicators, and the interdependency of the underlying quality domains illustrate the difficulty of measuring (and governing based on those measurements) the abstract concept of quality; a concept that is subjectively interpreted by those in the frontline of this complex adaptive system called healthcare.

2.1.2 Definitions of care quality in the English NHS

Competing and sometimes conflicting definitions of quality from a wide range of perspectives have influenced the breadth of terms and instruments used to measure NHS quality.

During its first three decades, NHS quality was something intuitive, implicit and assumed to be only understood and recognised by experts (i.e. health professionals) (Harrison and Pollitt, 1994). After the publication of the Griffiths Report (1983), when the newly established public management grew alongside the arrival of business advisors to public and health services, quality was seen as something that should be governed, monitored, and measured (Jowett and Rothwell, 1988, Klein, 2013).

Since then, performance indicators have determined the definition of quality, instead of following the classic measurement paradigm of concept-definition-measure. These indicators have served as the primary instrument used by governments to communicate what quality of care means to providers and consumers (Bevan, 2011), whilst external oversight institutions have assured[3] its existence since 2000 (Bevan and Cornwell, 2006). After the introduction of external oversight, the approach used by these institutions came to dictate the definition of quality and where efforts for improvement should focus (Nuffield Trust, 2015). For instance, between 2000 and 2005 the definition of quality was associated with the seven pillars of clinical governance (assessed through "Clinical Governance Reviews"[4]), and the "star ratings", which largely measured access to care (Bevan, 2011).These definitions, instead of one replacing the other, now coexist, influencing the regulatory environment where the CQC operates.

[3] External oversight institutions have two functions: quality assurance and quality improvement. Quality assurance refers to the capacity of the regulatory instruments to detect cases of non-compliance before they produced undesired consequences. Quality improvement refers to the capacity of the regulator to encourage and generate improvement in the quality of care delivered (Bevan, 2011).

[4] The seven pillars were: Consultation and patient involvement; Clinical risk management; Clinical audit; Research and effectiveness; Staff focus; Staffing and staff management; Education, training and continuing personal and professional development; Use of information; and Use of information to support clinical governance and health care delivery.

Lord Darzi (2008) in his "next stage review" provided a definition of quality of care by using domains that were deemed relevant for the improvement of the service:

> *High quality care should be as safe and effective as possible, with patients treated with compassion, dignity and respect.*

This definition made quality explicit, incorporating technical aspects and patient centeredness. Given that the previous decade focused on improving access, this new era was expected to improve safety, effectiveness, and patient-centeredness, which are some of the most common domains of care identified in the literature (Table 2.1), and were in tune with what NHS staff perceived as relevant (Darzi, 2008). The definition that the CQC introduced in 2013 superseded Lord Darzi's, and it is the first one appearing in law (Care Quality Commission, 2013a):

> *High care quality should be safe, effective, caring, responsive to people's needs and well-led.*

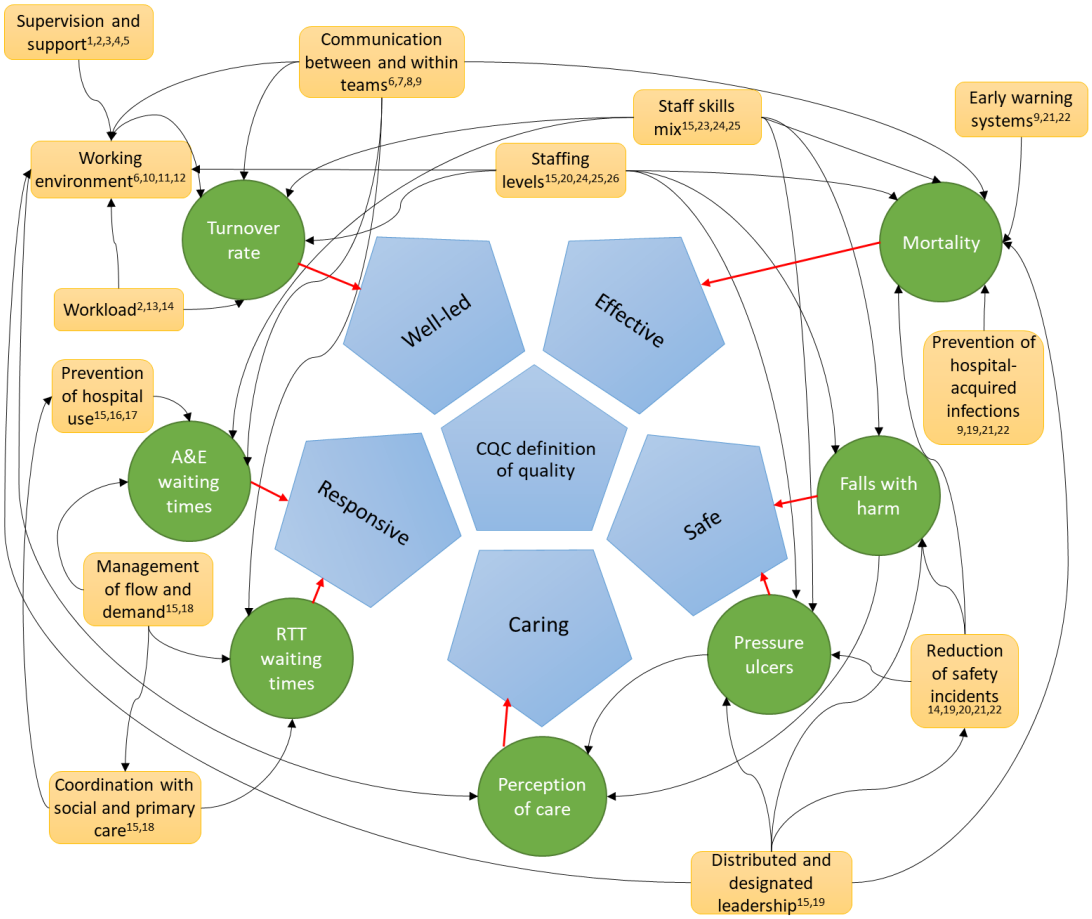
This definition was produced after a consultation process and followed the recommendations of the Francis Inquiry (Francis, 2013) (See Chapter 3, section 3.2.5 for more details on the Francis Inquiry). Although it largely overlaps with the previous definition (i.e. safe, effective, and patient-centred care), in practice, the CQC assessed more than 1,000 indicators in the pre-2013 era; and it currently focuses on around 150 indicators (Beaussier et al., 2015).

Safety, effectiveness, accessibility, and patient-centeredness are among the most commonly used features of quality identified in the literature (see Table 2.1). However, the CQC also assesses institutional governance, which is rarely included in other frameworks (Braithwaite et al., 2017b). This might be explained because institutional governance refers to organisational features linked to maintaining quality (i.e. a structural component in Donabedian's model), and can be seen by some, as not a measure of quality. Only Australia considers the capacity of the system to adapt to emerging need and support the workforce as an essential component of a quality health system. In the case of England, the focus on adequate internal governance arises from the findings of the Francis Inquiry and aims to remedy the failures detected in Mid-Staffordshire (Care Quality Commission, 2013a). This illustrates that definitions are highly context-dependent and change over time. Even when the domains to assess quality might coincide, the application of these definitions varies in practice.

2.2 Governing quality in a complex adaptive system

Defining, measuring and governing quality in healthcare is difficult because the concept is abstract and healthcare is a complex adaptive system. This means that components of the system such as hospitals, primary and social care interact with each other and are continually adapting to the environment. Each of these components has internal self-governing subsystems (e.g. wards), and the delivery of quality in one domain (regardless of how it is defined) depends on the interaction of these subsystems. In addition, attempts to improve quality can generate complex and unpredictable patterns of behaviour.

Figure 2.1 illustrates this phenomenon using the domains of the CQC's definition of quality, the seven measures chosen to evaluate the effect of inspections and some factors associated to improve these measures, as identified in the literature. For example, to improve Accident and Emergency (A&E) waiting times, which belongs in the domain of responsiveness, acute hospitals could target the management of flow and demand inside the institution (Oredsson et al., 2011, NHS Improvement, 2017). An essential component to managing the flow of patients is coordination with primary and social care (NHS Improvement, 2017), which could also help prevent hospitalisations for patients with chronic and complex needs (NHS England, 2015d). Other factors contributing to the reduction of A&E waiting times include the staff skills mix in A&E (Oredsson et al., 2011, Carter et al., 2014, CRD, 2015) and communication within and between teams inside and outside the hospital (NHS England, 2015d, NHS Improvement, 2017). Therefore, targeting one or a combination of these aspects of care could lead to improvements in one or many other indicators or produce unintended consequences.



1. Hellman, 1997.
2. Coomber and Barriball, 2007.
3. Cowden et al., 2011.
4. Gagnon et al., 2006.
5. Chen and Lou, 2014.
6. Shader et al., 2001.
7. Estryn-Behar et al., 2010.
8. DiMeglio et al. 2005.
9. Zegers et al., 2016.
10. NHS Confederation, 2011.
11. The Point of Care Foundation.
12. NICE, 2012.
13. Yin and Yang, 2002.
14. Aiken et al., 2002.
15. NHS England, 2015d.
16. Oredsson et al., 2011.
17. CRD, 2015.
18. NHS Improvement, 2017.
19. Wright et al., 2006.
20. Griffiths et al., 2014.
21. Robb et al., 2010.
22. Shekelle et al., 2013.
23. Aiken et al., 2008.
24. Aiken et al., 2016.
25. Griffiths et al., 2016.
26. Cano et al., 2015.

Figure 2.1 Domains of the CQC's definition of quality and the interaction of factors associated with their improvement

Key: The light-blue hexagons represent the domains of care quality according to the CQC definition. Green circles represent the outcome measures selected for assessing the effectiveness of CQC inspections (see Chapter 5). Beige rectangles contain factors associated with the improvement of outcome measures.

The relevance of complexity for this thesis is twofold. Firstly, since quality is an abstract concept, there is no universal consensus on how to define and measure it; therefore, the set of indicators has to be carefully selected based on evidence and theory to ensure and facilitate judgements of the internal validity of the measurements. Secondly, the improvement of one measure depends on several factors; consequently, if CQC inspections are to produce improvements, these should target various aspects related to providing better care.

In policy terms, quality is a contested arena in the delivery of healthcare. Professionals strive to deliver the best possible services, whilst managers seek to maximise the use of available resources at the frontline. Economists exert their influence during the policy-making process,

trying to maximise the return on investments made, whereas the legal profession provides a framework for and accountability for the quality of services.

Professionals, managers, economists, and lawyers have different ideas of what should be done to deliver quality services. Their perspectives try to simplify the complexity of quality in healthcare by focusing on specific aspects for improvement. For instance, managerialism sees quality as manageable and measurable, whilst professionals see it as amenable to the professional-patient relationship and self-regulation. Given the influence of these four perspectives on governance of quality in the NHS, their theoretical views are highlighted in the following section.

2.3 Theoretical perspectives on governance of healthcare quality

The previous section explored generic and healthcare-specific definitions of quality to illustrate that the concept arises from an array of distinct domains, often combined to measure a complex phenomenon. Since the improvement of quality requires addressing various aspects of care - as Figure 2.1 suggests - different schools of thought have devised various instruments to steer the delivery of care quality. This combination of instruments can be seen as a model of governance.

Bevan and Fasolo (2013) retrospectively analysed how quality assurance and improvement had been governed in the English NHS, identifying four models: trust and altruism, choice and competition, targets and terror, and naming and shaming (reputational) (Bevan and Fasolo, 2013, Bevan, 2015). The underlying components of these models were analysed to pinpoint the schools of thought and mechanisms explaining their potential effectiveness. These four schools of thought were chosen since their views can be seen to have shaped the structures and processes (and thus outcomes) throughout the history of the NHS.

2.3.1 The professional perspective

As has been argued, the professional perspective that dominated the discourse on quality pre-1980s, saw a combination of the altruistic intrinsic motivation of professionals (Saks, 1995) with peer feedback about performance as the primary mechanism for inducing behavioural changes without the threat of sanctions or promises of rewards (Berwick et al., 2003).

Professionals are members of knowledge-bound groups that - through specialisation – have gained a privileged position in society, allowing them to establish codes of ethics and exert self-regulation (Larson, 1977, Saks, 2015). Akerlof and Kranton (2010) suggest that our identify as a professional is rooted in the norms attached to belonging to that social category, which are learned by observation or by following what the commonly understood rules dictate as an

ideal. In general, professions claim to have altruistic motives, subordinating their personal interest to those of society. This implies that professionals are expected to express moral behaviour (Frank, 1989) or act in a "knightly" manner (Le Grand, 2003), along with having intrinsic motivation for improvement. The inherent features of behaviour, communication, and appearance that together determine appropriate professional conduct is what it is called professionalism (Morrow et al., 2014). Lesser et al. (2010) provide a modern definition of professionalism in healthcare using its desired behaviours: compassionate, respectful and collaborative orientation in service of the patient; integrity and accountability; the pursuit of excellence; and the fair and ethical management of healthcare resources. The pursuit of excellence combined with data about performance would constitute the intermediate components that exist between business as usual and implementing improvements.

This feedback about performance, usually coming from peers (Hibbard et al., 2003), should drive changes by offering information about the level of performance and clarifying what the criteria used to assess it are (Locke and Latham, 2002a). This model of self-regulation uses a close relational distance, that is, professionals from the same group who are aware of the internal functioning of the profession (Hood and Scott, 2000). This can have advantages in terms of providing an informed and friendly opinion for improvement; however, this alone is often viewed as insufficient since it does not state how to improve performance and is not bound to a goal-setting plan (Kluger and DeNisi, 1998). And even if it had all the components needed to incite improvement, internal peer-reviews are not a high-powered incentive (Bevan and Fasolo, 2013), because they remain private.

Fournier (1999) suggests that professionalism serves to instil appropriate work conduct and practices within a network of accountability. This allows governing "professional conduct at distance", whilst professionals retain their autonomy (Fournier, 1999). However, economic constraints and the introduction of new ideologies have led to a redefinition of professionalism to include budget awareness and performance management (Evetts, 2003).

Professionalism is needed for improving the delivery of healthcare, but professionalism is perceived as insufficient on their own (Maynard and Bloor, 2003). The condition of self-controlled and self-motivated healthcare professionals mean that the imposition of external methods of quality governance is often resisted (Evetts, 2003, Saks, 2015). However, when healthcare professionals, and in particular doctors, are convinced about the advantages of the change, the probabilities of success are higher (Best et al., 2012) (See Chapter 3 for an explanation on how professional perspectives interact with other perspectives to govern quality).

2.3.2 Managerialist perspective

Managerialist ideas about the governance of the health service and managerialism as a social process gained traction after the publication of the Griffiths Report (Griffiths, 1983). Griffiths found a lack of leadership and clarity regarding who was accountable for failures in the provision of care. From this perspective, delivery of care quality is achieved by managing performance and implementing continuous quality improvement (McLaughlin and Kaluzny, 2004). Quality is associated with the standardisation of processes and maximising efficiency, as suggested in the view of the manufacturing industry (Garvin, 1984).

Managing performance through targets and performance monitoring can drive improvements because targets direct efforts by establishing the desired results and level of achievement. Then the continuous monitoring process allows individuals to know how well they are performing against set standards (Bevan and Hood, 2006b). Goal setting theory says that targets affect persistence of effort and lead to the use and discovery of strategies to tackle the goal, motivating individuals to improve continually (Locke and Latham, 2002a), which would explain how targets might lead to improvement.

Performance monitoring systems can also be used for benchmarking performance. These systems can produce reputational incentives when they include four key elements: i) a ranking system that is ii) widely known and iii) understood by the public, and where iv) future reporting uses previous information to show how performance has changed (Hibbard et al., 2003). Bevan and Fasolo (2013) provide two interpretations that explain how reputation or the threat of reputational damage can change organisational behaviour. One incentive is derived from accountability, where the published rankings of straightforward information on providers' performance stick in the public's mind (Hibbard et al., 2005) and make accountability relationships salient. Accountability drives providers to exert an additional effort to improve certain aspects of care (Simonson and Nye, 1992), thus avoiding losing the public's trust. A second incentive relies on shame about being in the spotlight, which combines moral heuristics[5] (Sunstein, 2005) with affect[6] (Slovic and Västfjäll, 2010). "Do not betray" and "punish betrayals of trust" are moral heuristics ingrained in our minds (Sunstein, 2005, Bevan and Fasolo, 2013). They would be triggered by the public reporting of performance, generating a response arising from the fear of betraying the public's trust; thus, stressing a very urgent need to respond before the public punishes any such betrayal (Bevan and Fasolo, 2013).

[5] Cognitive shortcuts that can be useful on some occasions but tend to be sub-optimal in situations that are more general.
[6] Specific feelings of goodness or badness with or without awareness.

Continuous quality improvement, another managerial instrument for governing quality, refers to the initiatives used for the achievement of the organisational mission, vision and objectives (McLaughlin and Kaluzny, 2004). These initiatives involve collecting soft and hard data to measure performance and determine what is working and why (McLaughlin and Kaluzny, 2004); analysing core health processes and redesigning them to make them more efficient and effective; aligning incentives with improvement goals; and having leadership that can model and inspire care improvement (Berwick et al., 2003).

These techniques were created for improving processes in industry, where market incentives reduce costs and increase efficiency (McLaughlin and Kaluzny, 2004), with both producers and consumers agreeing on the desirability of the methods associated with these ideas. In healthcare, however, this consensus is far from established. Professionals, and in particular doctors, have resisted the introduction of "managerialism" as a route to quality (Clarke et al., 2000). Quality as a management tool has the potential to weaken the autonomy and perceived power of professionals. This could be explained because techniques such as continuous quality improvement seek to promote organisational learning, horizontal responsibility for quality improvement, and the use of best practices (McLaughlin and Kaluzny, 2004), which can go against the status quo (Berwick et al., 2003). Additionally, managerialism is often seen as the central government imposing a new way to work that goes against professional freedom (Clarke et al., 2000). This may often be compounded by limited evidence on the effectiveness of these techniques (Buetow and Roland, 1999).

2.3.3 Economic perspective

From an economic perspective, quality is observed in a free market through profit maximisation (Garvin, 1984) and satisfied customers, as the consumerism movement suggests (Pfeffer and Coote, 1991). Quality is improved when the right incentives are in place. In a perfect market, productive and allocative efficiency is achieved by the price mechanism (Begg et al., 2014). A large number of providers and consumers exchange services and goods using full information, there are no barriers to entry, and products are homogenous (Goddard, 2003). The questions of what, how and for whom to produce are addressed by market mechanisms (Begg et al., 2014). However, in healthcare these conditions are not met, producing market failure, which is used as the rationale for extensive governmental intervention. It is argued that for healthcare, government intervention is more likely to fulfil societal goals than are market forces with minimal regulation (Donaldson and Gerard, 1993).

The market in healthcare fails because full information about the quality of the services does not exist: information is asymmetric and the customer does not have enough knowledge to judge if care is appropriate. In addition, the specialised nature of healthcare means there are a

small number of competitors; therefore, sellers can generate demand, increase prices and reduce quality producing a welfare loss. Entry and exit have high associated costs. Finally, healthcare produces benefits that cannot be traded in a market (i.e. externalities), thus making a market inefficient. In the presence of market-failure, the alternatives are regulation and contracting (Laffont and Tirole, 1993).

Publicly funded and provided healthcare was implemented in England in 1948 to maximise societal welfare. However, in the late 1980s, market-like reforms were introduced in the NHS as a means of creating incentives to drive improvements (Enthoven, 1985), since theoretically, public monopolies (like the NHS) do not provide adequate incentives to deliver quality services (Laffont and Tirole, 1993), as a free market would. The rationale behind the introduction of a quasi-market in the NHS was that a purchaser could buy services from a different provider (i.e. increasing contestability of the market), which could drive competition among providers in the same region. This would improve the quality of the service, given that providers compete for quality in healthcare (Maynard, 1991). However, markets require accurate information about inputs, outputs and outcomes and their relationship to work (Maynard, 1991), which in healthcare it is still challenging to obtain.

Given the cooperative relationship between parties with different goals and a division of labour, all market-like reforms have a principal-agent problem (Eisenhardt, 1989). According to agency theory, the problem arises because the principal (i.e. purchaser or commissioner) cannot know how the agent (i.e. provider) is behaving, which can lead to opportunistic behaviour (i.e. gaming). Depending on the quality of information systems and certainty about the achievement of outcomes, agency theory proposes to contract services based on behaviour or outcomes (Eisenhardt, 1989). When there is not enough information about outcomes or their achievement is uncertain, the option is to contract based on behaviour (ibid), that is, payment for blocks of services.

The implementation of a quasi-market was supposed to help to create a better information system for contracting services based on outcomes (Maynard, 1991), but this has still not been achieved. Instead, contracts are based on activities with fixed prices for services (i.e. payment-by-results[7]), with the aim of driving efficiency and productivity since providers can redirect savings to other services (Mays and Dixon, 2011). Information is not only used to determine the best way to incentivise performance but also to choose providers (Berwick et al., 2003). The implementation of regulatory institutions conducting on-site inspections had the aim of

[7] Payment-by-results is an incentive-based funding system where hospitals are paid for the volume of services adjusted for differences in the case-mix. Prices are fixed nationally (i.e. a national tariff) for each type of procedure, which creates an incentive to reduce length of stay and increase efficiency (Mannion et al., 2008).

providing information on quality, monitoring performance on a regular basis, and helping control potential deviant behaviour (Stevens, 2004, Le Grand and Hunter, 2006). Increasing transparency through the publication of performance information is also associated with greater productivity, competition and quality. When transparency is linked to rewards and sanctions, it can also improve accountability (Raleigh, 2012).

Increasing contestability[8] of the market with more potential providers is supposed to incite adaptation of services to what is demanded, instead of what has been historically produced (Maynard, 1991). Giving a choice to consumers (i.e. commissioners or patients) should increase competition among providers to attract patients and income. For patients, this means they can access services in other geographical areas providing a better quality of care, which was not possible before, potentially reducing inequalities regarding the quality of treatment (Mays and Dixon, 2011). For commissioners, the option of exercising choice means they can tender for innovative services, driving the development of new models of care and innovation (Mays and Dixon, 2011).

In healthcare, however, there is insufficient information available for commissioners to exercise choice, contract, or monitor the quality of services. Additionally, entry and exit costs are high, the specialised nature of healthcare means that commissioners and patients often need an agent to make decisions (Maynard and Bloor, 2003), and healthcare professions tend to see market-related reforms as a threat to their autonomy (Saks, 1995). Therefore, the medical profession, in particular, has objected to every market-related reform of the NHS (Saks, 2015).

Additionally, Bevan and Fasolo (2013) suggest that in healthcare there are four circumstances where individuals exercise choice if this is provided:

- Individuals have a stable and well-defined preference before analysing the options available and making a decision.
- The array of options available fulfils the needs and preferences of different individuals.
- Individuals have the knowledge and expertise to make a choice, or they have the time and willingness to learn about the options before making a decision.
- The options available do not involve unpleasant outcomes and do not require trade-offs that could cause psychological pain.

[8] A contestable market has zero costs associated with entry and exit (Begg et al., 2014). The two main determinants of contestability are the presence, or absence, of sunk costs (i.e. costs that cannot be recovered) and economies of scale (i.e. reduction of costs when a business grows). In the case of the NHS before the introduction of a quasi-market, the district management team would pay for the services of a local hospital regardless of the performance of that hospital. The quasi-market would allow district health authorities to purchase services from other hospitals.

In healthcare, these conditions are rarely met: patients learn about care quality or the features of care in a given hospital during the process of receiving care, and it is difficult for them to have a preference in advance. Regarding treatment, all patients have the same need, which is to be cured, meaning that options should not differ between hospitals. An average patient does not have the expertise or medical knowledge to make a choice, whilst devoting time and effort to inform themselves about their condition and available options can be difficult during ill health. In the scenario where a patient decides to move to another hospital, there is a risk of potential complications or separation from next of kin; therefore, it is not a hazard-free situation. Therefore, giving a choice to patients is not an effective way to govern quality, because there is a limited number of situations where patients can exercise choice in healthcare.

2.3.4 Legal perspective

From a legal point of view, governments have a duty to protect the right to health (i.e. provision of safety and quality standards and non-discrimination) by regulating activities through legislation, contracts, regulatory institutions, or any other legal means deemed necessary (Mariner, 2009). These legal instruments provide a framework for what is accepted and the enforcement actions attached to illegal activity. Two particular theories underpin why individuals or organisations will abide by the law.

The first says that social influence (i.e. concerns about one's own social reputation) motivates compliance with the law (Sutinen and Kuperan, 1999). This theory sees compliance as a moral act, which has four defining characteristics (Sutinen and Kuperan, 1999). First, it is intrinsically motivated by non-material reward. Second, it involves sacrifice and denial of pleasure; therefore, an institution could incur extra costs for carrying out the moral act. Third, the act concerns intentions and processes, not outcomes, and when outcomes are taken into account, the means to the end are relevant. Fourth, institutions or individuals in similar circumstances receive similar treatment.

Social influence is stronger when there is a widespread understanding that compliance is a moral obligation, which is determined by the legitimacy of the overseeing institution (Sutinen and Kuperan, 1999). Evidence suggests that procedural justice (how just the process of regulation is) and distributive justice (the perception that benefits and sacrifices are shared fairly) influence the perception of legitimacy more than the effectiveness, efficiency and speed of the regulator to respond to problems within its authority and accomplish its mission (Sutinen and Kuperan, 1999).

The second theory is the general and specific deterrence theory, which refers to the power of legal punishment to prevent illegal activity. The commitment of a crime or illegal activity by individuals and organisations is prevented or restricted by the fear of legal punishment (Stafford and Warr, 1993). This fear is achieved because individuals are aware of the potential punishment, have experienced the punishment themselves, or have observed the punishment of others (Stafford and Warr, 1993). The certainty and severity of the sanction are the two main variables associated with deterrence and the capacity of legal provisions to prevent deviant performance (Stafford and Warr, 1993).

Since the costs related to constant on-site monitoring of compliance by a regulator are high, the relationship between the regulator and regulated institutions is based on trust that individuals and organisations are complying with the standards when the regulator is not there (O'Neill, 2002). Deceptions of trust often lead to an increase in central control: a new performance indicator, a more complex code of practice or a new standard (O'Neill, 2002). However, more regulations, stricter rules and more scrutiny does not guarantee compliance (Maynard, 2014) since it can lead to gaming or ritualistic compliance (Berwick 1989).

Another problem of the application of a legal perspective to healthcare is that sanctions and enforcement actions need to balance the probability of unintended consequences with their ability to deter deviant behaviour. When sanctions are severe, the likelihood that a regulatory institution will use them is low since the repercussions go beyond the provider, for example, revoking the license to an NHS trust implies that the whole population in that area will have to seek care somewhere else. Conversely, when sanctions are lenient, the gain of engaging in illegal or out of boundaries activities is greater than the costs of the sanction; therefore, the punishment does not act as a deterrent. In turn, the rule of law provides the foundation for a legal view in governing quality, but to be effective, it requires other strategies in place, such as professionalism and performance management.

2.4 Information, quality, and the unintended consequences of performance monitoring

All the perspectives mentioned require monitoring or obtaining information to govern quality. In the case of healthcare professionals, particularly the medical profession, information is used within the profession at least to benchmark the current level of performance against an ideal, and consequently, to guide future actions (Berwick et al., 2003). For managers, data can also serve to determine what is working and why (McLaughlin and Kaluzny, 2004). According to economics, information is a commodity, and there are costs associated with obtaining reliable information to reduce uncertainties for decision-making (e.g. for exercising choice,

contracting, and monitoring performance) (Arrow, 1962). This means that in the presence of imperfect information and market failure, other options such as regulation should be used to assure and incentivise the delivery quality (Laffont and Tirole, 1993). From a legal viewpoint, data is needed to monitor compliance with contracts, legal restrictions, and regulations (Mariner, 2009). However, collecting information for quality governance is not free; it has a cost and potential unintended consequences, especially, when the achievement of a target is linked to high-powered incentives (Bevan, 2015).

Collecting reliable, accurate and valid information on quality of care has a cost related to the effort and time spent obtaining that data and developing the information technology (IT) systems that will allow for collating the information in a centralised platform (Walker et al., 2005). This means that the value of quality indicators depends on a trade-off between the benefits that the information provides and the costs borne from obtaining it (Schuster et al., 2017).

When performance indicators were first introduced, there was rarely enough evidence to support a link between such measurement and patient outcomes. Therefore, the decision of what to measure was related to what was available and was measurable rather than what measures were good proxies of care quality (Buetow and Roland, 1999). The complexity of healthcare means that not everything that matters can be measured, and performance indicators usually reflect restricted subdomains of quality (Bevan and Hood, 2006a, 2006b). Indicators can be classified as those that prompt further investigations but in isolation give an incomplete picture of performance (i.e. “tin-openers”), or those that are direct measures of a process (i.e. “dials”) (Carter, 1991). Consequently, for governing quality of care, it is assumed that the combination of information available provides a good reflection of actual performance and that the measurement itself will not induce gaming (Bevan and Hood, 2006b). There can, however, be unintended consequences when performance is assessed based on the achievement of a target or the level of performance on a given indicator (Smith, 1995), this is particularly so when targets are supplemented by financial incentives (Bevan, 2015).

Since targets and performance indicators are supposed to direct effort, the measurement of indicators to give a more comprehensive view of performance can make providers lose track of the priorities. Conversely, measuring just a few indicators can create “tunnel vision” where providers only focus their efforts on meeting what is measured (Smith, 1995, Bevan and Hood, 2006). Gaming is the term used to refer to any creative “subversive reaction” from a provider to secure a strategic advantage (Bevan and Hood, 2006). Some examples of this are:

- Improving performance by focusing on the performance indicator instead of the goal that is reflecting,
- Falsification or manipulation of data to meet a target or to improve performance, and
- A lax interpretation of the definitions around a target.

Within acute NHS trusts, there is evidence of manipulation of performance data when providers under-report adverse events (Sari, 2006). There can be a fixation on what is measured when the A&E waiting time target is met by modifying when the waiting time started or by taking action right before the target is missed (Locker and Mason, 2006). A similar phenomenon happened when waiting lists were shuffled to meet the referral to treatment waiting time (Besley et al., 2009).

Gaming cannot be eliminated, but efforts can be made to minimise it. Some options are to audit the quality of reported data and introduce uncertainty in performance measurement, where organisations know what the target is but the specifics about the monitoring process remain unknown (Bevan and Hood, 2006). Improving reporting culture and adding some face-to-face scrutiny (e.g. inspections) might limit the extent of gaming and detect outliers that would not appear through statistical monitoring, although adding inspections can be burdensome and has its pitfalls (Bevan and Hood, 2006).

2.5 Conclusion

Quality can be understood intuitively, as fitness for purpose, as conforming to specifications, or meeting the needs of consumers. These views have influenced the way quality is seen in healthcare. However, healthcare represents a complex adaptive system where the lack of a universal definition of quality of care and the different instruments used to drive improvement are problematic. The interconnectedness of the health system hinders efforts to improve quality, where the improvement in one area can improve several indicators or harm improvement in other areas and the improvement of one indicator might require targeting various areas of care.

Four main perspectives have shaped the overall debate on how to govern quality in the NHS. Their influences come from the different roles they have for the functioning of the health service. Healthcare professions deliver care in the frontline, managers coordinate the work at the micro and meso levels of the system, economists participate in the policy-making process, and lawyers create the legal framework for each policy. They have consequently proposed different instruments to encourage social action and produce/assure quality. Whilst the healthcare professions' view of quality is reliant on professionalism and internal motivation, managerialism uses methods that create an external motivator such as performance

monitoring and continuous quality improvement to incentivise the delivery of quality. Economics uses a wider variety of instruments to create external motivators for improvement, including competition, incentives, sanctions, contracting, regulation and transparency. Lastly, the legal perspective considers that the rule of law is enough to direct efforts, assuming enforcement actions will deter illegal and improper activity and individuals and organisations will act morally. These instruments are all present in the current CQC dominated regulatory environment. The next chapter explains how this environment evolved.

3 The evolution of governance of quality in the English National Health Service

Theory is so much clearer than history (Thompson, 1978).

Given the complex interaction (in often unpredictable ways) of multiple factors affecting the effectiveness of quality improvement and assurance strategies (Greenhalgh et al., 2004), it is important to understand the obstacles and incentives for change when designing and evaluating interventions (Grol et al., 2007). This understanding comes from the theoretical assumptions and explanations behind the interventions implemented (Grol et al., 2007, Foy et al., 2011). Acknowledging the interactions between an intervention and the context in which it occurs allows accounting for confounding variables and finding explanations for the observed effects (Grol et al., 2007).

In Chapter 2, the underlying theories for quality governance through the use of four perspectives were explored. A theory is an abstraction of a phenomenon expressed in an organised, heuristic, coherent and systematic array of statements that together provide generalizable understanding of a phenomenon (Foy et al., 2011). Conversely, a model is a simplification of a specific process outlining how the different components of it (e.g. an intervention) interact to produce intermediate outcomes (Rogers, 2005). Therefore, whilst theories are generalizable to different situations where a given phenomenon occurs (e.g. competition as a driver for improvement), models are specific to a situation and may use several theories to explain how hypothesised outcomes are achieved.

In reality, the views of these four perspectives have combined, resulting in four distinguishable (with the benefit of hindsight) theoretical models of governance of quality: trust and altruism, targets and hierarchy, naming and shaming, and choice and competition (Bevan and Fasolo, 2013). How these theoretical models unfolded in practice helps us understand the current context in which CQC inspections happen, and therefore, informing the design of evaluations and the understanding of those evaluations findings.

In this chapter, the theoretical perspectives outlined in Chapter 2 will be used to define theoretical models of “quality governance”. Following this, evidence is presented on how these models of governance unfolded in practice. Finally, with reference to implicit theories of change and relevant research, the current model of inspection-based NHS governance is outlined.

3.1 Theoretical models of quality governance

Defining quality governance using the appropriate theory provides a lens through which to view the CQC and other initiatives designed to improve quality in the National Health Service. Governance of quality involves the instruments and mechanisms used by the government to steer behaviour for improving the quality of the care delivered (Braithwaite et al., 2007, Bevan and Fasolo, 2013).

In the NHS, the healthcare professions, management, economic and legal views outlined in Chapter 2 have – over time – merged into four distinct models of governance (Bevan and Fasolo, 2013) that are intended to drive improvement.

“Trust and altruism” posits healthcare providers as intrinsically motivated to perform well through professionalism. Consequently, there is no need for external monitoring or incentives. However, these “motivated” professionals require information or resources to implement change (Bevan and Fasolo, 2013). This method of governance was dominant in the pre-1990 era: failure was rewarded by targeting extra resources and success largely ignored (Bevan, 2010).

“Choice and competition” relies on an economic view of providers and service users as rational (Simon, 1955) or “econs” (Bevan and Fasolo, 2013). In this model, service users make informed choices regarding providers and providers compete to attract or maintain users (Bevan and Fasolo, 2013). Choice and competition as a model of governance requires a quasi-market with comprehensive information about performance and several providers free to manage their "business". The obvious appeal for governments is that they are divorced from the responsibility of dealing with poor performance; instead, the invisible hand of the market provides the pressure (Le Grand, 2007).

A ”targets and hierarchy” model (sometimes labelled “targets and terror”) (Bevan and Hood, 2006b) relies on active management to govern quality. As with the choice and competition model, providers are seen as rational collectives of social actors. Success is incentivised and failure punished (Bevan and Fasolo, 2013). The targets and hierarchy model requires tight monitoring; something which is costly and unpopular with professionals (Le Grand, 2007, Bevan and Hood, 2006b).

“Naming and shaming” assumes that in contrast to the view of users as “econs” (Le Grand, 2007) healthcare consumers rarely exercise choice (Bevan and Fasolo, 2013). Consequently, performance information is not used to switch providers. Service providers – as collectives of non-econ, “humans” - are motivated by the reputational threats arising from performance rankings (Bevan and Fasolo, 2013) rather than performance info *per se*. Reputational models

come with a considerable downside: implementing them requires naming and shaming providers based on monitoring information. Thus, this model is unpopular with professionals (ibid) and could undermine the intrinsic motivation of health professions (as could targets and hierarchy).

These four models explain, theoretically, NHS quality governance up to 2010. In 2010 there were elections and during the campaign, the conservatives claimed that "there will be no more of the tiresome, meddlesome, top-down re-structures that have dominated the last decade of the NHS" (The Economist, 2014). However , after coming to power, the coalition government spent two years trying to pass a bill to reform the commissioning system (Timmins, 2012). In parallel, the first Francis Report was published, which highlighted poor standards of care in Mid-Staffordshire, and the government commissioned a second inquiry to investigate the causes of the failure.

The time between 2010 (when the new administration took power) and 2013 (with the publication of the Francis Inquiry report) can be seen as a transition period with governance features that none of these models can explain. Therefore, in this thesis, two extra models have been added to the Bevan and Fasolo (2013) models. The first one has been named the macro-level inquiries model referring to the period 2010-2013.

The macro-level inquiries based model accepts the 'human' perspective of behaviour, where providers are perceived to respond to reputational threats and *sermons* (Vedung and Van der Doelen, 2017). The model requires high-profile failures of care to be investigated by a public or private inquiry since this will align providers' priorities regarding the implementation of changes to remedy the causes of the high-profile failure (Best et al., 2012).

The period after the Francis Inquiry also possesses special features that are not described by Bevan and Fasolo (2013) models of governance; this has been named the inspection state model. This model posits providers as responsive to reputational threats, but it is reputation among their peers that is a bigger incentive than reputation with the general public. The anticipatory pressure of an inspection would be the primary mechanism of change here, combined with the potential sanctions that a provider may receive if it is non-compliant. Additionally, for an inspection to drive improvement, each trust needs two types of leadership: designated leadership (i.e. someone formally in charge of the leading the process) and distributed leadership (i.e. professionals across teams sharing the responsibility for delivering changes and mobilising efforts) (Best et al., 2012). When both types of leadership are present, teams accommodate their inputs interactively to achieve the complex task (i.e. inspection), which requires credible leaders capable of mobilising influence (Best et al., 2012).

As a way of illustrating the principles of these models and identifying factors that could potentially explain the findings, the main mechanism of change, the systemic requirements and the claimed drivers for improvement in these six models are presented in Table 3.1.

Table 3.1 Mechanism of change, systemic requirements and theoretical foundation for different models of quality governance.

	1948-1989 Trust & Altruism	1990-1997 Quasi-markets	2000-2005 Targets & Terror Naming & Shaming	2006-2009 Choice & Competition	2010-2013 Macro level inquiries	2014-2017 Inspection state
Main Mechanism of Change	- Providers are intrinsically motivated to improve.	- Agents choose best providers. - Providers compete for patients.	- Incentives for success and punishments for failures. - Reputational threats motivate providers.	- Users choose best providers. - Providers compete for patients.	-Failures will be investigated and punished. -High care quality should be providers' top priority.	-Anticipatory pressure of the inspection
Requirements	- Altruistic individuals. - Professionalism drives improvement. - Information on performance.	- Quality performance information. - Several providers.	- Targets to guide performance. - Tight performance monitoring system. - Widely available and easy to understand public ranking of performance	- Quality performance information. - Several providers. - Patients exercise choice.	- High profile failure of care. - High profile inquiry or review into the causes. - Restructure of the regulatory legal framework.	- Inspectorate with legal powers to enforce compliance. - Targets to guide performance.
Drivers for improvement	- Internal motivation. - Feedback as an instrument to improve performance.	- Competition. - Contestability. - GP as a double agent. - Agency theory.	- Goal-setting theory. - Performance management. - Public accountability. - Reputation & trust with general public.	- Competition. - Contestability -Agency theory. - Rational choice theory.	- Reputational threats. - Alignment of priorities.	- Public accountability. - Enforcement powers. - Designated and distributed leadership.

In this chapter thus far, the quality governance models of the NHS have been explained, building upon the theoretical perspectives presented in Chapter 2. In the following section, practical unfolding and evolution of these models are explored over time, providing context for the current environment where the CQC operates.

3.2 Models for governance of quality in practice

In practice, the implementation of the models of governance did not always bring about the expected result. The discretionary authority that frontline public services employees have to implement policies gives them the power to adapt reforms, influencing their hypothetical effect and hindering their potential benefit (Lipsky, 2010). As a means to illustrate this phenomenon, empirical evidence on the effectiveness of the six previously mentioned models is presented. This informs what strategies worked and when in the NHS in the past, and therefore, permits the assessment of evidence on the effectiveness of CQC inspections.

Transitions between these models of quality governance have happened in the past when the previous model is deemed as a failure (e.g. after the Griffiths Report), after cases of demonstrably poor care (e.g. the case Mid-Staffordshire NHS FT), or when there has been a desire to incentivise further improvements (e.g. choice and competition, Stevens [2004]). The following analysis combines the Bevan and Fasolo (2013) models of governance with findings from a documentary analysis of policy documents (see Appendix Chapter 2, Table 2.1). It will argue that the current model of governance (i.e. the inspection state) is the product of a series of changes over time. It has "evolved" from perceived successes and failures of various initiatives, policies, and ideological shifts. The models of governance outlined in the following section provide a way of making sense of the chronology of "quality" and the evolution of the mechanisms used to assure society and govern care quality in one of the major functions of the UK state: the provision of public healthcare.

3.2.1 Trust and altruism: necessary, but insufficient

Healthcare professions are bound by a common knowledge that directly or indirectly creates social closure, with legal boundaries determining who is inside (Saks, 2015). Belonging to these groups infers a privileged social position in exchange for protecting the public through codes of ethics (Freidson, 2001). In medicine, codes of ethics reassure patients and funders of the health service that doctors will act in the patients' and funders' best interest (Maynard and Bloor, 2003). The specialised nature of healthcare means that neither patients nor payers have full information to make decisions, creating information asymmetry, where consumers seek the specialised advice of an agent in order to make decisions (ibid). Doctors act as agents for patients, advising them about best treatment options and at the same time acting as agents for funders, advising on what to purchase and where (Blomqvist, 1991). However, these agency relationships are imperfect since doctors are not impartial[9] and the response to this incomplete agency relies on professionalism and self-regulation (Maynard and Bloor, 2003).

For 40 years, it was thought that the administrative structure of the system was crucial for achieving efficiency and the integration of services (Webster, 2002); so for example, the restructuration of 1974 sought to streamline administration and money flow in the system whilst other components remained untouched. Governments relied on trust in the altruistic behaviour of healthcare professionals to work in a coordinated manner to run the service (Maynard and Bloor, 2003). Licensure and self-regulation were the main means to regulate

[9] Doctors have personal interests such as improving their income, professional satisfaction and enjoying leisure time. These interests can in part agree and in part disagree with the interests of patients and payers. To be a perfect agency relationship, doctors should take decisions from the patient's point of view, forgetting their personal aspirations (Maynard and Bloor, 2003). Supplier-induced demand is one example of this imperfect agency relationship (McGuire, 2000).

their activities, giving medics the freedom to practice (ibid). Efforts at improvement were based on information gathering exercises, and therefore, were a series of reports providing recommendations about the better use of material and human resources within the NHS. The Porritt Report (1962) looked at the organisation of the medical service with an emphasis on the tripartite structure,[10] seeing administrative changes as a way to improve healthcare provision. The Cogwheel Report (1967) also focused on medical services, but in the hospitals. Again, it proposed organisational changes so that consultants could work in sub-speciality teams. The Merrison Report (1975) found a lack of control over the standards of practice in the medical profession; therefore, it recommended that the General Medical Council should be responsible for regulating education, the practice of doctors, and maintaining a register of physicians. Although these initiatives proposed improvements to the service, none of them defied the ability of healthcare professionals to run the service.

Despite all these reports trying to drive change, the introduction of initiatives for quality improvement was sporadic. A sense of professional jealousy, and resistance to change (especially coming from outside the health professions), partially explains why this happened (Berwick, 2003). In general, the adoption of innovations in healthcare is slow. To be effective, quality improvement innovations should come from within the professions, requiring different leaders holding a diverse social capital to ignite positive change (Berwick, 2003, Greenhalgh et al., 2004).

One example of the pace of change in healthcare is the introduction of evidence-based practice. Cochrane (1972) outlined the fundamental idea that decisions about treatments should be based on randomised trials, but it became "the new big innovation" 20 years later when Sackett and Guyatt proposed the term "evidence-based medicine" (Guyatt et al., 1992). NICE, an institution producing guidelines on the effectiveness and cost-effectiveness of treatments, was created five years later. It took the health professions several years to realise that best evidence was not being used consistently in practice (Bero et al., 1998), creating a new discipline of "knowledge translation" or "implementation science" (Graham et al., 2006). Although this new discipline uses several of the principles of continuous quality improvement, the fact that it came from the internal realisation that improvement was not being brought about as expected, triggered a change.

The emergence of evidence questioning the effectiveness of interventions, highlighting unwarranted variations in practice, and the consequences of avoidable medical errors eroded

[10] The tripartite structure refers to how the service was organised in 1962. Regional hospitals boards administrated hospital services, the executive council was in charge of primary care (including dental and ophthalmic services), and local health authorities managed community services (Webster, 2002).

the trust of funders, who looked for ways to increase accountability, efficiency, effectiveness, and quality (Maynard and Bloor, 2003). Professionalism has driven most changes in the practice of healthcare, and the NHS still relies on the altruistic motives of healthcare professionals to provide services on a daily basis, but the erosion of trust translated "trust and altruism" into an underlying condition instead of the primary driver of quality.

The first change was the introduction of managers to the service in an environment with increasing financial pressure, rising consumer standards (Walshe, 2003), along with a wider societal shift toward neoliberal ideas of privatisation, de-regulation and containment of fiscal spending (Webster, 2002). This change was introduced after the publication of the Griffiths Report (1983), which looked into the management of the health services and suggested that:

> *If Florence Nightingale were carrying her lamp through the corridors of the NHS today, she would almost certainly be searching for the people in charge.*

There was discontent with medical self-regulation, and it was thought that managerial ideologies could increase efficiency (Ham, 2009a). However, filling those positions with medics instead of managers reduced the impact of the measure (Harrison and Pollitt, 1994). The patients' charter and the quasi-market reforms also had limited impact (see section 3.2.2 for more details about the quasi-market reform and its impact), partly due to the opposition of medics, except for GP fundholding, which gave power to GPs, strengthening their position and shifting the internal power within the medical profession (Saks, 2015). Since then (1991), any other reform perceived to strengthen the internal market has been opposed by the medical profession on the ground of increasing or leading to privatisation (Saks, 2015).

The reign of trust and altruism ended after several scandals related to poor medical conduct, which eroded the public's trust and provided evidence that this method alone was insufficient to govern quality (Maynard and Bloor, 2003). After holding inquiries to investigate the cause of these failures, it was found that in hospitals it was often viewed as not permitted to challenge specialist doctors or consultants because of their higher ranking (Ritchie, 2000), the culture was described as an "old-boys club", the approach to clinical safety was lax, and patients were left-out of clinical decisions (Kennedy, 2001). The unethical conduct of a few eroded the trust in doctors and health professionals, whilst the lack of reliable information on quality in the NHS hindered confirming or refuting the suspicions of poor care in other areas (Maynard and Bloor, 2003).

Professionalism still has the potential to be a more effective and efficient option for steering efforts to improve the NHS compared to using targets and external inspections (Maynard and Bloor, 2003). Firstly, it relies on and encourages internal motivation; secondly, it avoids the

unintended consequences of external methods of control, such as impaired self-determination (Frey, 1997); and thirdly, it can reduce the costs of external oversight institutions. However, returning to a reliance on trust would require better information systems and a cultural change to encourage improvement on a regular basis. The publication of surgical outcomes (Royal College of Surgeons, 2018) and the National Clinical Audit Programme (HQIP, 2018) are two examples of initiatives seeking to collect better information to increase transparency and drive improvements, which illustrates that a change of culture is already happening.

3.2.2 Quasi-markets

In 1987, the prime minister called for a review of the NHS since it was constantly under financial pressure. Several financing options were taken into consideration, trying to find an option that could increase efficiency, productivity, and quality regarding value for money (Klein, 2013). The final decision of the government was to follow Enthoven (1985) advice to implement an internal market. This would split providers and purchasers with the aim of increasing market contestability (i.e. reducing barriers to market entry and exit) by introducing contracts formalising the volume, quality and costs expected from providers (Maynard, 1991). Additionally, GP fundholding was implemented, where GPs could receive funds to purchase services for their patients (Maynard, 1986), although patients could not exercise choice themselves. Hospitals could choose to become NHS Trusts, which would confer on them more freedom to decide what services to provide (Maynard, 1991).

In practice, evidence suggests that the effect of the various implemented policies was mixed, although the quality of the studies was inconsistent (Le Grand et al., 1998, Brereton and Vasoodaven, 2010, The Health Foundation, 2011). However, it must be considered that attributing the impact of the reforms was difficult because the implementation of many of them was voluntary (i.e. GP fundholding and NHS trust status), no monitoring system was in place to allow measuring their impact, and the injection of extra financial resources into the NHS was a confounding factor (Le Grand et al., 1998).

Overall, GP fundholding seems to be the most successful policy since it led to improvements in secondary care quality and responsiveness; however, the quality of evidence is low (Le Grand et al., 1998, Brereton and Vasoodaven, 2010). Evidence on the impact of GP fundolding on referral rates and prescription costs appeared mixed (Surender et al., 1995, Stewart-Brown et al., 1995, Wilson et al., 1995, Redfern and Bowling, 2000, Dusheiko et al., 2006); costs decreased during the first two years, but increased later (Whynes and Reed, 1994, Stewart-Brown et al., 1995, Whynes et al., 1997, Propper et al., 1998, Dixon et al., 1998); waiting times decreased and patient satisfaction with non-medical aspects of care improved (Mahon et al., 1994, Dowling, 1997, Surender et al., 1998, Propper et al., 2002, Xavier, 2003, Dusheiko et al.,

2004, Dusheiko et al., 2007). Patient choice does not seem to have been affected by this reform (Le Grand et al., 1998). However, the practices choosing to be GP fundholders tended to be better organised and located in middle-class areas, which could partially explain the improvements seen (Brereton and Vasoodaven, 2010).

In terms of the effect of quasi-market reforms in hospital services, there is evidence suggesting improvements in productivity and reduced costs for those becoming NHS trusts (Söderlund et al., 1997, Hensher and Edwards, 1999). This suggests that hospitals found ways to respond to the incentives created. For example, the length of stay following surgery declined, but the proportion of patients being sent to nursing homes increased (Hamilton and Bramley-Harker, 1999). In terms of productivity, the number of elective admissions increased, whilst waiting times decreased (Propper et al., 2008). Conversely, the effect on quality of care might have been negative, since there is evidence that mortality rates got worse (Propper et al., 2004, Propper et al., 2008). Consequently, the overall effect of the quasi-market and the extra independence given to NHS trusts were mixed.

What this period taught us about governing quality of care through a quasi-market was that its creation was feasible without catastrophic consequences, but provisions for the internal market were not enough to drive competition or significant improvements, and patients' choice did not increase. However, the reforms did drive efficiency. It is contested that political interference and the lack of information on the quality of providers and the supply and demand available might have hindered the functioning of the market and the exploitation of its beneficial effects (Le Grand et al., 1998, Brereton and Vasoodaven, 2010).

3.2.3 Managing through "targets and terror" and "naming and shaming"

In the late 1990s, there was a series of cases of inadequate care in the NHS that led to a new regulatory cycle (Walshe, 2003).

1. The outgoing Conservative government agreed to conduct an inquiry into the deaths of 29 children receiving cardiac surgery at the Bristol Royal Infirmary in March 1997 (Kennedy, 2001);
2. In June 1997, the Secretary of State established a panel led by the Chief Medical Officer to investigate the cancer screening services at the Royal Devon and Exeter Hospital. The panel found that at least 11 women had died due to medical misconduct (NHS Executive, 1997);
3. In September 1998, the General Medical Council struck Rodney Ledward from the Medical Register after finding him guilty of medical misconduct during his practice as a gynaecologist (Ritchie, 2000) and
4. In the same month, Harold Shipman was arrested for killing his patients whilst he worked as a GP (Smith, 2005), and later convicted of murder.

These cases led to inquiries (Ritchie, 2000, Kennedy, 2001, Smith, 2005) highlighting perceived problems in the culture of the NHS (i.e. being highly hierarchical and secretive about adverse incidents and malpractice) and a lack of adequate processes to reduce harm to patients. These failings were addressed discursively through the language of "modernisation", the increasingly centralised control of resources (Klein, 2013) and with an emphasis on policy effectiveness as a goal (Blair 1997).

The first five years of the 21st Century saw an emphasis on governing quality based on targets and reputation. Targets arose from the promise of increasing spending to the European average and an NHS plan with ambitious standards for waiting times (Klein, 2013). Targets were introduced as "Public Service Agreements" and aimed at increasing the efficiency and accountability of all public services, setting annual targets to measure performance (Klein, 2013, Panchamia and Thomas, 2014). The targets for the NHS were integrated into star ratings, where NHS trusts received a star rating from zero to three based on meeting these standards (Bevan and Cornwell, 2006). Chief Executives of zero star hospitals were sacked (Besley et al., 2009). In 2002, the Commission for Healthcare Improvement (CHI) took responsibility from the NHS Executive for the assessment and publication of star ratings. This led to the combination of three pieces of information in a balanced score card to produce star ratings: CHI's assessment of progress implementing the seven pillars of clinical governance (i.e. Clinical Governance Reviews), and compliance with nine key targets and 40 additional indicators (Bevan and Cornwell, 2006). "Naming and shaming" came via the publication of hospital league tables – thus failures were more rapidly made more public than had been the case in the NHS's past.

Alongside "targets and terror", the government implemented a package of quality improvement strategies. The white paper outlining these reforms (A First Class Service, NHS Executive, 1998) tipped the focus from making structural changes for delivering quality into focusing on external governance arrangements to improve the processes and outcomes of care. The first strategy proposed was the standards of practice produced by the National Institute for Clinical Excellence (NICE). The second was a review of relevant pathways of treatment through the National Service Framework. The third and fourth strategies were monitoring of performance through external oversight carried out by the Commission for Healthcare Improvement (CHI) and clinical governance as a way to change the organisational culture within the NHS, directing it towards one that would encourage continuing improvement and learning from mistakes (Klein, 2013). Box 1 highlights the functions of CHI and the seven pillars of its clinical governance reviews.

The regulatory functions of the CHI

From April 2000, the CHI was responsible for:

- Clinical governance reviews of NHS trusts and primary care trust providers
- Developing and disseminating clinical governance principles and best practice
- Examining the implementation of National Service Frameworks and NICE guidelines
- Investigating serious or persistent problems of quality caused by systemic failures.

From April 2003, the CHI was additionally responsible for:

- Contracting for annual national surveys of staff and patients, and national clinical audits
- Publishing star-ratings
- Publishing an annual report to parliament on national progress on health care

The seven pillars of clinical governance

Processes for quality improvement

- Consultation and patient involvement
- Clinical risk management
- Clinical audit
- Research and effectiveness

Staff focus

- Staffing and staff management
- Education, training and continuing personal and professional development

Use of information

- Use of information to support clinical governance and health care delivery.

Box 1 CHI's functions and criteria for assessing clinical governance. Adapted from Bevan (2011)

Besley et al. (2009) used a difference-in-difference design to compare the effect of "naming and shaming" and "targets and terror" on hospital waiting lists using the pre-2000 era in England, and performance in Wales, as controls. They found that the successive targets introduced reduced the number of patients waiting longer than the target (compared to the median size of the waiting list in June 1999) to zero. Additionally, the new nine-month wait target reduced by 67% the number of patients waiting between nine and 12 months. However, evidence of gaming by means of shifting patients across waiting categories was also found. For instance, when the 15-month and 18-month targets were introduced, there was an increase in the number of patients waiting between three and nine months (Besley et al., 2009). This regime also had an effect on in-hospital mortality, which was reduced in England, but remained stable in Wales; whilst the number of finished consultant episodes increased to a greater extent in England than in Wales (Besley et al., 2009).

Despite the apparent success of this regime, official audits found issues with measurement of targets (National Audit Office, 2004), whilst patients reported worse performance than what was officially reported (CHI, 2004). One of the issues was the lack of a systematic auditing system that could reduce gaming in the absence of strong proxies for performance, or that

could measure the extent of gaming (Bevan and Hood, 2006b). This phenomenon can be seen to produce an "audit hole" where central government does not question the quality or reliability of performance information that appears as a remarkable success (ibid).

This governance model was successful (National Audit Office, 2003, Benson et al., 2004, Day and Klein, 2004) because of the combination of successive and ambitious targets, real and meaningful sanctions to chief executives, and the straightforward publication of a ranking of performance with reputational effects. However, this was implemented at a time when the health service had extra money injected, and it was common understanding that improving waiting times was a long-standing issue. Therefore, institutions made a public commitment to achieving this goal.

3.2.4 Choice and competition

The reforms necessary for the implementation of the governance model of choice and competition started with the creation of a quasi-market (i.e. 1989) and were further advanced with the implementation of Primary Care Groups (PCGs) in 1999, which were renamed Primary Care Trusts in 2002 (Klein, 2013). They continued with the introduction of the choice of an alternative provider for patients (2002) and an increase in taxes in 2003 to fund extra spending in the NHS (Stevens, 2004). In 2004, reforms followed with the creation of NHS Foundation Trusts; the introduction of payment-by-results; the creation of Monitor; and the Commission for Healthcare Audit and Inspection (CHAI). CHAI had the mission of incorporating patients' views of services, allowing users to make informed decisions about where to receive care (i.e. enabling informed choice) and promoting a culture of continuous quality improvement within the NHS (Haslam, 2007). These reforms were seen as a way to increase the incentives to improve efficiency and quality since strong performance management is effective for short periods of time (Stevens, 2004, Le Grand and Hunter, 2006, Timmins, 2010), and in the past only using competition had not been enough to drive improvements[11] (Stevens, 2004). Again, the institution regulating the quality of the health service (i.e. CHAI) was in charge of producing an annual 'health check', which provided information on how well each provider was doing; however, the primary mechanism to govern quality and drive improvement was based on patient and purchaser choice and competition. The rating provided through the annual health check was obtained by combining a self-assessment of performance, the views of third parties on the accuracy of the declaration, CHAI's desktop-based assessment of the trust, and the results of the inspection (if there was one) . Box 2 highlights the functions of CHAI and the standards assessed during the annual health check.

[11] The reforms implemented in 1990s had a limited effect on patient choice and were mainly based on increasing contestability of the market (Maynard, 1991).

The regulatory functions of the CHAI

The CHAI was responsible for:

- Assessing the performance of each NHS organisation and awarding an annual rating
- Regulating independent sector health care providers
- Investigating serious service failures in the NHS
- Carrying out reviews of the economy and efficiency of the provision of health care
- Considering complaints about NHS bodies that had not been resolved locally
- Reporting annually to parliament on the state of health care in England and Wales
- Promoting the effective co-ordination of reviews or assessments of health care provision.

Core and developmental standards for the annual health check 2006/2007

Safety	Health care processes, working practices and systemic activities prevent or reduce the risk of harm to patients
Clinical and cost-effectiveness	Health care meet their individual needs through health care decisions and services that provide effective clinical outcomes
Governance	Leadership and accountability, and the organisation's culture, systems and working practices ensure that probity, quality assurance and improvement, and patient safety are central to all the activities of the health care organisation
Patient focus	Health care respects needs, preferences and choices of patients and carers. It is co-ordinated with other organisations that can impact patient well-being
Accessible and responsive care	Services are prompt, patients have choice of services and treatments, and do not experience unnecessary delay at any stage of delivery or along the care pathway
Care environment and amenities	Care environments promote patient and staff well-being. They are designed for the effective and safe delivery of treatment, care or a specific function, provide privacy, are well maintained and are cleaned
Public health	Services are designed and delivered in collaboration with communities to promote, protect and improve health and reduce health inequalities

Box 2 CHAI functions and standards for the annual health check. Adapted from Bevan (2011).

Three econometric studies provide evidence about the effectiveness of the choice and competition model that advanced the market-like reforms introduced in the 1990s. Bloom et al. (2010) analysed the effect of selective contracting[12] on managerial practices and Acute Myocardial Infarction (AMI) mortality rates using an instrumental variable analysis. They found that more competition was associated with lower emergency AMI mortality rates and better management practices. An increase of three hospitals in an area would be associated with a reduction of 5.7% points in AMI mortality rates. These findings were robust after adjusting for population density, number of admissions, patients' age and case-mix, hospitals' characteristics, and sensitivity analyses using different measures of competition.

[12] Selective contracting was created as a way to integrate pathways of care for patients with chronic conditions. Primary, community and mental health care providers would liaise with the hospital sector to bid for package of services; therefore, competition was for the market (Siciliani et al., 2017).

Two other econometric studies showed lower emergency AMI and 28-day all-cause mortality rates after the introduction of competition and patient choice (Cooper et al., 2011, Gaynor et al., 2011). Cooper et al. (2011) used a difference-in-difference design to assess market concentration in seven different scenarios using Herfindahl-Hirschman Indexes (HHI), which measures competition for equal market share hospitals. Their findings were robust after adjusting for severity of illness, age, foundation trust status, volume of patients treated with AMI and changes in how competition was measured. The only confounding factor remaining is extra funds injected and the growth of the workforce in the same period. However, Gaynor et al. (2011) had similar findings even when adjusting for hospital expenditure. Their results come from a difference-in-difference analysis that adjusted for case-mix, health status and income of the catchment population, as well as distance from hospital, teaching status of hospital, total number of admissions, and proportion of doctors and nurses in the clinical staff.

Despite these promising results, questions have been raised about whether competition mechanisms that apply largely to elective surgery are likely to reduce acute mortality rates. In addition, there is a lack of association between Patient Reported Outcomes Measures (PROMs) and risk-adjusted mortality rates during the same period (Bevan and Skellern, 2011). Another plausible explanation for the changes observed is competing interventions such as external inspections and performance monitoring through the "annual checks" (Bevan, 2014).

During choice and competition, the NHS improved regarding efficiency, patient choice, and the care of long-term conditions; but the implementation of layered reforms with different objectives and messages makes it difficult to attribute changes to any specific reform and might have hindered a greater effect of the reforms (Mays and Dixon, 2011). Mays and Dixon (2011) contest that the impact of the market reforms was modest, mainly due to patchy implementation, although none of the fears about market-related changes materialised (ibid). Competition increased mainly in suburban areas between conurbations (i.e. adjacent cities), choice improved for diagnostic studies and elective procedures, whilst payment-by-results increased efficiency (Mays and Dixon, 2011).

The unintended consequences arising from this period were that continuously implementing reforms creates a sense of uncertainty in the NHS and confusion about priorities. The discourse of Labour followed three lines: meeting targets, increasing completion, and improving cooperative work. For providers, these may be competing goals, which makes the task of meeting NHS priorities difficult because it is not clear how these goals are ranked.

3.2.5 Macro level inquiries

Between 2010 and 2013 there was a transition period dominated by inquiries and reviews into the care provided by the NHS, which partly changed the tone of the reforms for governing

quality. Before this point, the views of management and economics were imposed on healthcare professionals following the maxim that the service could be more efficient, whereas external oversight institutions had a marginal role providing information on the quality of the services with variable success. The lighter touch approach to regulation of CHAI allowed Mid-Staffordshire NHS Foundation Trust to prioritise finances over quality (Bevan, 2015). The trust managed to reduce its deficit by cutting nursing staff whilst demanding waiting time targets were met, although the care provided was inadequate and mortality rates higher than expected (Bevan, 2015).

The first Francis Report (2010) investigated this failure of care, finding that the care provided was below the expected standard. Patients were not treated with dignity and respect, whilst there was a bullying culture that was not open to learning from previous mistakes (Francis, 2010). In 2010, a second Inquiry was commissioned to explore what actions had been taken by the regulatory structure in place between 2005 and 2009 (Francis, 2013). The Inquiry found that monitoring systems were ineffective, inspections lacked sensitivity to detect problems or prevent harm, commissioners and regulators did not share intelligence when they had it, and responses to any potential concern were slow (Francis, 2013).

Under the suspicion that the failures of Mid-Staffordshire could be happening in other hospitals, Sir Bruce Keogh, the Chief Medical Officer, reviewed the functioning of 14 acute trusts that had been outliers for two consecutive years on the Summary Hospital Mortality Index (SHMI) or the Hospital Standardised Mortality Ratio (HSMR). Keogh (2013) found five problematic areas associated with high mortality:

- Use of data: hospitals were dismissing data on mortality alleging it was inaccurate.
- Recruitment and retention of skilled staff.
- Management of the flow of patients in and out of the hospital, particularly elderly patients.
- Poor and defensive management of complaints.
- Board members and clinical leaders had inadequate competence to devise a quality improvement strategy, and triangulation of information was insufficient to identify main risk areas.

Thorlby et al. (2014) found that one year after the publication of the Francis Inquiry Report; NHS trusts were making efforts to change the culture, increasing openness, transparency and candour, but it was still difficult to balance financial constraints and the delivery of quality.

Another consequence of the Francis Inquiry was the Berwick report (2013) into safety and avoidable harm in the NHS. Its findings are particularly salient for this thesis since safety is one

of the domains assessed by the CQC. The report highlighted problems that had been identified in the past, for instance, the lack of a clear supervisory system had been identified in the Griffiths Report (1983); whereas patients who were not empowered and fully involved in clinical decision making, and lack of transparency with performance data were elements underscored after the Kennedy Inquiry (2001). Prioritising quality of care and patient safety, and ensuring that services were adequately staffed in terms of number, experience, and skill-mix were elements that resonated with the Francis Inquiry recommendations.

The Berwick Report also recommended simplifying the regulatory system since it was deemed of "bewildering" complexity, with areas not being regulated and others having agencies with overlapping functions. The level of coherence in the system was considered key; with goals, incentives, and regulations pointing in the same direction to maximise their effectiveness. Regarding the CQC, the Berwick Report (2013) suggested that the Trust Development Authority, Monitor, and CQC should cooperate with each other and any other agency managing care quality intelligence to detect failings early and streamline information requests from providers. Additionally, judgements about care quality should be made based on a thorough assessment by expert inspectors, founded on the principles of responsive regulation, where the CQC would have a range of enforcement options. Many of these recommendations were later implemented (e.g. using the principles of responsive regulation) to make the CQC more responsive (see section 3.3).

This period relied on the legal view of governance; therefore, it increased regulation and legislation as policy instruments to protect the right to health and deter any inappropriate behaviour. Consequently, the legal framework changed (2014), and several reviews were commissioned into the specific recommendations of the Francis Inquiry (e.g. the Cavendish Review (2013) into support workers in the NHS and social care, and the Clwyd and Hart Review (2013), looking into NHS hospitals complaints management systems). One of the consequences of this period was establishing the legal framework for more regulation. This involved the creation of fundamental standards of care enforceable by law, giving the CQC legal powers to issue sanctions, merging Monitor and the Trust Development Authority into NHS Improvement, and a revision of the CQC regime of inspections to prevent another gross failure of care. The legacy of this period was creating consensus that improving the safety and patient-centeredness of care was urgent, and that the case of Mid-Staffordshire was unacceptable. This created an adequate environment for providers to accept tougher regulations and more public scrutiny for regaining the population's trust in the service.

3.3 The current model of governance: the "inspection state"

The Care Quality Commission (CQC) was created in 2008 as the independent regulator for quality across the health and social care sector, inheriting the risk-based regulatory model previously used by the CHAI (Adil, 2008). However, a series of events led to a change of CQC inspection regime in 2013:

- The Health Select Committee (2011) criticised the CQC for not performing its duty as it was behind schedule with registrations of providers and was not performing enough on-site inspections. Additionally, despite being alerted by a whistleblower about poor care in the Winterbourne View Hospital - which appeared in BBC's Panorama - it had not investigated the potential issues or had contacted the whistleblower. The Health Select Committee said that the CQC was performing too much desktop monitoring and it was not possible to be confident that a provider was meeting the standards unless there was at least one announced visit per year.
- All CQC senior management was replaced after covering up poor care in the maternity services of Morecambe Bay NHS Trust (Health Select Committee, 2013). In 2010, the CQC had given false assurances to Monitor and the public about the quality of care provided by University Hospitals Morecambe Bay NHS Trust, which led to the authorisation of the trust to become a Foundation Trust. At that time, the trust had higher than expected mortality rates and there were several allegations that the maternity services were providing poor care. Senior management had ordered staff to delete and replace the report highlighting these failures.
- The Francis Inquiry questioned the CQC's ability to detect failures to comply with minimum standards (Francis, 2013). The many agencies, regulators, professional bodies, and commissioners, which were expected to detect and take action to ensure compliance with acceptable standards of care, failed to do so (Francis, 2013). Additionally, annual checks relied on self-reported information instead of putting more emphasis on actual inspections.[13] These self-assessments of compliance put emphasis on the presence of theoretical systems, rather than on patients' outcomes. This, together with a passive approach to regulation that did not challenge the information provided by hospitals, led to ineffective operation.

These three events in combination with all the recommendations of the Keogh Review (2013) and the Berwick Report (2013) led to the implementation of a more-resource intensive regime

[13] Between 2005 and 2009, which is the period that the Francis Inquiry examined, hospitals were subject to annual checks conducted by the CHAI. These included a self-assessment of performance and an inspection of those hospitals deemed at risk of failure (Bevan, 2011).

of inspections intended to detect any potential failures of care. It was conceived to move away from "tick-box" judgements of quality to more thorough, quantitative and qualitative intelligence-based assessments of performance (Care Quality Commission, 2013b). Before the change of regulatory regime, CQC assessed compliance with the essential standards and could issue an enforcement action when a trust was deemed non-compliant. Box 3 highlights the functions of the CQC up to 2013 and the essential standards assessed during on-site visits.

The regulatory functions of the CQC

The CQC was to monitor:

- The medical and clinical treatment given to people of all ages in hospitals, by the ambulance service and mental health services. Also, primary care (e.g. GP and dental practices)
- The care provided in residential homes, in the community, in adult patients' own homes, and in residential care homes for children
- The services provided for people whose rights are restricted under the Mental Health Act
- The care provided by the NHS and the independent sector.

CQC essential standards of quality and safety of care up to 2014.

- respecting and involving people who use services
- consent to care and treatment
- care and welfare of people who use services
- meeting nutritional needs
- co-operating with other providers
- safeguarding vulnerable people who use services
- cleanliness and infection control
- management of medicines
- safety and suitability of premises
- safety, availability and suitability of equipment
- requirements relating to workers
- staffing
- supporting workers
- assessing and monitoring the quality of service provision
- complaints
- Records

Box 3 CQC regulatory functions and essential standards of care. Adapted from Bevan (2011)

In assessing the effect of this change of regime, it must be considered that the CQC operates in a context in which all previous mechanisms to govern quality already exist: targets and standards, a split between providers and purchasers, commissioners' ability to buy services from any willing provider, payment-by-results, and some freedom of choice for patients. However, perhaps the most significant moderator of the potential effectiveness of the CQC is the complexity of the current structure of the NHS (Figure 3.1). As highlighted in the Berwick Report (2013), there are commissioning organisations and regulatory institutions with various degrees of power to oversee the delivery of quality. The CQC is one more of them. For example, NHS Improvement (formerly the Trust Development Authority and Monitor), the CQC, and the local Health Watch all exert regulatory functions over acute hospitals. Hospitals are also accountable to their clinical commissioning group (and NHS England for specialised services). This implies that incentives might not always be aligned and these institutions can convey mixed messages about priorities for improvement, making it difficult to isolate the influence of all these actors.

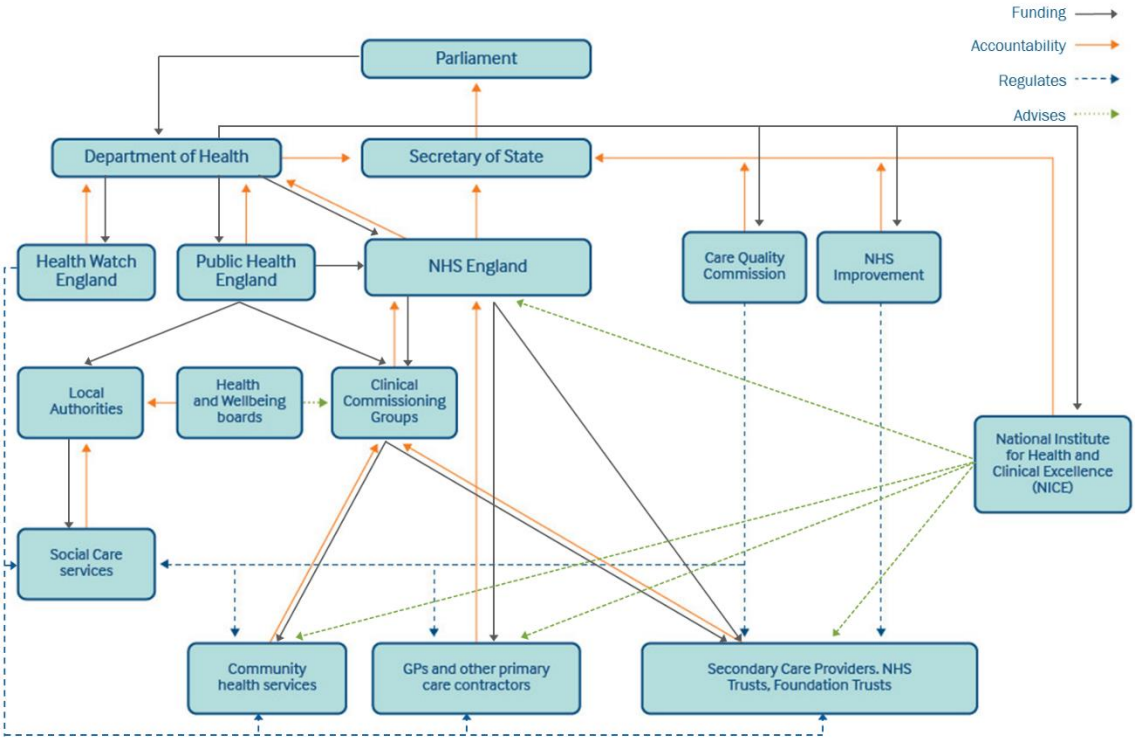


Figure 3.1 Diagram of current NHS structure. Modified from the Commonwealth Fund (2017)

3.3.1 The new regime of CQC inspections

The methodology used in the investigation led by Sir Bruce Keogh served as the basis for the new inspection model that the CQC piloted between September 2013 and September 2014 (Walshe et al., 2014). Although the main domains guiding inspections were re-organised to match the new definition of care quality, the fundamental standards and the definition of high

quality of care were changed after the Inquiry (Care Quality Commission, 2014a). The most important standards, therefore, should be clear to providers. Currently, high quality of care should be safe, effective, caring, responsive to people's needs and well-led (Care Quality Commission, 2015b). These characteristics are aligned with the "key lines of inquiry", which are the main topics that inspection focuses on, and with the fundamental standards that need to be met by law.

The current inspection regime of the CQC (see Appendix Chapter 3, Figure 3.2) is guided by a risk-based assessment called "intelligence monitoring", similar to the one employed by the CHAI (Haslam, 2007). The information collected is used to prioritise where to inspect first and guides which services within a provider may be failing, although all health and social care providers should be inspected in a three-year cycle (Care Quality Commission, 2015c). The method of inspection officially introduced since October 2014 was a radical change from the previous regime. Between 2009 and 2013, the CQC assessed a selection of 28 essential standards during each visit, judging compliance as "meeting standards", "requiring improvement" or "enforcement action required". Teams comprised two to five inspectors visiting for two to three days (Care Quality Commission, 2010a). In the case of the regime implemented in 2013, inspection teams comprised between 30 to 100 people depending on the size and variety of services given by the providers, including healthcare professionals with different backgrounds and experts by experience (Walshe et al., 2014). This model is similar to quality governance assessments of the CHI, which involved a small number of inspectors on-site for a week and was changed because it was time-consuming and reports were inconsistent (Day and Klein, 2004, Benson et al., 2004, Adil, 2008).

3.3.2 Is the "new" CQC regime of inspections effective?

Given the complexity of the regulatory environment with its competing priorities, a self-assessment of CQC performance was inadequate; therefore, the CQC commissioned The King's Fund to review the new inspection model during the first wave of inspections in 2013 (Walshe et al., 2014). In general, hospitals that were inspected found this process time-consuming, although knowing that the inspection was imminent was reported to have served as a catalyst for change and started mobilising leaders within each team (ibid). Several hospitals valued the inspections because it reflected some of the problems managers were trying to address and it helped them look for strategies to improve their service (ibid).

The definition of quality, fundamental standards and key lines of inquiry in the new inspection model are aligned with each other,[14] but there are problems of validity and reliability of the

[14] For example, the definition of quality says that care should be safe, which is one of the domains the CQC assesses. This domain contains five key lines of enquiry. The second one (lessons are learnt and

measurements (Boyd et al., 2014, Boyd et al., 2017). The CQC adopted an approach of "learning by doing" (Walshe et al., 2014), which was translated into changes in the regulations twice within one year (i.e. September 2014 and April 2015). The CQC developed the prompts for the inspection, the rationale to determine the ratings, and the format for the final report before the pilot implementation in September 2013, polishing it during the first six months. This produced anxiety among health and social care providers because they did not know how the inspection was going to go or how to prepare for it (Walshe et al., 2014). This approach of "learning by doing" has also produced inconsistent ratings, since the criteria for assessment are subjective and still under development (ibid).

CQC inspections aim to assure high quality of care and promote continuous improvement of the services provided by inspected institutions. Quality summits are held so that providers can present and agree on a plan for improvement (Walshe et al., 2014). One of the major problems to achieve the CQC's main goal is the depth of monitoring for the "action plan" (ibid). High performing institutions make considerable efforts to empower their employees to "own" change; they have a culture that learns from mistakes, and good leadership (Ham, 2014a). Currently, the CQC reviews how much of the action plan has been implemented after six months (Care Quality Commission, 2015b), without monitoring how this process is carried out or the impact it has on health outcomes (e.g., changes in mortality or waiting times). This poses the risk that providers can focus on "easy wins" without making more fundamental changes to the organisational culture that could be translated into better and safer care for the population.

Day and Klein (2004) propose four factors necessary for the effectiveness of inspection regimes in general:

i) Inspectors with experience in the service,
ii) Ability to balance local needs with national standards,
iii) Risks that are proportional to the cost of the inspection,
iv) Clear and explicit goals for the inspected organisation, and for the inspection regime.

CQC highlights that efforts have been made to address these factors (Care Quality Commission, 2015c). However, it is not clear yet if the costs of the inspection are proportional to the risk of failure. In 2016, CQC reported that the average cost of an inspection in the hospital directorate was £108,581, without specifying if there was a relationship between their

improvements made after adverse events) elicits the assessment of the fundamental standard of "duty of candour". This is measured by three indicators of the intelligent monitoring tool: proportion of reported patient safety incidents that are harmful, potential under-reporting of patient safety incidents, and proportion of staff who stated that the incident reporting procedure was fair and effective.

expenditure and the risk of failure of the trust (Care Quality Commission, 2016b). Moreover, the lack of a standard threshold to determine if a health policy is cost-effective hinders making a judgement as to whether this cost is reasonable for what the CQC delivers.

3.3.3 Why should CQC inspections improve quality?

The new regime of CQC inspections is embedded within the broader governance model of the "inspection state". This model (as suggested in Table 3.1) has as the main systemic drivers for improvement the anticipatory pressure and the potential enforcement actions of CQC[15]. When sanctions are not imposed, trusts would respond due to reputational concerns, since they do not want to be seen as inferior to trusts that are perceived as similar (Garcia et al., 2013). For individual trusts, Robertson et al. (2017) propose eight mechanisms of change regarding how CQC influences organisational performance and behaviour: anticipatory, directive, relational, organisational, informational, lateral, stakeholder, and systemic. For example, the publication of new standards incites providers to assess if they are meeting these new standards, and to implement remedial changes if they are not (i.e. systemic). Before the inspection, organisations may perform self-assessments to determine their level of compliance (i.e. anticipatory), or consult with similar providers previously inspected to obtain "inside information" (i.e. lateral). The anticipatory and lateral mechanisms can trigger remedial action or increase awareness about quality standards. During the inspection, CQC may use soft influence to suggest improvements (i.e. relational). After a CQC visit, the regulator may mandate changes to service provision (i.e. directive), but an organisation can decide to make changes that have not been requested, based on what they learned during the inspection process (i.e. organisational). Furthermore, stakeholders, such as commissioners and patients' groups, can influence organisations to make improvements after an inspection (i.e. stakeholders). Finally, the publication of the findings may lead to further changes to maintain or improve reputation (i.e. informational).

Based on Robertson et al. (2017); a formative qualitative assessment of the pilot phase of the new regime of inspections (Walshe et al., 2014); the CQC guidance for providers (Care Quality Commission, 2015c); and the findings from the Keogh Review (2013); a two-level logic model was constructed for this thesis. The logic model aims to explain how CQC inspections of acute NHS trusts could drive improvements in quality of care. The macro-level logic model (Figure 3.2) addresses the contextual variables that can influence the response of an acute NHS trust, considering the trust as a single unit. The micro-level logic model (Figure 3.3) depicts the steps

[15] When a trust is found non-compliant, CQC can enforce action and impose sanctions. Options available to them include compliance actions, modify conditions of registration, issue warning notices, recommend trusts are put under 'special measures' and even prosecute Trust Boards (CQC, 2015a).

taken by acute NHS trusts to implement improvements and how they relate to potential changes in selected measures of quality of care before and after the inspection and following the quality summit.

Regardless of how CQC inspections might drive changes, the final effect depends on the internal context of NHS trusts, where leadership and culture determine the size and depth of changes implemented before an inspection (Jacobs et al., 2013). Nevertheless, NHS trusts do not function in isolation; therefore, the external context is also seen to influence the performance and outcomes of each institution. Features of the catchment population such as rural or urban area, size, age, health status, socioeconomic level, and ethnicity mix will influence the overall level of measures of process of care and clinical outcomes (Buchan et al., 2017, Braithwaite et al., 2017a). It could be hypothesised that if two trusts have the same level of performance in one measure, the trust serving a more disadvantaged population might need to invest more resources for obtaining the same degree of improvement than the one serving a less disadvantaged population. This difference could, to some extent, be compensated for by the NHS funding formula that tends to allocate more resources to a materially-deprived area. There are also issues over the adequacy of the allowance for market forces on differences in costs of staff, which it is argued causes particular problems for the acute hospitals in London that are not teaching hospitals (Bevan, 2009).

The macro-context will also affect NHS trusts' capacity to respond in the face of an inspection. During the period used for the interrupted time-series studies (see Chapters 5 to 8) some important contextual events occurred. Firstly, the political decisions and systemic constraints of "austerity" from June 2010 (Seely and Webb, 2010). Secondly, the reform of the commissioning system that occurred between October 2012 and April 2013 (NHS Commissioning Board Authority, 2012). Thirdly, the more general trends of rising demands and costs, diminished funding for social care, and older patients with increasingly complex health needs (i.e. multi-morbidity or multi-speciality) (The King's Fund, 2017). Although these factors affected the whole system, their existence means the service is under stress, and its capacity to respond to an inspection might be reduced. Nonetheless, the internal context of the NHS trust is the key factor determining how much a trust can adapt to increasing environmental pressures (West et al., 2013, Taylor et al., 2015).

Inspections can also raise awareness about the quality of reporting standards. Safety incidents, waiting times, and patient case-mix for the estimation of risk-adjusted mortality rates require data to be reported by each hospital. If the hospital changes its reporting behaviour, then these indicators might artificially show an increase (or decrease) that is not related to changes in performance (Taylor, 2013). Conversely, the pressure of the inspection might trigger gaming

where data is modified to the advantage of the hospital or targets are met by neglecting other areas of care (Bevan and Hood, 2006). Another potential unintended consequence of external inspections and the imposition of targets is impaired self-determination (Frey, 1997). This refers to the process where an imposed external system of control, in particular in individuals with high levels of independence such as managers, doctors and healthcare professionals, can diminish self-determination by shifting the locus of control from inside to outside (Frey, 1997).

Macro context and contextual factors of the population served were considered potential confounders of the relationship between CQC inspections and measures of process and clinical outcomes because inspections are adapted based on these contextual factors (Care Quality Commission, 2015c), whilst at the same time, they can affect the performance of acute NHS trusts.

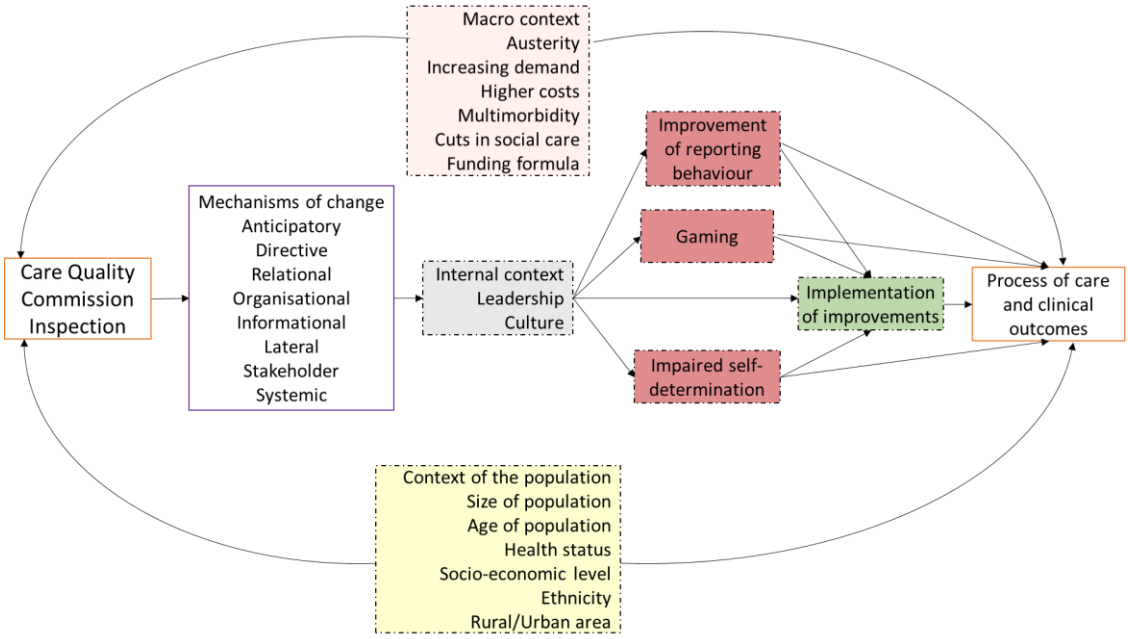


Figure 3.2 Macro level logic model of CQC inspections of acute NHS Trusts in England

A more detailed analysis of how CQC inspections might drive changes in acute NHS trusts is shown in Figure 3.3. Around 16 to 20 weeks before the inspection, the CQC announces its visit by sending out a provider information request (PIR). This announcement might lead to a self-assessment of performance against the standards used by the regulator and engagement with other trusts already inspected to obtain insight into the process. Once the trust identifies areas for improvement, senior management and clinical divisional managers agree on feasible actions that could lead to improvement in the time available. If necessary, managers will review risk registries, update policies, and review the management and security of drugs and patients' records since these are actions that can have an impact on their CQC rating and can be done within 16 weeks.

Clinical divisional managers are usually in charge of leading and transferring trust's plans to address the CQC inspection to the general staff working in each of the eight core services. In Figure 3.3, under the name of each of the core service, there is a simplified version of areas of care that could be improved during the announcement phase, eventually leading to improvement in measures of process of care and clinical outcomes. Once the CQC visits the trust, Robertson et al. (2017) suggest that there are three mechanisms that could trigger further changes in the delivery of care: i) the regulator can direct or advise changes based on the findings of the inspection; ii) inspectors can use soft intelligence or informal feedback to influence changes; and iii) the trust could decide to make changes not directed by the CQC but based on what they learnt during the visit.

After the visit, the trust's senior managers agree on an improvement plan to address the CQC findings, which are shared verbally at the end of the inspection. This starts a cycle of improvement where clinical divisional managers lead the implementation of changes, collect information on how it is progressing and feed back to the trust to make adjustments. This process itself can produce improvement in organisational performance and clinical outcomes. Three to six months after the inspection, the Clinical Commissioning Group(s), the trust board, patients' groups, and key stakeholders meet at a Quality Summit, where all the attendees agree on an action plan to remedy any problems found during the inspection. For instance, changes required could be opening extra beds, hiring more staff, changing triage systems in the Accident & Emergency (A&E) Department, improving risk assessments, or improving the storage of medications. The publication of a report following the Quality Summit can also trigger a request for improvements by other stakeholders such as local government and patients' groups not present at the actual meeting. With a new action plan, another improvement cycle starts, potentially leading to further improvements.

CQC's mission is to "make sure health and social care services provide people with safe, effective, compassionate, high-quality care and encourage care services to improve". This includes a component of quality assurance and one of quality improvement. If we were to assess the effectiveness of CQC, this could be performed from both perspectives, but for the purpose of this thesis, the quality improvement component is being tested Given the timeframe, the number of steps and the number of people involved in delivering any improvement of quality of care in response to a CQC inspection, the probability of producing improvements in measures of quality of care is limited. Although CQC's mission of "encouraging care services to improve" (Care Quality Commission, 2013) might be achieved as a process, it is difficult to see how CQC can achieve the outcome of improvement (or at least to prove it can produce improvements) even in the best-case scenario.

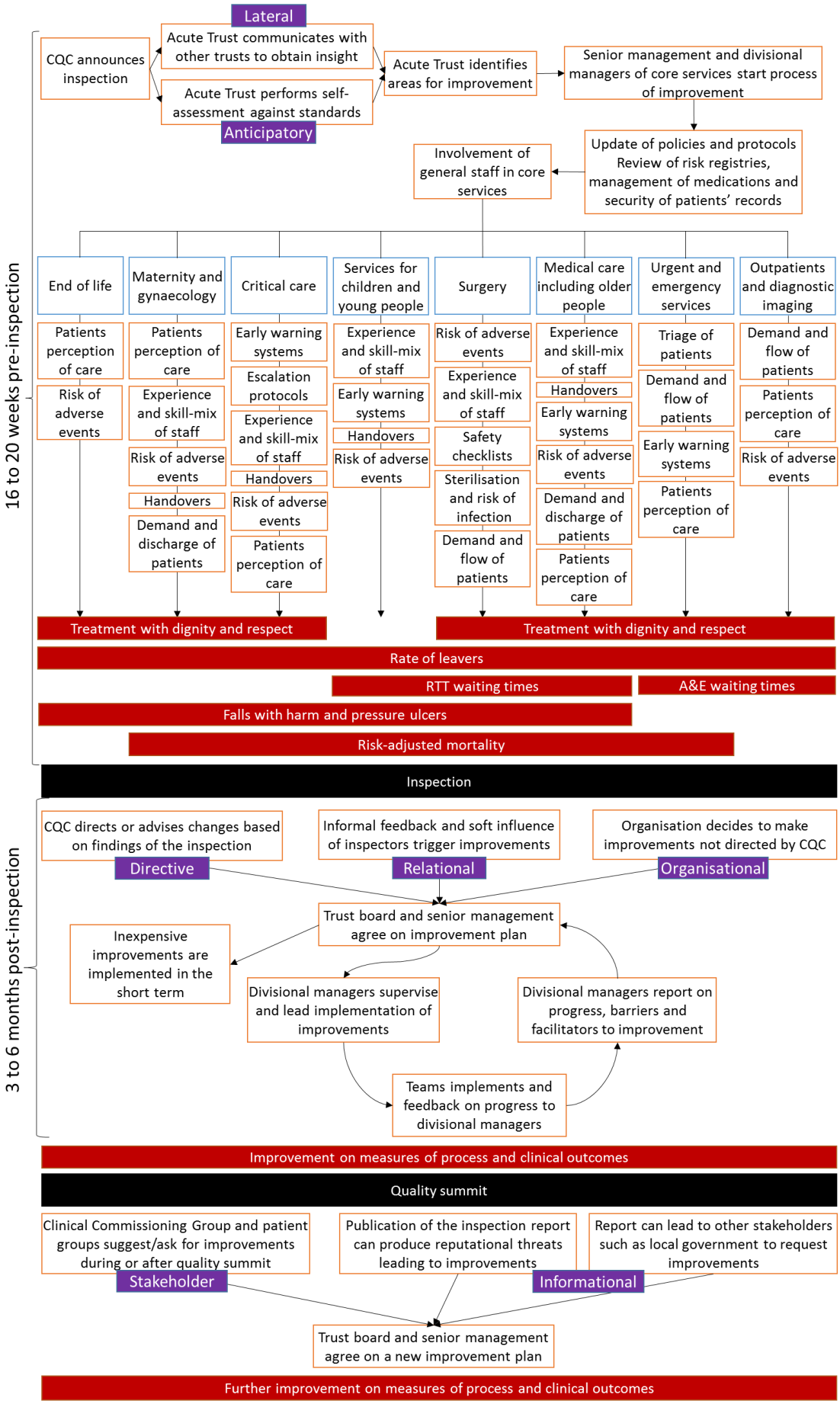


Figure 3.3 Micro-level logic model of CQC inspections of acute NHS Trusts in England

3.4 Conclusion

Clinical professionalism remains a relative constant throughout the evolution of quality governance, but was dominant in the pre-1990s when governments relied largely on trust and altruism to maintain and improve quality of care. Between 1991 and 1997, more "economic" perspectives gained traction, and 2000 to 2005 saw explicitly managerial perspectives laying the foundations for more components of the economic perspective on governance, which stretched from 2006 to 2009 (see Appendix Chapter 3, Figure 3.1).

Of these models, the combination of "targets and terror" and "naming and shaming" most demonstrably achieved policy goals (for example, reducing waiting times). Possible explanations include a limited number of targets, strong sanctions for unmet targets, and league tables enabling naming and shaming.

The inspections conducted by external oversight institutions during this time provided information about the quality of services to meet a purpose within the governance of quality agenda. For instance, the CHI produced the star ratings that were used to name and shame, whilst the CHAI conducted the annual health checks that could be used to choose providers.

In 2010, after recognising the poor care provided by Mid-Staffordshire NHS Foundation Trust, efforts to govern the quality of care became guided by inquiries and reviews, which served as a means of aligning priorities and redirecting efforts to solve the problems identified. This led to the current environment, the "inspection state", where CQC inspections dictate the direction of quality improvement efforts, although the main components of other models of governance are still present, creating competing priorities for NHS providers, and potentially, affecting the effectiveness of CQC inspections.

The method used for CQC inspections provides several potential pathways for impact; however, it is not clear to what extent the on-site visit modifies measures of process and clinical outcomes. Given that institutions similar to the CQC exist in other countries and this thesis examines the theoretical assumption that external regulation improves organisational performance and clinical outcomes, Chapter 4 tests this by systematically reviewing the global literature on inspection-based regulation.

4 Effectiveness of external inspections or accreditation on organisational behaviour and health outcomes: overview of reviews and update of the latest systematic review

The currently dominant quality governance strategy – the inspection state – relies on regulation to guide quality improvement efforts in health and social care in England, specifically, the work performed by the Care Quality Commission (CQC). The UK is not the only country that relies on this general approach to quality governance. Examining other jurisdictions with similar interventions for effectiveness may offer clues as to potential contained in the CQC's approach as well as when they have an effect and the size of it (if any), study designs used in the past, and outcomes that are sensitive to the intervention.

The inspection state model uses external oversight regulation (Sutherland and Leatherman, 2006), such as accreditation or external inspections, as an instrument to govern quality. Regulators are third party, independent of providers and users of the services, and use several interventions in tandem to modify behaviour: setting standards, monitoring performance and enforcement of compliance (Sutherland and Leatherman, 2006). External oversight is a complex intervention because the context, the content, the delivery, and the outcomes of the intervention vary for each provider (Walshe, 2007, Moore et al., 2014, Ng et al., 2013), which is one of the difficulties in assessing the impact of external oversight.

Accreditation is a widespread intervention with at least 23 different institutions worldwide performing similar functions at various levels of healthcare providers (e.g. laboratories, radiology departments, hospital care, and primary care) (World Health Organization, 2003); it is, therefore, crucial to provide information on its effectiveness to inform policy decision-making.

This chapter summarises the evidence on the effect of external inspection or accreditation regimes on organisational behaviour and health outcomes using a systematic approach. The first section is an "overview of [systematic] reviews"; whilst the second updates the highest quality systematic review identified to provide a state of the art of the effectiveness of inspection-based systems on improving quality in healthcare. This informs the methodological

design of this thesis and tests whether the theoretical relationship between external oversight visits and changes in organisational and clinical outcomes is based on empirical evidence.

4.1 Overview of systematic reviews

4.1.1 Why a review of systematic reviews?

External inspection and accreditation exist to ensure and encourage improvements on quality of care (Walshe, 2003). Consequently, it would be plausible to expect a relationship between the external oversight visit and better organisational and clinical outcomes; however, this association remains unclear (Flodgren et al., 2011). Since there are several systematic reviews looking into the effect of accreditation and external inspection on a variety of indicators, performing an overview of systematic reviews was deemed valuable to inform decision-making and methodological aspects of this thesis.

4.1.2 Description of external oversight based interventions

Regulation is a "sustained and focused control exercised by a public agency over activities which are valued by a community" (Selznick 1985: 383; taken from Walshe 2003, p9). Regulation centralises authority by giving power to an agency to oversee activities on society's behalf (Walshe 2003, p 10), as is the case in the CQC.

Besides being regulatory instruments, external inspection and accreditation mechanisms can be considered external approaches to quality improvement (Walshe, 2003). They have in common that they use several instruments to produce an effect, but there are subtle distinctions.

Accreditation can be voluntary (e.g. United Arab Emirates [Devkaran and O'Farrell, 2014]) or mandatory (e.g. Denmark [Falstie-Jensen et al., 2015a]). In general, institutions are required to establish a committee to lead the process, perform a self-assessment against accreditation standards, and a mock survey three to six months before the visit (Devkaran and O'Farrell, 2014, Bogh et al., 2016). The outcome of the accreditation visit could be full, partial or denial of accreditation (ibid). The relevance of the accreditation status is that it carries recognition, and for example in Denmark, hospitals must be accredited to provide care (Bogh et al., 2016).

In the case of external inspection regimes, like the CQC, the regulator is a governmental agency with certain freedoms to act. Visits are announced 3 to 4 months in advance (Walshe et al., 2014). Providers are requested to submit data in advance and help arranging engagement events with the service users (ibid). After the visit, organisations receive a rating, which carries certain prestige, but it does not limit their ability to provide services unless the external inspection agency withdraws the organisations' license (Care Quality Commission, 2015a).

4.1.3 How inspection and regulation works

The mechanism of action of external oversight is rarely articulated (Hovlid et al., 2017). However, by examining the theories underpinning each component of the inspection and regulatory model insight into possible mechanisms can be obtained. External standards – with which regulated organisations should comply - set a direction and a level of performance that should be reached, where that goal helps regulate behaviour by orienting attention, resources and strategic planning efforts toward its accomplishment (Locke and Latham, 2002b, Locke and Latham, 2006). Surveillance and public reporting of performance are intended to drive improvements by increasing competition, transparency, and public accountability (Walshe, 2003). Lastly, the enforcement actions should discourage non-compliance or unacceptable behaviour (Sutherland and Leatherman, 2006).

4.1.4 Methods

4.1.4.1 Research question

What is the effectiveness of external inspection or accreditation at institutional level on organisational performance and patients' health outcomes?

4.1.4.2 Criteria for considering studies for this review

4.1.4.2.1 Types of studies

Systematic reviews, defined as a secondary research study with explicit a priori inclusion criteria and search strategy and a quality assessment of the evidence. The process of the systematic review should be transparently reported and replicable.

4.1.4.2.2 Types of participants

Secondary and tertiary acute care institutions being subject to external inspection or accreditation interventions of the whole institution or a department.

4.1.4.2.3 Types of interventions

Intervention: External oversight in the form of inspection or accreditation.

Comparison: could be the period before intervention or a contemporary group receiving control or no intervention.

4.1.4.2.4 Types of outcome measures

Organisational performance: safety measures (e.g. falls, pressure ulcers, prescription errors, healthcare-associated infections), waiting times, institutional governance, composite measures of quality of care.

Patients' health outcomes (e.g., mortality, PROMs, readmission)

4.1.4.2.5 Language

No language restrictions were made.

4.1.4.3 Search methods for identification of studies

The terms “inspection”, “accreditation”, “external review” and “external oversight” were used as free text and controlled language to identify relevant systematic reviews. The search strategy was adapted to the individual search engines to maximise its sensibility. The reference lists of identified systematic reviews were also searched to identify more relevant studies.

4.1.4.3.1 Electronic searches

To identify systematic reviews the following resources were searched in February 2018

- Cochrane Central Register of Controlled Trials (CENTRAL) since 2003
- Cochrane Database of Systematic Reviews (CDSR) since 2003
- Centre for Review and Dissemination (CRD) databases since 1994
- Health Systems Evidence since 1978
- PDQ-Evidence since 1975
- Trip Database since 1970
- Electronic Theses Online (Ethos) since 1900
- International Society for Quality in Healthcare (ISQua) since 2009

4.1.4.3.2 Other sources

Reference lists of previous systematic reviews and institutional websites for Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Commonwealth Fund, King’s Fund, the Health Foundation, the Welcome Trust and the Nuffield Trust.

4.1.4.4 Data Collection and analysis

4.1.4.4.1 Selection of studies

All the records obtained were downloaded to a reference manager software (i.e. Endnote). One reviewer performed the initial screening of titles and abstracts, classifying citations in three groups: eligible, excluded or uncertain about eligibility. This information was stored in a Microsoft Excel file. Records deemed eligible and uncertain about eligibility were reviewed in their full-text version. The reasons and number of articles excluded were recorded to generate the PRISMA flow diagram. The decision whether a study meets the inclusion criteria was primarily based on the abstract using the inclusion criteria above mentioned. If there was not enough information to determine its inclusion, the lacking information was looked in the methods section of the full-text version. In the case there was still missing information to decide its inclusion, the author was contacted.

4.1.4.4.2 Data extraction and management

One reviewer extracted the data. For systematic reviews, data were obtained about the study designs included, aim and the question of the review, results reported, and conclusions. The data extraction form was piloted with one study screened as eligible and adapted to collect the relevant information. The authors were contacted in case of missing data because it was not available in the published study or was not clearly stated.

Data were obtained for the population, intervention, comparison, setting, outcomes measured and reported results for primary studies.

4.1.4.4.3 Assessment of quality of systematic reviews

One reviewer assessed the quality of included reviews using the AMSTAR tool (Shea et al., 2007).

4.1.4.4.4 Analysis Plan

High levels of heterogeneity among included reviews made it inappropriate to combine results in a meta-analysis; therefore, results are presented in a structured synthesis. The characteristics of the eligible reviews are displayed in a table including information about the design of the included studies, target population, details about the external inspection and comparison, and outcomes assessed. The quality assessment is shown in a table detailing, for every study included, whether each criterion is met and the overall score.

Additionally, to make judgements about the effectiveness of the intervention using the evidence from the overview, vote counting was performed considering the number of outcomes per intervention category that favoured accreditation. The following decision rule was used (Weir 2010):

- 0% of studies (outcomes) favour intervention = no effect;
- 1% to 33% of studies (outcomes) favour intervention = generally ineffective;
- 34% to 66% studies (outcomes) favour intervention = mixed effects;
- 67% or more studies (outcomes) favour intervention = generally effective.

Vote counting has two problems. One is that the definition of a positive study is made subjectively or based on statistical significance. In practice, the number of studies showing benefits and harms (regardless of effect size) should be reported (The Cochrane Collaboration, 2011, Cochrane Effective Practice and Organisation of Care (EPOC), 2017). The second issue is vote counting does not account for the sample size and, therefore, the relative weight of the estimate (ibid).

In this thesis, it was used as a last resort for summarising the large, heterogeneous body of literature available.

Sensitivity analysis

A sensitivity analysis according to quality was not justified due to heterogeneity.

4.1.5 Results

4.1.5.1 Description of included reviews

The search identified 1346 records. After removing 94 duplicated records and screening 1258 titles and abstracts, 17 reviews were analysed in their full-text version (see Figure 4.1). Reasons for and references of excluded studies are shown in Appendix Chapter 4 (Table 4.3). Characteristics of the included reviews are contained in Table 4.1 and Table 4.2. Two included reviews were Cochrane reviews. Since their results are the same, they are presented together (Flodgren et al., 2011, 2016).

The characteristics of the primary studies included in each review are summarised in Appendix Chapter 4, Table 4.2, Table 4.4 and Table 4.5.

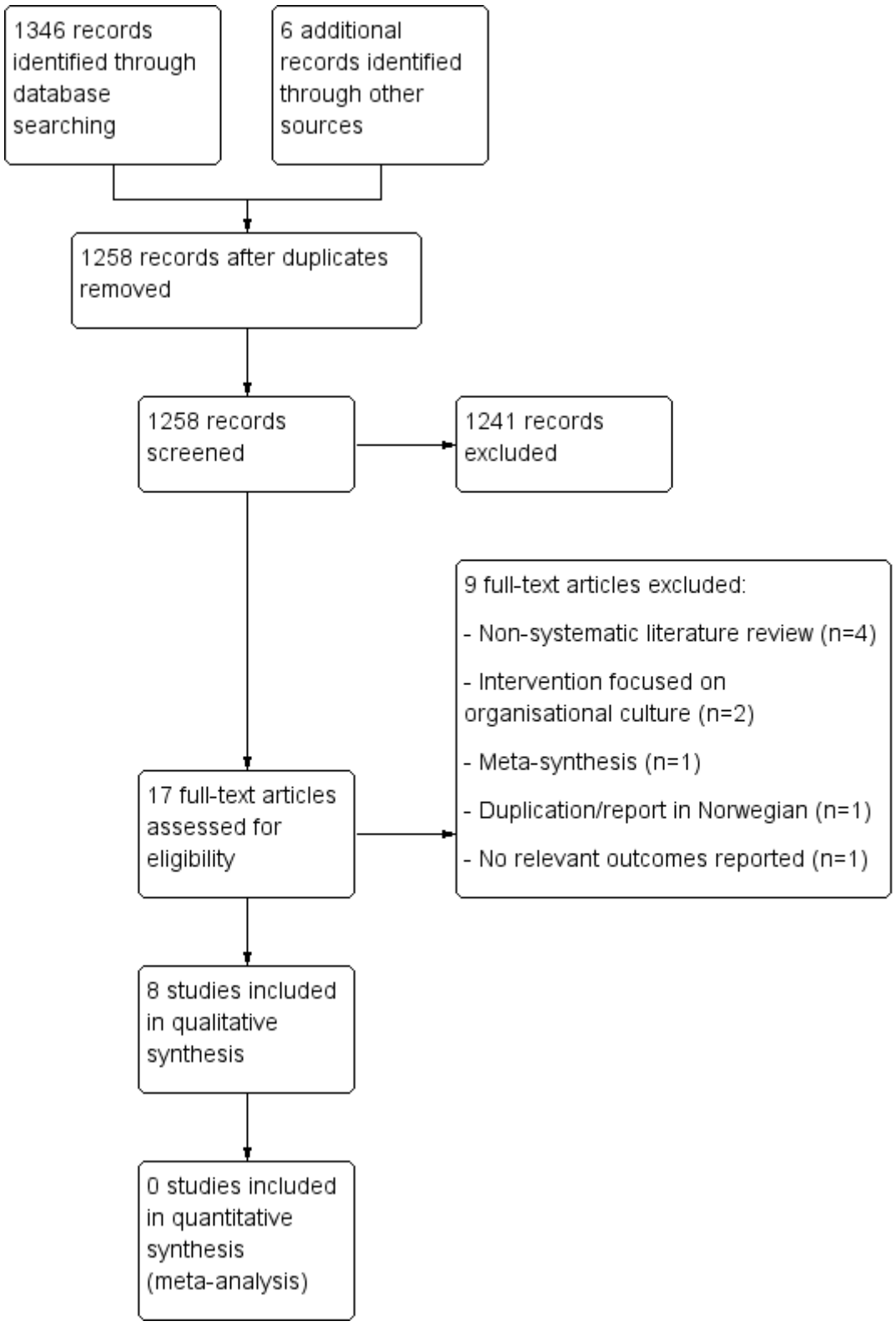


Figure 4.1: PRISMA flow diagram for the overview of systematic reviews

Brubakk et al. (2015)

Brubakk et al (2015) searched seven databases up to 2014, including three reviews (MATRIX knowledge group, 2010, Flodgren et al., 2011, Alkhenizan and Shaw, 2011) and one randomised clinical trial (Salmon et al., 2003) investigating the effect of any type of

accreditation or certification of hospitals on clinical outcomes or measures of process of care. Overall, evidence from 67 individual studies was summarised. In relation to the setting where the research took place, 26 studies sampled hospitals, 14 included other settings (e.g. primary care, psychiatric hospitals, trauma centres), 12 sampled patients within healthcare units, 9 included healthcare professionals, and one sampled healthcare insurance plans. The unit of analysis varied among included studies: 31 analysed information at patient or individual level, 22 at facility level, three at programme level, and one at healthcare insurance plan level. Thirty-three studies were based in the United States, nine in France, four in Australia, three in the United Kingdom, two in Zambia and the remaining sixteen studies were performed in different countries across Asia, Africa, Europe, and North America. In twenty-three of these studies, the accreditation agency was the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), whilst the remaining 25 studies addressed national agencies from Europe, Asia, North America and Africa.

Greenfield et al. (2012)

Greenfield et al. (2012) searched five databases and 36 websites of accreditation agencies up to 2011, including 13 studies looking into empirical research to support the development and implementation of healthcare accreditation standards. This review included research on standards development, implementation issues, and the impact on healthcare organisation of these standards. In consequence, the focus of this review was broader than that of this overview; therefore, four studies were relevant. Two studies sampled acute hospitals, one trauma centres, and one stroke centres. In relation to the level of analysis, all studies used patient-level data. Three studies were based in the United States, and one was based in South Africa. The accrediting agency was JCAHO for two of these studies (Stradling et al., 2007, Thornlow and Merwin, 2009), the Council for Health Service Accreditation of Southern Africa (COHSASA) for one of them (Salmon et al., 2003) and the American College of Surgeons for one study (Piontek et al., 2003).

Flodgren et al. (2011), (2016)

Flodgren et al. (2011) searched 14 databases and four websites of accreditation or quality in healthcare organisations up to 2011. Flodgren et al. (2016) searched eight databases and four websites of accreditation agencies up to June 2015. Both included two studies investigating the effect of external inspection system on organisational change, healthcare professionals behaviour or patient's outcomes (Salmon et al., 2003, OPM evaluation team, 2009). Despite having a broader aim than this overview, no articles were found addressing the effect of external inspection on professionals' behaviour. Both studies sampled acute hospitals, but one of them analysed the data at patient-level (Salmon et al., 2003) and the other at hospital-level

(OPM evaluation team, 2009). One study was based in South Africa, and one in the United Kingdom (UK). The external oversight body was COHSASA (Salmon et al., 2003) or the Healthcare Commission (OPM evaluation team, 2009).

Alkhenizan and Shaw (2011)

Alkhenizan and Shaw (2011) searched four databases up to 2009, including 26 articles assessing the impact of accreditation programmes on the quality of healthcare services. The setting where units were sampled were: 10 studies sampled hospitals, seven included other settings (e.g. substance abuse centres, primary care, laboratories, psychiatric hospitals, trauma centres), eight sampled patients within healthcare units, and one sampled healthcare insurance plans. Fifteen studies analysed data at patient or individual level, nine at facility-level, one analysed information at programme level and one at healthcare insurance plan level. The majority of studies (n=16) were carried out in the United States; whilst the rest took place in Canada, South Africa, Zambia, Egypt, Japan, Korea, Singapore, Philippines, Denmark, and Australia. For ten studies, the accrediting agency was JCAHO, in the case of seven articles the accrediting body was a professional or scientific organisation, and in nine studies, accreditation was carried out by a national agency.

MATRIX knowledge group (2010)

MATRIX knowledge group (2010) searched seven academic databases and several websites of accreditation agencies in French-speaking countries, including 56 studies. This review had two aims: to review the results and methodologies used to assess the impact of accreditation or certification of hospitals, and to assess the methodological approaches used. The definition of impact considered quantifiable effects or any change that could be attributable to accreditation. Consequently, results from qualitative and quantitative research were combined. MATRIX knowledge group (2010) classified their outcomes in three categories: clinical impact or patient satisfaction; managerial, organisational or cultural change; and change in professional practice. This implies that only a few studies within this review assessed the effect of accreditation or external inspection on the outcomes of interest for this overview. For instance, in the category “organisational change”, some measures reflect organisational performance, but most of them relate to organisational management and processes; therefore, they are not relevant for this piece of work. Fourteen studies reported relevant outcomes. Eleven studies sampled hospitals and three sampled patients. The unit of analysis was at patient-level in nine studies and facility-level in five studies. Nine studies were based in the United States, and one in South Africa, Zambia, and Australia. One study used information from six countries in Europe (Suñol et al., 2009). The accrediting agency was JCAHO for seven

articles, a professional organisation for two studies, and a national accreditation agency for five studies.

Greenfield and Braithwaite (2008)

Greenfield and Braithwaite (2008) searched six databases and 22 websites of accreditation or healthcare quality organisations, including 66 studies researching into accreditation and the accreditation process. The aim of this review was ill-defined, considering a broad spectrum of research into any aspect related to accreditation. Outcomes were also loosely defined. The results were organised in ten topic areas. Two of these areas were of interest for this overview: organisational change and quality measures. Twenty-three studies fell under these categories. The sampling frame comprised hospitals in fourteen studies, patients or individuals in five studies, and other setting in four studies (e.g. trauma centres, psychiatric hospitals). The unit of analysis was individual or patient-level in ten studies, facility-level for nine studies, programme-level in three studies, and healthcare insurance plan level in one study (Beaulieu et al., 2002). Sixteen studies were carried out in the United States, three in Australia, and one in South Africa, France, Canada, and Italy. The accrediting agency was JCAHO for eight references, a professional organisation for three studies, and a national accreditation agency for four studies. Only five studies included had relevant comparisons for this overview: Salmon et al (2003), Williams et al (2005), Barker et al (2002), Simons et al (2002), and Chen et al (2003).

Sutherland and Leatherman (2006)

Sutherland and Leatherman (2006) searched seven databases and several websites of policy think-tanks and patients' organisations, including 56 studies investigating the impact of interventions to improve performance and quality of care. Since the scope of this review was broader than the aim of this overview, only the evidence about external oversight interventions (i.e. accreditation or external inspection) is included. Sixteen studies explored the impact of external oversight schemes on performance. The sampling frame comprised hospitals in ten studies, patients in two articles, psychiatric hospitals in two studies, trauma centres in one article, and healthcare insurance plans in one reference. Only twelve studies analysed quantitative data: seven analysed the data at facility-level, four at patient-level, and one at healthcare insurance plan level. JCAHO was the accrediting agency in eight articles, professional organisations in three studies, and a national accreditation agency in one study. Only five studies included in this review of literature had relevant comparisons for the aim of this overview: Salmon et al (2003), Piontek et al (2003), Barker et al (2002), Simons et al (2002), and Chen et al (2003).

Table 4.1 Characteristics of included systematic reviews

Title	Author (year)	Aim declared	Study designs included	Databases (start-end date included)
A systematic review of hospital accreditation: the challenges of measuring complex intervention effects	Brubakk et al. (2015)	To systematically assess the effects of accreditation and/or certification of hospitals on both organisational processes and outcomes.	Systematic reviews Randomised controlled trials (RCT) Non-randomised controlled trials Controlled before and after studies Interrupted time series studies	Searches performed in 2006, 2009, 2013 and 2014. Last search performed in July 2014. • MEDLINE (from 1948) • EMBASE (from 1980) • Centre for Review and Dissemination (CRD) • Cochrane Database of Systematic Reviews (CDSR) • Database of Abstracts of Reviews of Effects (DARE) • Health Technology Assessment Database (HTA) • Google
The standard of healthcare accreditation standards: a review of empirical research underpinning their development and impact	Greenfield et al. (2012)	To identify and analyse the research literature in the following topics: -The rationale for standard development methodologies in use. -Research demonstrating how standards should be structured in order to be understandable, assessable and reliable. -Research into implementation in everyday practice of standards. -Impact on the practice of standards.	Peer-reviewed, empirical research	The last search was performed in August 2011 • MEDLINE (from 1980) • PsycINFO (from 1980) • EMBASE (from 1980) • Social work databases (from 1980) • CINAHL (from 1982) • Websites of 31 healthcare accreditation agencies worldwide and websites of 5 standards organisations from different countries.

Title	Author (year)	Aim declared	Study designs included	Databases (start-end date included)
Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes (Cochrane Review)	Flodgren et al. (2011, 2016)	To evaluate the effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour and patient outcomes.	Randomised controlled trials (RCT) Non-randomised controlled trials Controlled before and after studies Interrupted time series studies	The last search was performed in May 2011 • Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Library 2011 Issue 1, May 2011* • Cochrane Database of Systematic Reviews (CDSR) • Cochrane Library 2010 Issue 2, May 2011 • Database of Abstracts of Reviews of Effectiveness (DARE)* • Cochrane Library 2010 Issue 2, May 2011 • MEDLINE, Ovid (from 1950)* • EMBASE, Ovid (from 1980)* • CINAHL, EBSCO (from 1980) • Science Citation Index, Web of Knowledge (from 1970) • Social Science Citation Index, Web of Knowledge (from 1970) • ISI Conference Proceedings, Web of Knowledge (from 1970) • PsycINFO, Ovid (from 1806) • HMIC, Ovid (from 1983)* • Intute (www.intute.ac.uk) (searched May 2011) • Electronic Theses Online • Clinicaltrials.gov[#] • World Health Organization International Clinical Trials Registry Platform[#] • Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (http://www.jointcommission.org/)* • Accreditation Canada (www.accrediation.ca) * • ACHSI-Australian Council for Healthcare Standards International (www.achs.org.au/ACHSI) * • ISQua International Society for Quality in Health Care (www.isquaresearch.com) * • PDQ-evidence[#]

Title	Author (year)	Aim declared	Study designs included	Databases (start-end date included)
Impact of accreditation on the quality of healthcare services: a systematic review of the literature	Alkhenizan and Shaw (2011)	To evaluate the impact of accreditation programmes on the quality of healthcare services	Clinical trials Observational studies Qualitative studies	The last search was performed in June 2009 • MEDLINE (from 1996) • EMBASE (from 1980) • CINAHL (from 1982) • HealthStar (from 1980)
Literature review on the impact of hospital accreditation	MATRIX knowledge group (2010)	- To produce a general overview of the results obtained and methodologies used to assess the impact of certification of hospitals - To assess the methodological approaches of the studies reviewed	Empirical data about existing certification/ accreditation programme	The last search was performed in August 2010 • MEDLINE • EMBASE • CINAHL • HMIC • British Nursing Index (BNI) • Pascal • Banque de Données en Santé Publique • Websites for national (French) and International accreditation agencies

Title	Author (year)	Aim declared	Study designs included	Databases (start-end date included)
Health sector accreditation research: a systematic review	Greenfield and Braithwaite (2008)	To identify and analyse the research literature on accreditation.	Empirical work examining accreditation or accreditation process	The last search was performed in May 2007 • MEDLINE (from 1950) • EMBASE (from 1980) • CINAHL (from 1982) • 22 national agencies and ISQua (Irish Health Services Accreditation Board (IHSAB), the United Kingdom CHKS, Australian Council on Healthcare Standards (ACHS), Australian General Practice Accreditation Limited (AGPAL), Haute Autorité de santé (HAS), Italian Society for Quality of Health Care, JCAHO, Canadian Council on Health Services Accreditation (CCHSA) and the Spanish accreditation organization Fundación Avedis Donabedian (FAD)). • Web-of-science • Google Scholar • Scirus
Regulation and quality improvement: a review of the evidence	Sutherland and Leatherman (2006)	To assemble available evidence on the impact of interventions designed to improve performance and quality of care.	Randomised controlled trials (RCT) Quasi-experimental studies Case-controlled studies Cross-over studies Cohort studies Before and after studies Multi-site case studies Statistical studies such as multivariate analyses	Date of the last search not declared • MEDLINE • Cochrane Database of Systematic Reviews • Database of Reviews of Effects (DARE) • King's Fund Library • Agency for Healthcare Research and Quality (AHRQ) • World Health Organization (WHO) • Organization for Economic Cooperation and Development (OECD) • Websites of policy think tanks and patient organisations

*Databases also searched up to June 2015 in Flodgren et al. (2016). # Databases searched up to June 2015 only in Flodgren et al. (2016)

Table 4.2 Components of the question being addressed by each systematic review included

Author (year)	Population	Intervention	Comparison	Outcomes	Instrument for assessment of quality or risk of bias	Authors' conclusions	Studies included
Brubakk et al. (2015)	All types of hospitals	All types of accreditation or certification of hospitals	Any hospital not being accredited or certified, because of failure to comply or to apply for accreditation.	• Clinical and processes outcomes	AMSTAR tool Cochrane risk of bias assessment tool	Due to lack of methodologically strong evidence was not possible to conclude which strategies are effective	3 Systematic reviews 1 RCT
Greenfield et al. (2012)	Not declared	Accreditation standards for healthcare providers	Not declared	• Standard development • Implementation issues • Impact of standards	Australian National health and medical research council guidelines for level of evidence Checklist adapted from Cunningham et al. (2011)	The evidence on the impact of accreditation standards on healthcare organisations' and staff behaviour, and clinical outcomes is equivocal and highly influenced by circumstances.	Impact of standards 1 RCT 1 Interrupted time-series 1 time-series study 1 Cross-sectional analytical

Author (year)	Population	Intervention	Comparison	Outcomes	Instrument for assessment of quality or risk of bias	Authors' conclusions	Studies included
Flodgren et al. (2011, 2016)	Hospitals, primary healthcare organisations or other community-based healthcare organisations containing health professionals	External inspection against external standards in a healthcare setting compared with no inspection or with another form of inspection (e.g. against internally-derived standards)	No external inspection or another form of inspection (e.g. internal audit)	• Healthcare organisational change (e.g. organisational performance, waiting list times, inpatient hospital stay time) • Healthcare professional behaviour (e.g. referral rate, prescribing rate) • Patients' outcome (e.g. mortality and condition-specific measures of outcome related to patients' health) Other outcomes • Patient's satisfaction and patient involvement • Unanticipated or adverse consequences • Economic outcomes	Cochrane risk of bias assessment tool. GRADE system.	The scale, content and generalisability of the evidence found is limited. It is difficult to generate conclusions about the effectiveness of external inspection beyond the effect reported by the two studies included in this review.	1 RCT 1 ITS
Alkhenizan and Shaw (2011)	Health services	General or subspecialties accreditation programmes	Not declared	• Quality of the health service	US preventive services task force quality assessment	Evidence consistently shows that general accreditation programmes improve processes of care given by health services. For a wide variety of health conditions, accreditation programmes improved clinical outcomes.	1 RCT 1 Time series 1 Prospective cohort 3 Retrospective cohorts 4 Before and after studies 9 Cross-sectional analytical 6 Cross-sectional studies 1 Descriptive study

Author (year)	Population	Intervention	Comparison	Outcomes	Instrument for assessment of quality or risk of bias	Authors' conclusions	Studies included
Matrix Knowledge Group (2010)	Hospitals and health services	Accreditation or certification against external standards by an independent organisation	Comparison before and after accreditation/ certification, or between accredited/certified and non-accredited/ uncertified hospitals	• Clinical impact • Organisational change • Change in professional practice • Patient satisfaction	Critical appraisal	Most studies suggest a positive effect of accreditation programmes on organisational and professional performance, but the impact on health outcomes has not been proved yet.	1 RCT 3 Time series studies 2 Prospective cohorts 2 Retrospective cohorts 23 Cross-sectional analytical 8 Cross-sectional studies 3 Before and after studies 3 Descriptive studies 7 Qualitative studies 1 Book
Greenfield and Braithwaite (2008)	Not declared	Accreditation of healthcare institutions	Not declared	• Professions' attitudes to accreditation. • promote change. • Organisational impact. • Financial impact. • Quality measures. • Program assessment. • Consumer views or patient satisfaction. • Public disclosure. • Professional development. • Surveyor issues.	None	This literature review shows a complex picture about the accreditation of healthcare institutions. The findings are inconsistent and the views mixed. The impact of accreditation on quality measures was inconsistent and the methodological rigour variable.	1 RCT 1 Prospective Cohort 1 Retrospective Cohort 2 Before and after study with control 8 Cross-sectional analytical 5 Cross-sectional studies 1 Time-series 4 Descriptive studies

Author (year)	Population	Intervention	Comparison	Outcomes	Instrument for assessment of quality or risk of bias	Authors' conclusions	Studies included
Sutherland and Leatherman (2006)	Healthcare systems	Regulatory interventions (i.e. target setting, standard setting, professional regulation, market regulation, accreditation and external inspection)	Not declared	• Performance and quality of care.	None	Evaluations of accreditation programmes have focused on participants' perception of the potential benefits, instead of objectively measure the effect on processes of care and clinical outcomes.There is some evidence that external inspection promotes a transient improvement in performance. The inspection usually describes problems already identified by managers, helping to focus attention on potential solutions.	1 RCT 1 Interrupted time-series 1 Prospective Cohort 5 Cross-sectional analytical 4 Cross-sectional studies 1 Qualitative study 3 Multi-methods studies.

4.1.5.2 Methodological quality of included reviews

4.1.5.2.1 Quality of included reviews

AMSTAR scores for each review included are presented in Table 4.3. Only one review scored 10 out of 11 points in the AMSTAR tool, being considered of high (score 8 to 11) methodological quality (Flodgren et al., 2011, 2016). Two reviews were deemed of moderate (score 5 to 7) quality (Brubakk et al., 2015, Greenfield et al., 2012), whilst the other four reviews (Greenfield and Braithwaite, 2008, MATRIX knowledge group, 2010, Sutherland and Leatherman, 2006, Alkhenizan and Shaw, 2011) were judged of low quality (score below 5).

4.1.5.2.2 Quality of evidence in included reviews

Brubakk et al. (2015) report that one study was of high quality (Flodgren et al., 2011), two included reviews were of moderate quality (Alkhenizan and Shaw, 2011, MATRIX knowledge group, 2010), whilst the risk of bias of the primary study was unclear (Salmon et al., 2003). Overall, the quality of the evidence was moderate.

Greenfield et al. (2012) included four studies relevant for this overview with moderate overall quality. They provided an overall measure of quality. The RCT (Salmon et al., 2003), the ITS (Piontek et al., 2003) and the time-series study (Stradling et al., 2007) were deemed of moderate quality, whilst the cross-sectional study (Thornlow and Merwin, 2009) of high quality (i.e. all the quality criteria fulfilled).

Flodgren et al. (2011, 2016) found that the RCT (Salmon et al., 2003) and the ITS (OPM evaluation team, 2009) provided very low quality of evidence since the uncertainty about the estimates is very high.

Alkhenizan et al. (2011) included nine studies with relevant comparisons with fair quality of evidence. The RCT (Salmon et al., 2003) and one retrospective cohort (Ross et al., 2008) were deemed of fair quality, whilst quality was good for the prospective cohort (Barker et al., 2002) and two retrospective cohorts (Duckett, 1983, Pasquale et al., 2001). The quality of the evidence was considered good for two cross-sectional studies (Chandra et al., 2009, Simons et al., 2002), and fair for two articles (Chen et al., 2003, Sekimoto et al., 2008).

MATRIX knowledge group (2010) included fourteen studies relevant for this overview of moderate quality. Since this review did not use a standardised tool to assess quality, the judgements here given are an interpretation of critical appraisal performed by the authors. The RCT (Salmon et al., 2003), both retrospective cohorts (Duckett, 1983, Ross et al., 2008) and six cross-sectional studies (Landon et al., 2006, Longo et al., 2007, Sekimoto et al., 2008, Chandra et al., 2009, Lutfiyya et al., 2009, Suñol et al., 2009) were judged of moderate quality.

The two time-series studies (Stradling et al., 2007, Weeks et al., 2007) and one prospective cohort (Quality assurance project, 2005) were considered of poor quality. One prospective cohort (Barker et al., 2002) and one cross-sectional study (Casey et al., 2005) were deemed of good quality.

The reviews by Greenfield and Braithwaite (2008), and Sutherland and Leatherman (2006) did not use a standardised tool to assess the quality of evidence. Additionally, the description provided does not make judgements about the methodological rigour of the studies; therefore, it is not possible to establish the quality of the evidence included.

Table 4.3 Assessment of quality of included systematic reviews using the AMSTAR tool

	Brubakk et al. (2015)	Greenfield et al. (2012)	Flodgren et al. (2011, 2016)	Alkhenizan and Shaw (2011)	Matrix Knowledge Group (2010)	Greenfield and Braithwaite (2008)	Sutherland and Leatherman (2006)
1. Was an 'a-priori' design provided?	Can't answer	Can't answer	Yes	Can't answer	Can't answer	Can't answer	Can't answer
2. Was there duplicate study selection and data extraction?	Yes	Yes	Yes	No	Can't answer	Yes	Can't answer
3. Was a comprehensive literature search performed?	Yes	No, controlled language and search strategies are not provided	Yes	No, controlled language and search strategies are not provided	Yes	No, controlled language and search strategies are not provided	Yes
4. Was status of publication (e.g. grey literature) used as an inclusion criterion?	No	Yes	Yes	No	Yes	Yes	Yes
5. Was a list of studies (included/excluded) provided?	Yes	No	Yes	No	No	No	No
6. Were the characteristics of included studies provided?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Was the scientific quality of the included studies assessed and reported?	Yes	Yes	Yes	Yes	No	No	No
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	Yes	Yes	Yes	No	No	No	No
9. Were the methods used to combine the findings of studies appropriate?	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
10. Was the likelihood of publication bias assessed?	No	No	Yes	No	No	No	No
11. Was the conflict of interest stated?	Yes	Yes	Yes	No	No	Yes	No
AMSTAR SCORE	7/11	6/11	10/11	2/11	3/11	4/11	3/11

4.1.5.3 Effects of interventions

Table 4.4 displays outcome measures used by each individual study categorised by review. The classification of included studies per comparison category is available in the Appendix Chapter 4, Table 4.1. The cross-tabulation of primary studies and the review that included them is available in Appendix Chapter 4, Table 4.2. The summary of the numerical results for each study included is available in Appendix Chapter 4, Table 4.6.

4.1.5.3.1 Accredited compared to non-accredited institutions

Measures of disease-specific organisational performance

Accreditation had mixed effects on disease-specific organisational performance measures, improving 26/53 outcomes from six studies (Weeks et al., 2007, Ross et al., 2008, Chen et al, 2003, Chandra et al., 2009, Lutfiyya et al., 2009, Landon et al., 2006) reported in four reviews. None of them was a randomised controlled trial. The effect on measures of quality of care for Acute Myocardial Infarction (AMI) was mixed, generally ineffective on measures of quality of care for Pneumonia and had mixed effects for Heart Failure (HF). There was no effect on measures of prevention of surgical infection. Accreditation was generally effective in improving composite measures of treatment and diagnosis, and counselling and prevention.

Measures of generic hospital-level organisational performance

The intervention had mixed effect on hospital-level organisational performance measures, improving 23/46 outcomes from eight studies (Salmon et al., 2003, Casey et al., 2005, Sekimoto et al., 2008, Duckett, 1983, Suñol et al., 2009, Barker et al., 2002, Longo et al., 2007, Quality Assurance Project, 2005) reported in seven reviews. Only one study was an RCT (Salmon et al., 2003).

Measures of patients' outcomes

Accreditation was generally effective in improving patients' outcomes with 21/28 outcomes favouring the intervention from six studies (Pasquale et al., 2001, Simons et al., 2002, Chen et al., 2003, Quality assurance project, 2005, Chandra et al., 2009, Weeks et al., 2007) reported in four reviews (Alkhenizan and Shaw, 2011, Greenfield and Braithwaite, 2008, MATRIX knowledge group, 2010, Sutherland and Leatherman, 2006). None of these were an RCT. The intervention was generally effective on surgical mortality and survival from trauma injuries. Accreditation was generally ineffective in improving AMI outcomes, whilst it was generally effective in reducing all-cause in-hospital mortality.

4.1.5.3.2 Low performance compared to high performance

When comparing high-performing to low-performing institutions in Hospital Compare measures, 16/17 outcomes showed a higher rate of improvement in low-performing hospitals at baseline. High performance at baseline had no effect on inpatient AMI mortality

4.1.5.3.3 Performance before and after accreditation

Accreditation was generally effective in improving performance measures for stroke care. The intervention had mixed effects on hospital-level organisational performance, whereas accreditation was generally ineffective on patient's outcomes. There was no effect on complications or readmissions to the hospitals within 31 days, whilst mortality was reduced after accreditation.

4.1.5.3.4 Association between quality measures and clinical outcomes

The implementation of safety practices assessed by the accreditation survey had a mixed effect on measures of hospital-level performance with 2/4 outcomes favouring those organisations with better implementation of safety practices.

4.1.5.3.5 Effectiveness of external oversight by study design.

Measures of organisational performance

Evidence from an RCT showed that accreditation was generally ineffective (2/9 outcomes favouring intervention). The results from quasi-experimental designs suggest that external oversight is generally ineffective (10/43 outcomes favouring intervention); while the findings from observational studies suggest the intervention has mixed effects (43/75 outcomes favouring intervention) (Table 4.5).

Measures of patients' outcomes

Evidence from quasi-experimental designs suggest that external oversight is generally effective (13/18 outcomes favouring intervention); while the findings from observational studies suggest the intervention has mixed effects (9/14 outcomes favouring intervention) (Table 4.5).

4.1.5.3.6 Effectiveness of accreditation by Joint Commission on Accreditation of Healthcare Organisations (JCAHO).

Measures of organisational performance

Evidence from included studies showed that accreditation was generally ineffective (20/64 outcomes favouring intervention) on improving organisational performance (Table 4.5).

Measures of patients' outcomes

The findings suggest that JCAHO accreditation was generally effective (13/16 outcomes favouring intervention) on improving patients' outcomes (Table 4.5).

4.1.5.3.7 Effectiveness of accreditation by professional associations.

Five studies explored the effect of accreditation by professional Societies. For Simons et al. (2002), this institution was the Trauma Association of Canada. The accrediting body for Chandra et al. (2009) and Ross et al. (2008) was the Society of Chest Pain Centres (SCPC), and for Pasquale et al. (2001) and Piontek et al. (2003) was the American College of Surgeons (ACS).

Measures of organisational performance

The studies measuring the effect of SCPC accreditation focused on indicators of care quality for AMI. Chandra et al. (2009) found that 2/5 outcomes favoured the intervention. In the case of Ross et al. (2008), 8/8 measures favoured the accreditation group. There was consistent evidence that accreditation improved administration of Aspirin and Beta-Blockers at arrival and discharge from hospital.

One study assessing the effect of ACS accreditation reported the impact on measures of organisational performance (Piontek et al., 2003). It found that length of stay and overall costs were reduced after accreditation compared to another non-accredited centre.

Measures of patients' outcomes

ACS and Trauma Association of Canada accreditation seems to improve mortality rates. Simons et al. (2002) found lower than expected mortality rates; whilst Pasquale et al. (2001) found better survival for 6/9 trauma injuries after accreditation. In the case of Piontek et al. (2003), a lower mortality rate was also found. However, no effect was detected on rates of readmission and complications.

SCPC accreditation does not seem to influence patients' outcomes, since in-hospital deaths and post-admission infarction rates remained similar. However, this evidence comes from one study (Chandra et al., 2009)

Table 4.4 Measures of effect included in each review by type of outcome

	Disease-specific organisational performance	Hospital-level organisational performance	Patients' outcomes
Brubakk et al. (2015)		Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003)	
Greenfield et al. (2012)	3 measures of hospital performance for stroke (Stradling et al., 2007)	Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003) 4 measures of patient safety performance (Thornlow and Merwin, 2009) 5 measures of hospital performance (Piontek et al., 2003)	Mortality (Piontek et al., 2003) Readmission within 30 days (Piontek et al., 2003) Complications (Piontek et al., 2003)
Flodgren et al. (2011)		Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003) MRSA infection rates (OPM report, 2009)	
Alkhenizan and Shaw (2011)	8 measures from Hospital Compare database assessing care for AMI (Ross et al., 2008) 3 measures from hospital compare database assessing care for AMI (Chen et al., 2003) 2 measures from hospital compare assessing care for AMI (Chandra et al., 2009) 3 measures related to care of AMI (Chandra et al., 2009)	Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003) Medication errors (Barker et al., 2002) 6 indicators of hospitals' performance (Duckett, 1983) 13 measures of implementation of infection control programmes (Sekimoto et al., 2008)	Survival for 9 types of trauma injuries (Pasquale et al., 2001) Observed mortality compared to predicted mortality (Simons et al., 2002) Risk-standardised 30-day AMI mortality (Chen et al., 2003) In-hospital AMI mortality (Chandra et al., 2009) Post-admission infarction (Chandra et al., 2009)

	Disease-specific organisational performance	Hospital-level organisational performance	Patients' outcomes
Matrix Knowledge Group (2010)	17 measures from Hospital compare database assessing care for AMI, HF and Pneumonia (Weeks et al., 2007) Opportunity score for AMI, HF and Pneumonia indicators from Hospital Compare database (Landon et al., 2006) 2 composite measures common to AMI, HF, and Pneumonia (Landon et al., 2006) 2 measures from hospital compare assessing care for AMI (Chandra et al., 2009) 3 measures related to care of AMI (Chandra et al., 2009) 16 measures from Hospital Compare database assessing AMI, HF, Pneumonia and surgical infection prevention (Lutfiyya et al., 2009) 8 measures from Hospital Compare database assessing care for AMI (Ross et al., 2008) 3 measures of hospital performance for stroke (Stradling et al., 2007)	Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003) Pharmacists full-time equivalents (Casey et al., 2005) 4 medication safety practices (Casey et al., 2005) 13 measures of implementation of infection control programmes (Sekimoto et al., 2008) 6 indicators of hospitals' performance (Duckett, 1983) Clinical, Safety, Patient-centeredness, and Cross-border patient-centeredness intermediate outputs (Suñol et al., 2009) Medication errors (Barker et al., 2002) 7 measures of hospital performance (Quality Assurance Project, 2005) Composite measure of implementation of 7 patient-safety systems (Longo et al., 2007)	Mortality for 14 surgical conditions (Weeks et al., 2007) In-hospital mortality within two days of admission (Quality Assurance Project, 2005) In-hospital AMI mortality (Chandra et al., 2009) Post-admission infarction (Chandra et al., 2009)
Greenfield and Braithwaite (2008)	17 measures from Hospital Compare database assessing care for AMI, HF, Pneumonia (Williams et al., 2005) 3 measures from hospital compare database assessing care for AMI (Chen et al., 2003)	Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003) Medication errors (Barker et al., 2002)	Observed mortality compared to predicted (Simons et al., 2002) Risk-standardised 30-day AMI mortality (Chen et al., 2003) In-patient AMI mortality (Williams et al., 2005)

	Disease-specific organisational performance	Hospital-level organisational performance	Patients' outcomes
Sutherland and Leatherman (2006)	3 measures from hospital compare database assessing care for AMI (Chen et al., 2003)	Overall compliance with accreditation standards (Salmon et al., 2003) 8 measures of quality of care (Salmon et al., 2003) Medication errors (Barker et al., 2002) 5 measures of hospital performance (Piontek et al., 2003)	Observed mortality compared to predicted (Simons et al., 2002) Mortality (Piontek et al., 2003) Readmission within 30 days (Piontek et al., 2003) Complications (Piontek et al., 2003) Risk-standardised 30-day AMI mortality (Chen et al., 2003)

Abbreviations. AMI: Acute Myocardial Infarction; HF: Heart Failure; MRSA: Methicillin-Resistant Staphylococcus Aureus

Table 4.5 Summary of results by study design.

Studies	Sample	Quality measures	Results
RCT			
Salmon et al (2003)	18 hospitals	Overall compliance with standards 8 measures of quality of care	1 Positive effect 1 Positive effect 7 No effect
Overall result			2/9 (22%) favouring intervention
Quasi-experimental			
Piontek et al (2003)	7811 patients	5 measures of hospital performance 3 clinical outcomes	2 Positive effect 3 Negative effect 1 Positive effect 2 No effect
OPM report (2009)	168 trusts	MRSA infection rates	1 No effect
Weeks et al (2007)§	3446 hospitals	17 measures of hospital performance Mortality for 14 surgical conditions	5 Positive effect 12 No effect 12 Positive effect 2 No effect
Williams et al (2005)§	3087 hospitals	17 measures of hospital performance Inpatient AMI mortality	16 Negative effect 1 No effect 1 No effect
Stradling et al (2007)§	1161 patients	3 measures of hospital performance	3 Positive effect
Overall result			23/61 (38%) favouring intervention
Observational studies			
Barker et al (2002)§	36 hospitals	Medication errors	1 No effect
Quality assurance project (2005)	8 hospitals	7 measures of hospital performance In-hospital mortality < 48hrs	2 Positive effect 5 No effect 1 Positive effect
Ross et al (2008)	4197 hospitals	8 measures of hospital performance	8 positive effect
Pasquale et al (2001)	24 trauma centres	Survival for 9 trauma injuries	6 Positive effect 3 No effect
Chen et al (2003)§	134579 patients	3 measures of hospital performance Risk-adjusted 30-day AMI mortality	3 Positive effect 1 Positive effect
Chandra et al (2009)	33238 patients	5 measures of hospital performance In-hospital AMI mortality Post-admission infarction	2 Positive effect 3 No effect 1 No effect 1 No effect

Studies	Sample	Quality measures	Results
Landon et al (2006)	4059 hospitals	3 opportunity score measures 2 Cross-cutting performance measures	3 Positive effect 2 Positive effect
Lutfiyya et al (2009)§	218290 patients	16 measures of hospital performance	4 Positive effect 12 Negative effect
Sekimoto et al (2008)	460 hospitals	13 measures of implementation of infection control programmes	6 Positive effect 5 No effect 2 Negative effect
Simons et al (2002)	3 trauma centres	Observed vs predicted mortality	1 Positive effect
Longo et al (2007)§	107 hospitals	Composite measure of 7 safety practices	1 Positive effect
Suñol et al (2009)	389 hospitals	4 Intermediate outputs for patient-centeredness	2 Positive effect 2 No effect
Casey et al (2005)§	387 hospitals	2 measures of safe dispensing of drugs	2 Positive effect
Thornlow and Merwin (2009)§	115 hospitals	4 measures of patient safety	2 Positive effect 2 No effect
Duckett (1983)	23 hospitals	6 measures of hospital performance	6 Positive effect
Overall result			52/89 (58%) favouring intervention

§ Studies where intervention was a JCAHO accreditation visit.

4.1.5.3.8 Overall effectiveness across intervention categories

When the effect of accreditation is assessed across outcomes categories (Table 4.6), it had mixed effects on disease-specific organisational performance with 29/73 outcomes favouring the intervention (eight studies in five reviews). In the case of hospital-level organisational performance, the effect was mixed with 28/56 outcomes favouring accreditation (eleven studies in seven reviews). In terms of the effect on patients' outcomes, the intervention was generally effective with 22/32 outcomes improving (eight studies in five reviews). Overall, the effect of accreditation across outcomes and intervention categories was mixed with 79/161 outcomes showing improvement. The summary of the negative effects of accreditation are available in the Appendix Chapter 4, Table 4.7.

Table 4.6 Summary of outcome measures favouring the intervention by type of measure and interventions being compared

	Disease-specific organisational performance	Hospital-level organisational performance	Patients' outcomes	Overall effect within intervention
Accredited versus non-accredited institutions	27/54 outcomes from six studies included in four reviews	21/43 outcomes from eight studies included in seven reviews	21/28 outcomes from six studies included in four reviews	69/125 (55%) 16 studies 7 reviews
High versus low performance in accreditation	0/17 outcomes from one study included in one review		0/1 outcomes from one study included in one review	0/18 (0%) 1 study 1 review
Before and after accreditation	3/3 outcomes from one study included in two reviews	3/6 outcomes from two studies included in three reviews	1/3 outcomes from one study included in two reviews	7/12 (58%) 3 studies 4 reviews
Association quality measures and outcomes		2/4 outcomes from one study included in one review		2/4 (50%) 1 study 1 review
Overall effect within outcomes	30/74 (40%) 8 studies 5 reviews	26/53 (49%) 11 studies 7 reviews	22/32 (69%) 8 studies 5 reviews	78/159 (49%) 21 studies 7 reviews

4.1.6 Discussion

Eight reviews were identified examining the effect of external inspection or accreditation on organisational performance or patients' outcomes. These reviews included 88 individual studies, but only 21 of them provided relevant comparisons for this overview. The methodological quality of the reviews was low to high, and the rating of the quality of the evidence from primary studies was low to moderate.

4.1.6.1 Summary of main results

Accreditation showed mixed effects on disease-specific and hospital-level performance, whilst it was generally effective in improving patients' outcomes. Overall, the intervention showed mixed effects when all comparisons and outcome measures were combined. Regarding the negative effects of accreditation or external inspections, overall 5% reported negative effects, whilst 46% reported no effect (see Appendix Chapter 4, Table 4.7). Only one interrupted time-series study (Piontek et al., 2003) reported a high proportion of negative effects (i.e. three of five outcomes) associated with increased hospital spending.

When studies were grouped by study design, the RCT showed the most conservative results, whilst observational studies presented more positive findings. The subgroup analysis including only those studies where JCAHO accreditation was the intervention showed that these are

generally ineffective on improving organisational performance, but they were generally effective on improving patients' outcomes.

ACS and Trauma Association of Canada Accreditation had mixed effects on lowering mortality rates for trauma with 8/13 outcomes favouring the intervention. SCPC accreditation was generally effective in improving organisational performance with 10/13 outcomes favouring the intervention.

4.1.6.2 Overall completeness and applicability of evidence

Despite the number of individual studies identified by the included reviews, only one of them assessed the effect of an external inspection regime on organisational performance (OPM evaluation team, 2009). Most research studies on the subject have focused on the effect of accreditation, mainly by the Joint Commission in the United States or overseas.

The active components of accreditation or the hypothesised theory of change were rarely described; although JCAHO accreditation was the intervention assessed in 48% of the studies.

The categories used to organise the results were created based on the studies included instead of being defined "a priori". They reflect the study designs of the research found and not the intensity of intervention or different types of external oversight.

Likewise, the classification of measures of organisational performance was based on the outcomes reported by the included studies. The main purpose of this classification was to maximise the number of studies within each category and to draw meaningful conclusions about the effect of the intervention. This implied that a myriad of hospital-level performance measures was combined together even when they reflected different aspects of care.

Most outcomes fell under the category of disease-specific measures. These studies were all carried out in the United States, and seven of them used a public database named Hospital Compare that reports performance in several conditions. When it was first set-up, it had 18 measures reflecting the use of standardised processes for Acute Myocardial Infarction, Heart Failure and Pneumonia; which were the main outcomes included in these studies. Therefore, the results for disease-specific performance measures have restricted applicability to other conditions in other settings.

The country of origin of the research included was mainly the United States, Australia, several countries in Europe and two countries in Africa. The applicability of the evidence here presented to developing and low-income countries is very restricted due to the limited amount of published research coming from those settings. Only one study was carried out in England (OPM evaluation team, 2009).

Most research studies were carried out between 2000 and 2010; therefore, the evidence is at least 8 years old. It is not clear to what extent the spread of accreditation as a quality improvement intervention might diminish its effect over time (i.e. diminishing returns).

4.1.6.3 Quality of evidence

The review traded-off only including methodologically rigorous reviews and comprehensively capturing research on the effects of accreditation in healthcare. There were two main consequences: the quality of the included reviews was low to moderate, and individual studies had a high risk of bias due to study design and low-quality review processes.

Differences in study design and outcome measures negated combining the results quantitatively. Instead, a vote counting method was used to determine the direction of the effect; therefore, there is a high level of uncertainty around the estimates. Vote counting is not a reliable method because it does not account for the relative weight of each study and only considers the number of studies with positive and negative results. In addition, when a study shows no effect, it is not possible to determine if there is no effect or the study was underpowered for that measure. In the case of this overview, only two studies (Salmon et al., 2003, Quality assurance project, 2005) finding accreditation generally ineffective were potentially underpowered. Despite the limitations of vote counting, this method was used as a last resort to condense a large body of literature. The true effect of external oversight remains unknown.

In the case of patients' outcomes, 23 measures were retrieved from two studies looking into mortality of surgical procedures (Weeks et al., 2007) and mortality of patients with traumatic injuries (Pasquale et al., 2001). If only these two studies are combined, 78% of outcomes favoured the intervention. If these results were removed, the effect of accreditation changes from generally effective to mixed effects.

In the case of disease-specific indicators, seven studies used outcome measures from the Hospital Compare database with 37 indicators reflecting processes of care for AMI. If the results for these indicators are removed, only 27% of measures of effect favoured the intervention, which makes it generally ineffective. There were two measures showing consistent positive results: receiving aspirin and beta-blockers within 24 hours after admission. These indicators reflect processes of care that do not involve complex decision-making, which suggest that accreditation might be encouraging a tick-box culture to improve the quality of care.

4.1.6.4 Potential biases in the overview process

The processes of screening, quality assessment and summarising of results have been performed by one assessor, which reduces the reliability of the results.

Additionally, only 25% of all the studies included in the reviews addressed the effect of accreditation on organisational performance or health outcomes, making subject to questioning the process of selection of reviews and individual studies to be summarised.

4.1.6.5 Agreements and disagreements with other studies or reviews

To the best of my knowledge, there is no other overview of reviews addressing the effect of accreditation or external inspection on organisational performance and health outcomes. Individual reviews' discussions and conclusions support the findings of this overview.

4.2 Update of systematic review

When the first version of the overview was finished in 2015, the most rigorous systematic review identified was four years old, and at least one new publication eligible was identified (Devkaran and O'Farrell, 2015). Therefore, it was deemed worthwhile to update the review by Flodgren et al. (2011) to have a more recent knowledge base for methodological decision-making. In 2016, Flodgren et al. published an update of their review; however, their results remained the same. This section was updated again in February 2018 combining the search strategy of Flodgren et al. (2011) and Flodgren et al. (2016).

4.2.1 Methods

4.2.1.1 Criteria for considering studies for this review

The systematic review with the highest quality was updated. For this purpose, randomised controlled trials (RCTs), non-randomised controlled trials, controlled before-after studies (CBA) and interrupted-time-series studies (ITS) were included. In the case of ITS, at least three time points before and after the intervention should be reported to include the article.

The criteria for type of participant, intervention, and outcomes are the same than the ones used for the overview of systematic reviews.

4.2.1.2 Search methods for identification of studies

The search strategy used by Flodgren et al. (2016) was updated for the databases searched in that systematic review to find other relevant primary research.

This review was chosen because of its rigorous methods and quality was the highest.

4.2.1.3 Electronic searches

To identify other primary studies, the following databases were searched from 2011 to February 2018:

- CENTRAL and Cochrane Database of Systematic Reviews Issue 2, February 2018
- Database of Abstracts of Reviews of Effectiveness (DARE)
- MEDLINE, Ovid
- EMBASE, Ovid
- CINAHL, EBSCO
- Science Citation Index, Web of Knowledge
- Social Science Citation Index, Web of Knowledge
- ISI Conference Proceedings, Web of Knowledge
- PsycINFO, Ovid
- The Healthcare Management Information Consortium (HMIC), Ovid
- Electronic Theses Online

4.2.1.4 Data collection and analysis

The strategy for selection of studies and data extraction was the same than the one used for the overview of systematic reviews.

4.2.1.4.1 Assessment of quality of individual studies

In the case of new primary research, the criteria suggested by the Effective Practice and Organisation of Care (EPOC) Cochrane group was used for randomised controlled trials, controlled before-and-after studies, and interrupted time series studies. For controlled studies, this tool considers sequence generation, concealed allocation, similar baseline characteristics, management of missing data, blinding of primary outcome assessor, prevention of contamination, selective reporting of outcome, and other potential biases. For ITS, it is also assessed that intervention effect is independent of other changes, intervention effect shape is pre-specified, and data collection is independent of the intervention.

4.2.1.4.2 Analysis plan

Research studies identified were heterogeneous, thus a structured synthesis was planned. The GRADE tool was used to generate conclusions based on the available research. Information regarding population, intervention, comparison, outcomes measured, setting, study design and risk of bias assessment are presented in tables. Results are presented as medians (range) for ordinal variables, means ± standard deviations for continuous or discrete data, proportions (95% CI) for categorical outcomes and pre-post slope differences for ITS. For graphical information, PlotDigitizer (http://plotdigitizer.sourceforge.net/) was used to extract data.

4.2.2 Results

4.2.2.1 Results of the search

The PRISMA flowchart detailing the screening and reviewing process is in Figure 4.2. Using the search strategy, 9608 records were retrieved. After removing 1068 duplicated records and screening 8451 titles and abstracts, only 58 primary studies were analysed in their full-text version. Reasons and references excluded are shown in the Appendix Chapter 4, Table 4.10. Table 4.7 displays the characteristics of the five primary studies included.

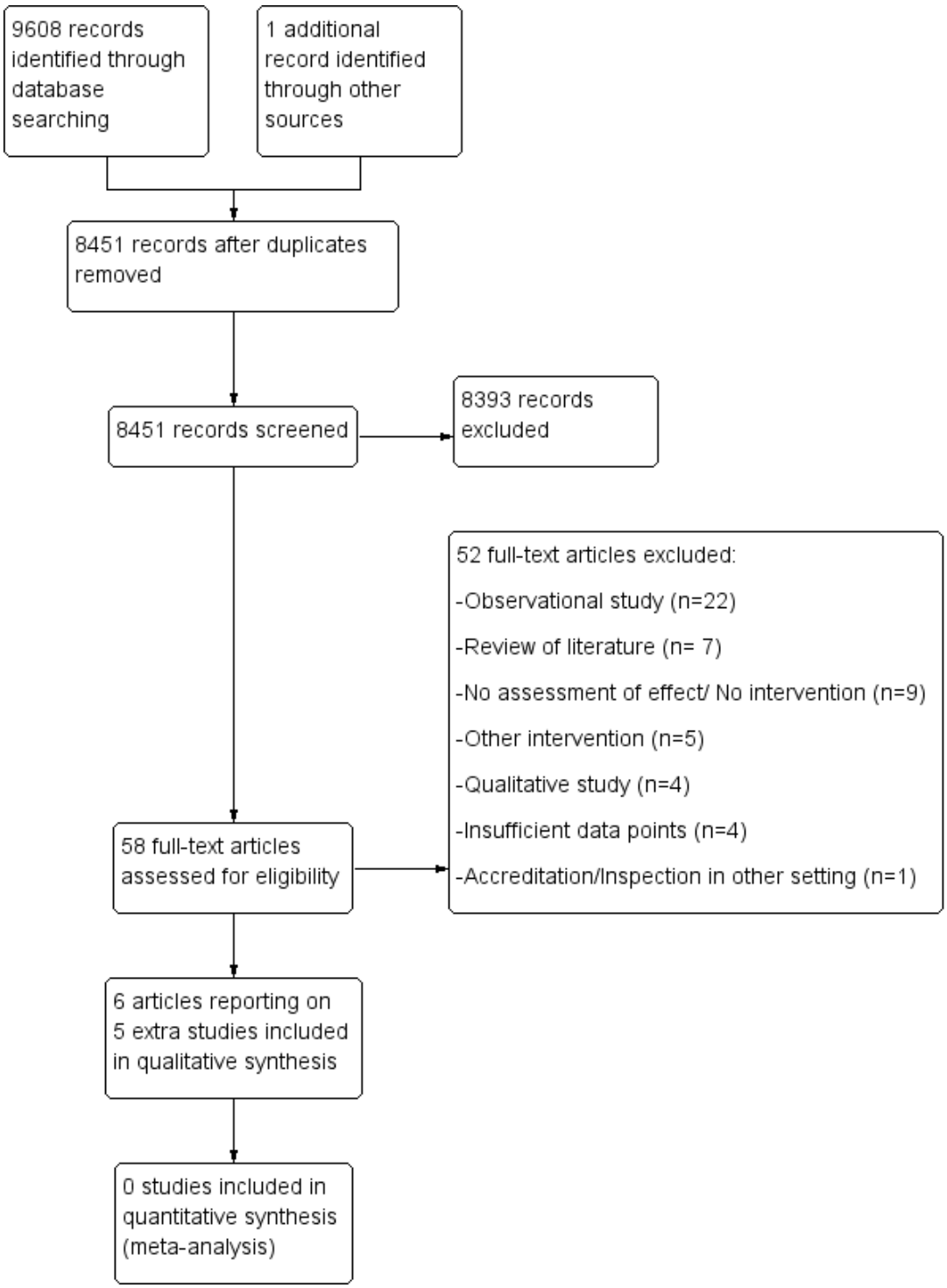


Figure 4.2: PRISMA Flow diagram of primary studies for the update of the best systematic review

4.2.2.2 Included studies

Four ITS studies and one CBA study met the inclusion criteria. All of them were performed in high-income countries. One included one hospital applying for voluntary accreditation (Devkaran and O'Farrell, 2015), another included 58 hospitals going through mandatory accreditation (Towers and Clark, 2014); whilst the other three included all accredited hospitals in Denmark (Bogh et al., 2015, Bogh et al., 2016, Bogh et al., 2017). All accreditation regimes were applied at the organisational level.

4.2.2.3 Targeted behaviour

Devkaran and O'Farrell (2015) and Towers and Clark (2014) assessed regimes targeted to improve a wide range of behaviours, processes and outcomes across the healthcare organisation, reflecting the accreditation approach of The Joint Commission. The three studies performed in Denmark assessed The Danish Healthcare Quality Programme, which established a framework for high-quality work in hospitals, making mandatory the evaluation and use of clinical registries data.

4.2.2.4 Participants and settings

In the case of Devkaran and O'Farrell (2015), the setting was a 150-bed private hospital in Abu Dhabi, United Arab Emirates. Towers and Clark (2014) included data for 10 years from 58 hospitals in New Jersey, United States. No further information about the setting is provided. Bogh et al. (2015) included data in 2004, 2006 and 2008 of 33 public hospitals in Denmark of which six had been accredited. Bogh et al. (2016) and Bogh et al. (2017) used data for 5 years from 25 public hospitals accredited between 2010 and 2013 by The Danish Healthcare Quality Programme.

4.2.2.5 Outcomes

In the study of Devkaran and O'Farrell (2015), 27 measures of quality of care and one composite indicator were used to determine the effect of the on-site accreditation visit. These indicators were grouped into nine categories: patient assessment, laboratory safety, surgical procedures, medication error use and near misses, anaesthesia and sedation use, completeness of medical records, healthcare-associated infections, mortality and international safety goals. These were chosen to reflect most aspects of care assessed by the JCI.

In the study of Towers and Clark (2014), risk-adjusted mortality was used as outcome. Additionally, the effect of belonging to a network of healthcare providers, technological development, financial buffer capacity, and unannounced accreditation visits were explored.

The three studies from Denmark assessed process of care performance measurements for stroke, heart failure, and ulcers (perforated or bleeding) at different time points. Bogh et al. (2015) present compliance for each measure plus two composite measures: an opportunity-based and an all-or-none score for each condition. Bogh et al. (2016) and Bogh et al. (2017) used more measures for the three conditions aforementioned and added measures for breast cancer, lung cancer and diabetes totalling 43 indicators.

4.2.2.6 Data Collection

For Devkaran and O'Farrell (2015), 12000 patients' records were checked retrospectively, representing 24% of patients treated between January 2009 and September 2012.

For Towers and Clark (2014), data about mortality for a 10-year period was collected from the healthcare cost and utilization state inpatient database. No information on the size of sample size is provided.

The three studies from Denmark used national disease-specific clinical registries, but sample sizes differed. Bogh et al. (2015) included data from 27,274 patients, whilst Bogh et al. (2016, 2017) analysed data from 1,624,518 processes of care provided during 5 years.

4.2.2.7 Risk of bias of included studies

The risk of bias assessment for included studies is in Table 4.8 and Table 4.9.

In the case of Devkaran and O'Farrell (2015), five methodological aspects were assessed with a low risk of bias: Intervention independent of other changes, pre-specified shape of intervention, intervention unlikely to affect data collection, selective reporting of outcomes, and risk of other biases. The two remaining aspects were considered unclear: knowledge of allocation adequately protected and incomplete outcome data.

For Towers and Clark (2014), three methodological aspects had a low risk of bias: knowledge of allocation adequately protected, selective reporting of outcomes, and risk of other biases. The remaining four criteria were deemed as low risk of bias.

Three methodological aspects of Bogh et al. (2015) were deemed at high risk of bias: generation of allocation sequence, allocation concealment, and similar baseline characteristics. Other five features were deemed at low risk of bias (i.e. similar baseline outcomes, management of incomplete outcome, protection of allocation, selective reporting and other biases) and one as an unclear (protection against contamination).

Bogh et al. (2017) is an extension of Bogh et al. (2016) analysis; therefore, they share most of methodological aspects. Five of them were deemed at low risk of bias: intervention unlikely to affect data collection, knowledge of allocation protected, incomplete outcome data, selective reporting of outcomes, and risk of other biases. It was not clear if the intervention was independent of other changes and only Bogh et al. (2016) specified the shape of the intervention.

4.2.2.8 Effects of interventions

The effect of the interventions is reported in detail in the Appendix Chapter 4, Table 4.9. The summary of finding for the main comparison are reported in Table 4.10.

4.2.2.8.1 Mortality

The effect of accreditation on mortality was mixed: Devkaran and O'Farrell (2015) found no difference in mortality rates the month after the inspection (β=-0.01 [-0.016 to 0.14]), whilst Towers and Clark (2014) found a significant positive effect on risk-adjusted mortality (β=-0.0454; p<0.05).

4.2.2.8.2 Composite measure of quality of care

Using a composite measure of quality, Devkaran and O'Farrell (2015) found an improving trend before inspection (β=2.19; p<0.001), an abrupt decrease in compliance the month after the inspection (β=-3.95 [-6.39 to -1.51]) and a maintained trend towards decline of compliance (β=-2.16 [-2.52 to -1.8]).

Bogh et al. (2016) had similar findings. More than 6 months prior to the accreditation, the probability of meeting the 43 process performance measures under assessment increased by 0.7% per week (p<0.001). In the 6 months before the accreditation visit, the improvement further increased by a non-significant 0.2% per week. After the visit, the improvement trend flattened compared to the pre-accreditation periods (-0.6% change per week, p=0.04). Bogh et al. (2017) present a subgroup analysis of Bogh et al. (2016) for six conditions finding that compliance improved more than 6 months before the visit, and then remained static.

Bogh et al. (2016) also present a subgroup analysis including only processes with sub-standard compliance 6 months before the accreditation. For this subset of measures, improvement was significant but slower more than 6 months prior to the visit (0.4% per week, p<0.001). It accelerated in the next 6 months by 0.6% per week (p=0.04) and stagnated after the visit (change by -0.08% per week, p=0.04). In the subgroup analyses by condition (Bogh et al., 2017) this pattern -improvement, accelerated improvement and stagnation- was only observed for diabetes standards. These data represented 58.8% of processes of care analysed, which could explain the findings of Bogh et al. (2016). For the other five conditions analysed by Bogh et al. (2017), there was a significant improvement only more than 6 months before the accreditation.

Bogh et al. (2015) found that between 2004 and 2008, non-accredited hospitals improved more their overall opportunity-based composite score than accredited hospitals (absolute difference 3.8; 95% CI 0.8 to 8.3). In addition, non-accredited hospitals improved their opportunity-based and all-or-none scores for stroke and heart failure; whilst accredited hospitals only improved their stroke opportunity-based score.

Table 4.7 Characteristics the five extra studies included in the update of the systematic review

Study	Study design	Participants	Intervention	Comparison	Outcomes
Devkaran and O'Farrell (2015). Devkaran and O'Farrell (2014)	Interrupted time series	Al-Noor hospital in Abu Dhabi. Private, 150-bed, multispecialty, acute care hospital	Joint Commission International (JCI) accreditation	One-year prior to accreditation (2009) versus three-year after accreditation visit.	- Initial medical assessment done within 24 h of admission - Initial nursing assessment within 24 h of admission - % of pain assessments completed per month - % of completed pain reassessments per month - Hours for complete blood count as routine lab result - Turnaround time of troponin lab results (in minutes) - Completion of the surgical invasive procedure consent - % of operating room (OR) cancellation of elective surgery (transformed) - Unplanned return to OR within 48 h (transformed) - Reported medication errors (transformed) - % of completed anaesthesia, moderate and deep sedation consents - % of completed modified Aldrete scores (pre, post, discharge) - % of completed pre-anaesthesia assessments - % of completed anaesthesia care plans - % of completed assessments of patients receiving anaesthesia - Effective communication of risks, benefits and alternatives of anaesthesia - Hospital-acquired MRSA rate (transformed) - Healthcare-associated infections at hospital level - Surgical site infection rate (transformed) - % of typed post-operative report completed within 48 h - Mortality rate (transformed) - Compliance with surgical site marking - Compliance with the time-out procedure - Screening for patient fall risk - Overall hospital hand hygiene compliance rate - Patient fall rate - Fall risk assessment and reassessment - Mean Composite score (It includes only 23 measures)

Study	Study design	Participants	Intervention	Comparison	Outcomes
Towers and Clark (2014)	Interrupted time series	58 hospitals in New Jersey. Non-specialist and non-paediatric acute hospitals	Joint Commission on Accreditation of Healthcare Organizations (JCAHO) scheme	3 months before and 3 months after accreditation visit	Risk-adjusted mortality. Authors explored the association between system affiliation and technological status with risk-adjusted mortality. Additionally, the effect of an unannounced visit was determined.
Bogh et al. (2015)	Controlled before and after study	6 accredited and 27 non-accredited public, non-psychiatric hospitals in Denmark.	Joint Commission International or Health Quality Service Accreditation Programme	Non-accredited hospitals	- An opportunity-based (proportion of care recommended provided) and an all-or-none score (patients receiving 100% of care recommended). **Stroke:** - Early admission to a stroke unit - Early antiplatelet therapy initiated - Oral anticoagulant therapy initiated - Early examination with CT/MRI - Early assessment by a physiotherapist - Early assessment by an occupational therapist - Early assessment of nutritional risk **Heart failure:** - Echocardiography - NYHA classification - ACE/ATII inhibitors therapy - Beta-blockers therapy - Physical training - Patient education **Perforated ulcer:** - Early surgery - Control of body weight - Control of fluid balance - Control of blood pressure, pulse, temperature, saturation, respiratory rate and level of consciousness **Bleeding ulcer:** - Endoscopy - Therapeutic endoscopy - Endoscopic treatment of recurrent bleeding - Avoided surgical treatment

Study	Study design	Participants	Intervention	Comparison	Outcomes
Bogh et al. (2016)	Interrupted time-series study	25 public, acute, non-psychiatric hospitals in Denmark.	From announcement of the Danish Healthcare Quality Programme visit (6 months in advance) to the visit.	Pre-accreditation (more than 6 months before visit) and post accreditation (a week after the visit) periods	Probability of meeting 43 processes of care performance measures for six conditions: stroke, heart failure, diabetes, ulcers (perforated and bleeding), breast cancer and lung cancer.
Bogh et al. (2017)	Interrupted time-series study	25 public, acute, non-psychiatric hospitals in Denmark.	From announcement of the Danish Healthcare Quality Programme visit (6 months in advance) to the visit.	Pre-accreditation (more than 6 months before visit) and post accreditation (a week after the visit) periods	Probability of meeting the standards for each of the six conditions included: stroke, heart failure, diabetes, ulcers (perforated and bleeding), breast cancer and lung cancer.

Table 4.8 Risk of bias assessment for interrupted time-series studies

Domain	Devkaran and O'Farrell (2015) and Devkaran and O'Farrell (2014)	Towers and Clark (2014)	Bogh et al. (2016)	Bogh et al. (2017)
Intervention independent of other changes				
Judgement	Low risk	Unclear risk	Unclear risk	Unclear risk
Support for judgement	Page 2 paragraph 3, 2015 The hospital analysed did not undergo any significant organisational changes between 2009 and 2012. Thus, both the leadership, organisational structure and the scope of services remained the same.	There is no reference to other potential changes during the observation period (i.e. 10 years)	It does not refer to any other potential changes during the observation period (i.e. 5 years).	It does not refer to any other potential changes during the observation period (i.e. 5 years).
Pre-specified shape of intervention				
Judgement	Low risk	Unclear risk	Low risk	High risk
Support for judgement	Pages 2-3, 2014 The initiation phase will be characterised by a gradual positive change in slope. A marked improvement (ramp up) in compliance is expected to occur during the pre-survey phase. We hypothesise that a sharp drop in levels of compliance will occur immediately following the accreditation survey followed by a negative change in slope over time. During this stagnation phase, we hypothesise that there will be an undulating plateau of compliance characterised by sporadic changes but at an overall level above the pre-accreditation values.	Potential shape of the effect of the interventions is not mentioned	Page 716, paragraph 3 Hypothesis 1: an increased trend in process performance measures during accreditation compared to prior to accreditation. Hypothesis 2: the improved trend would decrease post-accreditation. Hypothesis 3: the improvement effect would be more evident for process performance measures where the hospitals prior to the accreditation delivered quality of care at an unsatisfactory level.	It is not specified

Domain	Devkaran and O'Farrell (2015) and Devkaran and O'Farrell (2014)	Towers and Clark (2014)	Bogh et al. (2016)	Bogh et al. (2017)
Intervention unlikely to affect data collection				
Judgement	Low risk	Unclear risk	Low risk	Low risk
Support for judgement	Patients' records were checked retrospectively; therefore, the interventions could not have affected data collection.	Data about mortality was collected from the healthcare cost and utilization state inpatient database. There is no information about a potential effect of site visits and this database.	Page 716, paragraph 7 Patient-level data were obtained from national clinical quality registries. To be approved as a national clinical quality registry at least 90% of all patients treated at hospitals should be included. Reporting to these registries is mandatory for all hospitals according to Danish law.	Page 478, paragraph 8 43 different process performance measures were included from national clinical quality registries that related to the six included conditions. Data on the processes of care were prospectively collected. It is mandatory all hospitals report to the registries under Danish law.
Knowledge of allocation adequately protected				
Judgement	Unclear risk	Low risk	Low risk	Low risk
Support for judgement	It is not clear if the person extracting information was aware of the period covered by each patient's record (i.e. pre or post-accreditation). Most outcomes are objective (e.g. mortality rate, healthcare-associated infection), but a minority was subject to assessor judgement (i.e. effective communication of risks, benefits and alternatives of anaesthesia explained to patients)	The primary outcome was mortality, therefore, the measure is objective.	Performance measurement was collected for the National Registry, regardless of the intervention.	Performance measurement was collected for the National Registry, regardless of the intervention.

Domain	Devkaran and O'Farrell (2015) and Devkaran and O'Farrell (2014)	Towers and Clark (2014)	Bogh et al. (2016)	Bogh et al. (2017)
Incomplete outcome data (attrition bias)				
Judgement	Unclear risk	Unclear risk	Low risk	Low risk
Support for judgement	There is no reference to a percentage of incomplete outcome data.	There is no reference to a percentage of incomplete outcome data.	Page 717, paragraph 2 We excluded processes with missing data from our analyses, but the proportion of missing data for the individual processes of care was in general low (<10%) and expected to be missing completely at random.	Page 479, paragraph 2 Processes with missing data were excluded from the analyses; however, it should be noted that the proportion of missing data for the individual processes of care was generally low (<10%) and expected to be missing at random.
Selective reporting (reporting bias)				
Judgement	Low risk	Low risk	Low risk	Low risk
Support for judgement	Results were reported for all outcomes described in the methods section.	Results were reported for all outcomes described in the methods section	Results were reported for all outcomes described in the methods section	Results were reported for all outcomes described in the methods section.
Other bias				
Judgement	Low risk	Low risk	Low risk	Low risk
Support for judgement	No other risk of bias were identified	The analysis accounted for monthly, yearly and hospital effects; therefore, potential bias due to autocorrelation, seasonality and clusters is low.	No other risk of bias were identified.	No other risk of bias were identified.

Table 4.9 Risk of bias assessment for the controlled before and after study

Domain	Bogh et al. (2015)
Adequate generation of allocation sequence	
Judgement	High risk
Support for judgement	Page 2, paragraph 3 In 2002, 2005, 2008 and 2011 five hospitals were accredited by the Joint Commission International (JCI), whilst four hospitals in 2004 were accredited by the Health Quality Service (HQS).
Allocation concealment	
Judgement	High risk
Support for judgement	Hospitals accredited applied voluntarily.
Similar baseline outcome measurements	
Judgement	Low risk
Support for judgement	19 of 21 measures were similar at baseline. Although there was no adjustment in the analysis for these differences, results are presented as absolute difference, which takes into consideration the baseline values.
Similar baseline characteristics	
Judgement	High risk
Support for judgement	Accredited hospitals were more likely to be located in the capital region.
Incomplete outcome data (attrition bias)	
Judgement	Low risk
Support for judgement	Page 2, paragraph 4 The proportion of patients with missing data for the individual process of care performance measures was in general low (i.e. <10%). We excluded patients with missing data from the analyses of the individual performance measures.
Knowledge of allocation adequately protected	
Judgement	Low risk
Support for judgement	Performance measurement was collected for the National Registry, regardless of the intervention.
Protection against contamination	
Judgement	Unclear risk
Support for judgement	Hospitals apply to be accredited, and accreditation became mandatory in 2010; therefore, control hospitals were probably preparing for their visit.
Selective reporting (reporting bias)	
Judgement	Low risk
Support for judgement	Results were reported for all outcomes described in the methods section.
Other bias	
Judgement	Low risk
Support for judgement	No other risk of bias were identified.

4.2.3 Discussion

4.2.3.1 Summary of main results

Four interrupted time-series studies and one controlled before and after study were added in this updated systematic review. Devkaran and O'Farrell (2015) found an inconsistent effect of accreditation on individual measures of organisational behaviours and health outcomes. However, a composite measure shows steady improvement before the accreditation visit, a drop in performance the month after the visit, and a declining trend afterwards (Devkaran and O'Farrell, 2014). The findings of Bogh et al. (2016, 2017) support this pattern of improvement before the visit and stagnation of performance afterwards. Bogh et al. (2015) found greater improvement of performance for non-accredited than accredited hospitals over four years. Towers and Clark (2014) found a significant decrease in risk-adjusted mortality the month after the accreditation.

The studies included in Flodgren et al. (2016) suggest that accreditation improves compliance with accreditation standards, but it does not affect measures of care quality (Salmon et al., 2003). Also, the inspections of the Healthcare Commission in England were not associated with changes in rates of in-hospital MRSA infection (change in trend 24.27 infections per quarter, 95% CI -10.4 to 58.9; p = 0.15) (OPM evaluation team, 2009)

4.2.3.2 Overall completeness and applicability of evidence

The results of this systematic review are limited in terms of generalizability and translation to other settings. All studies but one (Salmon et al., 2003) were implemented in high-income countries. The seven studies were conducted in secondary care, and the intervention was an accreditation visit; therefore, this information is unlikely applicable to other contexts.

The finding of Salmon et al. (2003) suggest that elements related to the management of healthcare services improved more in accredited than non-accredited hospitals (21 out of 28 service elements. Overall improvement in compliance 30 [23 to 37] points, $p<0.001$). Results from Devkaran and O'Farrell (2015) and Bogh et al. (2016, 2017) highlight that the pressure of a future accreditation visit seems to drive improvement, whilst performance declines after the visit. Although more research would be needed to assure consistency, these findings suggest cyclic changes of performance driven by the accreditation visit. Additionally, accreditation seems to drive the implementation of protocols and standard management processes, which are not affecting clinical outcomes. Apparently, the cyclical changes of performance produce a transient drop of risk-adjusted mortality in the short term.

In Devkaran and O'Farrell (2015) only five (18.5%) performance measures are clinical/health outcomes and only one of them improved before the accreditation visit (i.e. MRSA infection

rate). In the case of measures of organisational performance, 50% improved before the visit. Salmon et al. (2003) found a similar pattern, where the quality measures improved equally in accredited and non-accredited hospitals, except nurses' perception of quality of care that improved more in hospitals receiving accreditation. However, 75% of the organisational processes improved. This suggests that hospitals prepare for on-site visits by implementing quick fixes for simple processes (for example, time-out procedure before starting a surgery). Nevertheless, evidence is sparse to draw strong conclusions about this.

4.2.3.3 Quality of evidence

Overall quality of evidence is low to moderate with small, inconsistent and imprecise effects.

4.2.3.4 Potential biases in the review process

The processes of screening, quality assessment and summarising of results have been performed by one assessor, which introduces biases and decreases the reliability of the results.

4.2.3.5 Agreements and disagreements with other studies or reviews

These results are in line with those of Flodgren et al. (2011) and Flodgren et al. (2016) that found inconsistent evidence on the effect of external oversight on organisational behaviour or health outcomes, although the inclusion of the three studies from Denmark has improved the quality of evidence available.

The greatest limitation of the available evidence is the methodological design and limited applicability of results to different contexts.

4.3 Conclusion

Despite the large number of articles analysed (7 reviews and 90 individual studies) addressing whether external inspection or accreditation improves organisational behaviour or health outcomes, effects remain highly uncertain.

The overview of systematic reviews found mixed evidence on the effect of the interventions. These findings were driven by a large body of studies using disease-specific measures to determine effectiveness; when these are removed, the intervention is generally ineffective. The studies included in the update of the systematic review support the conclusion that the effect of accreditation is cyclical; therefore, evaluations of external oversight regimes should consider time as a moderating variable.

There is still a lack of robust studies using generic measures of quality of care to increase certainty around the real effect of external oversight regimes. The costs associated with external oversight are still rarely explored and reported, leaving room to determine the cost-effectiveness of the intervention.

Table 4.10 Summary of findings

Accreditation for improving organisational behaviour and health outcomes

Patient or population: improving organisational behaviour and health outcomes
Setting: Secondary care
Intervention: Accreditation
Comparison: Pre-accreditation period

Outcomes	Impact	№ of participants (studies)	Quality of the evidence (GRADE)
Composite measure of quality of care follow up: 3 years	Trend before accreditation: 2.19; p<0.001 Immediately after accreditation: -3.95 [-6.39 to -1.51] Trend after accreditation: -2.16 [-2.52 to -1.8]	12000 (1 observational study)	⊕◯◯◯ VERY LOW [1]
Composite measure of process of care follow-up: 5 years	Trend >6 m before accreditation: 1.007 [1.005 to 1.008] Change in trend during accreditation: 1.002 [0.997 to 1.006] Change in trend after accreditation: 0.99 [0.988 to 0.999]	1624518 (1 observational study)	⊕⊕◯◯ LOW [1]
Mortality follow up: range 7 months to 3 years	Risk-adjusted mortality: Beta -0.045; p<0.05 Mortality: Beta -0.01 [-0.16 to 0.14]	12000? (2 observational studies)	⊕◯◯◯ VERY LOW [1]

[1] The evidence was downgraded on the basis of small effect, imprecision and inconsistency.

GRADE Working Group grades of evidence
High quality: Author is very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: Author is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Author is confident that the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: Author has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

5 Design of the evaluation of CQC inspections

The CQC, an external oversight regulatory agency, is not the first one of its kind in the NHS or worldwide. Evidence from other similar institutions suggests mixed effects on improving disease-specific and hospital-level organisational performance, whilst external oversight appears to be generally effective to improve patients' outcomes. However, much of this evidence comes from low quality, and heterogeneous studies.

In the case of the NHS, evaluations of the work of the CQC predecessors have used qualitative methods and surveys (Benson et al., 2004, Day and Klein, 2004, Healthcare Commission, 2008a, Healthcare Commission, 2009), without assessing the premise that the mission of encouraging improvement should translate into better health outcomes and organisational performance.

Based on a large body of literature, in this chapter different study designs available for evaluating the effect of a health policy are considered along with their strengths and weaknesses. Then, it is explained what design choices were made and the potential measurement issues associated with answering the overarching research question:

What is the effect of CQC inspections of NHS acute trusts in England on measures of process of care and clinical outcomes?

This research examines the potential contribution of *inspections* to the improvement of acute hospitals' care quality and does not assess the effectiveness of the Care Quality Commission as a whole.

5.1 Objectives

The objectives of the empirical analyses that follow are to:

1. Determine the effect of CQC inspections of NHS acute trusts on measures of process of care and clinical outcomes.
2. Compare the effect of the old and new CQC inspection regime of NHS acute trusts on measures of process of care and clinical outcomes.
3. Compare the effect of the old and new CQC inspection regime of NHS acute trusts on measures of process of care and clinical outcomes when accounting for the previous level of improvement to address how ability to improve affects the response to an inspection.

4. Determine the incremental costs for CQC and the opportunity costs for acute NHS trusts of performing an inspection cycle.
5. Consider the cost-effectiveness of the new CQC inspection regime considering measures of process of care and clinical outcomes.

5.2 Methodology

In health services and policy research, the pragmatic approach has become more predominant in the recent years, because it allows gaining a greater understanding of the phenomena under study (O'Cathain et al., 2007). Shortly after this thesis started, Walshe et al. (2014) published the findings of their qualitative assessment of CQC new regime of inspections. Consequently, it was considered that taking a quantitative approach to research would provide more valuable results than expanding on the qualitative knowledge available (Benson et al., 2004, Day and Klein, 2004, Healthcare Commission, 2008a).

A quasi-experimental approach was chosen(Cook and Campbell, 1986) because it was not possible to manipulate the intervention. This encompasses the use of quantitative methods, assuming that procedures are systematic, reproducible and valid (Broom and Willis, 2007). Also, this approach assumes it is possible to measure the effect of the intervention on quality of care whilst controlling sources of bias and confounding (Cook and Campbell, 1986, Bowling et al., 2012). Nonetheless, it does not intend to provide a prediction or full explanation of the relationship between intervention and outcomes, because of the difficulties conceptualising social objects (such as quality of care) and dealing with human behaviour as a causal force (Cook and Campbell, 1986). Moreover, quasi-experimentation assumes that the particular, complex, multivariate causal relationships under study behave in a probabilistic way, which makes it difficult to predict exactly the response of one unit at a given time (ibid).

CQC inspections are complex interventions taking place in a complex adaptive system (Braithwaite et al., 2017a) and theory around the mechanism of change of inspections and factors associated with an effect are underdeveloped and rarely articulated (Hovlid et al., 2017). There is no direct evidence to select confounding variables, and exploring the potential influence of context on the effect estimates is limited by sample size and data quality. This means that the number of analyses and outcomes measures had to be carefully selected to avoid finding spurious relationships associated with familywise error rate[16] (Bartroff and Song,

[16] Familywise error rate refers to the expected rate of type I errors when testing multiple times pairwise comparisons (i.e. a family of null hypothesis). This rate increases with the number of tests performed (Hochberg and Tamhane, 2008).

2014). This research contributes to the overall information on the effect of the CQC on quality of care, which can inform pragmatic research exploring when and why the intervention works.

The following sections explore study design options within the framework of quasi-experiments, highlighting their strengths and weaknesses, and how these relate to the limitations of this thesis regarding the availability of data and features of the intervention.

5.2.1 The analysis of the effectiveness of health policies

As with any other intervention, the best study design to make causal inferences, such as estimating the effect of a health policy, is a randomised controlled trial (Stuart and Naeger, 2017). However, researchers rarely have a chance to devise an experiment to test the effect of a health policy before it is implemented. Therefore, the second best option is a quasi-experiment (Shadish et al., 2002). Among quasi-experiments, Shadish et al. (2002) highlight regression discontinuity designs followed by interrupted time-series studies as the options yielding more robust conclusions. Economists suggest a third quasi-experimental design to estimate the effect of a health policy: difference-in-difference analyses (Dimick and Ryan, 2014).

The validity of quasi-experiments relies heavily on assumptions, especially about plausibility, that is, the existence of a logical, evidence-based explanation for the cause-effect relationship (Bradford Hill, 1965). The concept of plausibility plays a pivotal role in deciding which threats to validity (or risk of bias) are relevant, which design elements should be added to rule out or minimise the effect of a threat to validity, to what extent biases have been reduced, and whether the additive effect of all remaining biases might be greater than the hypothetical effect size (Shadish et al., 2002). In consequence, the choice of study design is bound to meeting the underlying assumptions and the possibility of adding elements to control biases and sources of confounding.

In the following sections, the three quasi-experimental designs available to assess the effect of a health policy are explored, highlighting assumptions, strengths and limitations of each of them to justify the design selected.

5.2.1.1 Regression discontinuity studies

Regression discontinuity designs require a treated and a control group and perfect knowledge of the selection process (Shadish et al., 2002). The variable or algorithm that defines who receives the treatment or control is what is called the forcing variable. However, one fundamental assumption is that individuals cannot precisely manipulate their own values of the forcing variable; therefore, individuals close to the cut-off point will have a similar

probability of being assigned to the control or intervention group (Lee and Lemieux, 2009), which makes allocation almost random. The analysis then looks at the behaviour of the outcome of interest depending on the value of the forcing variable (ibid) (Figure 5.1). This is the first option when conducting quasi-experiments since it is the most robust design if the assumptions are met (Shadish et al., 2002, Lee and Lemieux, 2009). However, if there is no knowledge about the forcing variable, this design is not feasible.

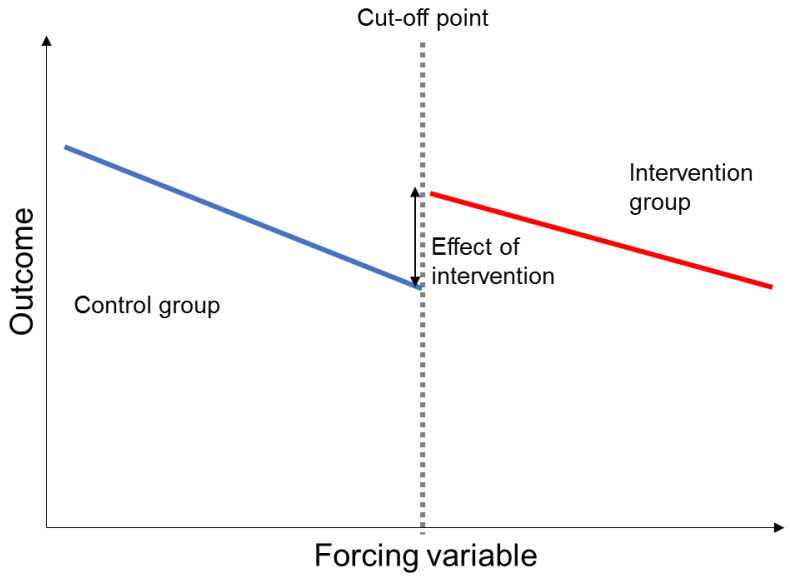


Figure 5.1 Scheme of a regression discontinuity design

In the case of CQC inspections, the process to define who and when will receive an inspection is not entirely clear. This is particularly problematic when it comes to defining who received the new regime inspection during the pilot and early implementation phase, which is the intervention under consideration in this thesis. The use of a regression discontinuity design to answer the research question posed was unfeasible because there is no forcing variable.

5.2.1.2 Difference-in-difference studies

Difference-in-difference studies estimate the effect of an intervention with regression techniques modelling longitudinal data from two groups: one exposed to an intervention and another group that serves as a comparison (Ryan et al., 2015). One of the assumptions is that trends for these groups are parallel before the intervention (Dimick and Ryan, 2014). This allows determining the differential effect of the intervention by calculating the difference between treatment and control at the beginning (i.e. difference 1) and the difference at a later time point (i.e. difference 2 or 3) (Figure 5.2). If this assumption is not met, estimates from a difference-in-difference analysis will be biased. Therefore, another comparison group should be sought or a different analytical strategy used (Dimick and Ryan, 2014). The second assumption is that shocks are common, that is if an event occurs before or after the implementation of the policy its effect will be similar for both groups (Ryan et al., 2015).

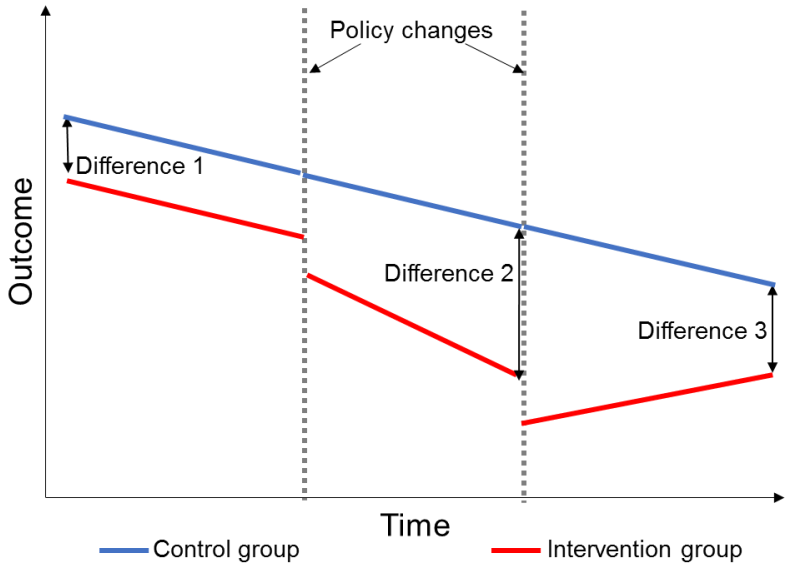


Figure 5.2 Scheme of a difference-in-difference design

In this thesis, the assumption of parallel pre-intervention trends was met for most of the datasets used, but not all (see Chapter 7), and consequently, a different analytical strategy should have been used to answer the same research question, making the overall interpretation more difficult. Difference-in-difference analyses can provide information on the overall effect of an intervention, but they do not allow making inferences about changes in level and slope. Regarding the assumption of common shocks, the intrinsic features of acute NHS trusts such as culture or leadership of senior staff may affect their ability to respond to shocks; therefore, it is not clear to what extent this assumption was met. Consequently, a difference-in-difference design was ruled out, because all datasets did not meet the assumption of pre-intervention parallel trends and obtaining more information than the difference between two groups after the intervention was being sought.

5.2.1.3 Interrupted time-series studies

Interrupted time-series analysis refers to a variety of analytical strategies used to determine the effect of an intervention, where the general features are longitudinal data pre and post-intervention and a specific time point when the intervention was introduced (Shadish et al., 2002). Changes in level and trend after the intervention are usually calculated using a segmented regression (Wagner et al., 2002) (Figure 5.3). Since the effect of the intervention is determined based on the pre-intervention trend for each group, comparison groups can be non-equivalent (Shadish et al., 2002).

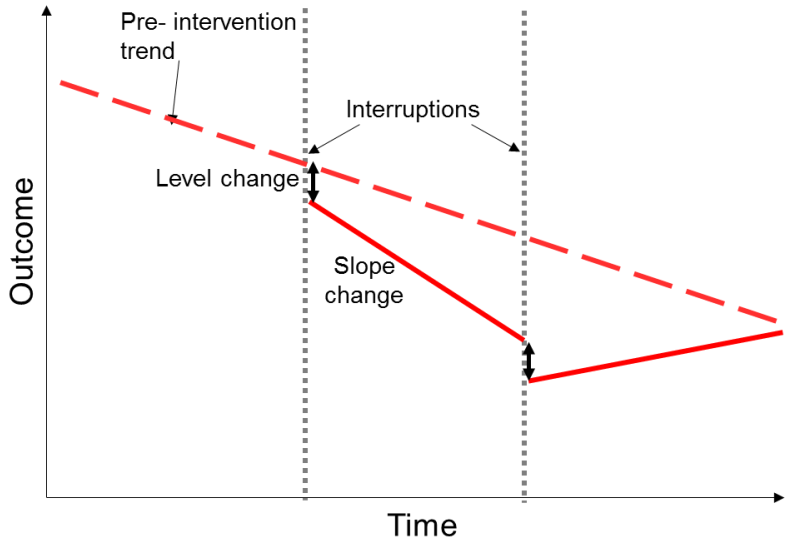


Figure 5.3 Scheme of an interrupted time-series

Estimates are not as robust as findings of an RCT (as with any observational study), but certain design features can reduce the potential for bias (Cook et al., 2008). These are adding a comparison group with similar characteristics, increasing the number of data points before and after the intervention, and adding other variables correlated with selection into treatment and the outcome (Cook et al., 2008). Given that this is a robust design to analyse the effect of health policies (Wagner et al., 2002, Penfold and Zhang, 2013, Kontopantelis et al., 2015a) and it is more versatile than the other quasi-experimental designs explored, the three research questions regarding the effectiveness of CQC inspections were answered using an interrupted time series design.

To understand design elements and main features of interrupted time-series studies, it is necessary to expand on one of its fundamental elements: time-series.

5.2.1.4 Time-series

Since time-series modelling violates fundamental assumptions of Ordinary Least Square (OLS) regression models, such as independence of observations and uncorrelated error terms, some assumptions must be checked before using that type of analysis (Ostrom, 1990).

The first assumption refers to being stationary, which means that mean and variance of the time-series are constant (ibid). However, the time-series can be analysed as a trend-stationary time-series when the trend (i.e. average changes over time) is included in the model (ibid). Another option is to integrate the time-series by working with the first differential (i.e. the previous data point is subtracted to each one of them) (Ostrom, 1990). To test statistically if the time-series is stationary, the Augmented Dickey-Fuller test is used (Dickey and Fuller, 1979).

When modelling observations that are not independent, such as the case of time-series, OLS regression can generate smaller and biased standard errors, increasing the probability of finding spurious statistically significant results (McDowall et al., 1980). Therefore, data must be tested for autocorrelation.

There are two types of autocorrelation (ibid):

- Autoregressive (AR): when error term at time t (ε_t) is correlated with the error term of previous observations (ε_{t-n}).For example, an autoregressive process of order 1 AR (1) means that the error term at time 2 is correlated in a magnitude ϕ with the error term at time 1 plus a random disturbance v_t, which it is denoted:

$$\varepsilon_t = \phi\, \varepsilon_{t-1} + v_t$$

- Moving average (MA): when random disturbances (v_t) are correlated to each other (v_{t-n}) and to the error term (ε_t). For example, a moving average process of order 1 MA (1) means that the random variation at time 2 is correlated, by a magnitude ϑ, with the random variation at time 1, which it is denoted:

$$\varepsilon_t = \vartheta\, v_{t-1} + v_t$$

Box and Jenkins (1976) suggested a three-step iterative process to model time-series: model identification, estimation and validation. Three strategies are recommended to identify the autocorrelation structure:

1. Durbin-Watson test, where values close to two indicates no autocorrelation, below two may indicate positive autocorrelation and above two may indicate negative autocorrelation. The number of lags that are significant indicates what AR structure should be used.
2. Visual inspection of residuals to detect patterns of correlation or seasonality.
3. Autocorrelation plots against time, such as autocorrelation function (ACF) and partial autocorrelation function (PACF) (Figure 5.4).

   In the case of autoregressive processes, ACF will show exponential decay, whilst PACF will have some lags significant, before dropping to 0. The number of significant lags will indicate the number of previous error terms correlated, which is denoted by *p* or AR(p) (McDowall et al., 1980).

   In the case of moving average processes, PACF will show an exponential decay, whilst ACF will have some lags significant, before dropping to 0. The number of significant lags will indicate the number of random disturbances correlated, which is denoted by *q* or MA(q) (McDowall et al., 1980).

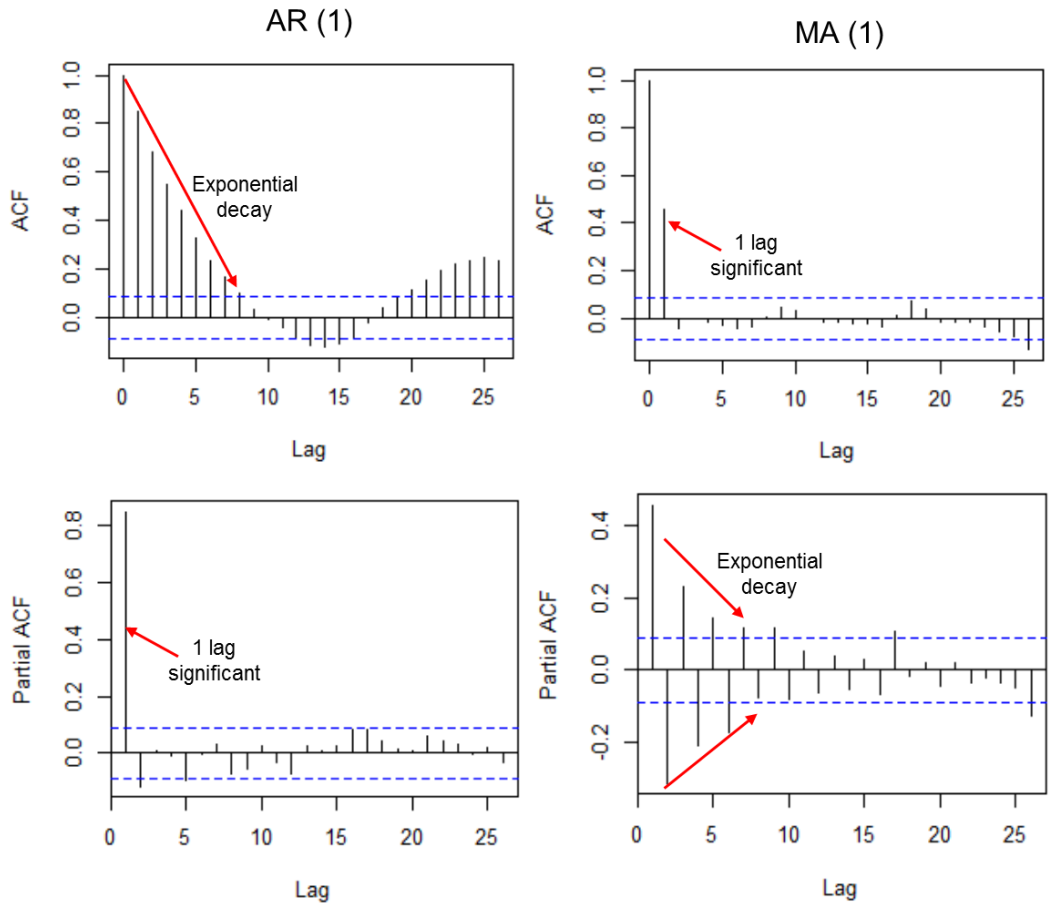


Figure 5.4 Autocorrelation and partial autocorrelation function for AR (1) and MA (1) using simulated data

When autocorrelation is present, different regression techniques capable of accounting for these processes should be utilised (McDowall et al., 1980). What these techniques do is to calculate a coefficient for each AR or MA lag that is significant and then, adds them to the model (ibid). The most used one is called ARIMA (Autoregressive Integrated Moving Average) regression, which accounts for AR and MA processes and can integrate the time-series (McDowall et al., 1980). Given that these techniques add terms to the regression model, traditional model selection techniques are used to determine the best structure (e.g. likelihood ratio tests).

Since interrupted time-series are particular cases of time-series, the iterative process of identifying the correct form, estimating and checking model assumptions are an essential part of the statistical analysis.

5.2.1.5 Consideration of the design of interrupted time-series studies to establish a causal relationship

A counterfactual scenario is needed to determine a causal relationship between an intervention and changes in an outcome (i.e. an effect). In an experiment, the counterfactual represents what would have happened in the absence of the intervention. Therefore, "an effect is the difference between what did happen and what would have happened" (Shadish et

al., 2002). In an interrupted time-series, the counterfactual is constructed based on the pre-intervention trend.

The effect can be described in terms of its form (i.e. changes in level, slope, and variance), permanence (i.e. continuous or one-time effect), and immediacy (i.e. immediate or delayed) (Figure 5.5) (Shadish et al., 2002).

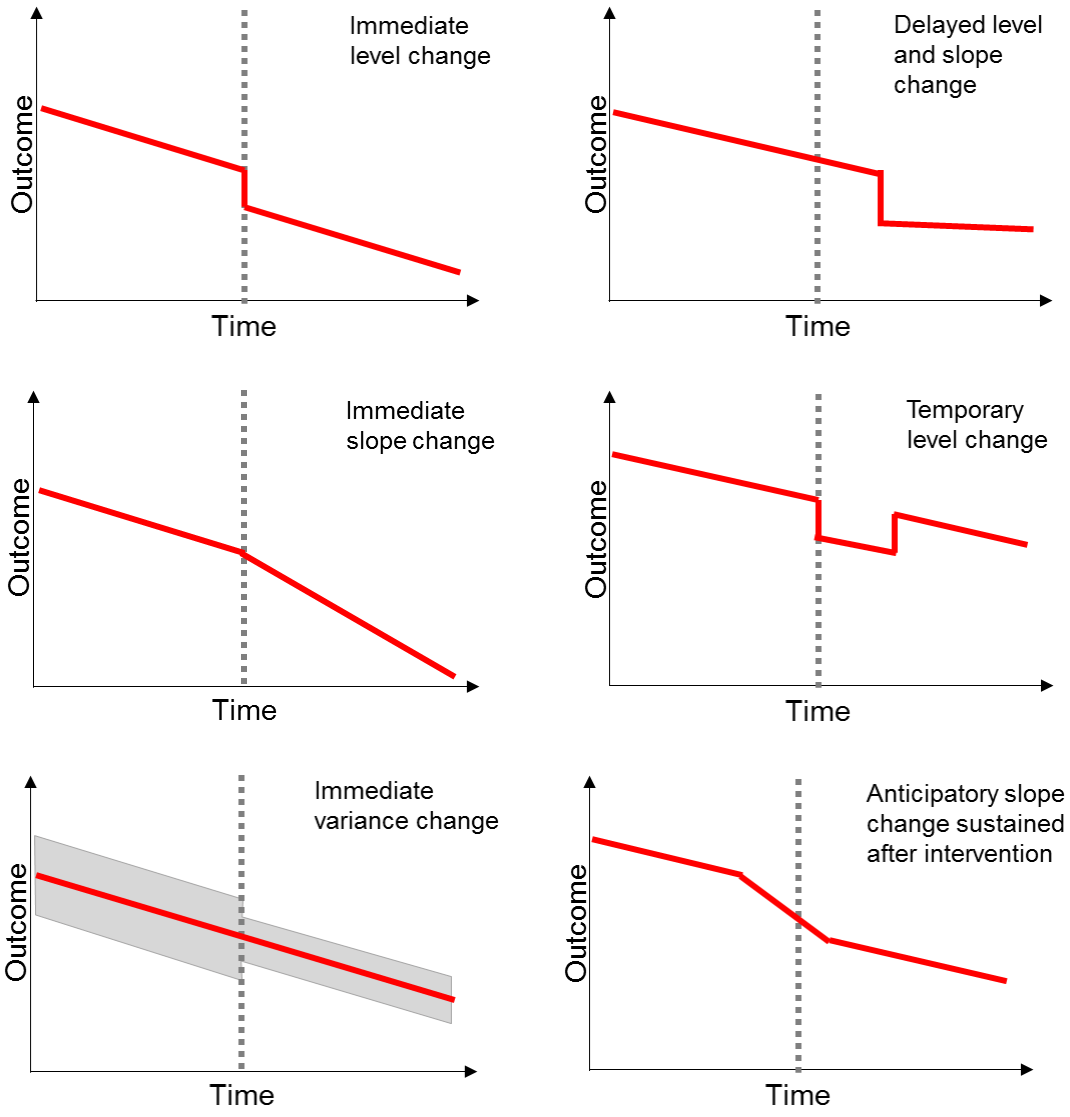


Figure 5.5 Examples of effects used in interrupted time-series. Adapted from Lopez Bernal et al. (2017).

The ability of this design to detect a post-treatment change depends heavily on the effect occurring at a specific time point and on having a data set with short time intervals (Cook and Campbell, 1986, Shadish et al., 2002). When the effect is gradual instead of producing an abrupt change, it is important to know the form of the diffusion process or use analytical strategies that can account for the stepped implementation (ibid). For CQC inspections to have an abrupt effect, all wards and departments within an acute trust should implement measures to improve an outcome immediately after the visit. Despite this being unlikely, the form of the

diffusion process is unpredictable and might differ for each acute trust; therefore, for simplicity, it has been assumed that the effect is abrupt and detectable in the next time interval.

Having a theory about what pattern will be observed depending on what factors are in play can help rule out alternative explanations (Shadish et al., 2002). For CQC inspections, it was expected that the announcement of the visit would produce an increase in the rate of improvement in those outcomes that can be modified in a short span, such as waiting times, which suggest that adding a segment to measure this anticipatory effect could help testing this hypothesis. Given the frequency of measurement, it was less likely to detect changes prior the inspection for variables measured on a yearly or quarterly basis, for instance, risk-adjusted mortality and patients' perception of quality of care.

Delayed effects can be problematic when there is no background theory to support a particular lag between the intervention and its impact (Shadish et al., 2002). When a theory is not available, delayed effects can be obscured by historical events taking place between the intervention and the lagged effect (ibid). Switching-replication designs, that is comparing two or more time-series with intervention points at different times, allows testing whether the delay between treatment and effect is similar across time-series, reducing the potential impact of history bias (ibid).

For external inspections, there is no theoretical background to predict clearly when the effect of the on-site visit will manifest. It not only depends on the actions mandated by the inspectorate but on trusts capacity to implement changes effectively. Pressures from other stakeholders such as CCGs and groups of patients might affect the size and how fast the effect is apparent (Robertson et al., 2017); therefore, it is not possible to include in the model a specific lag. However, since inspections were spread out over a 12-month period (allowing the use of switching replications designs), the potential effect of historical events is reduced.

It is noteworthy that causal inference is particularly challenging when delayed effects are combined with slow diffusion (Shadish et al., 2002). Hence, it is fundamental to test the robustness of the hypotheses and findings through a process of falsification (i.e. deliberately trying to falsify the conclusion it wants to be drawn). Popper (2005) argued that premises withstanding falsification are accepted as true until better evidence is produced. This process is done during the discussion of findings (see Chapter 10), but the identification of variables correlated with the null hypothesis can help rule out alternative explanations.

Adding a control group can improve the validity of the estimations, producing similar estimates to those of experiments, when sampling of the comparison group(s) is designed to minimise

initial differences in outcomes (Cook et al., 2008). When more than one group is included in the analysis, changes will be statistically significant when they are different to what is observed in the control group. For example, in Figure 5.6 the level change in the intervention group will be significant if it differs, in magnitude and/or direction, from the change observed in the control group; consequently, there are two counterfactuals: the pre-intervention trend and the control group.

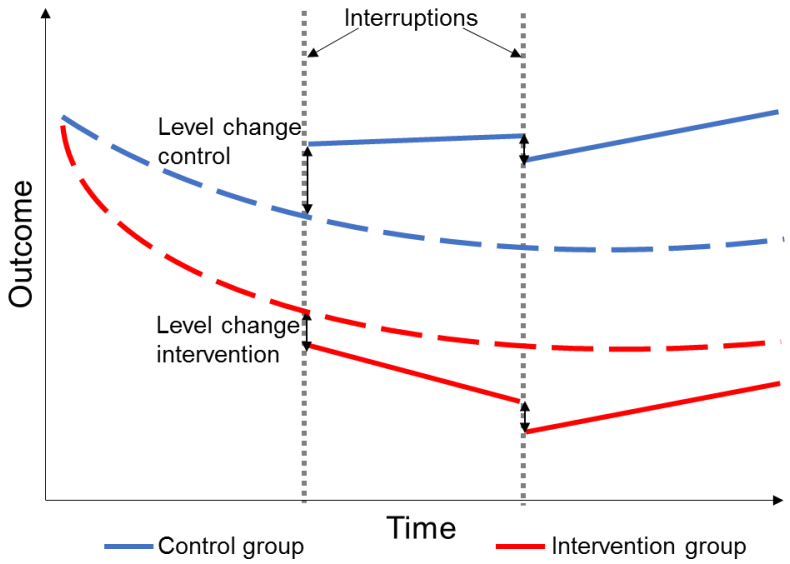


Figure 5.6 Scheme of a controlled interrupted time-series

Potential bias of the estimates can be further reduced by matching or adjusting for variables determining the selection process to the intervention or comparison group, which is a superior alternative to using demographic variables to match intervention and comparison groups (Cook et al., 2008). When the selection process is unknown, as the case of CQC inspections, it is crucial to use strategies to rule out the influence of potential confounders to obtain estimates of the treatment effect that are more valid (Shadish et al., 2002).

Even when several strategies can be used to improve the rigour of interrupted time-series studies, there are at least four biases that should be considered (Shadish et al., 2002):

- Selection-maturation: this refers to the intrinsic ability of each group to improve, therefore, if the treated group has more ability to improve, an effective intervention will increase the baseline gap.
- Selection-instrumentation: this happens when pre-test performance of non-equivalent groups lies in different points of the performance scale and detecting change is easier in a specific range, for instance, in the middle of the distribution.
  The bias is greater when initial or pre-post intervention differences are larger and mean performance of a group is closer to the extreme of the measurement scale.

This bias can also occur when there is a change in the measurement instrument before and after the intervention. In the case of having a control group, the change is problematic when is implemented for one group only.

- Selection-regression: this happens when the distribution of performance of two matched groups do not overlap at the beginning. The impact is that when a researcher tries to match them, individuals from one group come from the lowest end and individuals from the other group are at the highest end of the distribution. That means that their possibility of improvement is different tending towards the average of their group and consequently, differences in treatment effect can be explained by a selection-regression phenomenon.
- Selection-history: this refers to historical events happening between the pre and post intervention period, and that affect one group more than the other.
  For example, a greater proportion of trusts inspected by the new regime had been or were part of the Keogh review and subsequently put under special measures.

For this thesis, it was not possible to select the control groups to avoid selection-maturation, selection-instrumentation, and selection-regression biases; therefore, these biases were controlled for in the analysis. In the case of selection-history bias, the use of a switching-replication design was used as a method to control for differential macro shocks.

Other problems may arise from underdeveloped theories about what variables may mediate or confound the cause-effect relationship under test (Cook and Campbell, 1986). For instance, variations in effect size might not be detected because relevant underlying theories are underdeveloped. Therefore, there is restricted knowledge about potential mediators or moderators, outcome measures are not entirely valid, treatment contrast is attenuated, or the sample available for variables implicated in the causal pathway is too small to test their influence (Shadish et al., 2002). The rationale to pose three research objectives regarding the effectiveness of CQC inspections is that the knowledge about the underlying mechanism of action is limited. Hence, posing three objectives with increasing complexity could help elucidate whether the type of inspection mediates the size of the effect or if the response may be different depending on previous performance.

When different populations are aggregated to test a hypothesis, as is the case for the first research objective, results will inform the strength of a causal relationship despite the many sources of variability present in the analysis (Shadish et al., 2002). Consequently, using subgroup analyses would help to determine which of the potential sources of variability used explain the different effect sizes observed.

Shadish et al. (2002) suggest that using more than one theory to explain observations and valuing the rigour of independent replications can yield more robust conclusions, which is the rationale to assess the effect of the intervention on different process and outcomes measures since they are proxies of the various features of care quality.

5.2.1.6 Multi-level modelling

Techniques such as ARIMA regression can be used with a single time-series, but when the analysis involves looking at several time-series (or several panels) at the same time, other strategies capable of accounting for clustering should be used (Goldstein, 2005). This implies that ARIMA regression could have been used to answer the research questions of this thesis if data were aggregated. Although this is feasible, aggregating data involves losing granularity, where acknowledging the multilevel structure of data can yield useful inside into variables associated with different effect sizes. Therefore, instead of using an ARIMA regression, a multilevel modelling strategy was employed.

The advantage of using multilevel models, instead of other strategies to account for clustering such as White-Huber sandwich estimators or robust standard errors, is that the hierarchical structure is not considered a nuisance, but a feature that can enrich the analysis and help exploring sources of variability at different levels (Leyland and Goldstein, 2001). This allows the researcher to avoid atomistic fallacies (i.e. transferring conclusions from individuals to populations) or ecological fallacies (i.e. transferring conclusions from populations to individuals) (Diez Roux, 2002) since the influence of time-varying variables (level 1) can be explored in conjunction with variables varying at trust level (level 2).

Multilevel models fit a regression line for the average trust, and then, the model estimates the random variation of the other units in respect of the trust with average performance (Rabe-Hesketh and Skrondal, 2012). As any other regression model, covariates can be introduced to explain better variability in the data, making it possible to control for sources of bias and explore potential mediator variables. When a variable is added as a fixed effect, the model estimates a different intercept for each unit based on the value of that variable (Figure 5.7) (ibid).

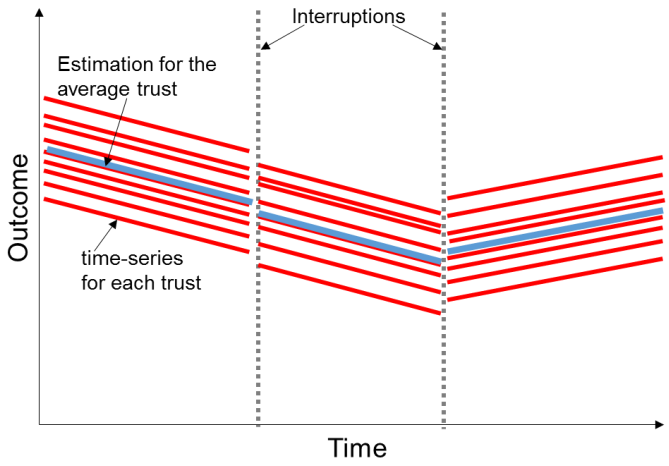


Figure 5.7 Example of a random intercept model

Conversely, when a variable is introduced as a random effect, the model estimates a different slope for each unit depending on the value of that variable (Rabe-Hesketh and Skrondal, 2012). When fixed and random effects are introduced, the model is called “random coefficients” (Figure 5.8).

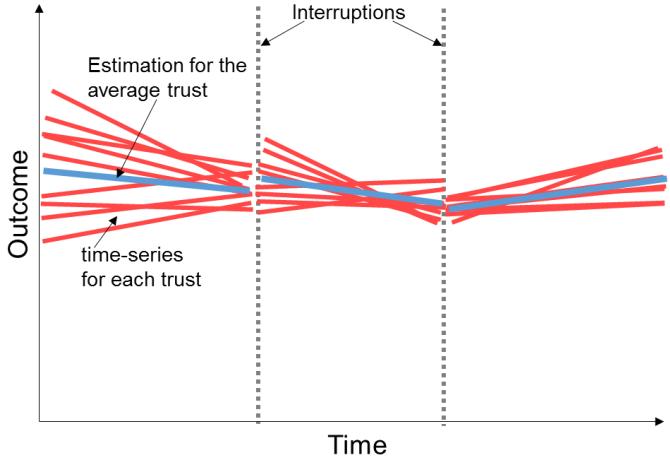


Figure 5.8 Example of a random coefficients model

In summary, the effect of CQC inspections was estimated using an interrupted time-series design given that regression discontinuity and difference-in-difference designs were not feasible. The estimations were obtained from a segmented multilevel random coefficients regression model to test for the influence of different variables on the estimates of effect and control for potential biases. A switching-replication design was also employed to control for history bias. Two interruptions (i.e. announcement and on-site visit) were added since the literature suggested an anticipatory effect of inspections (Robertson et al., 2017). Control groups were used to compare the effectiveness of CQC inspections depending on the type of inspection received and the performance before the inspection, which increases the robustness of the estimates.

5.3 Methods

5.3.1 Population

All acute NHS acute Trusts in England with available data for the selected process and outcome measures and in operation in June 2016 (n=155).

5.3.2 Intervention

The Care Quality Commission officially implemented a new regime of inspections to health and social care providers in October 2014; however, the new regime was phased-in between September 2013 and September 2014, which allows comparison of the old and new regime. This new, more resource-intensive approach was adapted from the Keogh review and involves several changes to the previous regime:

- a simplification of the fundamentals standards of care which are enforced by law;
- the incorporation of intelligent monitoring of over 150 indicators to guide the inspection into services that might be failing;
- an increase in the length of inspections and the size of inspection teams;
- the addition of ratings for core services, sites and the whole trust;
- an unannounced visit after the inspection;
- a new understanding of agreement with Monitor/TDA (now named NHS Improvement) to perform joint inspections.

5.3.3 Comparison

The old regime of inspections focused on a selection of the 28 essential standards (Care Quality Commission, 2010) and compliance with each standard was judged as “met standards”, “requires improvement” or “enforcement action”. Inspection teams comprised two to five inspectors and visits averaged 2 to 3 days.

5.3.4 Outcome measures

Using the CQC’s definition of care quality (i.e. Care provided should be safe, effective, caring, responsive and well-led), at least one measure was chosen for each domain. The overview of reviews did not provide a definitive answer regarding what indicators were more sensitive to external inspections and accreditation. Hence, the selection of measures that could reflect quality of care according to the CQC’s definition was performed through a qualitative documentary analysis (see Appendix Chapter 5, Table 5.1). This analysis mapped the fundamental standards reinforced by law; the Key Lines of Enquiry (KLOE) and the prompts used during on-site inspections, intelligent monitoring measures, two CQC reports and the

recommendations from the Francis Inquiry. The criteria to choose an outcome measure were pragmatic and are listed below:

- Data freely and publicly available at least since September 2012 to have data from one-year pre-inspection. When possible, data reported monthly were preferred over quarterly or yearly data.
- The indicator was associated with a prompt for the inspection and was included in the intelligent monitoring tool.
- Performance on that measure was highlighted in CQC's reports indicating it was a relevant measure for its own regime.
- The Francis Report made judgements or recommendation related to the performance measure.
- The measure is a nursing-sensitive outcome or reflects desirable qualities of good governance.

For Instance, the caring domain has three key lines of inquiries and 16 prompts. Patients' perception of being treated with dignity and respect was the only indicator meeting all the criteria; hence, it was included in the analysis (Table 5.1). The full list of outcomes selected is available in Table 5.2.

Table 5.1 Example of documentary analysis for outcome selection

	Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures	Trust rated as outstanding	Francis Report
5	Staff respect dignity and privacy of patients	Dignity and respect	"Overall, did you feel you were treated with respect and dignity while you were in the hospital?"	We observed staff holding discussions about patients' conditions and care plans in communal areas on wards and in some outpatient areas.	Treating patients with dignity and respect, as well as valuing them as individuals was evident throughout the organisation and fundamentally part of the culture	The knowledge and skills framework should be reviewed with a view to giving explicit recognition to nurses' commitment to patient care and the priority that should be accorded to dignity and respect in the acquisition of leadership skills.

Table 5.2 List of outcomes measures included in this study

Quality domain	Outcome measure	Indicator	Time Span	Available from	Frequency	Level
Effectiveness	Mortality	Standardised hospital mortality ratio	Apr 2011-Oct 2015	NHS Digital	Quarterly	Trust
Safety	Avoidable events	Falls with harm Pressure ulcers	Apr 2012-Jun 2016	NHS safety thermometer	Monthly	Trust

Quality domain	Outcome measure	Indicator	Time Span	Available from	Frequency	Level
Caring	Dignity and respect	Inpatient adult survey. Q67 "Overall, did you feel you were treated with respect and dignity while you were in the hospital?"	Jul 2005-Jul 2015	Picker Institute Europe	Yearly	Trust
Responsive	Access	A&E waiting time	Nov 2010-Jun 2015	NHS Digital	Weekly	Trust
	Access	Referral to treatment waiting time-admitted	Aug 2007-Jul 2016	NHS Digital	Monthly	Trusts/ wards
Well-led	Rate of leavers	Proportion of staff that has left during the last month	May 2012-Mar 2016	Electronic staff records data warehouse	Monthly	Trusts

Pressure ulcers and falls with harm are outcome measures not assessed as part of the intelligent monitoring; therefore, they were included to test for the presence of managerial tunnel vision (i.e. focus only on those performance indicators under assessment).

It must be noted that due to the number of outcome measures chosen and the number of research questions, there is a risk of finding spurious statistical significant associations because the family-wise error rate increases with more comparisons (Bartroff and Song, 2014).

5.3.5 Data sources, data collection processes and definitions

Data on adverse events, waiting times, and risk-adjusted mortality were publicly available from NHS Digital. Information on patients' perception of being treated with dignity and respect was obtained in February 2017 from the Picker Institute Europe and NHS Digital provided the dataset of rate of leavers in July 2016 upon formal request.

5.3.5.1 Avoidable harm

Falls with harm and pressure ulcers are measures of avoidable harm and nursing-sensitive outcomes (Currie et al., 2005, Butler et al., 2011), which reflect the quality of nursing care.

Data on these adverse events are collected through the NHS Safety Thermometer (NHS ST) and are aggregated at ward, provider, regional and national levels (Power et al., 2012). NHS ST was implemented in two phases as a national collaborative quality improvement initiative to reduce the number of adverse events related to the four most common harms (i.e. falls with

harm, pressure ulcers, urinary infection in patients with catheters and venous thromboembolism) (Power et al., 2014, Power et al., 2016). The first phase ran between September 2010 and April 2012 with the aim of testing the instrument and achieving consistent definitions for the adverse events under assessment (ibid). The second phase (implemented between April 2012 and March 2013) rolled the thermometer out to all NHS providers in England. A financial incentive was used – the Commissioning for Quality and Innovation (CQUIN) scheme - to reward providers meeting data collection standards (ibid).

An NHS ST census survey is carried out on one day of the month by trained frontline staff. These data are entered via a website to allow trends over time and institutional comparison to national and regional estimates to occur (Power et al., 2014).

The NHS ST is the only database on adverse events in acute NHS trusts publicly available, collected nationally using the same definitions and standards on a monthly basis. However, data can be inconsistent due to variable data entry skills, flexible interpretations of operational definitions, and variations in patients' case-mix across sites (Power et al., 2014). Sari et al. (2006) performed a study in a large acute NHS Trusts comparing the number of incidents reported through the routine incident reporting system with the number found by reviewing medical records. They found that 56% of falls and 23% of pressure ulcers were reported to the routine system (Sari et al., 2006). This means that adverse events are underreported, and inspections could improve performance or reporting behaviour; however, without central information on the magnitude of the problem in a wide variety of trusts, it is not possible to isolate the cause of any observed effect. Despite the reliability issues of the data from the NHS ST, this information was used because hospital and the CQC itself assess progress on these indicators based on that data. Therefore, the NHS ST provided a picture of performance.

Fall with harm and pressure ulcers are indicators considered within CQC documentation and inspection reports (e.g. CQC report Northamptonshire Healthcare NHS Foundation Trust, p.19); however, they are not included in the CQC intelligent monitoring. Consequently, its analysis can show if inspections affect other outcome measures not formally included in the assessment.

Falls with harm are an unplanned or unintentional descent to the floor with injury, regardless of cause (slip, trip or fall from a bed or chair). It is considered to have produced harm when the patient at least requires first aid, minor treatment or extra observation or medication (Madsen, 2014).

Pressure ulcers are any pressure ulcer developed 72 hours or more after patient admission. The European Pressure Ulcer Scale is used to categorise them (Madsen, 2014).

For the analysis, the number of events divided by the number of patients surveyed was used for these two measures.

5.3.5.2 Risk-adjusted mortality

Mortality is contested as a measure of quality of care (Park et al., 1990, Pitches et al., 2007, Goodacre et al., 2015, Hogan et al., 2015, Kobewka et al., 2017b). When it is used as crude mortality rates, large variations between trusts could be attributed to differences in case-mix (Pitches et al., 2007). Risk-adjusted measures can account for case-mix; however, these measures are not perfect, and some residual variation is still present due to randomness and differences in disease severity (Thomas and Hofer, 1999, Pitches et al., 2007, Goodacre et al., 2015). The residual variation that can be attributed to preventable death, and therefore, to poor quality of care is low ranging between 3.6% and 8.4% (Hayward and Hofer, 2001, Hogan et al., 2015, Kobewka et al., 2017a). This means that only a small proportion of variation in risk-adjusted mortality is associated with preventable deaths, which makes it difficult to differentiate actual poor care from random variation (Hogan, 2016). Girling et al. (2012) estimated that the predictive value of risk-adjusted mortality to detect hospitals providing poor care was around 9% when the proportion of preventable deaths was 6%. However, mortality is an undesirable outcome, highly visible, and although, by itself it cannot indicate what the sources of preventable deaths are (Kobewka et al., 2017b), it can prompt further investigations.

The Summary Hospital-level Mortality Index (SHMI) is a measure of risk-adjusted mortality. It is calculated as a ratio between observed in-hospital or within 30 days of discharge deaths and the expected number of deaths for a Trust. The expected number of deaths is calculated using a risk-adjusted model, which includes patient case-mix of age, gender, admission method, year index, Charlson comorbidity index and diagnosis grouping (Campbell et al., 2012).

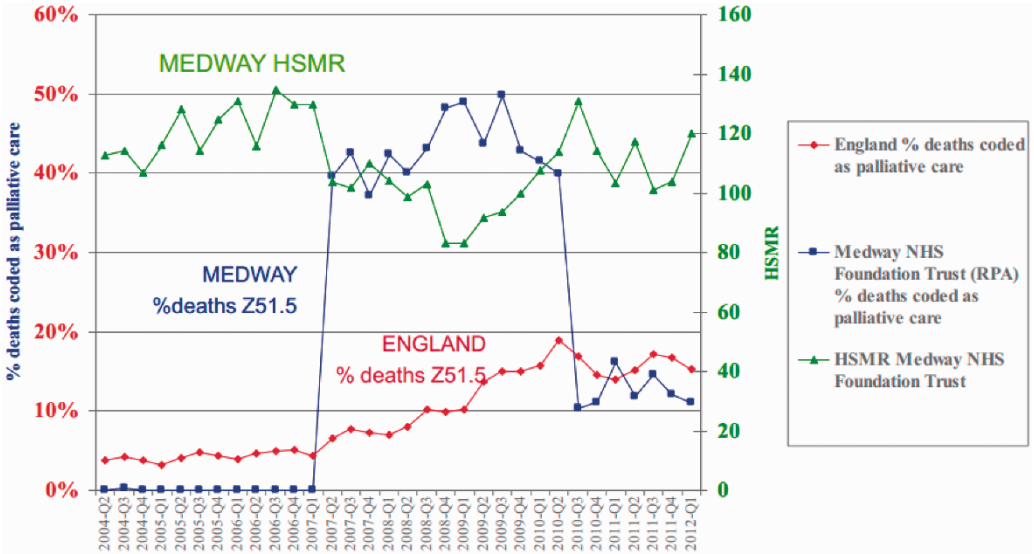
The measure is produced by HSCIC using information from the Hospital Episodes Statistics (HES) and the Office of National Statistics (ONS). Crude mortality rates are highly reliable, but some problems can arise from the reporting of variables for the risk adjustment (Clinical Indicators Team, 2017). The main problem with SHMI is that data is not extracted directly from patients' records. Instead, the information is stored in one database for internal purposes (i.e. Patient Administration System), which is later submitted to the Secondary Uses Service (SUS). NHS Digital (formerly HSCIC) uses the latter to create HES data (Clinical Indicators Team, 2017). This means that a trained coder must transform the primary diagnosis and all the comorbidities into ICD-10 codes (ibid). NHS Digital reports that there are some variations between organisations in the accuracy of clinical coding, but these do not affect the calculation of SHMI (ibid). Other factors that might affect the indicator such as palliative care are not

included due to high inconsistency in the coding (HSCIC, 2013b). The data submitted by the providers have to comply with validation rules and goes through an audit (Clinical Indicators Team, 2017); therefore, the possibility of manipulating data to the advantage of the trust is low.

This indicator is used to compare the performance of hospitals across the country even when the risk of dying is different. Data is published quarterly at NHS Trust level since October 2011. The first publication included data from March 2010 to March 2011, being label as April 2011 for the analysis. Thus, SHMI were not assigned to their publication date, but to the month after the 12-month period used to calculate it.

According to the researchers that devised the model to calculate the SHMI, 82% of the variance can be explained by the model. Therefore, a proportion of the deaths might be falsely identified as outliers (Campbell et al., 2012). The main issue with standardised indicators is that variation in measurement error can lead to higher than expected values in the index (ibid), whilst, hospitals can game by making patients look sicker than they are (Hawkes, 2010).

An analysis of the effect of coding practices on another standardised mortality ratio (i.e. Hospital Standardised Mortality Ratio) showed that increasing the number of deaths coded as palliative care from 8% to 37% reduced the HSMR by a third in Medway NHS Foundation Trusts (Taylor, 2013). Mid-Staffordshire NHS Foundation Trusts was another hospital increasing the number of patients coded as palliative care to reduce risk-adjusted mortality, which coincided with the announcement of an investigation of the trust (Taylor, 2013). These examples are shown in Figure 5.9. The model used to calculate SHMI is less prone to gaming and highly reliable.



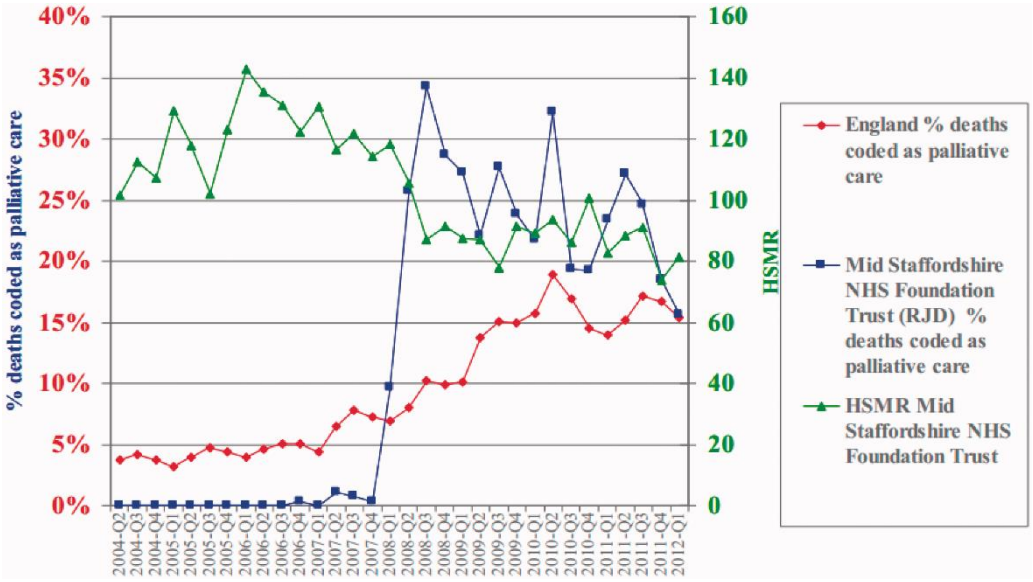


Figure 5.9 Impact of changing coding practices on a standardised mortality ratio. Taken from Taylor (2013).

5.3.5.3 Waiting times

As an initiative to reassure the general public about the government's commitment to quality of care and the reduction of waiting lists, waiting times standards were introduced in 2002. A&E and RTT waiting times were established first as a political commitment to quality that later turned into legal rights in the NHS constitution (DOH, 2009). The reporting is mandatory for all healthcare providers. NHS England collects and publishes the information which serves as an accountability measure.

Although improving access was the primary purpose of imposing waiting times targets, later research has shown an association of long waits and patients outcomes (Day, 2013, Carter et al., 2014). For instance, seven days after an A&E visit, non-admitted patients have an incremental increase in the risk of admission with each extra hour of wait (adjusted odds ratio for mean wait > 6 hours: 1.95 [1.79 to 2.13]) (Guttmann et al., 2011). A potential pathway explaining these findings is that in overcrowded A&E departments some processes of care might be altered or shortened, leading to wrong or missed diagnoses, incomplete or delayed treatment, or miscommunication of treatment plan after discharge (Guttmann et al., 2011, Carter et al., 2014).

In the case of long waits for elective non-urgent care, evidence suggests that the risk of adverse events and poor outcomes increases with the length of wait (Day, 2013, Barua et al., 2014). For example, the findings of 17 studies looking at the effect of waiting times for patients requiring cardiovascular surgery (i.e. coronary angioplasty or angiography, coronary artery bypass graft, valve replacement, and cardiac catheterisation) suggest an increased risk of adverse events such as myocardial infarction and death whilst waiting (Day, 2013). Likewise,

longer waiting times diminishes physical function and quality of life of patients with spinal stenosis (Braybrooke et al., 2007, Bailey et al., 2016) and requiring joint replacement surgery (Montin et al., 2008, Vergara et al., 2011, Desmeules et al., 2012).

A&E waiting times measures the time spent from arrival until admission, transfer or discharge. The target is that 95% of attendances should be resolved within 4 hours (since April 2011). Until the first quarter 2010, the target was 98% of attendances resolved within 4 hours. Data were published weekly at NHS Trust level between November 2010 and June 2015, which is the period used for the analyses.

The number of patients waiting more than 4 hours in A&E divided by the number of all attendances was used for the analysis.

Waiting times are official statistics reported to Unify2, which is the standard tool for the collection of performance data in the NHS (NHS England, 2015a). These statistics have to comply with the code of practice for official statistics and the national statistician's guidance (UK Statistics Authority, 2009, UK Statistics Authority, 2016), which should suggest data are accurate and reliable

Consultant-led referral to treatment (RTT) waiting time – admitted pathways measures the time since referral (i.e. referral letter is received by the hospital or patient books first appointment) until admitted treatment is received. The target is that 90% of admitted and 95% of non-admitted treatment should start within 18 weeks. Data is published monthly at NHS Trust level since April 2007.

The number of patients waiting more than 18 weeks to see a consultant divided by the number of patients referred was analysed.

Reporting standards of RTT waiting times are higher since providers submit data to Unify2 and the database used to determine payment for services (SUS) (NHS England, 2015c). However, before October 2015 the rules for reporting of RTT waiting times were open to interpretation, leading to incorrect recording (National Audit Office, 2014). The application of different rules to measure waiting times means that comparability of data decreases and it can give way to data manipulation to avoid fines (ibid). In October 2015, the Department of Health published a new rules suite to ensure consisting reporting and eliminated the possibility of pausing or suspending the waiting time (DOH, 2015c). This change of rules might have affected the trend observed in the post-inspection period, but it occurred at least one-year after the end of the pilot period. Consequently, it should not affect the estimates of effect.

Although the statistics are collected centrally, data is reported by each trust, therefore can be prone to gaming as econometric studies during the implementation of the star ratings have shown (Locker and Mason, 2005, Besley et al., 2009). Locker and Mason (2005) found that although the 4-hour wait target was being met, 12.3% of admitted patients and 3.6% of discharged patients waited between 220 and 239 min, meaning that a higher proportion of admitted attendances were resolved just before missing the target. Consequently, the average waiting time had not decreased as much as expected (Locker and Mason, 2005). In the case of referral to treatment waiting times, Besley et al. (2009) found that the introduction of more stringent targets (i.e. 15- and 18-month target) translated into an increase in the number of patients waiting between three and nine months. Therefore, observed average waiting time was higher than the expected. The magnitude of gaming is not assessed on a regular basis, and there is no information examining if inspections affect the size of it. Consequently and similarly to what happens with adverse events and risk-adjusted mortality, it is not possible to model the effect of changes in reporting behaviour on the estimates of the effect of the inspection.

5.3.5.4 Patients' perception of being treated with dignity and respect

Patients' perception of care has been linked to staffing levels, staff skill mix, safety outcomes (Aiken et al., 2016) and the working environment (NHS Confederation, 2011, NICE, 2012, The Point of Care Foundation); therefore, to certain extent, it reflects the climate and culture of each NHS trust (The Point of Care Foundation).

It is measured through the NHS adult inpatient survey since 2004. The Picker Institute Europe collects the data and publishes the annual results on behalf of the Care Quality Commission. The response rate to this survey has dropped over time from 59% in 2005 to 47% in 2015 (Boyd et al., 2007, Care Quality Commission, 2016a). Most of the data collection occurs in July of the year of the survey, and only small trusts collect information from patients discharged in previous months (Care Quality Commission, 2016a). These two features make data prone to bias (i.e. non-response bias and seasonal effect). To control for the potential effect of changes in case-mix, the results of the survey were standardised.

This question in the inpatient survey has three options: 1) Yes, always; 2) Yes, sometimes; and 3) No. These three options were transformed, assigning 0 to the most critical responses and 100 to the most favourable, so results are comparable to other studies (Raleigh et al., 2015b).

Demographic characteristics of patients responding to the survey differ by question, among Trusts and over time. Longitudinal and cross-sectional studies suggest that there is a positive correlation between better perception of care and age, male sex, planned admission and being white British (Sizmur, 2011, Raleigh et al., 2015a, Raleigh et al., 2015b). Whilst, female

respondent, individuals admitted through A&E and patients from ethnic minorities tend to perceive care as of lower quality (Sizmur, 2011). In consequence, to make comparisons between different trusts, the perception of care was standardised to account for the composition of patients' sample (see Statistical analysis).

5.3.5.5 Staff leaving acute NHS trusts (staff turnover or rates of leavers)

Staff turnover is associated with quality of care through two interrelated pathways: the work environment and staffing levels. Research on factors associated with intention to leave is mainly focused on nurses, is low quality and inconsistent. It suggests that high workload (Coomber and Barriball, 2007, Yin and Yang, 2002), lack of stability due to work schedule, low group cohesion (Shader et al., 2001), ineffective supervision (Hellman, 1997, Coomber and Barriball, 2007) and time pressure affecting quality of care (Estryn-Behar et al., 2010) are contributing factors to job dissatisfaction that increase intention to leave and turnover. Therefore, staff turnover might serve as a proxy for working environment and culture in each trust. The other pathway comes from the relationship between staffing levels and work stress (Coomber and Barriball, 2007). Low retention or poorly staffed wards are related to high workload, high levels of job dissatisfaction, burnout (Aiken et al., 2002) and work stress. In addition, once staff have decided to leave, their productivity and efficiency decrease, which affects those remaining by increasing their work pressure and decreasing their morale (Gauci Borda and Norman, 1997). Therefore, high turnover rates can reflect or can lead to inadequate staffing, which is linked to adverse events and mortality (Aiken et al., 2008, Aiken et al., 2016, Griffiths et al., 2016).

NHS Digital generates the NHS workforce statistics using information trusts report to the electronic staff records (ESR), where rates of leavers are part of these official statistics published quarterly (Electronic Staff Record Programme, 2017). The definitions are standardised through Information Standards Notices to achieve consistent reporting (ibid). Since April 2012, NHS Digital performs validation checks of the workforce data in ESR, including crosschecking and validation rules (HSCIC, 2013a). The results of this exercise produce a score for each trust with suggestions on how to improve data quality. The areas with more errors are pay bands, job roles, and missing information (NHS Digital, 2017). Since rates of leavers are linked to the payment for services of staff, it was expected to be accurate, but there is no formal study validating the dataset included.

NHS Digital publishes rates of leavers as an official workforce statistics quarterly since April 2012. However, monthly data were requested to improve the robustness of results for this measure. Rate of leavers is the number of staff leaving each acute NHS trusts every month, regardless of the reasons for leaving, divided by the average number of staff employed during

that period. It excludes personnel that transfer to another unit or move from a clinical to a managerial position.

It was initially planned to use the staff stability index as another measure of governance since it provides information on the proportion of members of staff that have worked in the trusts for at least one year. However, the rate of staff leaving acute NHS trusts is negatively correlated to the staff stability index ($r= -0.99$, $p<0.0001$), being almost perfectly complementary. This means that analysing the staff stability index was not going to provide more insight on the effect of CQC inspections on measures of care quality and, consequently, it was removed from the analyses.

5.3.5.6 Descriptive information and potential confounders

From the CQC website (http://www.cqc.org.uk/) the following information was retrieved:

- Descriptive information on acute NHS trusts (including number of beds, location, type of trust, number of sites, catchment population).
- Reporting culture rating by the CQC (2016).
- Z-score for potential underreporting of safety incidents reported by the National Reporting and Learning System (NRLS).
- Dates and number of inspections since September 2012.
- Type of inspection.
- Ratings given during the first inspection under the new regime.

Performance ratings given in 2009 were retrieved from the archived CQC website. Information on financial performance (i.e. continuity of service or escalation score), mergers, and enforcement actions were obtained from other regulatory agencies (Monitor, Trust Development Authority, NHS Improvement). Information on the main commissioner was obtained from the annual account report of each acute NHS trust. Data on the multiple deprivation index of the main commissioner and the monthly number of staff members were obtained from NHS Digital.

5.3.6 Statistical analysis

To address the first three aims of this research, an interrupted time series (ITS) analysis was used, which is considered a strong quasi-experimental design to assess the impact of policies that cannot be randomised (Penfold and Zhang, 2013). The design was adapted for each measure under analysis and each scenario under testing. Two interruptions were added: the month of the inspection and four months prior when the inspection was officially announced. Two interruptions meant it could be determined whether the announcement or the inspection

itself had a greater effect since previous studies had reported that the announcement triggered more changes than the visit (Healthcare Commission, 2008a).

To model an interrupted time-series, time is introduced as an explanatory variable, indicating the rate of change before the intervention (i.e. counterfactual). For each interruption, two new variables are added: a dummy and time indicating the period post-intervention. The coefficient for the dummy variable represents the change in level, whilst the coefficient for the post-intervention time variable indicates the change in slope. Since inspections were spread out across one year, time was centred on the inspection month, with negative values before the inspection and positive values after.

Since data over time is nested within acute NHS Trusts, a multilevel random-coefficients model was used. The unit of analysis was individual acute NHS trusts, and one single unadjusted model was fitted to each outcome measure.

For a single time-series, the autocorrelation structure can be determined using a Durbin-Watson test, but this is not applicable to panel data. In the case of multilevel longitudinal models, the Woolridge test can be employed instead. However, it can only test for the presence of autocorrelation with the previous data point (i.e. AR=1) (Drukker, 2003), but if this correlation occurs with data points further away, it cannot be tested. For these analyses, auto-correlation structures from 1 to 12 were introduced and the different models were compared using a likelihood ratio test. The model with the most parsimonious AR structure is reported.

To account for potentially confounding variables, the following were included as fixed effects:

- Number of beds,
- Trust size,
- Foundation trust status,
- Number of trust hospitals and locations,
- Number of inspections since September 2012,
- Months since previous CQC inspection,
- Number of staff members per month,
- Merger activity,
- Region,
- Financial performance and
- Reporting culture.

These variables were chosen as proxies of performance over time and trusts' capacity to respond to an inspection. Additionally, to account for the potential effect of the reform of the

commissioning system, a dummy variable was introduced for the period between October 2012 and April 2013. Variables with a p-value <0.2 in the univariate model were entered into the adjusted model. The most parsimonious model is reported based on the lowest Bayesian Information Criterion (Gurka, 2006).

Adverse events, waiting times and rate of leavers were logarithmically transformed to have a linear relationship between explained and the explanatory variables. Once the model was fitted, the exponential of the coefficients was calculated to express them in the original scale. The assumptions of uncorrelated and normally distributed model residuals were met for all the models.

Since demographic features, which vary across NHS trusts, influence patients' perception, data had to be standardised to be comparable. Estimated marginal means were calculated using the transformed responses from 2005 to 2015 for all acute NHS trusts. This analysis calculates the relative influence of age, sex, ethnicity, and route of admission into patients' perception of care and estimates for each year and trust, a mean value weighted by the sample composition.

Strategies such as adding cosine and sine functions and a squared time term were tested to account for seasonal patterns and obtain the correct functional form. The model for pressure ulcers included a cosine function, whilst A&E waiting times included sine and cosine functions. In the case of RTT waiting times and rate of leavers, a Fourier function (i.e. cosine, sine, cosine*2 and sine*2) were added to the models. Additionally, to obtain a correct functional form for RTT waiting times, a squared time term was included. Rates of leavers had a regular pattern of outliers in August of each year, which coincides with the rotation of junior medical staff. Therefore, a term reflecting this phenomenon was added.

Trusts inspected by the new, old regime and those not inspected significantly differed regarding Foundation Trust status, number of inspections and reporting culture rated by the CQC. To check the robustness of the findings, the models were run on a smaller sample of trusts matched by these variables. Since the results remained unchanged, the models with the whole sample are reported.

For each model, coefficients with 95% confidence intervals are reported, the rate of change before and after both announcements and inspections, change in levels and trends the month after inspection, and the rate of change one-year post inspection.

P-values <0.05 were considered significant. Analyses were performed in Stata SE/14.0.

5.3.6.1 Model specification

To determine the effect of any inspection, the model specification for each outcome was as follows:

$$outcome_{ij} = \beta_{0j} + \beta_{1j} corrected\ time_{ij} + \beta_{2j} announcement_{ij} + \beta_{3j} time\ after\ announcement_{ij} + \beta_{4j} inspection_{ij} + \beta_{5j} time\ after\ inspection_{ij} + U_{0j} + U_{1j} corrected\ time_{ij} + U_{3j} time\ after\ announcement_{ij} + U_{5j} time\ after\ inspection_{ij} + \phi_{nj}(t-n) + \varepsilon_{ij}$$

This model was used as the basis to build the other models by introducing six interaction terms for each comparison group added. This means that for the comparison of the effect of the new and old regime of inspections, the model had 18 fixed effect coefficients, whilst the model accounting for previous performance had 36 fixed effects coefficients.

β denotes the coefficient for the average trust, U_0 represents the random variation in level of each trust in relation to the average trust, $U_1\ U_3\ U_5$ represent the random variation in slope of each trust in relation to the average trust, ϕ is the coefficient for each AR component of the model and ε_{ij} is the error term of the model.

5.3.7 Ethics

Given that this study does not involve measurements of human participants and all data used was freely and publicly available, it was not viewed as requiring Research Governance Committee approval. Findings will be published to disseminate the knowledge and, potentially, benefit the public.

5.4 Summary of methodology and methods

An interrupted time-series design is a strong quasi-experimental design to determine the effect of an intervention when randomisation is not feasible. Adding a control group, interventions at different time points and measuring varied aspects of the same construct are strategies to reduce confounding, which have been implemented in this thesis.

Three research aims were posed to determine the effect of CQC inspections of acute NHS trusts on rates of falls with harm, pressure ulcer, risk-adjusted mortality, waiting times in A&E and for referral to treatment, patients' perception of being treated with dignity and respect, and rate of staff leaving their job. The increasing complexity of the research aims allows testing for the effect of previous performance and different CQC inspection regimes, separately and in combination.

The use of a multilevel random coefficient regression model enriched the analysis and enabled us to test for sources of variability, which is not possible when aggregate measures are used or with different modelling strategies such as difference-in-difference analyses.

Features of the NHS trusts regarding number of beds, region, members of staff, financial position, governance rating, and proxies of reporting culture were introduced to the models to test their potential influence on the effect of the inspections.

In summary, an Interrupted time series study using a multilevel random-coefficients model was chosen to determine the effect of CQC inspections, regardless of the type of inspection. A subgroup analysis by quality rating in 2009 was performed to test for a differential effect of inspections depending on historical performance. Then, two control groups were added to estimate the effect of the new regime of inspections of the English NHS acute trusts in comparison to non-inspected trusts and those inspected under the old regime between September 2013 and September 2014. Furthermore, the effect of the new and old regime of CQC inspections was compared accounting by previous performance (i.e. improving or not improving before on-site visit) using an interrupted time-series with control.

6 The effect of Care Quality Commission inspections on clinical and health outcomes

The overarching question for this thesis is whether CQC inspections have an effect on measures of quality of care. Previous chapters have given the historical context on how quality of care and quality improvement is understood within the National Health Service in England, the rationale for institutional regulation in healthcare, evidence regarding the effect of external oversight on organisational and clinical outcomes, and lastly, the methodological approach chosen to address the overarching research question.

Three scenarios were analysed to provide evidence to answer this question. Firstly, the effect of any inspection on measures of quality of care (Chapter 6). Secondly, the comparison of the new and old regimes of inspections (Chapter 7), and finally, the effect of both regimes accounting for previous performance (Chapter 8). Performance ratings given in 2009 were considered as another measure of previous performance, and therefore, a subgroup analysis was carried out to test for any differential effect.

6.1 **Findings of the analysis of any inspection**

The universe for this analysis is 155 acute NHS trusts in England (Table 6.1). A third of them are located in the North, whilst in terms of size, medium acute trusts are the most common (29%). In the South and North regions, large and medium trusts are predominant (63.9% and 58%, respectively). Medium and small trusts are more common in the Midlands (53.3%), whilst in London, teaching and specialist trusts (50%) are more predominant.

In terms of new regime CQC ratings, 90 (60%) were deemed as “requiring improvement”, 40 (26.7%) as “good”, eight (5.3%) were rated as “outstanding” and 12 (8%) as “inadequate”. Regarding the geographical distribution of ratings, 42% of trusts rated as “outstanding” or “good” are located in the North, whilst 58% of trusts rated as “inadequate” are in the Midlands and East region. Considering trusts that were deemed as “requiring improvement”, 14% were in London, whilst the other regions had a similar proportion of trusts in this category (31% North, 30% Midlands and 26% South). Regarding type of trust, acute specialist trusts were more likely to be rated as “outstanding”; whilst large trusts more likely to be “inadequate”. Trusts rated as “good” or “requiring improvement” has a similar distribution across trust types (between 77% specialist and 89% medium trusts).

The Clinical Commissioning Groups (CCGs) of acute trusts in the South region had lower values for the Index of Multiple Deprivation (IMD) compared to trusts in other regions (16.8 vs 26.9 North, 22.4 Midlands, and 22.8 London, p=0.002). In contrast, the North region has the highest IMD for the health domain compared to the other regions (0.6 vs 0.00007 Midlands, -0.36 South, and -0.2 London, p<0.0001).

Monitor sustainability rating was similar across regions; however, the governance rating differed. All acute trusts in London were rated as "no evident concerns", whilst 58% of trusts subject to enforcement actions were located in the Midlands.

The CQC aims to inspect acute trusts every 2 to 3 years, but the median (P_{25}-P_{75}) months since the previous inspection is 10 (7-15) months, which illustrates the level of scrutiny these institutions have been subject to in the previous five years.

Table 6.1 Descriptive information for all acute NHS trusts

	All acute NHS trusts n=155
Foundation Trust	100 (64.5%)
Type of trust	
Large acute trust	41 (26.5%)
Medium acute trust	45 (29.0%)
Small acute trust	26 (16.8%)
Acute teaching trust	25 (16.1%)
Acute specialist trust	18 (11.6%)
NHS England region	
North	50 (32.3%)
Midlands and East	45 (29.0%)
South	36 (23.2%)
London	24 (15.5%)
Number of beds, median (IQR)	703 (488, 1020)
Population in thousands, median (IQR)	453.3 (340, 600)
Number of hospitals, median (IQR)	3 (2, 5)
Number of locations, median (IQR)	4 (2, 7)
Special measures	19 (12.3%)
Inspection Sep 2013 to Sep 2014	
New regime	67 (43.2%)
Old regime	48 (31.0%)
No inspection	40 (25.8%)
Overall rating	
Outstanding	8 (5.3%)
Good	40 (26.7%)
Requires improvement	90 (60.0%)
Inadequate	12 (8.0%)

	All acute NHS trusts n=155
Merged trusts	13 (8.4%)
Index Multiple Deprivation[17], median (IQR)	21.46 (16.64, 27.58)
Index Multiple Deprivation-Health[17], median (IQR)	0.075 (-0.38, 0.54)
Monitor Sustainability rating	
Significant risk	8 (8.2%)
Material risk	10 (10.2%)
Emerging or minor concerns	52 (53.0%)
No evident concerns	25 (25.5%)
Lowest risk	3 (3.1%)
Monitor Governance rating	
Subject to enforcement action	19 (19.4%)
Under review	12 (12.2%)
No evident concerns	67 (68.4%)
TDA escalating score	
Enforcement action	6 (10.5%)
Significant delivery issues	22 (38.6%)
Some delivery issues	16 (28.1%)
Limited/no issues	11 (19.3%)
Sound FT application	2 (3.5%)
Number of inspections, median (IQR)	4 (3, 5)
Months since previous inspection, median (IQR)	10 (7, 15)
Reporting culture 2016	
Poor	26 (16.8%)
Significant Concerns	54 (34.8%)
Good	65 (41.9%)
Outstanding	10 (6.5%)
Performance rating - Overall Quality 2009	
Excellent	37 (24.2%)
Good	73 (47.7%)
Fair	37 (24.2%)
Weak	6 (3.9%)
Performance rating - Financial 2009	
Excellent	72 (47.1%)
Good	58 (37.9%)
Fair	19 (12.4%)
Weak	4 (2.6%)

[17] The index of multiple deprivation (IMD) is a relative measure of deprivation across England considering seven domains: income, employment, health, education, barriers to housing, crime, and living environment deprivation. The IMD average scores for the main CCG is presented in Table 6.1. The index is calculated for each Lower Layer Super Output Area (LSOA) and then a population-weighted average is obtained considering the average score of all LSOAs within a CCG. Higher values indicate more deprivation. A value of 21.46 corresponds to a CCG ranked 103 out of 209. In the case of the Health IMD average score, a value of 0.075 corresponds to a CCG ranked 105 out of 209 in 2015 (Ministry of Housing, 2015).

Data for all the indicators assessed were available at least from April 2012. Inspections included in this analysis were performed between September 2012 and April 2015; therefore, there are at least five data points before and after the inspection for each trust. November 2013 had the highest number of inspections (23 [15%]), but they are spread out in the observation period, which reduces the possibility of finding an effect attributable to other competing interventions. One trust was excluded from this analysis because it was not inspected in this time period. Since changes in level and slopes were very small in magnitude, these are shown per 10,000 events/month in order to have meaningful figures. The regression model used interaction terms to obtain changes in level and slope. The values presented in the tables are absolute numbers.

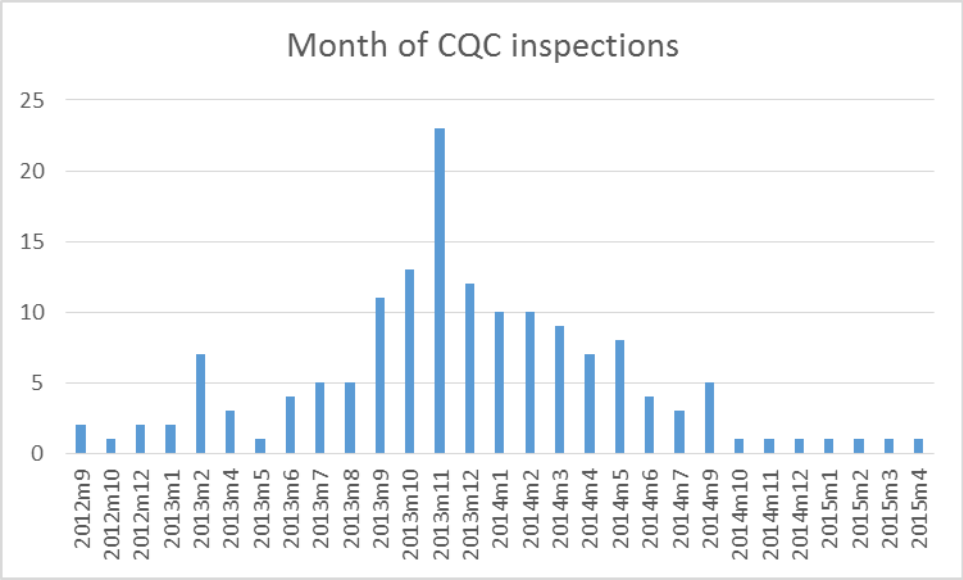


Figure 6.1 Frequency distribution of CQC inspections of all acute NHS trusts in England

6.1.1 Adverse events

There were 5 specialist trusts not reporting data to the NHS thermometer, which were Foundation trusts, were rated as “no evident concerns” by Monitor, and had fewer beds than those trusts with available data (253.5 [230, 328.5] vs 707 [500, 1024]).

Over time, rates of adverse events have decreased although compared to falls with harm, pressure ulcers are more common, present a higher variability for each period and the improvement is more pronounced (Figure 6.2).

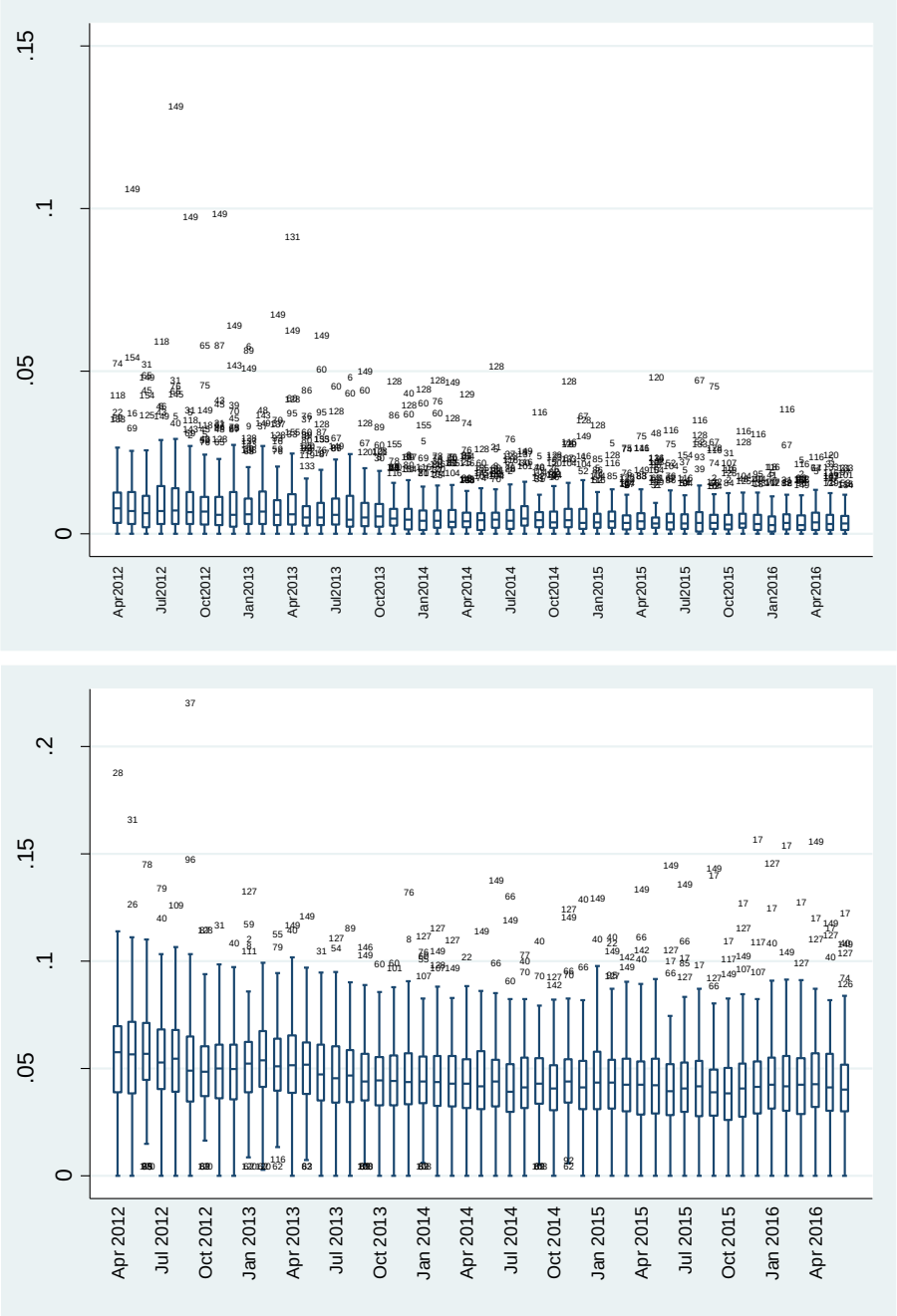


Figure 6.2 Rates of falls with harm and pressure ulcers in all acute NHS trusts in England

6.1.1.1 Falls with harm

In April 2012, the rate of falls with harm (95% CI) was 0.0098 (0.0079 to 0.011), whilst in June 2016 it was 0.004 (0.003 to 0.005) showing a decrease over time. One trust was excluded from this analysis because it did not report data before the inspection.

For an average trust before the inspection, there were -2.77 (-4.26 to -1.28) fewer falls with harm per 10,000 patients/month. The announcement and the inspection itself did not produce a significant change in the level or slope of falls with harm. After the inspection for an average trust, there were -0.59 (-0.82 to -0.37) fewer falls with harm per 10,000 patients/month which represents a decrease in the speed of improvement (Table 6.2). This change in trend produced

an increase for an average trust of 5.52 (-2.67 to 13.7) falls per 10,000 patients 12 months after the inspection compared to the counterfactual (Figure 6.3). Tables with the model coefficients are available in the Appendix to Chapter 6, table 6.3.

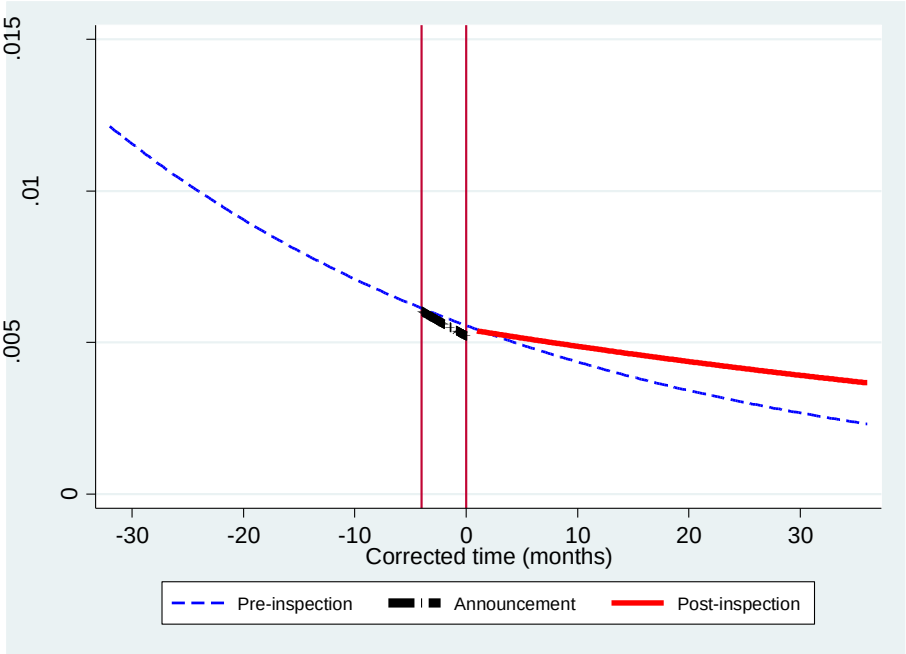


Figure 6.3 Predicted rates of falls with harm for an average acute NHS trust before, after the announcement and CQC inspection

Key: Lines represent the mean rate of falls with harm obtained from the multilevel model for each period. The first vertical line signals the announcement, while the second the inspection. Dash lines show the trends observed during the pre-inspection period, which were extended for the post-announcement and post-inspection periods. Long-dash lines represent the observed trends in the period between the announcement and the inspection. Solid lines show the trends after the inspection. The same applies for all graphs in this chapter.

6.1.1.2 Pressure ulcers

In April 2012, the rate of pressure ulcers (95% CI) was 0.056 (0.05 to 0.06), whilst in June 2016 it was 0.04 (0.038 to 0.045) showing a downward trend for this particular adverse event. One trust was excluded from this analysis because it did not have any pressure ulcers during the observation period.

For an average trust before the inspection, there were -6.28 (-10.05 to -2.5) fewer pressure ulcers per 10,000 patients/month. No change was observed in level or slope after the announcement or the inspection itself. After the inspection for an average trust, there were -1.38 (-2.42 to -0.34) fewer pressure ulcers per 10,000 patients/month which represents a lower speed of improvement (Table 6.2). This change in trend produces an increase for an average trust of 20.89 (-20.86 to 62.66) pressure ulcers per 10,000 patients 12 months after the inspection compared to the counterfactual (Figure 6.4).

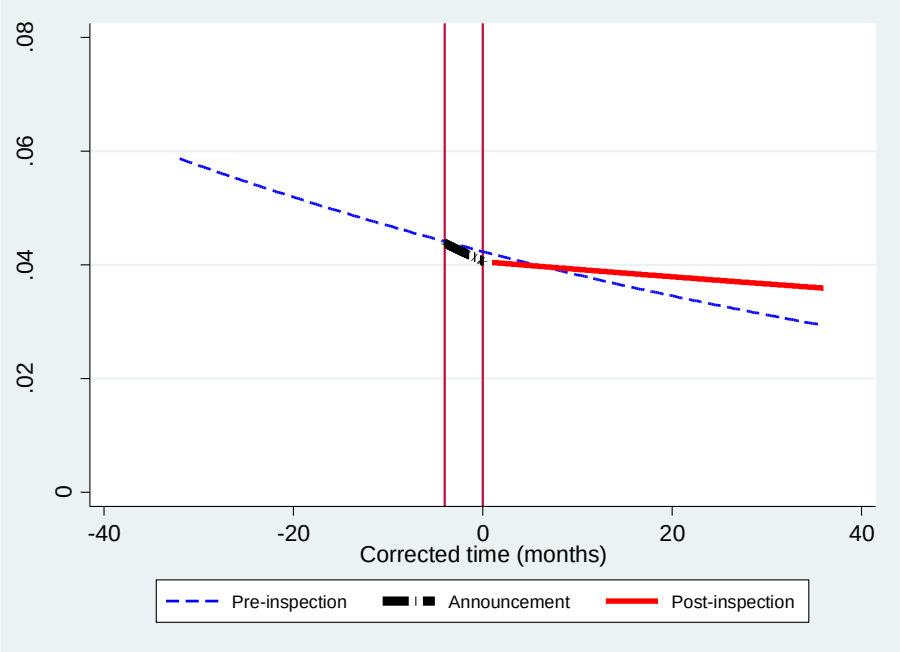


Figure 6.4 Predicted rate of pressure ulcers for an average acute NHS trust before, after the announcement and CQC inspection

Table 6.2 Slopes and changes in level before, after the announcement and CQC inspection for falls with harm and pressure ulcers

	Unadjusted model of rates of falls with harm (95% CI)	Unadjusted model of rates of pressure ulcers (95% CI)
Baseline rates	118.15 (96.62, 144.5)	586.89 (520.03, 662.35)
Pre-inspection slope	-2.77 (-4.26, -1.28)*	-6.28 (-10.05, -2.5)*
Change in level		
Post-Announcement	-3.19 (-9.25, 2.86)	-8.95 (-28.92, 11.02)
Post-inspection	1.55 (-3.54, 6.63)	-0.98 (-18.32, 16.35)
Slope		
Post-announcement	-2.02 (-4.89, 0.84)	-7.86 (-17.84, 2.11)
Post-inspection	-0.59 (-0.82, -0.37)	-1.38 (-2.42, -0.34)

* Significant values at 0.05 level

Values presented in number of events per 10,000 patients/month. Figures were calculated using model coefficients to present the absolute instead of relative value. For example, the pre-inspection slope is calculated as exp(β0j + β1j*corrected time ij). The same applies for all tables in this chapter.

6.1.2 Summary Hospital Mortality Index

The Summary Hospital Mortality Index is not calculated for specialist trusts. In comparison with all other acute trusts, these are smaller in terms of number of beds (219.5 [157 to 255] vs 719.5 [536 to 1047], p<0.001) and numbers of hospitals (1 [1 to 2] vs 3 [2 to 5], p<0.001), are more likely to have a Monitor sustainability rating of “no evident concerns” or “lowest risk” (86% vs 16.9%, p<0.00001) and are more likely to have a CQC reporting culture rating of “outstanding” or “good” (83.3% vs 47.2%, p=0.004). Summary Hospital Mortality Indexes (SHMI) over time are shown in Figure 6.5.

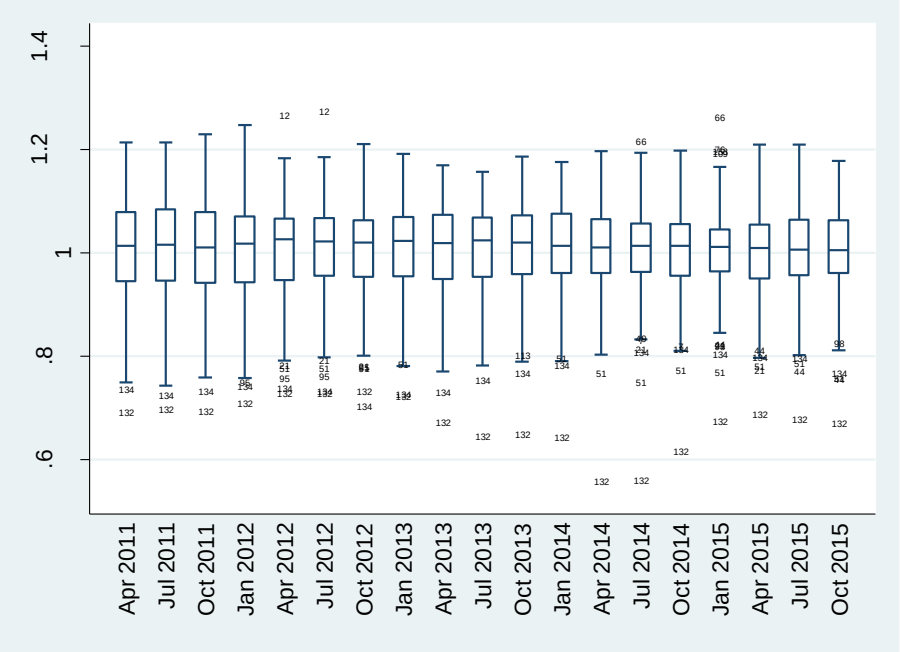


Figure 6.5 Summary Hospital Mortality Index for all acute NHS trusts in England from April 2011 to October 2015

Sine and cosine functions were introduced to the model to attempt to correct for seasonal patterns, but the period was not consistent across trusts; therefore, these functions did not improve the goodness of fit. Woolridge test for autocorrelation in longitudinal datasets revealed the presence of autocorrelation; however, models with an autoregressive structure from 1 to 12 did not converge.

The average (95% CI) SHMI has remained relatively constant over time with a value of 1.007 (0.98 to 1.02) in April 2011 and 1.004 (0.98 to 1.019) in October 2015.

Before the inspection, for an average trust SHMI remained stable. No change in level or trend of SHMI was observed after the announcement or the visit on-site. After the inspection for an average trust, there was an increase of 0.0009 (-0.002 to 0.004) points in the SHMI per month (Table 6.3). For a trust with an expected mortality of 2,000 patients, this increase translates into 1.8 (-4 to 8) deaths. The change in trend produces an increase for an average trust of 0.015 (-0.04 to 0.07) points in the SHMI 12 months after the inspection compared to the counterfactual (Figure 6.6).

Table 6.3 Slopes and changes in level before, after the announcement and CQC inspection for Summary Hospital Mortality Index

	Unadjusted model of the Summary Hospital Mortality Index (95% CI)
Baseline rates	1.005 (0.98, 1.02)
Pre-inspection slope	-0.0001 (-0.0007, 0.0005)
Change in level	
Post-Announcement	0.0005 (-0.007, 0.008)
Post-inspection	-0.003 (-0.008, 0.001)
Slope	
Post-announcement	0.002 (-0.01, 0.014)
Post-inspection	0.0009 (-0.002, 0.004)

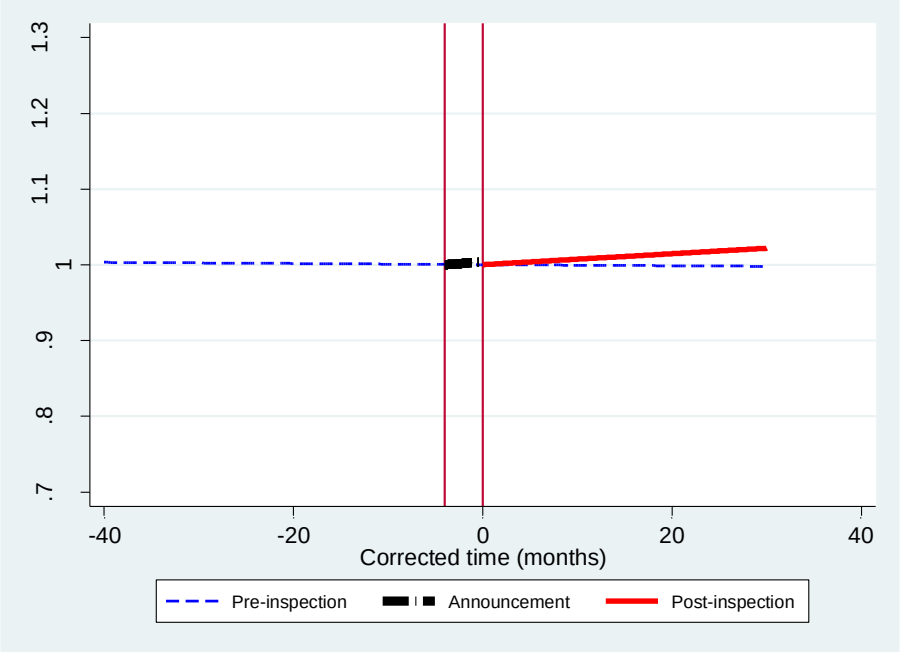


Figure 6.6 Predicted Summary Hospital Mortality Index for an average acute NHS trust before, after the announcement and CQC inspection

6.1.3 Waiting times

6.1.3.1 Accident and Emergency department (A&E) waiting times

Accident and Emergency department waiting times are not reported by specialist trusts without these facilities (12 trusts). In comparison with all other acute trusts, these are smaller in terms of number of beds (219.5 [193 to 255] vs 706 [520 to 1024], p<0.001) and numbers of hospitals (1 [1 to 2] vs 3 [2 to 5], p<0.001), but have a greater catchment population (3.2 [2.3 to 3.5] millions vs 450 [350 to 600] thousands, p<0.001). In terms of Monitor sustainability rating, trusts without A&E department are more likely to be rated as “no evident concerns” or “lowest risk” (70% vs 23%, p=0.002) and are more likely to have a CQC reporting culture rating of “outstanding” or “good” (83.3% vs 45.5%, p=0.01). Rates of all attendances to A&E waiting more than 4 hours over time are shown in Figure 6.7.

Sine and cosine functions were introduced to the model to correct for seasonal patterns with higher rates of attendances waiting more than 4 h during the winter months (December and January) and beginning of the Spring (March and April). The most parsimonious model included an autoregressive structure of 8 periods.

The average (95% CI) rate of over 4 h A&E wait was 0.035 (0.03 to 0.04) in November 2010 and 0.058 (0.05 to 0.06) in June 2015, which reflects an upward trend over time.

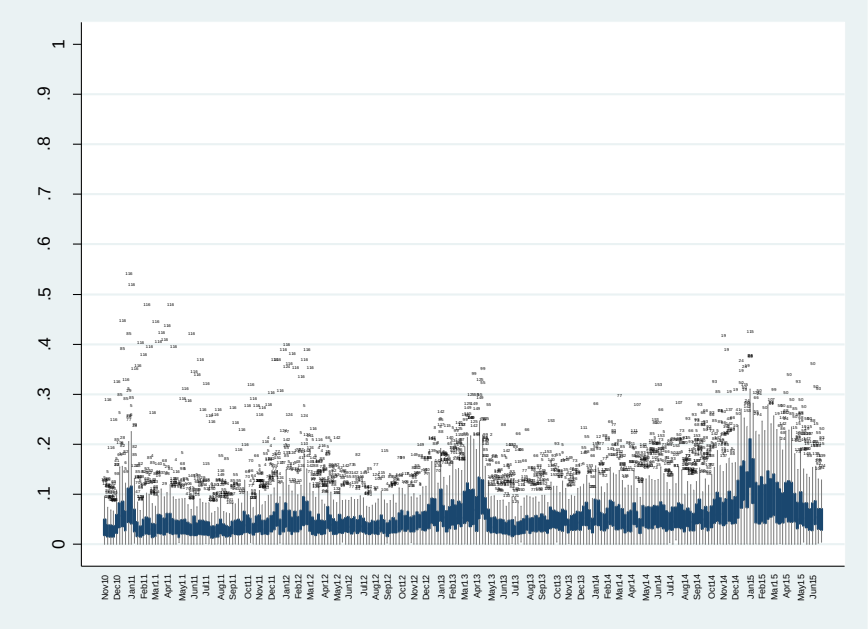


Figure 6.7 Rate of all attendances to A&E departments waiting more than 4 hours in all acute NHS trusts in England

Before the inspection for an average trust, attendances to A&E waiting more than 4 h have increased at a pace of 0.75 (0.63 to 0.87) per 10,000 attendances/month. No change in the trend of over 4h A&E wait was observed after the announcement or the visit on-site. After the announcement, for an average trust, there was an abrupt decrease of 44.5 (63.7 to 25.2) fewer cases waiting over 4h per 10,000 attendances/month. After the inspection for an average trust, the speed of change is 2.4 (1.8 to 3) extra attendances waiting more than 4 h in A&E per 10,000 attendances/month (Table 6.4). The change in trend produces an increase for an average trust of 20.7 (-40.7 to 82.1) attendances waiting more than 4 h 12 months after the inspection compared to the counterfactual (Figure 6.8).

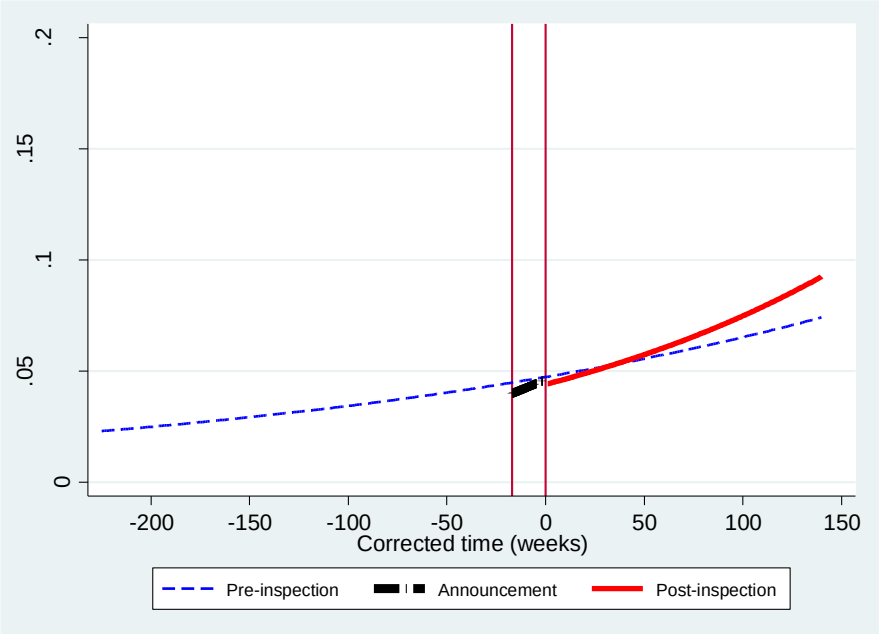


Figure 6.8 Predicted rate of all attendances waiting more than 4 h in A&E before, after the announcement and after CQC inspection

6.1.3.2 Consultant-led referral to treatment (RTT) waiting times (admitted)

Consultant-led referral to treatment waiting times were not available for three acute NHS trusts, which were similar to all other acute trusts. The rates of all admitted referrals to treatment waiting more than 18 weeks since August 2007 are shown in Figure 6.9.

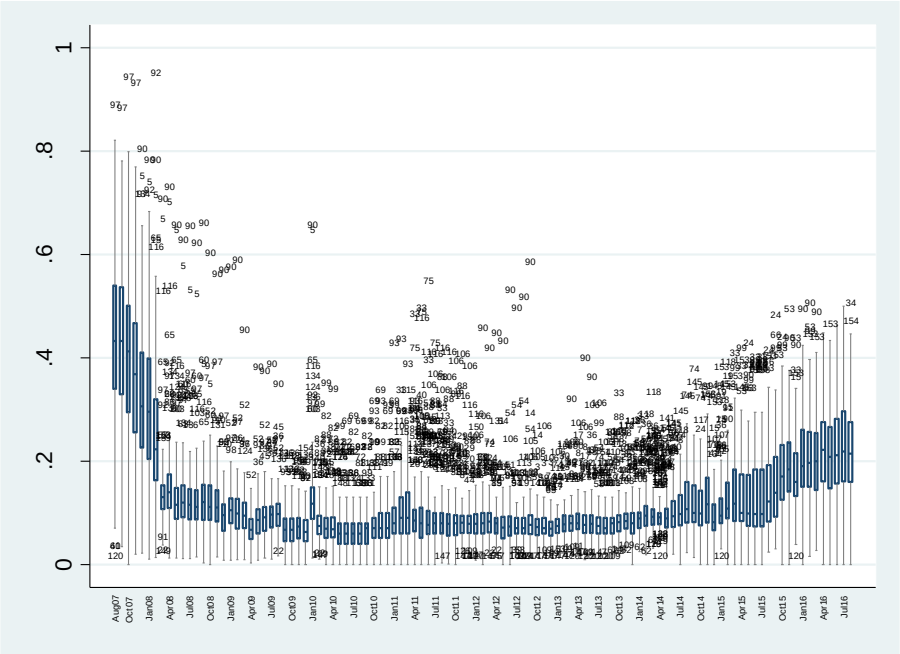


Figure 6.9 Rate of admitted referrals to treatment waiting more than 18 weeks in all acute NHS trusts in England

Given the rapid decline at the beginning of the observation period, the model included a quadratic term for time. Sine and cosine functions were introduced to the model to correct for seasonal patterns with higher rates of referrals waiting more than 18 weeks during the winter months (December and January) and beginning of the Spring (March and April). Woolridge test was significant for autocorrelation; however, models with an autoregressive structure from 1 to 12 did not converge.

Average (95% CI) rate of referrals to treatment waiting over 18 weeks was 0.43 (0.4 to 0.46) in August 2007 and 0.22 (0.21 to 0.24) in July 2016, which gives the impression of a downward trend, but the pattern over time reveals a rapid decrease during the first year and a constant increase since October 2013.

Before the inspection for an average trust, referrals waiting more than 18 weeks have decreased at a pace of 614 (895.7 to 332.4) per 10,000 referrals/month. After the announcement, no change in trend was observed, but for an average trust, there was an abrupt decrease of 44.5 (63.7 to 25.2) fewer referrals waiting more than 18 weeks per 10,000 referrals. After the inspection for an average trust, the speed of change is 8.8 (5.65 to 11.95) extra referrals waiting more than 18 weeks per 10,000 referrals/month (Table 6.4).

Introducing a polynomial function of degree 2 for the variable time in the pre-inspection period improved the fit of the model, but it creates a counterfactual for the post-inspection period with quadratic growth. Since it is questionable how appropriate this counterfactual is, the gap between the observed and hypothetical trend 12 months after the inspection was calculated for two scenarios: flat rates and quadratic growth after the on-site visit. For the former, the gap is 166.6 (54.2 to 279.1) extra referrals waiting more than 18 weeks (Figure 6.11), whilst for the latter, the difference is 946 (1236.5 to 655.5) fewer patients waiting more than 18 weeks (Figure 6.10).

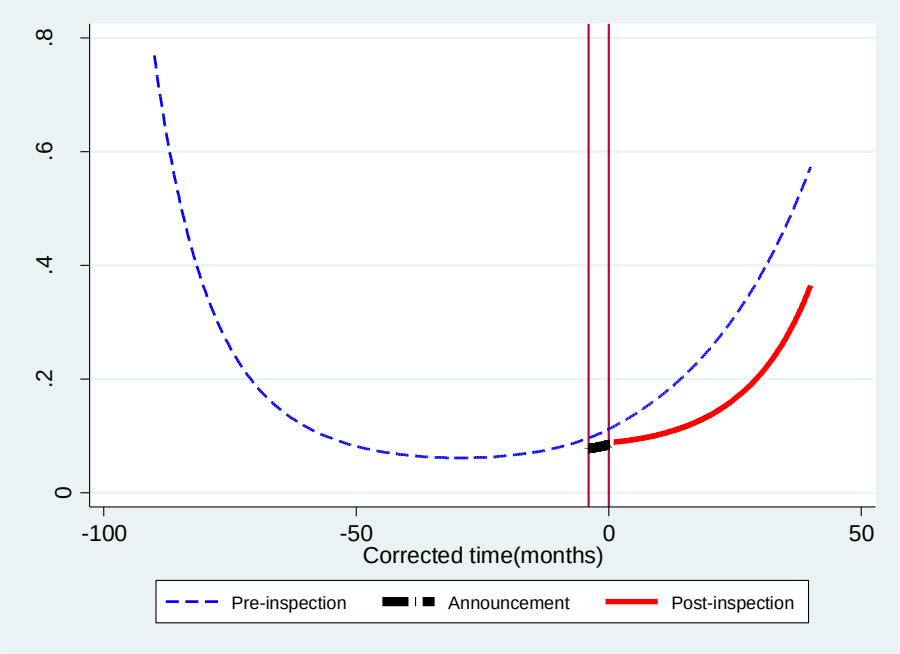


Figure 6.10 Predicted rate of referrals to treatment waiting more than 18 weeks before, after the announcement and after CQC inspection. The pre-inspection trend includes a quadratic term for time

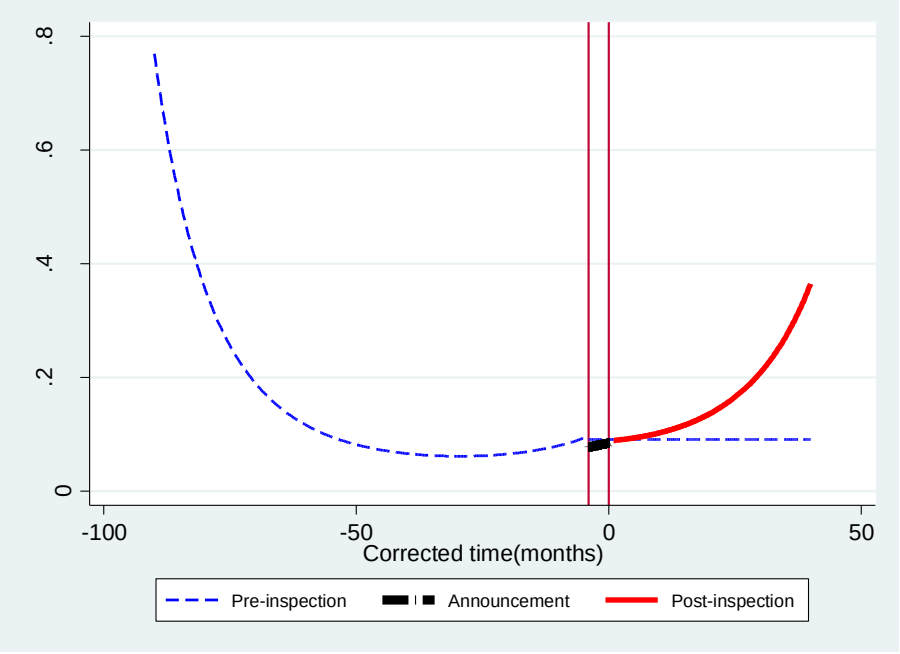


Figure 6.11 Predicted rate of referrals to treatment waiting more than 18 weeks before, after the announcement and after CQC inspection. The pre-inspection trend includes a quadratic term for time only before inspection

Table 6.4 Slopes and changes in level before, after the announcement and CQC inspection for rates of attendances to A&E waiting over 4 h and rate of referrals to treatment with a wait longer than 18 weeks

	Unadjusted model of rates of over 4 h A&E wait (95% CI)	Unadjusted model of rates of over 18 weeks RTT wait (95% CI)
Baseline rates	233.1 (203.97, 266.5)	7697.2 (6437, 9204)
Pre-inspection slope	0.75 (0.63, 0.87)*	-614 (-895.7, -332.4)*
Change in level		
Post-Announcement	-44.5 (-63.8, -25.2)*	-44.5 (-63.8, -25.2)*
Post-inspection	-20.7 (-42.8, 1.5)	16.5 (-9.7, 42.7)
Slope		
Post-announcement	3.5 (1.0, 5.9)	44.2 (-3.6, 92.1)
Post-inspection	2.3 (1.8, 2.9)	8.8 (5.7, 11.95)

* Significant values at 0.05 level

6.1.4 Treatment of patients with dignity and respect

Patients' perception of being treated with dignity and respect is collected as part of the adult inpatient survey; therefore, it is not reported for the four acute children's specialist trust existing in England. In comparison with all other acute trusts, these are smaller in terms of number of beds (331 [270.5 to 389] vs 700 [491 to 1020], p=0.01) and numbers of locations (1.5 [1 to 2] vs 4 [2 to 7], p=0.03). In terms of Monitor sustainability rating, acute children specialist trusts are more likely to be rated as "no evident concerns" (100% vs 22%, p=0.02). Patients' perceptions of being treated with dignity and respect over time for all trusts in England are shown in Figure 6.12.

Average patients' perception was 88.4 (87.9 to 88.9) in 2005 and 90.4 (90 to 90.8) in 2015, which reflects an upward trend over time.

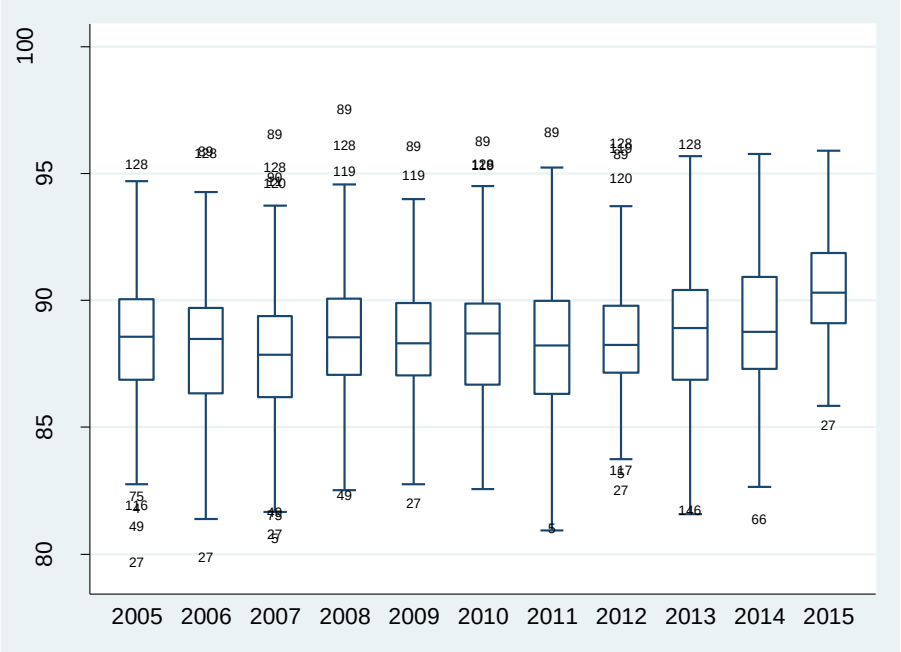


Figure 6.12 Patients' perception of being treated with dignity and respect in all acute NHS trusts in England

Before the inspection for an average trust, patients' perception has improved at 0.0035 (0.0002 to 0.007) points per month. No change in level was observed after the announcement or the visit on-site. After the CQC inspection for an average trust, the pace of improvement increased 0.08 (0.06 to 0.09) more points per month (Table 6.6). The change in trend produces an increase for an average trust of 1.02 (0.75 to 1.29) points 12 months after the inspection compared to the counterfactual (Figure 6.13).

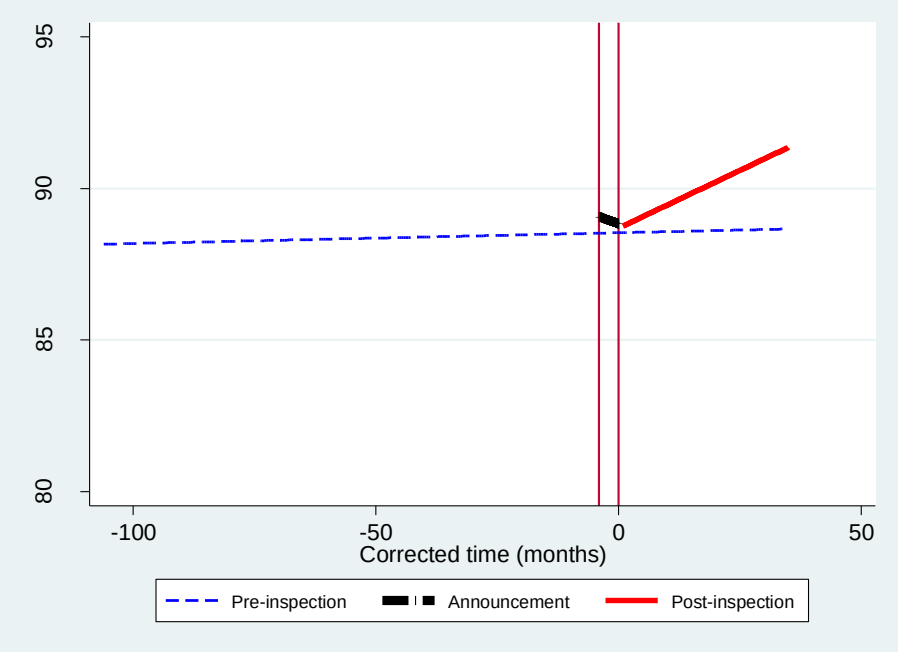


Figure 6.13 Predicted patients' perception of being treated with dignity and respect before, after the announcement and after CQC inspection

Table 6.5 Slopes and changes in level before, after the announcement and CQC inspection for patients' perception of being treated with dignity and respect

	Unadjusted model of patients' perception of being treated with dignity and respect (95% CI).
Baseline rates	88.2 (87.7, 88.6)
Pre-inspection slope	0.0035 (0.0002, 0.007)*
Change in level	
Post-Announcement	0.48 (-0.07, 1.04)
Post-inspection	-0.07 (-0.92, 0.78)
Slope	
Post-announcement	-0.06 (-0.42, 0.31)
Post-inspection	0.08 (0.06, 0.09)

* Significant values at 0.05 level

6.1.5 Staff leaving acute NHS trusts

There were three trusts without data for rate of staff leaving a trust, which were similar to those with available data. Over time, rates of staff leaving acute NHS trusts have remained stable with peaks associated with doctors in training leaving trusts in August each year (Figure 6.14).

The mean (min-max) rate of staff leaving a trust has remained stable over time with 0.017 (0.0078 to 0.055) in May 2012 and 0.018 (0.0089 to 0.038) in March 2016.

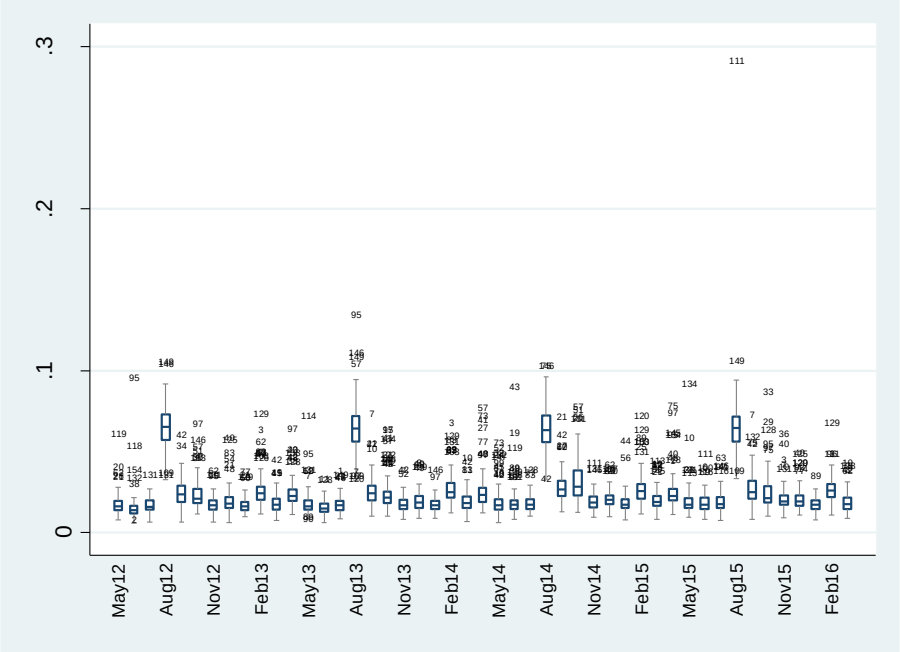


Figure 6.14 Rate of staff leaving trusts in all acute NHS trusts in England

For an average trust before the inspection, there were 0.39 (0.07 to 0.71) members of staff leaving per 10,000 staff/month. The announcement did not produce a significant change in the level or slope of rate of leavers. After the inspection for an average trust, there was a significant change in the slope (0.017 [-0.18 to 0.22] per 10,000 staff/month) which represents a decrease in the rate of change (Table 6.6). This change in trend did not produce a significant difference 12 months after the inspection compared to the counterfactual (Figure 6.15).

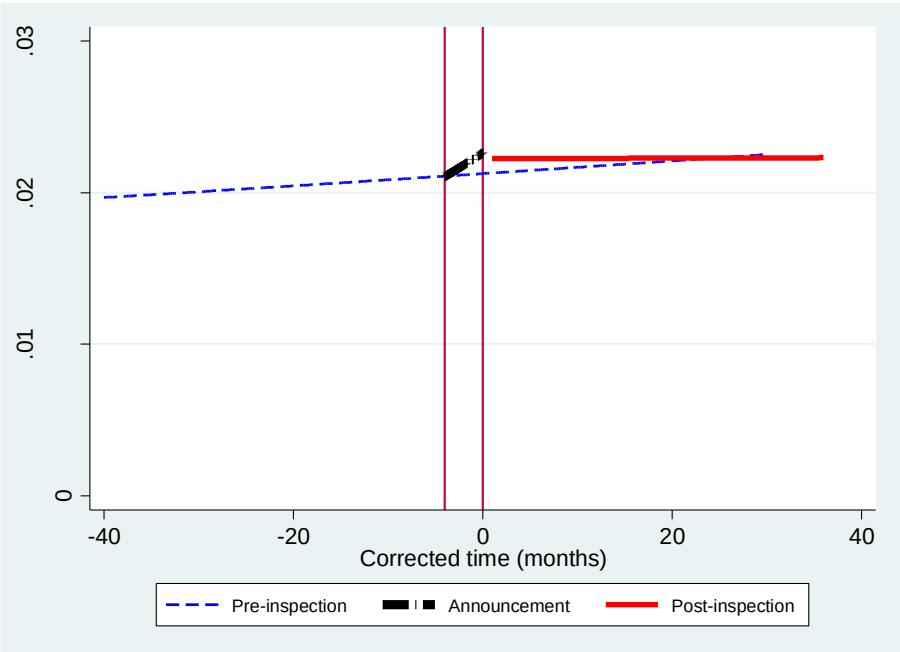


Figure 6.15 Predicted rate of staff leaving a trust before, after the announcement and after CQC inspection

Table 6.6 Slopes and changes in level before, after the announcement and CQC inspection for rates of staff leaving a trust

	Unadjusted model of rates of staff leaving (95% CI)
Baseline rates	199.8 (191.4, 208.6)
Pre-inspection slope	0.39 (0.07, 0.71)*
Change in level	
Post-Announcement	3.62 (-3.77, 11)
Post-inspection	3.86 (0.39, 7.32)
Slope	
Post-announcement	-3.85 (-11.3, 3.6)*
Post-inspection	0.017 (-0.18, 0.22)

* Significant values at 0.05 level

6.2 Subgroup analysis by performance rating

Acute NHS trusts were classified according to their overall quality performance rating in 2009 in order to explore whether performance affected the response to a CQC inspection.

Trusts rated as excellent were more likely to be Foundation trusts (78%), located in the North region (38% vs 22% Midlands, 16% South, and 24% London), and be acute teaching trusts (27% vs 22% large, 22% medium, 8% small, and 21% specialist). In contrast, trusts rated as weak were more likely to be large (83% vs 17% medium), located in the South (50% vs 17% Midlands, and 33% London) and not have foundation trusts status (83%). Full table with details according to performance rating is available in the Appendix Chapter 6, Table 6.4.

6.2.1 Adverse events

6.2.1.1 Falls with harm

The rates of falls with harm have decreased over time for all the groups and there was no difference between groups at the beginning or at the end of the observation period. For trusts rated as weak, fair and good, there was no change in level or trend after the announcement or the inspection. Those trusts rated as excellent showed a significant increase in level (23 [5 to 40.9] extra falls per 10,000 patients) and decrease in the slope after the announcement of the inspection (-13.4 [-3.4 to -23.5] falls per 10,000 patients/month) (Table 6.7).

Any potential change in slope after the inspection did not produce significant changes 12 months after the visit regardless of performance rating (Figure 6.18).

Table 6.7 Slopes and changes in level before, after the announcement and CQC inspection for rate of falls with harm by performance rating

	Unadjusted model of rates of fall with harm (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	115.9 (73.3, 183.1)	121.1 (89.7, 163.5)	114.1 (78.2, 166.4)	151.2 (59.4, 385)
Pre-inspection slope	-2.7 (-6.1, 0.6)	-3.1 (-5.4, -0.7)*	-2 (-4.5, 0.4)	-5.5 (-16, 5)
Change in level				
Post-Announcement	23 (5, 40.9)*	-3.3 (-11.7, 5)	-17 (-29.3, -4.7)	-10.7 (-33.7, 12.3)
Post-inspection	11.1 (0.6, 21.5)	-1.9 (-9.3, 5.5)	1.2 (-9.9, 12.3)	3 (-18.6, 24.6)
Slope				
Post-announcement	-13.4 (-23.5, -3.4)*	-0.7 (-4.5, 3.2)	0.5 (-4.7, 5.7)	1.3 (-8, 10.7)
Post-inspection	-0.8 (-1.4, -0.3)	-0.6 (-0.9, -0.3)	-0.5 (-1, -0.07)	-0.25 (-1.1, 0.7)

* Significant values at 0.05 level

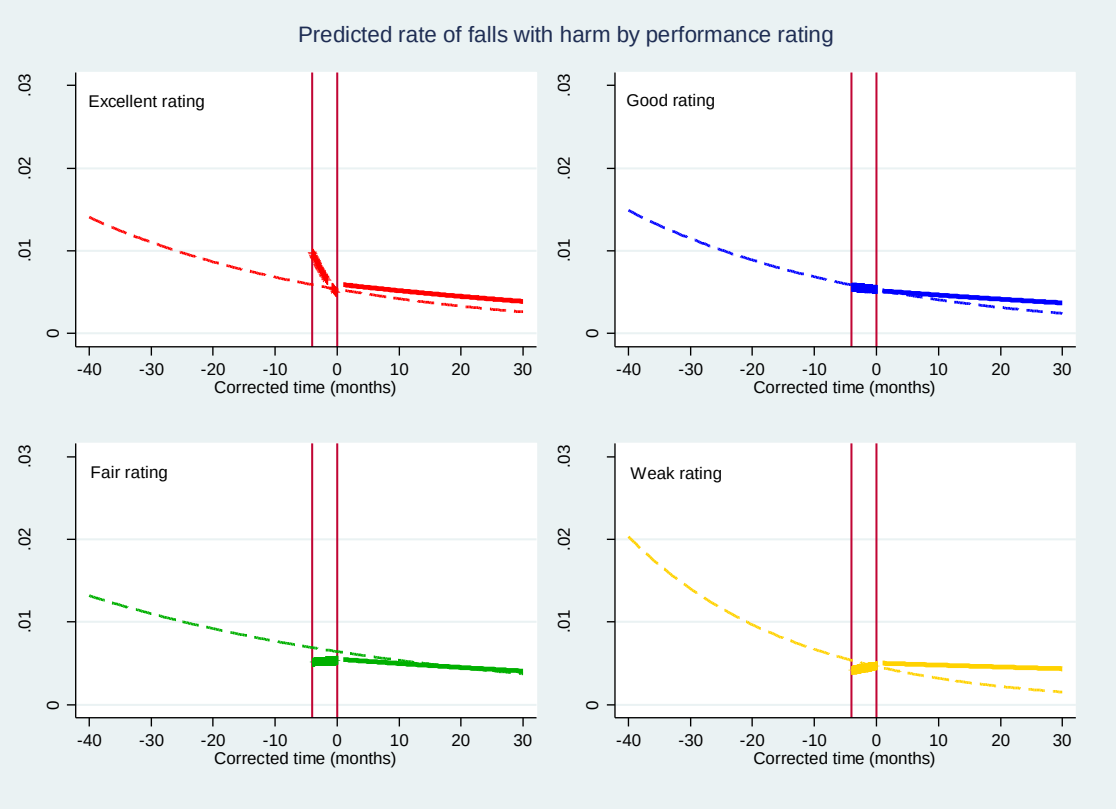


Figure 6.16 Predicted rate of falls with harm before, after the announcement, and CQC inspection by performance rating

6.2.1.2 Pressure ulcers

Cross-sectional rates of pressure ulcers at the beginning and end of the observation period are similar across groups. However, for those trusts rated as excellent, rates remained stable over time; whilst rates of pressure ulcers were improving before the inspection for trusts rated as good, fair and weak (Table 6.8).

No changes in trend or level of pressure ulcers were observed for any of the groups after the announcement or the CQC visit. The change in trend after the inspection in those trusts rated as weak produced an increase of 121.4 (6.8 to 236) pressure ulcers per 10,000 patients 12 months after the visit (Figure 6.17). Any other change after the inspection was not significant.

Table 6.8 Slopes and changes in level before, after the announcement and CQC inspection for rate of pressure ulcers by performance rating

	Unadjusted model of rates of pressure ulcers (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	477.4 (371.6, 613.4)	651 (548.2, 773)	555 (445.1, 691.9)	1058.3 (617, 1815.5)
Pre-inspection slope	-0.3 (-5.6, 4.9)*	-9.9 (-16.2, -3.6)*	-4 (-10.1, 2)	-38.8 (-82.4, 4.9)
Change in level				
Post-Announcement	-3.7 (-49.1, 41.6)	-6.5 (-34.7, 21.8)	-4.4 (-46.3, 37.6)	-50.7 (-129, 27.6)
Post-inspection	-26 (-65.9, 13.9)	-7.4 (-31.9, 17.2)	24.2 (-12.1, 60.5)	24.3 (-41, 89.6)
Slope				
Post-announcement	-4.7 (-27.1, 17.6)	-6.3 (-20.3, 7.8)	-13.9 (-35.5, 7.6)	-5 (-41.5, 31.4)
Post-inspection	-2.5 (-4.7, -0.2)	-1.1 (-2.5, 0.3)	-1.1 (-3.4, 1.1)	-0.4 (-4.5, 3.6)

* Significant values at 0.05 level

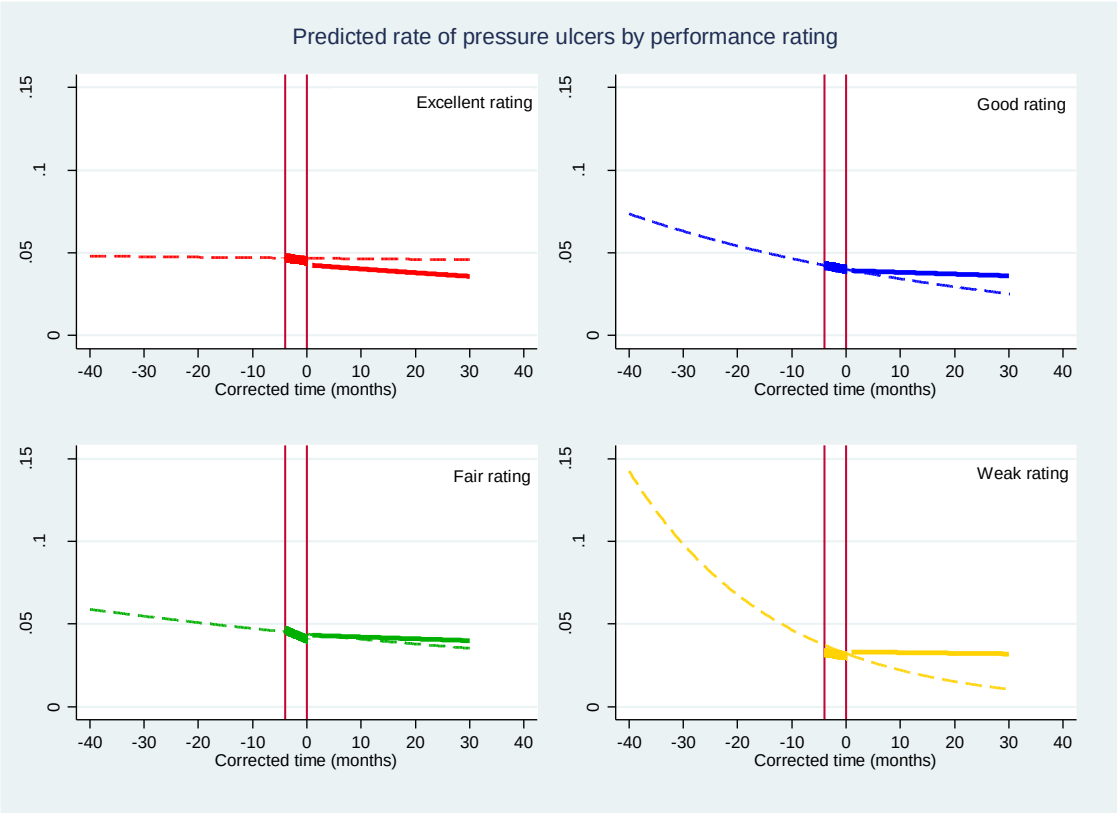


Figure 6.17 Predicted rate of pressure ulcers before, after the announcement, and CQC inspection by performance rating

6.2.2 Summary Hospital Mortality Index

The values of SHMI at the beginning and end of the observation period have remained similar for the four groups. However, for those trusts rated as fair, there was a downward trend in the pre-inspection period of -0.0009 (-0.0017 to -0.00009) points per month (Table 6.9), which translates into 2 fewer deaths per month for a trust with 2,220 expected deaths.

No changes in trend or level of SHMI were observed for any of the groups after the announcement or the CQC visit. Any potential change in slope after the inspection did not produce significant changes 12 months after the visit regardless of performance rating (Figure 6.18).

Table 6.9 Slopes and changes in level before, after the announcement and CQC inspection for summary hospital mortality index by performance rating

	Unadjusted model Summary Hospital Mortality Index (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	0.96 (0.93, 1.00)	1.003 (0.98, 1.02)	1.04 (1.0, 1.07)	0.98 (0.89, 1.06)
Pre-inspection slope	0.0003 (-0.0005, 0.001)	0.0002 (-0.0004, 0.0008)	-0.0009 (-0.0017, -0.00009)	0.000007 (-0.002, 0.002)
Change in level				
Post-Announcement	0.003 (-0.01, 0.02)	0.0004 (-0.01, 0.01)	-0.003 (-0.02, 0.01)	0.01 (-0.02, 0.05)
Post-inspection	-0.006 (-0.016, 0.005)	-0.0009 (-0.008, 0.005)	-0.003 (-0.01, 0.006)	-0.015 (-0.037, 0.007)
Slope				
Post-announcement	0.009 (-0.02, 0.04)	-0.002 (-0.02, 0.02)	0.0008 (-0.02, 0.02)	0.01 (-0.05, 0.07)
Post-inspection	-0.002 (-0.006, 0.002)	0.001 (-0.002, 0.004)	0.003 (-0.001, 0.007)	0.0009 (-0.008, 0.01)

* Significant values at 0.05 level

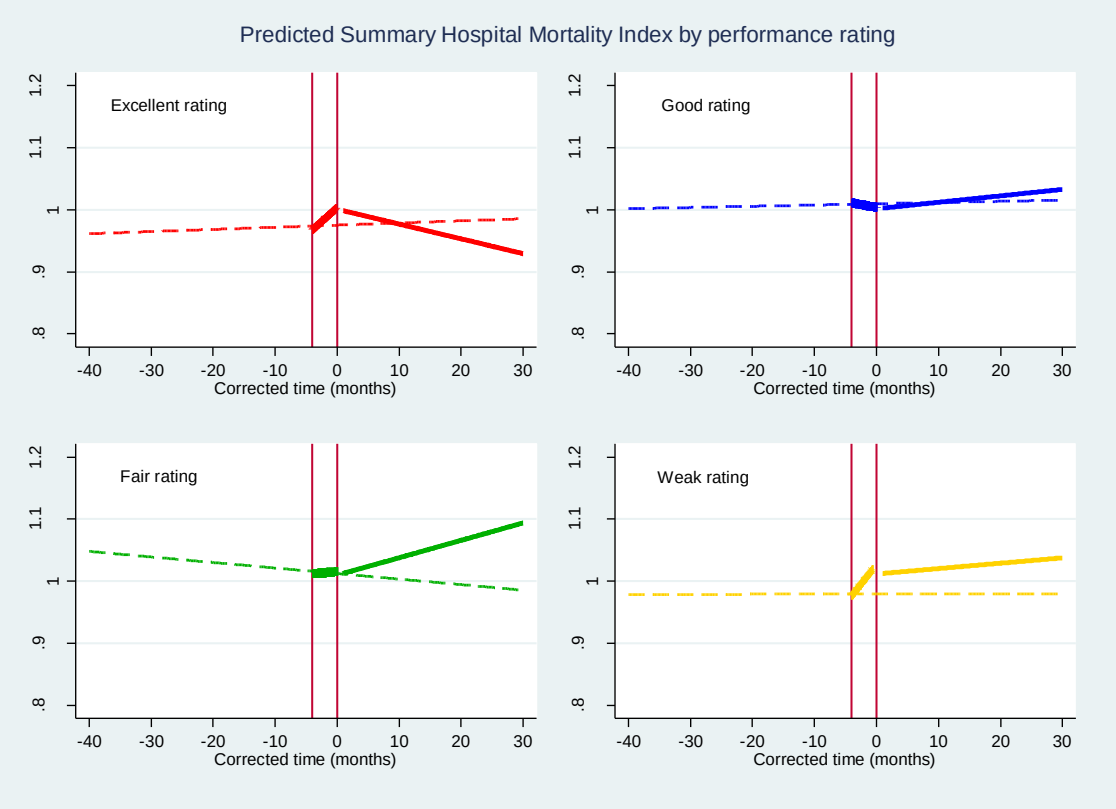


Figure 6.18 Predicted summary hospital mortality index before, after the announcement, and CQC inspection by performance rating

6.2.3 Waiting times

6.2.3.1 Accident and Emergency department (A&E) waiting times

In November 2010, rates of attendances waiting over 4 h in A&E were higher for trusts rated fair compared to those rated as good (323.4 [249.5 to 419.2] vs 201.1 [167.5 to 241.4]). There were no differences across groups at the end of the observation period (i.e. June 2015). The trend over time was also different for trusts rated as fair, which had stable rates of

attendances waiting over 4 h, whilst for the other groups these rates were increasing before the inspection (Table 6.10).

No changes in trend or level were observed for any of the groups after the announcement or the CQC visit. For the group of trusts rated as fair, the observed change in slope after the inspection translated into a significant increase of 220.8 (102.2 to 339.3) attendances waiting over 4 h 12 months after the visit (Figure 6.19).

Table 6.10 Slopes and changes in level before, after the announcement and CQC inspection for rates of attendances waiting more than 4 hours in A&E by performance rating

	Unadjusted model of rates of attendances to A&E waiting over 4 hours (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	221.6 (167, 294)	201.1 (167.5, 241.4)	323.4 (249.5, 419.2)	211.5 (112, 399.5)
Pre-inspection slope	0.6 (0.4, 0.9)	0.8 (0.7, 0.9)*	0.5 (-1.4, 2.4)	1.3 (0.8, 1.8)
Change in level				
Post-Announcement	-72.9 (-110, -35.8)	-54.6 (-82.5, -26.7)	-53.5 (-91.9, -15)	-35.6 (-191.7, 120.6)
Post-inspection	-26.6 (-69.6, 16.3)	-9.1 (-38.1, 19.8)	5.7 (-45.1, 56.6)	56.3 (-103.6, 216.1)
Slope				
Post-announcement	4.3 (0.07, 8.6)	1.4 (-2.2, 4.9)	6.7 (2.1, 11.4)	1.271 (-19.8, 22.3)
Post-inspection	1.5 (0.4, 2.6)	2.4 (1.6, 3.2)	3.3 (1.8, 4.7)	0.8 (-4.1, 5.8)

* Significant values at 0.05 level

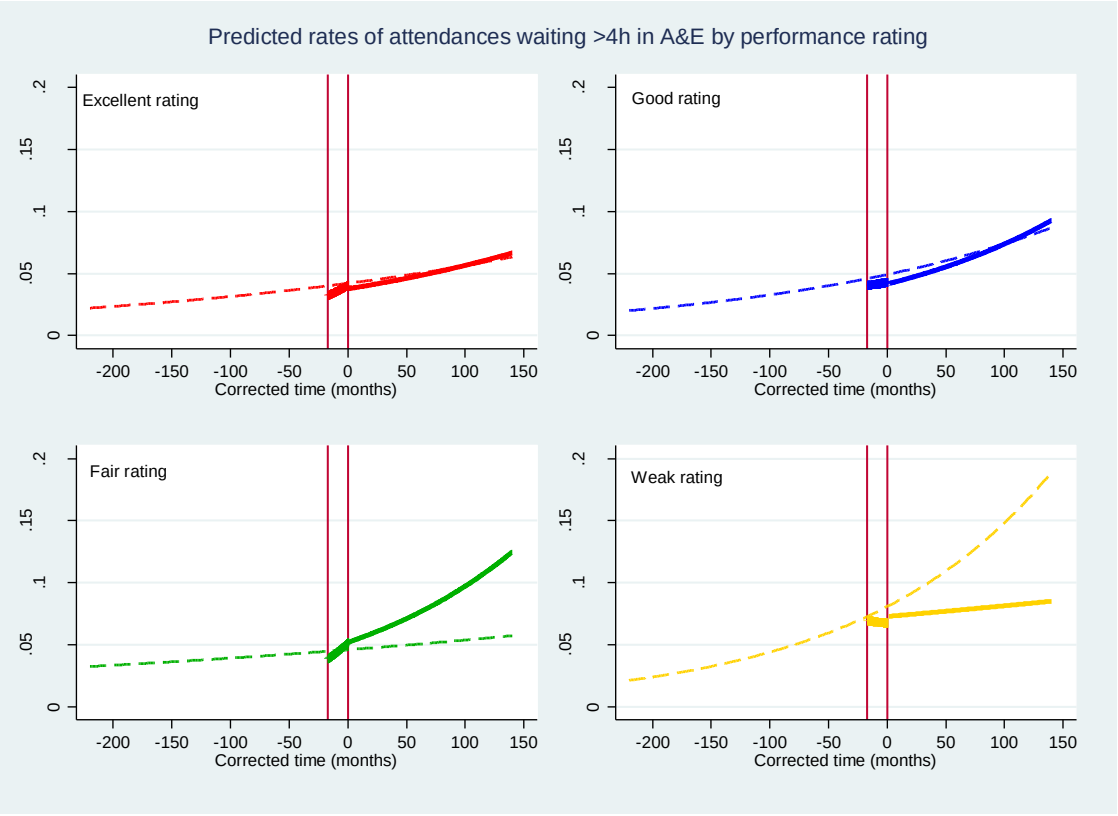


Figure 6.19 Predicted rates of attendances waiting over 4 hours in A&E before, after the announcement and CQC inspection by performance rating

6.2.3.2 Consultant-led referral to treatment (RTT) waiting times (admitted)

Rates of referrals to treatment waiting more than 18 weeks are similar across groups at the beginning (i.e. August 2007) and at the end of the observation period (August 2016). However, improvements occurred at different rates. Trusts rated as good or fair had a similar speed of improvement, around 600 fewer referrals waiting over 18 weeks per 10,000 referrals/month (good: -691.6 [-1018.4 to -364.9] and fair: -559.5 [-843.2 to -275.8]). In the case of trusts rated as excellent, this speed of improvement was slower with 135.8 (36.1 to 235.5) fewer cases per 10,000 referrals/month waiting more than 18 weeks (Table 6.11).

No changes in trend were observed for any of the groups after the announcement or the CQC visit. However, there was a significant decrease the month after the announcement for all groups except the group rated as weak (Table 6.11). If the curve with a quadratic term for time is used as counterfactual (Figure 6.20), trusts rated as excellent (-0.12 [-0.17 to -0.07]), good (-0.08 [-0.12 to -0.05]) and fair (-0.1 [-0.15 to -0.05]) had lower rates of referrals waiting over 18 weeks 12 month after the inspection.

Table 6.11 Slopes and changes in level before, after the announcement and CQC inspection for rates of referrals waiting more than 18 weeks by performance rating

	Unadjusted model rate of referrals to treatment waiting over 18 weeks (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	3052.5 (2506.7, 3717.2)	3565 (3082.9, 4122.6)	3109 (2567, 3765.5)	4955.1 (3048.5, 8054.4)
Pre-inspection slope	-135.8 (-235.5, -36.1)	-691.6 (-1018.4, -364.9)*	-559.5 (-843.2, -275.8)	-1031.4 (-1846.8, -215.9)
Change in level				
Post-Announcement	-181 (-296, -66)	-164.8 (-236.7, -93)*	-186.3 (-298.1, -74.4)	-47.9 (-332.5, 236.8)
Post-inspection	-10.3 (-68.3, 47.8)	20.9 (-14.4, 56.3)	29 (-26.4, 84.4)	43.2 (-111.5, 197.9)
Slope				
Post-announcement	6.8 (-86.7, 100.3)	46.7 (-19.8, 113.3)	61.6 (-46.4, 169.5)	57.8 (-264.8, 380.4)
Post-inspection	7.2 (2.1, 12.3)	8.8 (4.9, 12.8)	10.4 (4, 16.8)	-2.4 (-24.1, 19.2)

* Significant values at 0.05 level

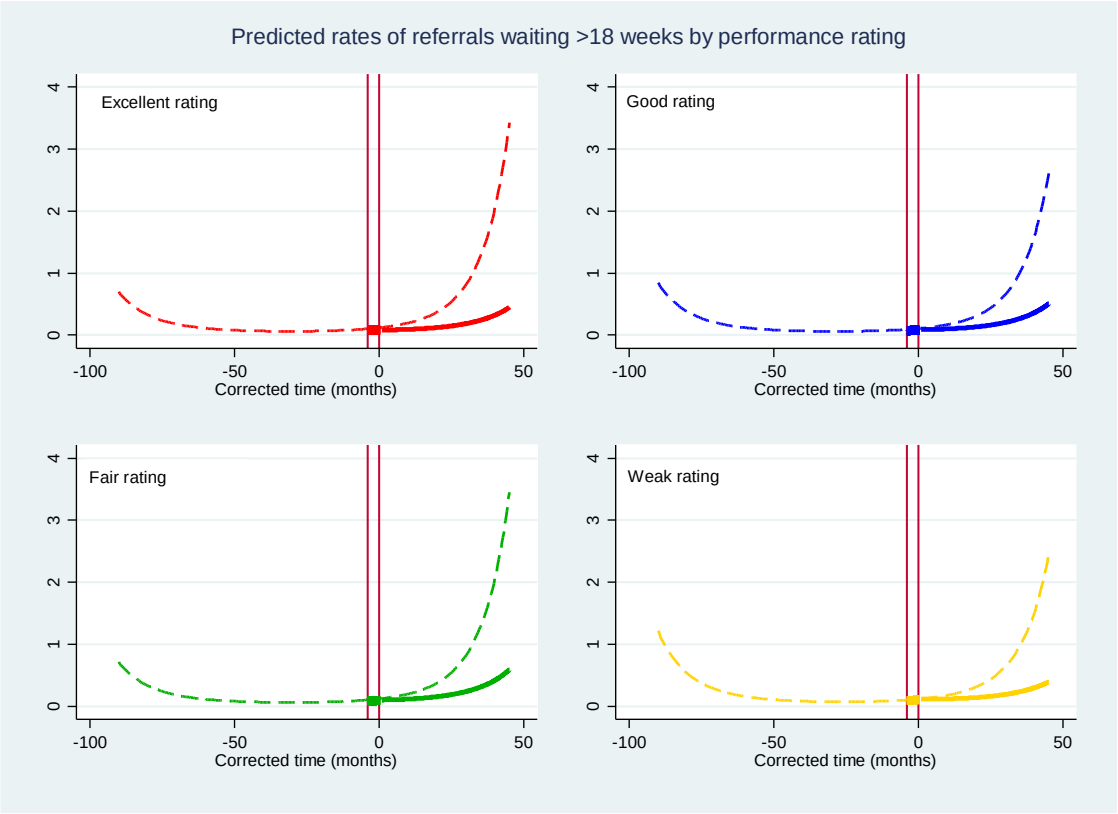


Figure 6.20 Predicted rates of referrals waiting over 18 weeks before, after the announcement and CQC inspection by performance rating

6.2.4 Treatment of patients with dignity and respect

During the observation period, patients' perception of being treated with dignity and respect was higher for trusts rated as excellent. This difference was significant in 2005 when compared with trusts rated as good and weak (89.7 [88.6 to 90.7] vs 88.2 [87.3 to 88.6] and 86.1 [83.4 to 88.8]), and in 2015, compared to trusts rated as good and fair (89.7 [88.6 to 90.7] vs 88.2 [87.3 to 88.6] and 86.1 [83.4 to 88.8]). Overall, patients' perception remained stable over time before the inspection (Table 6.12).

The CQC visit produced no change in level, but it increased the rate of improvement for all trusts, with trusts rated as weak having the greatest improvement (Table 6.12). When compared to the counterfactual, this change in slope translated 12 months after the inspection into a significant improvement for trusts rated as good (1.05 [0.66 to 1.44]), fair (1.4 [0.9 to 2]) and weak (1.38 [0.02 to 2.7]) (Figure 6.22). However, post-inspection trend considers only two data points; therefore, it is not reliable.

Table 6.12 Slopes and changes in level before, after the announcement and CQC inspection for patients' perception of being treated with dignity and respect

	Unadjusted model patients' perception of being treated with dignity and respect (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	89.4 (88.6, 90.3)	88 (87.4, 88.6)	87.6 (86.8, 88.5)	86.3 (84.3, 88.4)
Pre-inspection slope	0.005 (-0.002, 0.01)	0.005 (-0.0001, 0.01)*	-0.001 (-0.008, 0.006)	0.0009 (-0.02, 0.02)
Change in level				
Post-Announcement	0.4 (-0.85, 1.6)	1.1 (0.29, 1.9)	-0.46 (-1.59, 0.68)	-0.13 (-2.28, 2)
Post-inspection	-1.46 (-3.1, 0.24)	1.05 (-0.18, 2.28)	0.4 (-1.5, 2.3)	-5.7 (-15.4, 4)
Slope				
Post-announcement	0.29 (-0.5, 1.09)	-0.59 (-1.13, -0.05)	0.2 (-0.56, 0.9)	1.7 (-1.8, 5.2)
Post-inspection	0.08 (0.04, 0.12)	0.07 (0.04, 0.09)*	0.08 (0.04, 0.13)	0.19 (0.07, 0.3)

* Significant values at 0.05 level

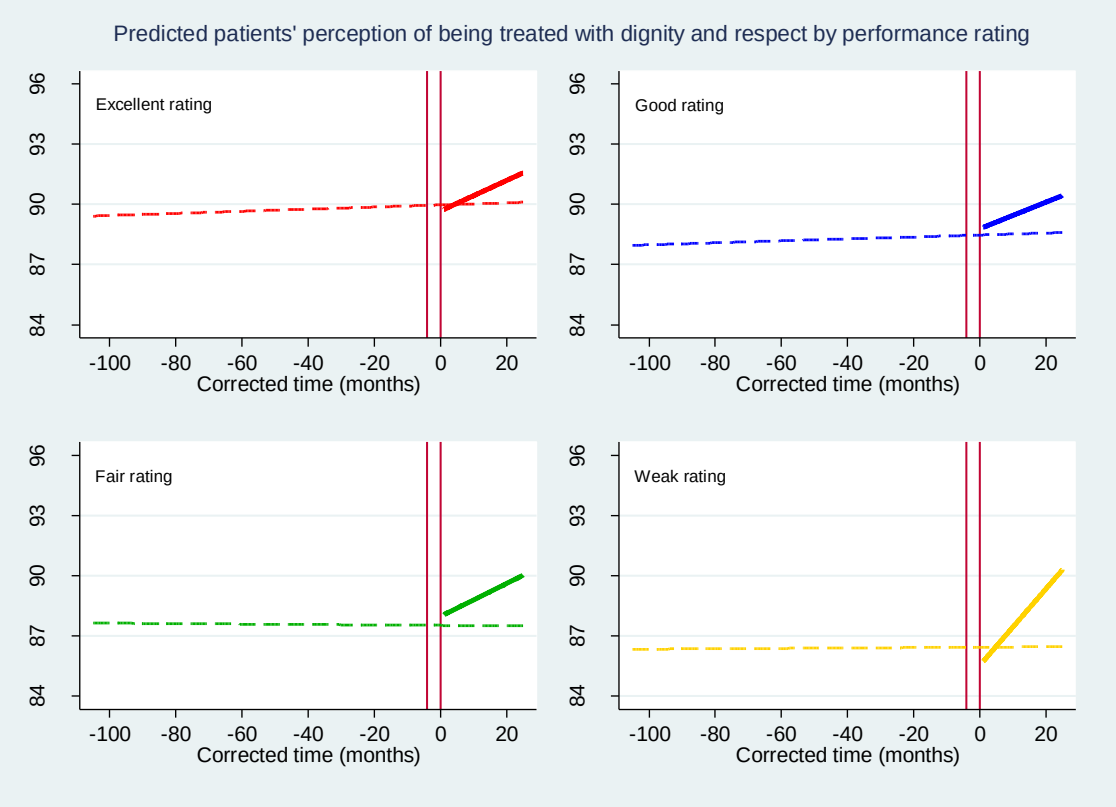


Figure 6.21 Predicted patients' perception of being treated with dignity and respect before, after the announcement and CQC inspection by performance rating

6.2.5 Staff leaving acute NHS trusts

Rates of staff leaving NHS trusts are similar across groups at the beginning and end of the observation period. However, for those trusts rated as excellent, there was an upward trend in the pre-inspection period of 0.95 (0.3 to 1.6) staff leaving per 10,000 staff/month (Table 6.13), whilst for the other groups rates remained stable.

For trusts rated as excellent, the announcement of the inspection produced a significant decrease in rates of staff leaving (-13.4 [-29.9 to 3] members of staff per 10,000) and a shift in

trend (12.7 [5.1 to 20.2] per 10,000 staff/month), whilst after the inspection, this index continued to increase, but at a slower pace (0.5 [0.2 to 0.9] staff per10,000 staff/month).

No changes in trend or level were observed for the other groups after the announcement or the CQC visit. Any potential change in slope after the inspection did not produce significant changes 12 months after the visit regardless of performance rating (Figure 6.22).

Table 6.13 Slopes and changes in level before, after the announcement and CQC inspection for rates of staff leaving NHS trusts by performance rating

	Unadjusted model rate of staff leaving NHS trusts (95% CI)			
	Excellent	Good	Fair	Weak
Baseline rates	190.5 (173.048, 209.7)	193 (180.6, 206.3)	202.1 (186.3, 219.3)	226.3 (177.3, 289)
Pre-inspection slope	0.95 (0.3, 1.6)	0.4 (-0.05, 0.9)	0.4 (-0.2, 0.96)	-0.7 (-3, 1.7)
Change in level				
Post-Announcement	-13.4 (-29.9, 3)*	6.5 (-5, 18)	5.6 (-11.1, 22.2)	22 (-21.6, 65.6)
Post-inspection	-21.8 (-39.9, -3.6)	4.5 (-6.7, 15.7)*	7.8 (-8.9, 24.5)	-19 (-65.2, 27.1)
Slope				
Post-announcement	12.7 (5.1, 20.2)*	1.4 (-4, 7)	1.9 (-6.1, 10)	8.7 (-11.8, 29.1)
Post-inspection	0.5 (0.2, 0.9)*	-0.09 (-0.4, 0.2)	-0.5 (-0.9, -0.08)	-0.7 (-1.7, 0.4)

* Significant values at 0.05 level

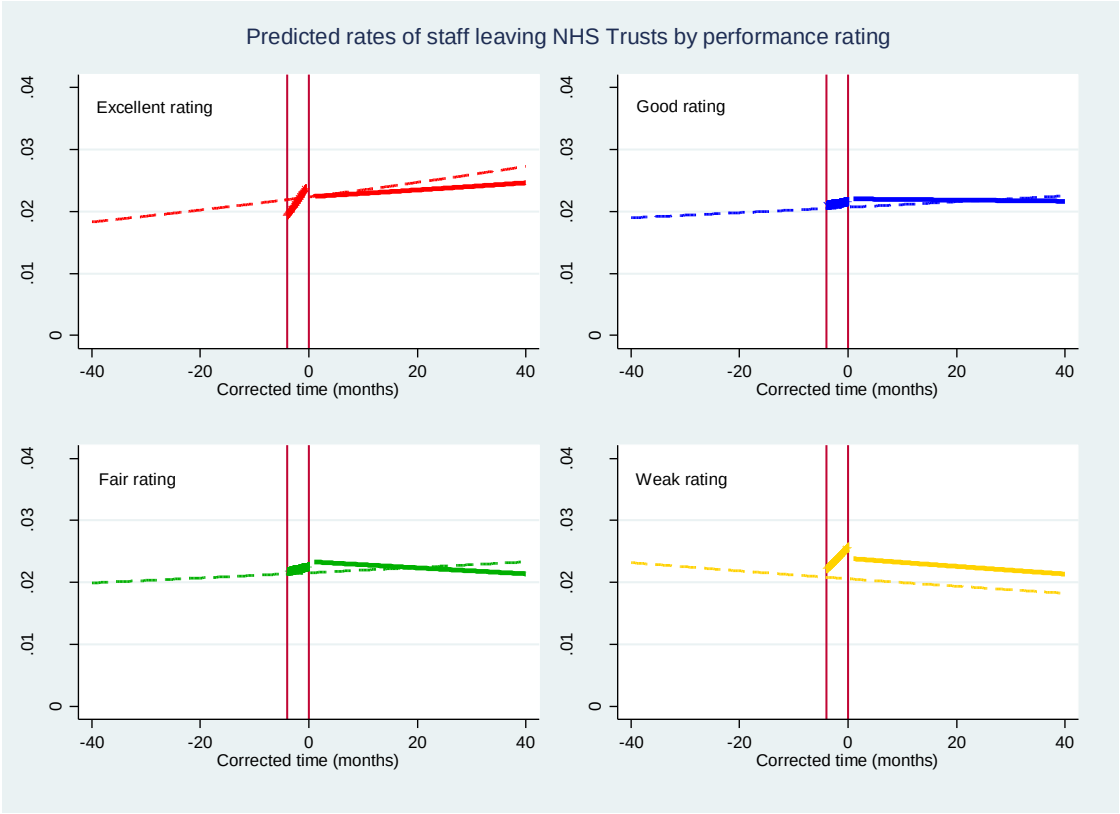


Figure 6.22 Predicted rates of staff leaving NHS trusts before, after the announcement and CQC inspection by performance rating

6.3 Summary

In summary, the analysis of the effect of CQC inspections on measures of quality of care suggests no significant changes after the announcement or the visit on-site. It seems to produce a decrease in waiting times after the announcement, but these changes are not sustained over time. Similarly, it produced a shift in the slope for rates of leavers, but this did not translate into a significant change in the long run (Table 6.14).

Table 6.14 Summary table indicating significant changes for any inspection in the outcome measures analysed

	Pre-inspection slope	Level change		Change of slope	
		Announcement	Inspection	Announcement	Post-inspection
Falls with harm	↓	–	–	–	–
Pressure Ulcers	↓	–	–	–	–
SHMI	–	–	–	–	–
>4 h A&E wait	↑	↓	–	–	–
>18w RTT wait	↓	↓	–	–	–
Dignity and respect	↑	–	–	–	–
Leavers	↑	–	–	↓	–

Key: Arrows are placed where a significant effect was observed. Blue arrows signal a positive effect, whilst yellow arrows signal a negative effect. The direction of the arrow indicates whether there was an increase (upwards) or decrease (downwards).

In the case of the subgroup analysis by performance rating in 2009, no changes in level or trend were observed after the announcement or the on-site CQC visit for those trusts rated as fair or weak. Conversely, trusts rated as excellent showed a significant increase in the rate of falls with harm after the announcement and a downward shift in trend. For rates of staff leaving NHS trusts, there was a significant drop after the announcement and an upward shift in trend, which was compensated by a downward shift in the slope after the inspection. In the case of trusts rated as good, the only significant changes observed were a significant decrease in the rate of referrals waiting over 18 weeks after the announcement of the inspection, a significant increase in the rate of staff leaving NHS trusts after the inspection and an increase in the rate of improvement of patients' perception of being treated with dignity and respect after the inspection.

For falls with harm, summary hospital mortality index and staff leaving NHS trusts, these changes did not produce a significant difference one year after the inspection. However, they generated a significant increase in pressure ulcers for trusts rated as weak, a significant increase in attendances waiting over 4 h in A&E for trusts rated as fair and significant increase in patients' perceptions for trusts rated as good, fair, and weak.

Given that potential explanations for these results are common to the analyses presented in Chapters 7 and 8, the discussion of all the empirical studies conducted for this thesis is available in Chapter 10.

Table 6.15 Summary table indicating significant changes in the outcome measures analysed by performance ratings 2009

	Pre-inspection slope	Level change		Change of slope	
		Announcement	Inspection	Announcement	Post-inspection
Excellent					
Falls with harm	–	↑	–	↓	–
Pressure Ulcers	↑	–	–	–	–
SHMI	–	–	–	–	–
>4 h A&E wait	↑	–	–	–	–
>18w RTT wait	–	–	–	–	–
Dignity and respect	–	–	–	–	–
Leavers	–	↓	–	↑	↓
Good					
Falls with harm	↓	–	–	–	–
Pressure Ulcers	↓	–	–	–	–
SHMI	–	–	–	–	–
>4 h A&E wait	↑	–	–	–	–
>18w RTT wait	↓	↓	–	–	–
Dignity and respect	↑	–	–	–	↑
Leavers	–	–	↑	–	–
Fair					
Falls with harm	–	–	–	–	–
Pressure Ulcers	–	–	–	–	–
SHMI	↓	–	–	–	–
>4 h A&E wait	–	–	–	–	–
>18w RTT wait	–	–	–	–	–
Dignity and respect	–	–	–	–	–
Leavers	–	–	–	–	–
Weak					
Falls with harm	–	–	–	–	–
Pressure Ulcers	–	–	–	–	–
SHMI	–	–	–	–	–
>4 h A&E wait	↑	–	–	–	–
>18w RTT wait	–	–	–	–	–
Dignity and respect	–	–	–	–	–
Leavers	–	–	–	–	–

Key: Arrows are placed where a significant effect was observed. Blue arrows signal a positive effect, whilst yellow arrows signal a negative effect. The direction of the arrow indicates whether there was an increase (upwards) or decrease (downwards).

7 Comparison of the effect of the old and new Care Quality Commission inspection regimes on measures of process of care and clinical outcomes

The previous chapter presented the results of the effect of any CQC inspection on seven selected measures of care quality: falls with harm, pressure ulcers, risk-adjusted mortality, waiting times in A&E, waiting times for a referral to treatment, patient's perception of care and staff leaving NHS trusts.

These measures were selected to represent the domains the CQC uses for its assessment of acute trusts. Overall, it could be seen that the CQC inspection was not associated with a clinically significant effect on the measures selected; whilst the announcement produced a statistically significant drop in waiting times.

In this chapter, results of the comparison of the new and old regime are presented. Between September 2013 and September 2014, a new more resource-intensive regime of inspections of acute care was introduced. At the same time, the previous regime of inspection was still in use, which allows the comparison of the effect of both regimes of inspections on measures of care quality (see a full description of the components of the new and old regime of inspections in Chapter 5, section 5.3.2).

7.1 Findings of the comparison of CQC inspection regimes

This analysis comprises 155 acute NHS trusts, of which 67 (43%) were inspected under the new regime, and 40 (26%) did not receive an on-site CQC visit in the period between September 2013 and September 2014 (Table 7.1). The regression model used interaction terms to obtain changes in level and slope using the old regime group as control.

Trusts inspected under the new regime were less likely to be Foundation trusts (53% vs 71%, p=0.02), more likely to be in special measures (28% vs 1%, p<0.001), more likely to have low financial and governance ratings by Monitor (significant financial risk: 18% vs 3%, p=0.01; under review or subject to enforcement actions: 50% vs 22%, p=0.004) and more likely to be rated as poor or significant concerns by the CQC regarding reporting culture (67% vs 42%, p=0.002).

Table 7.1 Descriptive information for all acute NHS trusts by type of inspection

	Old regime	New regime	No inspection	p-value
	n=48	n=67	n=40	
Foundation trust	33 (69%)	36 (54%)	31 (78%)	0.035
Type of trust				
Large acute trust	14 (29%)	18 (27%)	9 (23%)	0.69
Medium acute trust	14 (29%)	19 (28%)	12 (30%)	
Small acute trust	7 (15%)	13 (19%)	6 (15%)	
Acute teaching trust	5 (10%)	13 (19%)	7 (18%)	
Acute specialist trust	8 (17%)	4 (6%)	6 (15%)	
NHS England region				
North	16 (33%)	18 (27%)	16 (40%)	0.63
Midlands and East	17 (35%)	18 (27%)	10 (25%)	
South	9 (19%)	18 (27%)	9 (23%)	
London	6 (13%)	13 (19%)	5 (13%)	
Beds, median (IQR)	637 (453, 980)	738 (544, 1020)	719 (485, 1024)	0.55
Population in thousands, median (IQR)	465 (325.7, 610)	462.5 (350, 600)	450 (320, 600)	0.98
Number of hospitals, median (IQR)	2 (1, 4)	3 (2, 5)	3 (1, 4)	0.21
Number of locations, median (IQR)	3 (2, 6)	5 (2, 7)	4 (1.5, 7)	0.30
Special measures	0 (0%)	18 (27%)	1 (3%)	<0.001
Overall rating				
Outstanding	3 (7%)	2 (3%)	3 (8%)	0.81
Good	12 (27%)	16 (24%)	12 (32%)	
Requires improvement	27 (60%)	42 (63%)	21 (55%)	
Inadequate	3 (7%)	7 (10%)	2 (5%)	
Merged trusts	2 (4%)	8 (12%)	3 (8%)	0.32
Index Multiple Deprivation, median (IQR)	18.7 (15.83, 29.05)	22.7 (18.02, 27.16)	19.53 (16.38, 27.4)	0.44
Index Multiple Deprivation-Health, median (IQR)	-0.04 (-0.42, 0.59)	0.09 (-0.33, 0.48)	0.09 (-0.39, 0.64)	0.99
Monitor Sustainability rating				
Significant risk	0 (0%)	6 (18%)	2 (6%)	0.024
Material risk	6 (18%)	1 (3%)	3 (10%)	
Emerging or minor concerns	18 (55%)	17 (50%)	17 (55%)	
No evident concerns	9 (27%)	10 (29%)	6 (19%)	
Lowest risk	0 (0%)	0 (0%)	3 (10%)	
Monitor Governance rating				
Subject to enforcement action	2 (6%)	12 (35%)	5 (16%)	0.022
Under review	5 (15%)	5 (15%)	2 (6%)	
No evident concerns	26 (79%)	17 (50%)	24 (77%)	
TDA escalating score				
Enforcement action	0 (0%)	6 (18%)	0 (0%)	0.11
Significant delivery issues	7 (47%)	10 (30%)	5 (56%)	
Some delivery issues	7 (47%)	7 (21%)	2 (22%)	
Limited/no issues	1 (7%)	9 (27%)	1 (11%)	
Sound FT application	0 (0%)	1 (3%)	1 (11%)	
Number of inspections, median (IQR)	4 (3, 5)	4 (3, 5)	3 (2, 4)	0.001
Months since previous inspection, median (IQR)	10 (7, 13.5)	11 (8, 14)	9.5 (6, 16)	0.46

	Old regime	New regime	No inspection	p-value
	n=48	n=67	n=40	
Reporting culture 2016				
Poor	6 (13%)	18 (27%)	2 (5%)	0.010
Significant Concerns	14 (29%)	27 (40%)	13 (33%)	
Good	23 (48%)	21 (31%)	21 (53%)	
Outstanding	5 (10%)	1 (1%)	4 (10%)	
Performance rating - Overall Quality 2009				
Excellent	12 (26%)	15 (23%)	10 (25%)	0.73
Good	24 (51%)	29 (44%)	20 (50%)	
Fair	9 (19%)	18 (27%)	10 (25%)	
Weak	2 (4%)	4 (6%)	0 (0%)	
Performance rating - Financial 2009				
Excellent	21 (45%)	29 (44%)	22 (55%)	0.16
Good	21 (45%)	21 (32%)	16 (40%)	
Fair	4 (9%)	13 (20%)	2 (5%)	
Weak	1 (2%)	3 (5%)	0 (0%)	

Inspections under the old regime were concentrated between September and November 2013 (58%), whilst inspections under the new regime were spread out across the intervention window. Most inspections under the new regime were carried out within two waves, one between September and December 2013 comprising 17 (25%) trusts, and a second one comprising 30 (45%) trusts between February and May 2014.

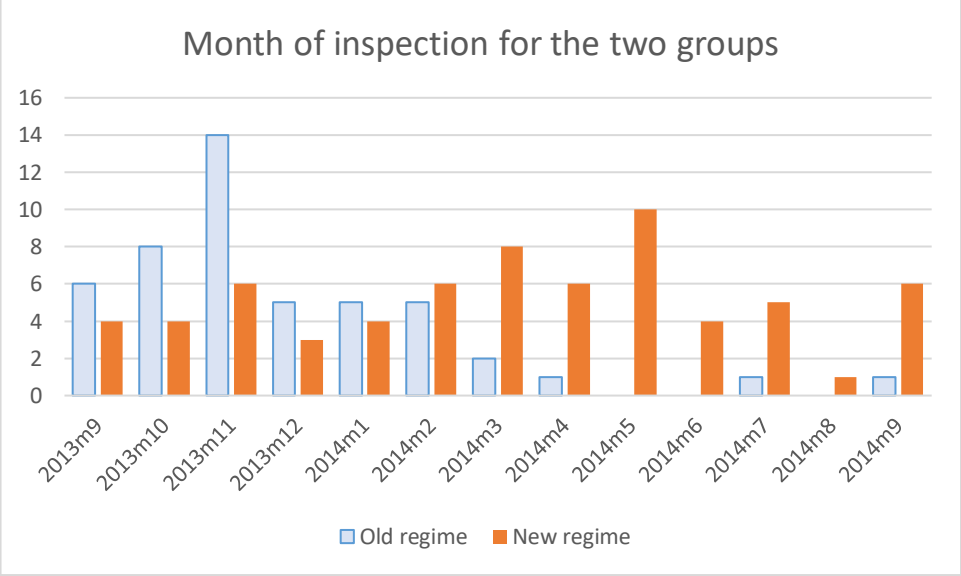


Figure 7.1 Inspections per month by type of regime

7.1.1 Adverse events

7.1.1.1 Falls with harm

The average (95% CI) rate of falls in April 2012 was 0.9% (0.5% to 1.2%) for the old regime group, 1% (0.7% to 1.4%) for the new regime group and 0.9% (0.6% to 1.2%) for the group not inspected.

Rates of falls with harm were improving before the CQC inspection for all groups, but the speed of improvement was faster for the old inspection regime (Table 7.2).

Announcing the inspection did not produce a significant increase or decrease in level or trend for any of the groups; however, the response to the announcement was different for trusts inspected under the old and new regime. Whilst rates of falls with harms increased for trusts inspected under the old regime, these decreased for the new regime group (8.75 [-2.87 to 20.37] vs -7.52 [-15.18 to 0.15] falls per 10,000 patients/month).

The CQC inspection had no immediate effect on the rate of falls with harm for either group, but a non-significant decrease in the speed of improvement was observed for all the groups.

The change in speed of improvement after the inspection would translate one year later into 2.89 (-7.25 to 13.02) per 10,000 patients/month extra falls with harm for the new regime, 20.87 (11.36 to 30.39) extra falls with harm for the old regime and -1.35 (-20.36 to 17.67) for the group not inspected. No significant changes were found in a subsample analysis matched by foundation trust status, special measures and reporting culture.

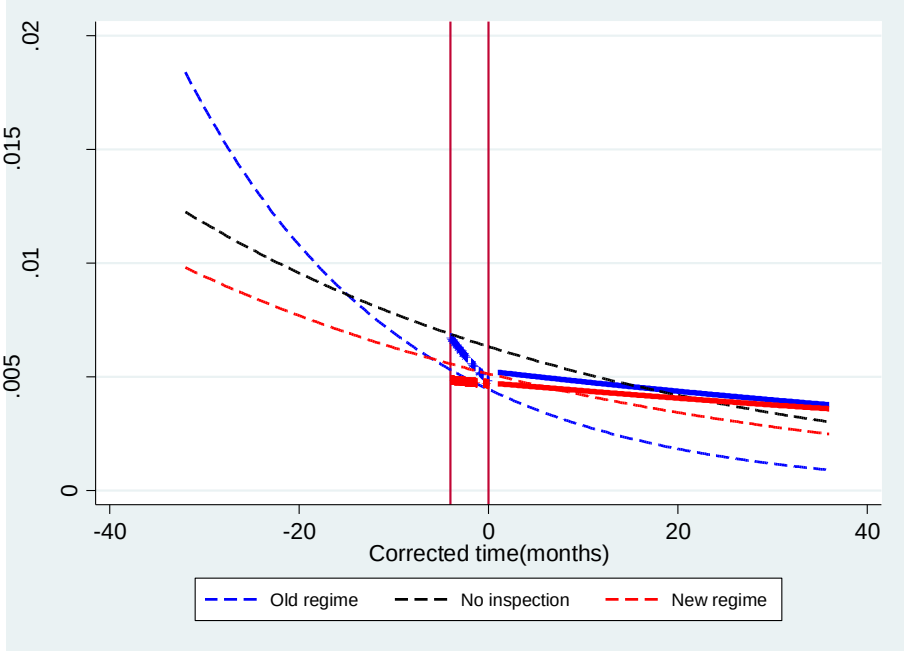


Figure 7.2 Predicted falls with harm for an average acute NHS trust before, after the announcement, and after inspection by type of inspection

Lines represent the mean rate of falls with harm obtained from the multilevel model for each period. The first vertical line signals the announcement, while the second signals the inspection. Dash lines show the trends observed during the pre-inspection period, which were extended for the post-announcement and post-inspection periods. Long-dash lines represent the observed data in the period between the announcement and the inspection. Solid lines show the trends after the inspection. Data for the hospitals inspected by the old regime is shown in blue, new regime in red and hospitals not inspected in black. The same applies for all figures in this chapter.

When adjusting for confounding, the coefficients for NRLS z-score, type of trust, specialist, IMD score, beds and number of staff members were significant, but the most parsimonious model was the one adjusted by type of trust.

When compared to large trusts, small trusts had 26% (2% to 56%) extra falls with harm, whilst specialist trusts had 99% (47% to 169%). In the case of teaching trusts, the rate of fall with harm was 27% (9% to 41%) lower. Adjusting the model for potential confounders changed the magnitude of the model estimates, but did not modify the conclusions.

Table 7.2 Slopes and changes in level before, after the announcement and CQC inspection for falls with harm by type of inspection. Values are number of events per 10,000 patients

	Unadjusted model rates of falls with harm (95% CI)			Adjusted model rates of falls with harm (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	97.4 (75.9, 125.1)	180 (126.4, 256.5)	121.5 (81.8, 180.4)	98 (76, 126.4)	184 (128.5, 263.4)	101.7 (77.4, 133.7)
Pre-inspection slope	-1.9 (-3.4, -0.5)	-7.7 (-12.9, -2.6)*	-2.5 (-5.3, 0.4)	-1.9 (-3.4, -0.5)	-8 (-13.4, -2.6)*	-2.5 (-5.4, 0.4)
Change in level						
Post-Announcement	-7.1 (-14.7, 0.6)*	8.7 (-2.9, 20.2)	-7. 2 (-20.2, 5.7)	-7.5 (-15.2, 0.2)*	8.8 (-2.9, 20.4)	-7.2 (-20.1, 5.8)
Post-inspection	-0.6 (-7.4, 6.3)	3.7 (-5.1, 12.6)	-7 (-18.3, 4.3)	0.1 (-6.8, 7)	3.9 (-5, 12.8)	-6.8 (-18.1, 4.5)
Slope						
Post-announcement	-0.4 (-3.9, 3.1)	-4.9 (-10.8, 0.9)	-0.3 (-6, 5.5)	-0.4 (-3.9, 3)	-4.9 (-10.9, 0.9)	-0.3 (-6, 5.5)
Post-inspection	-0.4 (-0.7, -0.06)	-0.5 (-0.9, -0.09)	-0.6 (-1, -0.1)	-0.4 (-0.7, -0.05)	-0.5 (-0.9, -0.08)	-0.6 (-1, -0.1)

* Significant values at 0.05 level

Values presented in number of events per 10,000 patients/month. Figures were calculated using model coefficients to present the absolute instead of relative value. For example, the pre-inspection slope for hospitals inspected by the new regime is calculated as $\exp(\beta_{0j} + \beta_{1j}$*corrected time $_{ij} + \beta_{6j}$*new inspection $_j + \beta_{7j}$*corrected time new inspection $_{ij})$.

7.1.1.2 Pressure ulcers

The average (95% CI) rate of pressure ulcers in April 2012 was 5.7% (4.7% to 7%) for the group inspected using old regime, 5.9% (5% to 7%) for the group inspected using new regime and 5% (4% to 6%) for the group not inspected.

Given that pressure ulcers have a seasonal pattern with higher rates in the spring (i.e. March and April) and autumn (i.e. September and October), a cosine function was introduced.

Rates of pressure ulcers were improving before CQC inspection for these three groups (Figure 7.3). After announcing the inspection there was no change in level, whilst the rate of improvement remained similar to the pre-inspection period. After CQC inspection, no detectable effect was observed on the level or trend for the three groups analysed (Table 7.3).

The non-significant change in trend after the inspection would translate one year later into 15.3 (-40.0 to 70.7) per 10,000 patients/month extra pressure ulcers for the new regime, 21.9 (-48.8 to 92.6) extra pressure ulcers for the old regime and 52.3 (-16.1 to 120.8) for the group

not inspected. No significant changes were found in a subsample analysis matched by foundation trust status, special measures and reporting culture.

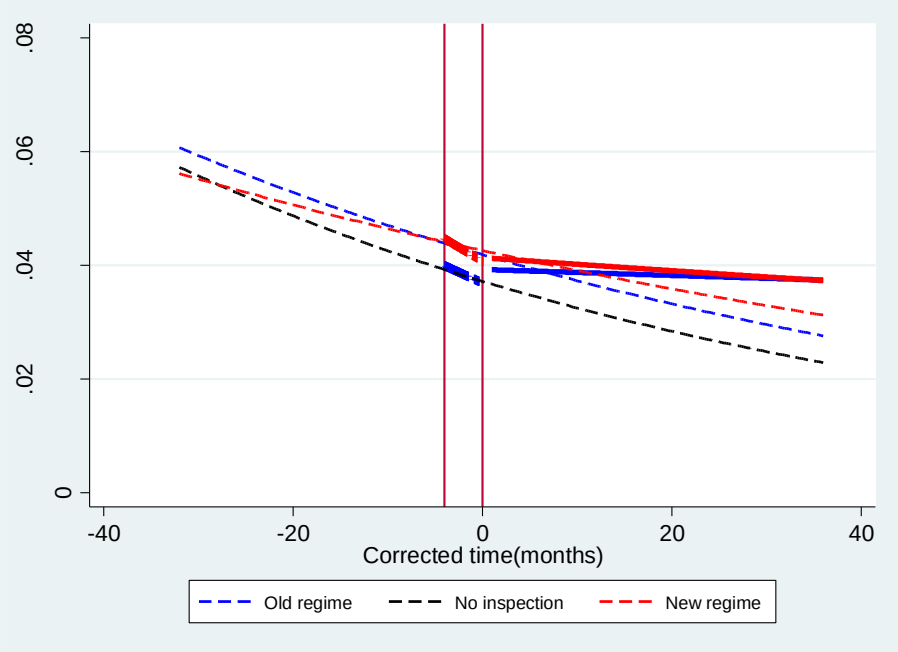


Figure 7.3 Predicted pressure ulcers for an average acute NHS trust before, after the announcement and after inspection by type of inspection

Catchment population, type of trust, specialist trust, and IMD score were significant when introduced to the model, but the most parsimonious was the one adjusted by specialist trust.

Compared to all other types of trusts, specialist trusts had on average 47% (37% to 55%) lower rates of pressure ulcers. Adjusting the model for potential confounders changed the magnitude of the model estimates, but did not modify the conclusions.

Table 7.3 Slopes and changes in level before, after the announcement and CQC inspection for pressure ulcers by type of inspection. Values are number of events per 10,000 patients

	Unadjusted model rates of pressure ulcers (95% CI)			Adjusted model rates of pressure ulcers (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	565.1 (492.9, 647.7)	612.8 (506.1, 742)	569.4 (458.8, 706.7)	561.4 (492.6, 640)	607.2 (504.3, 731.1)	572.6 (464.1, 706.5)
Pre-inspection slope	-4.9 (-9, -0.8)	-7.2 (-13.7, -0.6)*	-7.5 (-14.5, -0.6)	-4.8 (-8.9, -0.7)	-7 (-13.5, -0.6)*	-7.7 (-14.7, -0.6)
Change in level						
Post-Announcement	-6.1 (-36.4, 24.3)	-48.9 (-83.7, -14.2)	25.9 (-12.2, 63.9)	-4.6 (-34.9, 25.8)	-47.4 (-81.9, -12.9)	25.9 (-12.1, 63.9)
Post-inspection	3.7 (-23.9, 31.4)	22.6 (-8.1, 53.4)	10.7 (-23.8, 45.1)	4.7 (-23, 32.3)	23 (-7.7, 53.7)	10.4 (-24, 44.8)
Slope						
Post-announcement	-9.9 (-23.7, 3.9)	-7.6 (-22.6, 7.4)	-12 (-29.6, 5.7)	-9.9 (-23.7, 3.9)	-7.6 (-22.5, 7.4)	-12 (-29.6, 5.6)
Post-inspection	-1.2 (-2.9, 0.5)	-0.6 (-2.3, 1.2)	-2.4 (-4.4, -0.4)	-1.2 (-2.9, 0.1)	-0.5 (-2.3, 1.3)	-2.4 (-4.4, -0.4)

* Significant values at 0.05 level

7.1.2 Summary Hospital Mortality Index

The average (95% CI) summary hospital mortality index for the period March 2010-11 was 1.02 (0.99 to 1.04) for the group inspected using old regime, 1.00 (0.97 to 1.03) for the group inspected using new regime and 0.99 (0.96 to 1.02) for the group not inspected.

The index was improving before the inspection for trusts inspected by the new regime, whilst for the other two groups the SHMI remained constant. After the announcement and the on-site visit, there were no changes in the level or trend for the three groups analysed (Table 7.4).

The non-significant change in trend after the inspection would translate one year later into 0.02 (-0.04 to 0.09) extra points in the index for the new regime, -0.003 (-0.08 to 0.08) points for the old regime and 0.03 (-0.06 to 0.11) for the group not inspected. None of these changes were statistically significant.

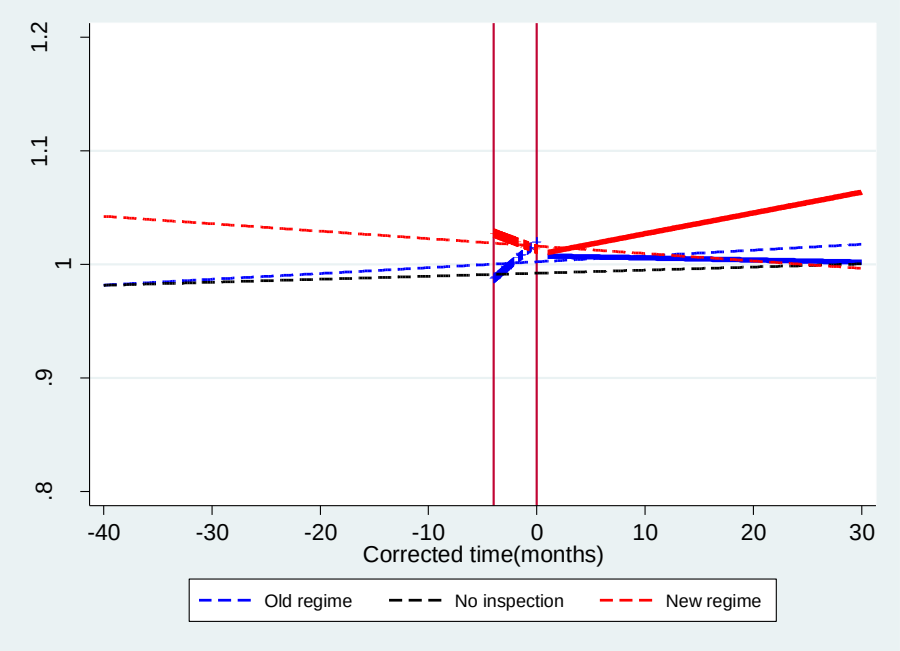


Figure 7.4 Predicted summary hospital mortality index for an average acute NHS trust before, after the announcement and after inspection by type of inspection

NHS region, governance rating, type of trust, IMD health domain and catchment population were significant when introduced to the model.

The model adjusted by NHS region was the most parsimonious. Compared to the North region, the South has 0.04 (0.02 to 0.07) fewer points and London has 0.17 (0.14 to 0.21) fewer points in the Index. For a trust with 1,000 expected deaths, this difference would translate into 40 fewer deaths in the South and 170 fewer deaths in the London area. Adjusting the model for potential confounders changed the magnitude of the model estimates, but did not modify the conclusions.

Table 7.4 Slopes and changes in level before, after the announcement and CQC inspection for summary hospital mortality index by type of inspection

	Unadjusted model summary hospital mortality index (95% CI)			Adjusted model summary hospital mortality index (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	1.01 (0.98, 1.04)	0.99 (0.96, 1.03)	0.99 (0.96, 1.03)	1.04 (1.01, 1.06)	0.98 (0.96, 1.01)	0.98 (0.95, 1.01)
Pre-inspection slope	-0.0006 (-0.0012, -0.00005)*	0.0005 (-0.0002, 0.001)	0.0002 (-0.0006, 0.001)	-0.0006 (-0.001, -0.00005)*	0.0005 (-0.0002, 0.001)	0.0003 (-0.0005, 0.001)
Change in level						
Post-Announcement	0.005 (-0.006, 0.01)	-0.008 (-0.02, 0.005)	0.005 (-0.008, 0.02)	0.005 (-0.005, 0.01)	-0.005 (-0.02, 0.008)	0.004 (-0.009, 0.02)
Post-inspection	-0.002 (-0.02, 0.01)	0.008 (-0.009, 0.02)	0.004 (-0.008, 0.01)	-0.003 (-0.02, 0.01)	0.008 (-0.009, 0.02)	0.004 (-0.008, 0.01)
Slope						
Post-announcement	-0.001 (-0.008, 0.005)	-0.008 (-0.01, 0.0006)	0.01 (0.001, 0.02)	-0.002 (-0.009, 0.004)	-0.01 (-0.02, -0.004)	0.02 (0.006, 0.03)
Post-inspection	0.002 (-0.001, 0.005)	-0.0001 (-0.004, 0.004)	-0.0004 (-0.006, 0.005)	0.002 (-0.001, 0.005)	-0.0002 (-0.004, 0.004)	-0.00002 (-0.005, 0.005)

* Significant values at 0.05 level

7.1.3 Waiting times

7.1.3.1 Accident & Emergency department waiting times

The average (95% CI) rate of attendances waiting over 4 h in A&E in November 2010 was 3% (2.5% to 4%) for the group inspected using old regime, 4% (3% to 4.5%) for the group inspected using new regime and 0.03 (0.026 to 0.04) for the group not inspected.

Rates of attendances waiting over 4h in A&E were worsening before CQC inspection for all three groups. After announcing the inspection there were no changes in level or trend for any of the groups. After the CQC inspection, there was a significant drop for the group inspected by the old regime, whilst the one inspected by the new regime showed an increase in rate of attendances waiting over 4 h in A&E (-55.6 [-106.4 to -4.9] vs 60.8 [5.5 to 116.1] attendances waiting over 4 h per 10,000 attendances) (Table 7.5).

The non-significant change in trend after the inspection would translate one year later into 66.1 (-27.7 to 160) extra attendances per 10,000 patients waiting over 4 h for the new regime, 3 (-96.9 to 102.9) for the old regime and 16.4 (-103.6 to 136.4) for the group not inspected.

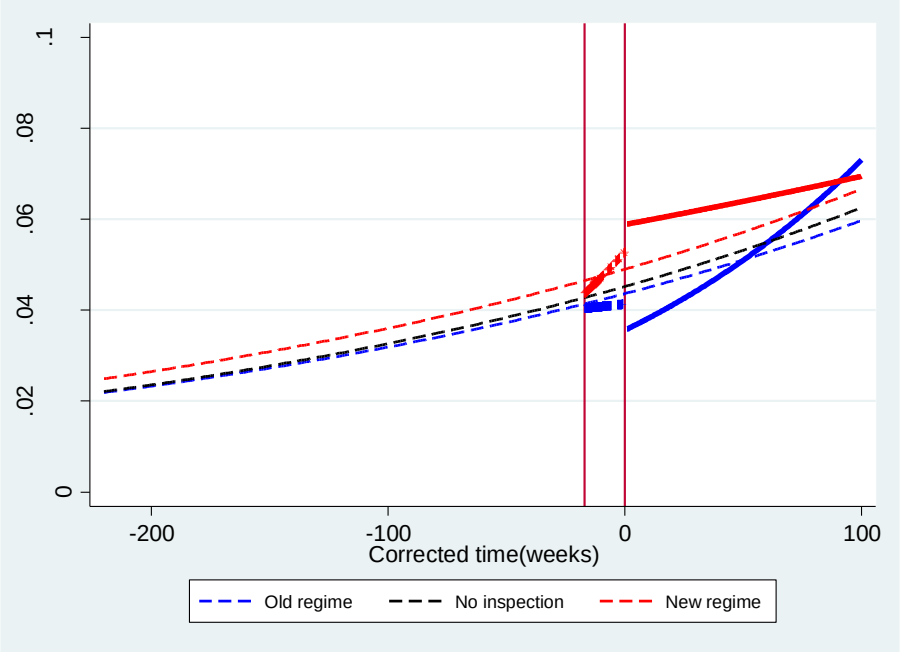


Figure 7.5 Predicted attendances waiting over 4h in A&E for an average acute NHS trust before, after the announcement and after inspection by type of inspection

The coefficients for number of inspections, Foundation trust status, type of trust, specialist trust, IMD score for health domain, catchment population, beds, NHS reform, CQC reporting culture, and number of staff members were significant when introduced to the model.

The model adjusted by reporting culture according to the CQC was the most parsimonious. Compared to a trust with a poor reporting culture, trusts with significant concerns have 20% (3% to 35%) fewer attendances waiting over 4 h, trusts with good reporting culture have 31% (16% to 43%) lower rates and trusts with an outstanding reporting culture have 46% (23% to 62%) fewer attendances waiting over 4 h. Adjusting the model for potential confounders changed the magnitude of the model estimates, but did not modify the conclusions.

Table 7.5 Slopes and changes in level before, after the announcement and CQC inspection for attendances waiting over 4 h in A&E by type of inspection. Values are number of episodes per 10,000 patients

	Unadjusted model rates of over 4 h A&E wait (95% CI)			Adjusted model rates of over 4 h A&E wait (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	249 (207.6, 298.8)	218.9 (173.9, 275.6)	220.9 (171.8, 284.2)	249.2 (208.5, 297.9)	218.9 (174.6, 274.4)	221 (172.6, 282.9)
Pre-inspection slope	0.8 (0.6, 0.9)	0.7 (0.5, 0.9)*	0.7 (0.5, 0.9)	0.8 (0.6, 0.9)	0.7 (0.5, 0.9)*	0.7 (0.5, 0.9)
Change in level						
Post-Announcement	-23.2 (-66.8, 20.4)	-9.3 (-57.4, 38.9)	20 (-31.8, 71.9)	-23.1 (-66.7, 20.5)	-9 (-57.2, 39.2)	21.4 (-30.7, 73.4)
Post-inspection	60.8 (5.5, 116.1*)	-55.6 (-106.4, -4.9)*	-11 (-57, 35)	60.8 (5.5, 116.1)*	-55.5 (-106.2, -4.8)*	-9.3 (-55.4, 36.8)
Slope						
Post-announcement	5 (0.8, 9.1)	0.6 (-4.3, 5.5)	-6.3 (-11.3, -1.2)	5 (0.8, 9.1)	0.6 (-4.3, 5.4)	-6.4 (-11.4, -1.4)
Post-inspection	0.98 (-0.3, 2.3)	2.6 (1.8, 3.4)	3.2 (2.2, 4.3)	0.9 (-0.3, 2.3)	2.6 (1.8, 3.4)	3.3 (2.3, 4.3)

* Significant values at 0.05 level

7.1.3.2 Consultant-led referral to treatment waiting times (admitted)

The average (95% CI) rate of referrals waiting over 18 weeks in August 2007 was 44% (38% to 49%) for the group inspected under the old regime, 46% (43% to 50%) for the group inspected under the new regime and 38% (33% to 43%) for the group not inspected.

Rates of referrals waiting over 18 weeks were improving at a similar pace before the CQC inspection. After announcing the inspection there was a significant decrease for the new and old regime group of similar magnitude (-149.8 [-232 to -67.5] and-151.3 [-200.4 to -102.2] fewer referrals per 10,000 cases waiting over 18 weeks), whilst the rate of improvement flattened for the three groups. After the CQC inspection, there was a significant increase and a shift in trend for both groups which no longer were improving, but worsening over time (Table 7.6).

When the curve with a quadratic term is used as counterfactual, the change in trend after the inspection would translate one year after into 10 (13.5 to 6.5) fewer referrals per 100 cases waiting over 18 weeks for the new regime, 10.6 (13.9 to -7.3) fewer referrals for the old regime and 4.4 (7 to 1.8) fewer for the group not inspected (Figure 7.6). In the case of using a flat trend as counterfactual, the change in trend after the inspection translates into 2.9 (1.2 to 4.6) extra referrals per 100 cases waiting over 18 weeks for the new regime, 0.1 (-1.1 to 1.4) extra referrals for the old regime and 1.1 (-0.3 to 2.5) extra referrals for the groups not inspected (Figure 7.7).

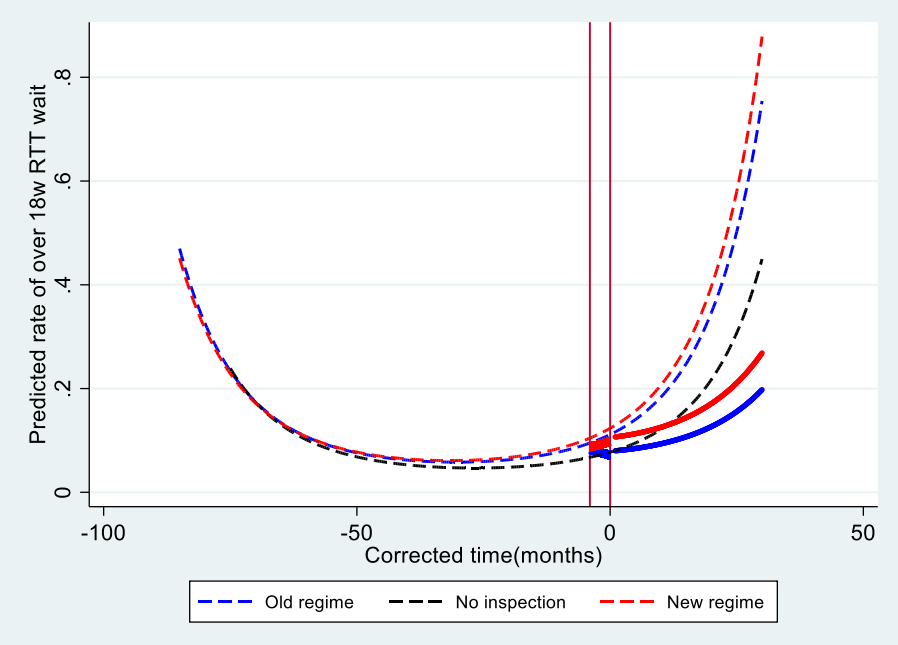


Figure 7.6 Predicted referrals waiting over 18 weeks for an average acute NHS trust before, after the announcement and after inspection by type of inspection. The pre-inspection trend includes a quadratic term for time

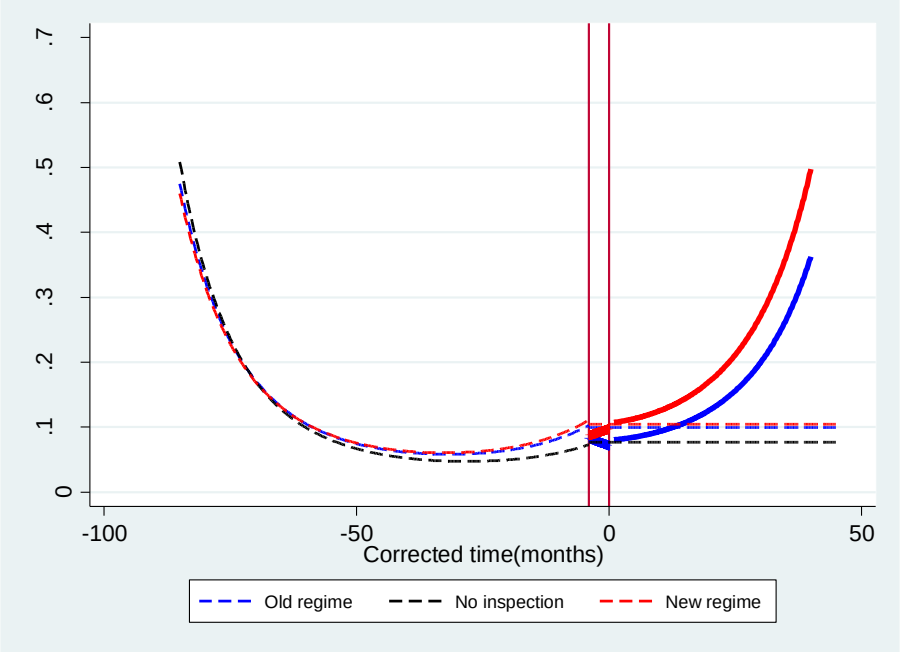


Figure 7.7 Predicted referrals waiting over 18 weeks for an average acute NHS trust before, after the announcement and after inspection by type of inspection. The pre-inspection trend includes a quadratic term for time only before inspection

Reporting culture, Foundation trust status, NHS reform, type of trust, IMD score in the health domain, beds and number of staff members were significant when introduced to the model. After combining these variables into different models, the model adjusted by NHS reform and beds was the most parsimonious.

During the implementation of the NHS reform between October 2012 and April 2013, referrals waiting over 18 weeks decreased by 16% (13% to 18%). On the contrary, there was a 3% (1% to 4%) increase in referrals waiting over 18 weeks per 1,000 beds. Adjusting the model for potential confounders changed the magnitude of the model estimates, but did not modify the conclusions.

Table 7.6 Slopes and changes in level before, after the announcement and CQC inspection for referrals waiting over 18 weeks by type of inspection

	Unadjusted model rates of referrals waiting over 18 weeks (95% CI)			Adjusted model rates of referrals waiting over 18 weeks (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	4379.9 (3729.1, 5144.2)	4880.2 (4083, 5833.2)	3830.9 (3158.2, 4646.8)	4598.6 (3901.4, 5420.5)	4977.6 (4147.1, 5974.3)	3889.2 (3203, 4722.4)
Pre-inspection slope	-310.5 (-457.5, -163.6)	-340.2 (-502.9, -177.5)*	-296.7 (-437.9, -155.5)*	-339.7 (-499.8, -179.6)	-356.8 (-527.3, -186.3)*	-310.3 (-457.7, -162.9)*
Change in level						
Post-Announcement	-149.8 (-232, -67.5)	-151.3 (-200.4, -102.2)*	121.4 (54.8, 188.1)*	-210.9 (-295.9, -126)	-226.9 (-283.1, -170.7)*	71.5 (2, 141)*
Post-inspection	91.3 (4.8, 177.8)	83.7 * (13.9, 153.6)	-77.7 (-131.4, -24)	94.1 (8.1, 180.1)	91 (21.4, 160.3)*	-76 (-129.7, -22.4)
Slope						
Post-announcement	25.2 (-16.1, 66.6)*	-28.6 (-58.2, 0.9)*	7.9 (-13.1, 29)*	24.4 (-16.7, 65.5)*	-30.5 (-60.1, -0.9)*	7.6 (-13.6, 28.8)*
Post-inspection	13.2 (7.8, 18.6)*	9.4 (4.9, 13.9)*	8.8 (3.1, 14.5)	12.1 (6.7, 17.6)*	8.5 (3.9, 13.1)*	7.8 (2, 13.6)

* Significant values at 0.05 level

7.1.4 Treatment of patients with dignity and respect

The average (95% CI) patients' perception of being treated with dignity and respect in 2005 was 88.4 (87.5 to 89.25) for the group inspected under the old regime, 87.8 (87.1 to 88.5) for the group inspected under the new regime and 89.4 (88.5 to 90.2) for the group not inspected.

Perception of being treated with dignity and respect was improving for trusts inspected under the old regime but it was stable over time for trusts inspected under the new regime similarly for those not inspected (Table 7.7). After the CQC inspection, there was a significant decrease for the old regime group (-2 [-0.3 to -3.7] points), whilst there was a shift in trend that was now improving for the three groups.

This change in trend after the inspection would translate one year later into 1.53 (1.13 to 1.93) more points in the inpatient survey for this question for those trusts inspected under the new regime, 0.72 (0.23 to 1.21) more points for the old regime and 0.88 (0.29 to 1.47) more points for the group not inspected (Figure 7.8). In real terms and if patient-mix remains unchanged, for a trust with a score of 85, one extra point means two more people per 100 patients answering that they always felt they were treated with dignity and respect.

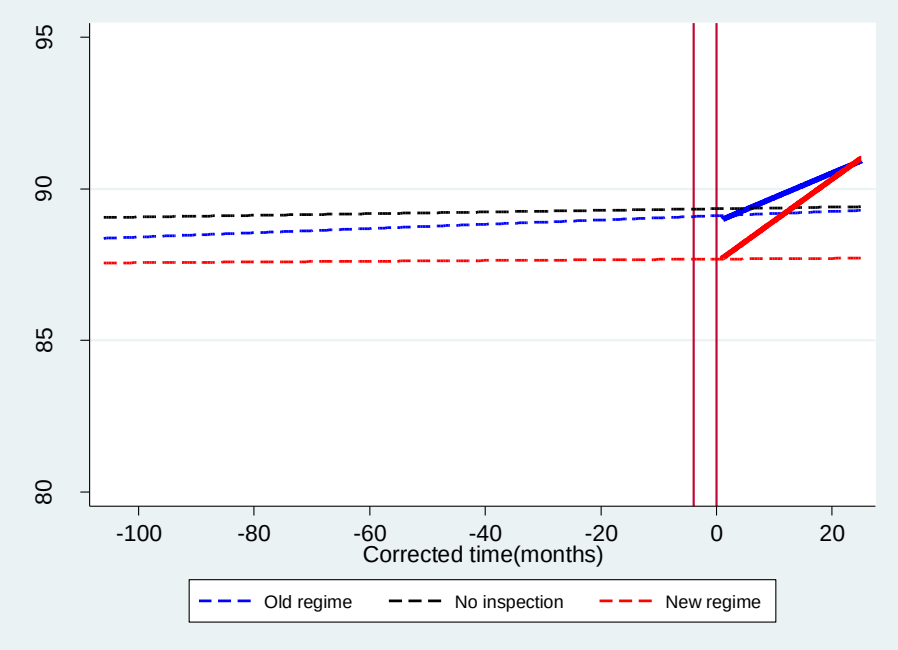


Figure 7.8 Predicted patients' perception of being treated with dignity and respect for an average acute NHS trust before, after the announcement and after inspection by type of inspection

Reporting culture, Foundation trust status, time as Foundation trust, type of trust, beds, population and specialist trust were significant when introduced to the model. After combining these variables into different models, the one adjusted by Foundation trust (FT) status and specialist trust was the most parsimonious.

Compared to a non-FT trust, patients' perception of being treated with dignity and respect is 1.21 (0.68 to 1.75) points higher in trusts with FT status. In the case of specialist trusts, the perception was 4.71 (3.82 to 5.6) points higher compared to other types of acute trusts. Adjusting the model for potential confounders changed the magnitude of the model estimates, but did not modify the conclusions.

Table 7.7 Slopes and changes in level before, after the announcement and CQC inspection for patients' perception of being treated with dignity and respect by type of inspection

	Unadjusted model patients' perception of being treated with dignity and respect (95% CI)			Adjusted model patients' perception of being treated with dignity and respect (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	87.6 (86.9, 88.2)	88.3 (87.6, 89.1)	89 (88.2, 89.9)	87.6 (87.1, 88)	88.4 (87.8, 88.9)	89 (88.4, 89.7)
Pre-inspection slope	0.001 (-0.003, 0.006)	0.007 (0.0007, 0.01)*	0.002 (-0.004, 0.009)	0.001 (-0.003, 0.006)	0.007 (0.001, 0.01)*	0.003 (-0.004, 0.009)
Change in level						
Post-Announcement	1.0 (-0.06, 2.07)	-0.05 (-0.86, 0.75)	0.42 (-0.13, 0.98)	0.94 (-0.12, 2)	0.03 (-0.75, 0.81)	0.3 (-0.25, 0.86)
Post-inspection	0.17 (-1.2, 1.53)	-2 (-3.7, -0.3)*	-2.56 (-4.8, -0.35)	0.21 (-1.15, 1.6)	-1.87 (-3.5, -0.2)*	-2.3 (-4.48, -0.13)
Slope						
Post-announcement	-0.37 (-1.03, 0.29)	0.7 (0.003, 1.33)	0.68 (0.01, 1.34)	-0.37 (-1.03, 0.29)	0.58 (-0.06, 1.23)	0.59 (-0.06, 1.25)
Post-inspection	0.14 (0.1, 0.17)*	0.08 (0.04, 0.12)*	0.09 (0.04, 0.14)*	0.14 (0.1, 0.17)*	0.08 (0.04, 0.12)*	0.09 (0.04, 0.14)*

* Significant values at 0.05 level

7.1.5 Staff leaving acute NHS trusts

The average (95% CI) rate of staff leaving NHS trusts was 2% (1.8% to 2%) in May 2012 for the three groups.

Rates of staff leaving NHS trusts were stable and similar for all trusts included in this analysis. There were no changes in level or slope for any of the groups after the announced inspection. After the CQC inspection, there was an increase in rate of staff leaving NHS trusts, which had a greater magnitude for trusts inspected under the old regime compared to those inspected under the new regime (3 [-11.8 to 17.9] vs 0.6 [-12 to 13.3] staff leaving per 10,000 members of staff) (Table 7.8).

The non-significant change in trend after the inspection would translate one year later into 2.8 (-9 to 14.7) extra people leaving per 10,000 staff for the new regime, 17 (-0.04 to 34) extra people leaving for the old regime and 18.9 (-2.5 to 40.3) for the group not inspected. None of these changes are significant.

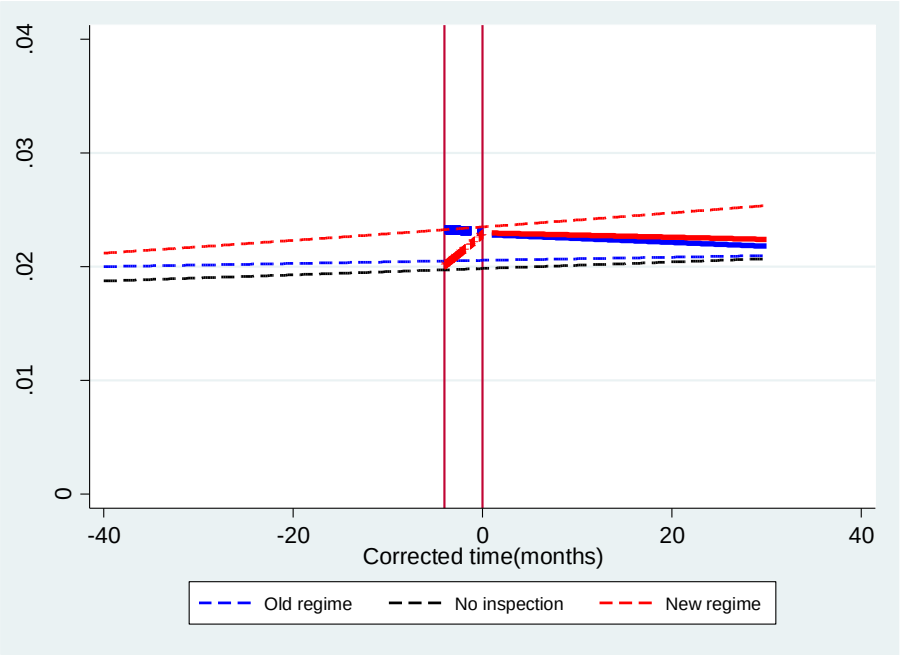


Figure 7.9 Predicted staff leaving NHS trusts for an average acute NHS trust before, after the announcement and after inspection by type of inspection

Region, governance rating, type of trust, specialist trust, IMD score in the health domain, the number of locations and the number of hospitals were significant in the univariate model. After combining these variables into different models, the one adjusted by region and type of trust was the most parsimonious.

By comparison with large acute trusts, rates of staff leaving for medium trusts were 6% (1% to 10%) higher, teaching trusts were 9% (3% to 14%) higher and in specialist trusts were 13% (7% to 20%) higher. In contrast, compared to rates of trusts in the North, trusts in the Midlands had 8% (4% to 12%) higher rates of staff leaving, whilst the South had 6% (2% to 11%) higher rates and London area had 36% (30% to 43%) higher rates. Adjusting the model for potential confounders changed the magnitude of the model estimates, but it did not modify the conclusions.

Table 7.8 Slopes and changes in level before, after the announcement and CQC inspection for staff leaving NHS trusts by type of inspection. Values are number of events per 10,000 staff

	Unadjusted model rates of staff leaving NHS trusts (95% CI)			Adjusted model rates of staff leaving NHS trusts (95% CI)		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Baseline rates	200.3 (188.8, 212.6)	187 (171.2, 204.3)	189.5 (169.4, 211.9)	216.3 (203.1, 230.3)	201.1 (185.4, 218.2)	189.5 (170.5, 210.6)
Pre-inspection slope	0.5 (0.1, 0.9)	0.1 (-0.6, 0.8)	0.3 (-0.6, 1.1)	0.6 (0.1, 0.9)	0.1 (-0.6, 0.8)	0.3 (-0.6, 1.1)
Change in level						
Post-Announcement	-7.4 (-19.3, 4.5)	27.2 (11.6, 42.9)	78.4 (57.9, 98.8)	-24.4 (-39.1, -9.8)	27.1 (11.4, 42.7)	78.4 (58.1, 98.7)
Post-inspection	0.6 (-12, 13.3)*	3 (17.9, -11.8)*	-32.5 (-50.7, -14.4)	0.8 (-11.9, 13.4)*	3.1 (17.9, -11.7)*	-32.5 (-50.6, -14.4)
Slope						
Post-announcement	6.7 (1.1, 12.3)	-0.3 (-7.9, 7.2)	-6 (-16.1, 4.1)	6.7 (1.1, 12.3)	-0.3 (-7.8, 7.2)	-6 (-16.1, 4.1)
Post-inspection	-0.2 (-0.5, 0.2)	-0.4 (-0.7, -0.01)	-0.4 (-0.8, -0.08)	-0.2 (-0.5, 0.1)	-0.3 (-0.7, -0.003)	-0.4 (-0.8, -0.08)

* Significant values at 0.05 level

7.2 Summary

In the case of adverse events, rates were improving for falls with harm and pressure ulcers before the inspection. No changes were observed after the announcement or the on-site visit, except for an abrupt decrease of falls with harm after the announcement of the new regime inspection.

For waiting times in A&E, rates of attendances waiting over 4 h were worsening before the inspection for all the groups. The announcement had no effect on level or slope, but after the CQC visit, there was a decrease for trusts inspected under the old regime and an increase for those inspected under the new regime.

For referral to treatment waiting times, referrals waiting over 18 weeks were improving before the inspection for all the groups. There was a decrease in the level after the announcement, whilst the improving trend flattened. After the CQC visit, the trend shifted, and it worsened for all groups.

Neither the announcement nor CQC visit had an effect on the level or trend of the summary hospital mortality index.

Patients' perception of being treated with dignity and respect was improving for trusts inspected under the old regime. After the inspection, this indicator improved over time for all groups.

Level or trend of rates of staff leaving NHS trusts were not affected by the announcement of a CQC inspection; however, after the visit, there was an increase for the group inspected by the old regime and a decrease for the group inspected by the new regime.

Table 7.9 Summary table indicating significant changes in the outcome measures analysed by type of inspection

	Pre-inspection slope	Level change		Change of slope	
		Announcement	Inspection	Announcement	Post-inspection
Old regime					
Falls with harm	↓	–	–	–	–
Pressure Ulcers	↓	–	–	–	–
SHMI	–	–	–	–	–
>4 h A&E wait	↑	–	↓	–	–
>18w RTT wait	↓	↓	↑	↑	↑
Dignity and respect	↑	–	↓	–	↑
Leavers	–	–	↑	–	–
New regime					
Falls with harm	↓	↓	–	–	–
Pressure Ulcers	↓	–	–	–	–
SHMI	↓	–	–	–	–
>4 h A&E wait	↑	–	↑	–	–
>18w RTT wait	↓	↓	↑	–	↑
Dignity and respect	–	–	–	–	↑
Leavers	–	–	↓	–	–
No inspected					
Falls with harm	↓	–	–	–	–
Pressure Ulcers	↓	–	–	–	–
SHMI	–	–	–	–	–
>4 h A&E wait	↑	–	↑	–	–
>18w RTT wait	↓	↑	–	–	↑
Dignity and respect	–	–	–	–	↑
Leavers	–	–	–	–	–

Key: Arrows are placed where a significant effect was observed. Blue arrows signal a positive effect, whilst yellow arrows signal a negative effect. The direction of the arrow indicates whether there was an increase (upwards) or decrease (downwards).

8 Comparison of the effect of old and new Care Quality Commission inspection regimes on measures of process of care and clinical outcomes by previous performance

Chapter 6 addressed the effect of any CQC inspection, including a subgroup analysis by previous level of performance, whilst Chapter 7 presented the results for the comparative effect of the old and new regime of inspections on selected measures of care quality. According to these previous analyses, if CQC inspections have any effect on the performance of acute NHS trusts, this has not been detected on the outcomes selected.

Trusts' ability to respond, implement changes, and improve measures of care quality in preparation for an inspection may differ depending on measurable and unmeasurable intrinsic characteristics of the trust. Previous performance may be a proxy for improvement culture, which might affect the way clinical and managerial teams respond to a coming inspection.

Therefore, this chapter expands on the subgroup analyses presented in Chapter 6, by exploring how the trend of improvement, instead of the level, influences the effect of new and old regime CQC inspections. The a priori hypothesis is that inspections will have a greater effect on trusts with improving performance compared to the effect on those trusts with worsening performance, assuming that previous improvement is a proxy of the trust's capacity to manage and implement changes for quality improvement.

8.1 Findings of comparison of inspection regimes by previous performance

This analysis included 155 acute NHS trusts, of which 100 (65%) had data available to estimate a pre-inspection trend for all seven measures of process of care and clinical outcomes. Trusts with missing data for at least one measure were more likely to be Foundation Trusts (78.2% vs 57%, p=0.008), to be acute specialist trusts (32.7% vs 0%, p<0.001) and not to have been inspected between September 2013 and September 2014 (72.7% vs 0%, p<0.001). However, these were less likely to have been under special measures (2% vs 18%, p=0.003). Additionally,

they were more likely to have a Monitor Financial Sustainability rating of “no evident concerns” or “lowest risk” (42% vs 18%, p=0.01), a Monitor Governance rating of “no evident concerns” (81% vs 58%, p=0.01) and a CQC reporting culture rating of “good” or “outstanding” (61.8% vs 41%, p=0.01).

Within those trusts without missing data, only one trust had improving performance for all seven measures, whilst improving performance for three measures was the most common pattern (36%).

Overall, 99 different combinations of improvement were observed, with improvement of falls with harm, pressure ulcers and patients’ perception of being treated with dignity and respect the most common combination (i.e. 7 trusts).

Trusts that had information available for 6 or more measures and had improving performance for at least 50% of them (i.e. 69 trusts) were more likely to be medium or teaching trusts (63% vs 32%, p<0.001) and less likely to be specialist trusts (1% vs 20%, p<0.001). In terms of geographical location, these trusts were more likely to be in the South or London (47% vs 31%, p=0.04) and less likely to be in the North (22% vs 41%, p=0.01).

Trusts with improving performance of clinical outcomes before the inspection (i.e. falls with harm, pressure ulcers, and summary hospital mortality index) were more likely to have been in special measures (21.6% vs 9.3%, p = 0.05) and less likely to be Foundation Trusts (45.9% vs 70.3%, p=0.007).

The regression model included interaction terms to obtain changes in level and slope. Trusts inspected under the old regime that were not improving were used as controls. Values here presented are the absolute number of events per 10,000 patients/month. The model coefficients are available in the Appendix to Chapter 8, tables 8.1 to 8.5.

8.1.1 Adverse events

8.1.1.1 Falls with harm

Trusts with improving safety records were more likely to be small or teaching trusts (40.4% vs 18%) and to have been inspected between September 2013 and 2014 (79% vs 62%).

Trusts that improved adverse events before the inspection had higher rates of falls with harm at the beginning and changed performance at a faster pace than those with steady or worsening performance. The announcement of the old regime inspection produced a significant but small change in the trend, decelerating progress in trusts that were improving

and accelerating improvement in trusts with worsening performance (Figure 8.1). After the inspection, the rate of falls dropped for trusts with worsening performance receiving a new regime inspection (-27.1 [-0.4 to -53.8] falls per 10,000 patients). No other changes in level or slope were observed after the inspection (Table 8.1).

At 12 months after the inspection there is a difference between the expected (i.e. counterfactual) and the observed rates of falls with harm. For trusts with improving performance inspected under the old regime, this difference equals an increase of 24.5 (16.9 to 32.1) falls per 10,000 patients, and for the new regime is 12.2 (5.7 to 18.8) falls per 10,000 patients. For trusts with worsening performance inspected under the new regime the difference is equal to a decrease of 106.8 (183.8 to 29.8) falls per 10,000 patients.

Table 8.1 Slopes and level changes after the announcement and on-site inspections for rates of falls with harm by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=510 Trusts=10	Obs=714 Trusts=14	Obs=765 Trusts=15	Obs=1,836 Trusts=36	Obs=2,550 Trusts=50	Obs=1,173 Trusts=23
Baseline rates	31.6 (16.6, 59.9)	39.9 (26.9, 59.3)	53.3 (31.4, 90.3)	264.4 (192, 364)	125.5 (101.5, 155.2)	217.6 (142.1, 333.1)
Pre-inspection slope	0.9 (0.3, 1.4)*	1.3 (0.8, 1.8)*	0.6 (-0.3, 1.5)	-15.4 (-23.2, -7.6)*	-4.3 (-6, -2.5)*	-9.1 (-16.3, -1.9)*
Level change						
Announcement	-3.1 (-26.8, 20.7)	-18.6 (-46.8, 9.6)	-	10.4 (-1.4, 22.1)	-5.4 (-12.7, 2)	-
Inspection	15.8 (-3.5, 35.1)	-27.1 (-53.8, -0.4)*	-	1.2 (-8, 10.4)	3.8 (-2.9, 10.5)	-
Slope						
Announcement	-5.1 (-11.8, 1.6)*	2.3 (-9.5, 14.1)	-2.1 (-14.8, 10.6)	-4.6 (-10.2, 1.1)*	-0.8 (-4.2, 2.6)	0.3 (-2.6, 3.2)*
Post-inspection	-0.7 (-1.9, 0.4)	-0.2 (-1.0, 0.6)	1.0 (-4.4, 6.4)	-0.4 (-0.8, -0.04)	-0.4 (-0.7, -0.05)	1.9 (-2.3, 6.3)

* Significant values at 0.05 level

Values presented in number of events per 10,000 patients/month. Figures were calculated using model coefficients to present the absolute instead of relative value. For example, the pre-inspection slope for hospitals inspected by the new regime that were improving is calculated as $\exp(\beta_{0j} + \beta_{1j}$*corrected time old inspection not improving $_{ij} + \beta_{6j}$*new inspection improving $_{j} + \beta_{7j}$*corrected time new inspection improving $_{ij})$. The same applies for all tables in this chapter.

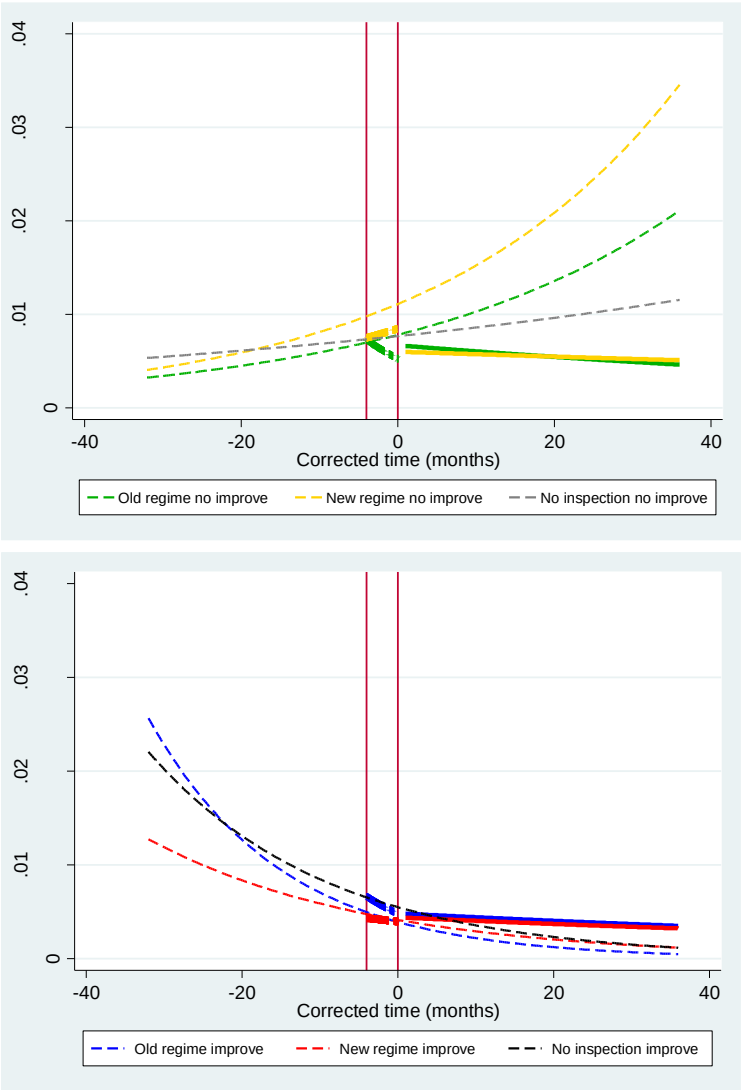


Figure 8.1 Rates of falls with harms before the inspection, after the announcement and the inspection by previous performance

Key: Lines represent the mean rate of falls with harm obtained from the multilevel model for each period. The first vertical line signals the announcement, while the second signals the inspection. Dash lines show the trends observed during the pre-inspection period, which were extended for the post-announcement and post-inspection periods. Long-dash lines represent the observed data in the period between the announcement and the inspection. Solid lines show the trends after the inspection. Data for the hospitals inspected by the old regime that were improving are shown in blue and those not improving in green. Hospitals inspected by the new regime that were improving are in red and those not improving in yellow. Trusts not inspected that were improving are in black and those not improving in grey. The same applies for all figures in this chapter.

8.1.1.2 Pressure ulcers

Both groups of acute trusts were similar, except that trusts with improving performance were greater in terms of number of hospitals (2 [1 to 4] vs 3 [2 to 5], p=0.04) and locations (3 [1 to 6] vs 5 [2 to 7], p=0.04).

The pattern is similar to that observed for falls with harm, where trusts with improving performance had higher rates of pressure ulcers at the beginning and their improvement was

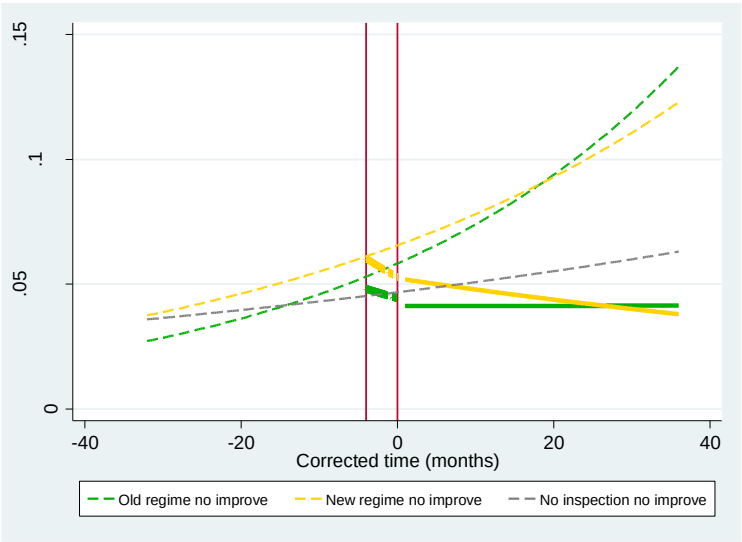
faster. The announcement of the old regime inspection produced a significant shift of the previous trend, slowing down progress in trusts that were improving and speeding up improvement in trusts with worsening performance (Figure 8.2). Trusts inspected under the new regime showed a similar pattern, but changes were not significant. After the inspection, the rate of pressure ulcers increased for trusts with improving performance receiving an old regime inspection (38.8 [5.9 to 71.7] pressure ulcers per 10,000 patients). No other changes were observed after the inspection (Table 8.2).

At 12 months after the inspection the change of slope results in a significant increase for trusts with improving performance inspected under the old (102.8 [48.5 to 157.2] pressure ulcers per 10,000 patients) and new regime (94.9 [55.1 to 134.7] pressure ulcers per 10,000 patients) and a significant decrease for trusts not improving inspected by the old (-362.8 [-616.7 to -108.8] pressure ulcers per 10,000 patients) and new regime (-337.9 [-523.5 to -152.2] pressure ulcers per 10,000 patients).

Table 8.2 Slopes and level changes before, after announcement and inspections for rates of pressure ulcers by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=561 Trusts=11	Obs=969 Trusts=19	Obs=663 Trusts=13	Obs=1,734 Trusts=34	Obs=2,346 Trusts=46	Obs=1,224 Trusts=24
Baseline rates	271.9 (203.4, 363.6)	374.6 (306.5, 457.9)	358.7 (266.8, 482.3)	860 (717.6, 1030.8)	681.4 (600.7, 772.9)	718.1 (578.2, 891.8)
Pre-inspection slope	6.5 (4, 9)*	6.6 (3.9, 9.2)*	2.9 (-1, 6.9)*	-21.6 (-31.6, -11.6)*	-13.8 (-18.8, -8.8)*	-17.2 (-27, -7.3)*
Level change						
Announcement	-58.4 (-135.5, 18.8)	-28.9 (-105.6, 47.9)	-	-44.9 (-83, -6.9)	3.4 (-29.2, 35.9)	-
Inspection	-31.8 (-92.9, 29.4)	-8.9 (-74.8, 56.9)	-	38.8 (5.9, 71.7)*	1.7 (-28.5, 31.9)	-
Slope						
Announcement	-9.5 (-29.6, 10.6)*	-18.8 (-55.9, 18.3)	-22.3 (-63.1, 18.4)	-8.3 (-24, 7.4)*	-5.6 (-21.5, 10.2)	-12.2 (-34.3, 9.9)
Post-inspection	0.06 (-3.8, 3.9)	-4.6 (-8.6, -0.6)	-8.3 (-28.4, 11.7)	-0.7 (-2.8, 1.4)	-0.08 (-1.9, 1.7)	-3.4 (-15.5, 8.6)

* Significant values at 0.05 level



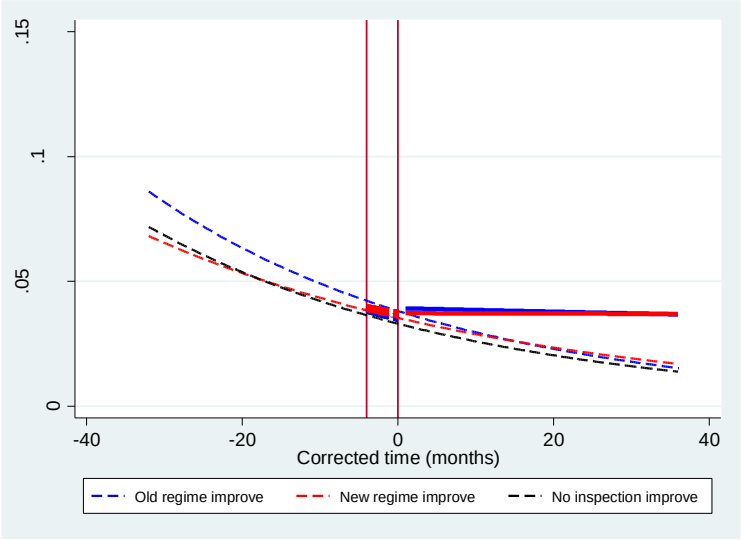


Figure 8.2 Rates of pressure ulcers before the inspection, after the announcement and the inspection by previous performance

8.1.2 Summary Hospital Mortality Index

Trusts with improving safety records were more likely to have been in special measures (23% vs 7%, p=0.005) and to have been inspected between September 2013 and 2014 (71% vs 52%, p=0.05).

Trusts with improving records before the visit and inspected under the new regime had higher SHMI values at the beginning compared to those with worsening performance inspected under the old and new regimes (1.06 [1.02 to 1.095] vs 0.97 [0.94 to 0.99] and 0.97 [0.93 to 1]); however, in terms of magnitude the speed of change was similar for trusts with improving and worsening performance. The old regime inspection produced a significant but small change in the level for trusts with improving SHMI (Figure 8.3). No changes in level or slope were observed after the announcement and changes in the rate of improvement after the inspection were not significant (Table 8.3).

Table 8.3 Slopes and level changes before, after announcement and inspections for summary hospital mortality index by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=494 Trusts=26	Obs=532 Trusts=28	Obs=418 Trusts=22	Obs=266 Trusts=14	Obs=646 Trusts=34	Obs=228 Trusts=12
Baseline rates	0.97 (0.93, 1.008)	0.97 (0.93, 1.0)	0.98 (0.94, 1.02)	1.05 (0.99, 1.1)	1.05 (1.02, 1.09)	1.03 (0.97, 1.08)
Pre-inspection slope	0.002 (0.001, 0.002)*	0.001 (0.0009, 0.002)*	0.002 (0.001, 0.002)*	-0.002 (-0.003, -0.001)*	-0.002 (-0.003, -0.002)*	-0.002 (-0.003, -0.002)*
Level change						
Announcement	-0.008 (-0.02, 0.005)	0.0006 (-0.01, 0.01)	-	-0.01 (-0.03, 0.008)	0.008 (-0.004, 0.02)	-
Inspection	0.002 (-0.01, 0.015)	-0.007 (-0.02, 0.006)	-	-0.02 (-0.04,-0.004)*	0.003 (-0.009, 0.02)	-
Slope						
Announcement	-0.001 (-0.009, 0.006)	-0.002 (-0.009, 0.006)	-0.0002 (-0.008, 0.008)	0.006 (-0.005, 0.02)	-0.001 (-0.008, 0.006)	-0.001 (-0.009, 0.006)*
Post-inspection	-0.0008 (-0.002, 0.0005)	-0.001 (-0.002, 0.0002)	0.0005 (-0.0009, 0.002)	0.002 (0.0003, 0.004)	0.001 (-0.0001, 0.002)	-0.0008 (-0.003, 0.001)

* Significant values at 0.05 level

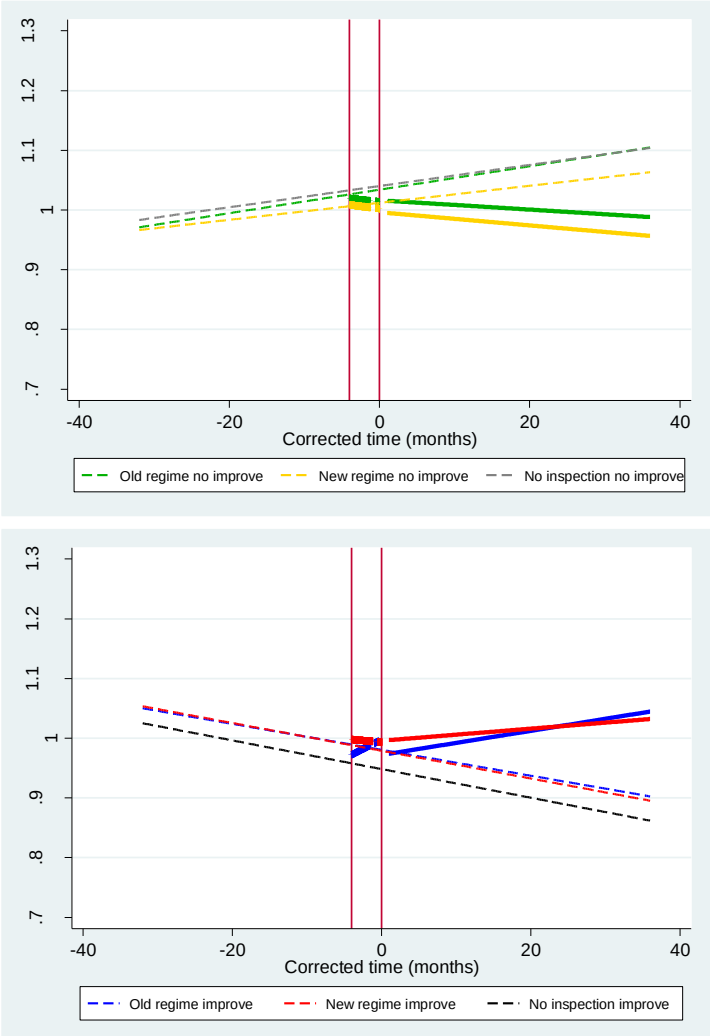


Figure 8.3 Summary Hospital Mortality Index before the inspection, after the announcement and the inspection by previous performance

However, 12 months after the inspection the change of slope translate into a significant increase for those trusts with improving performance (old regime: 0.04 [0.009 to 0.07] new regime: 0.06 [0.04 to 0.08] and no inspection 0.07 [0.04 to 0.11]) and in a significant decrease for trusts with worsening SHMI pre-inspection (old regime: -0.05 [-0.07 to -0.02] new regime: -0.05 [-0.07 to -0.02] and no inspection -0.04 [-0.06 to -0.01]) (Figure 8.3). For a trust with an expected mortality of 2,000 patients, an increase of 0.02 points translates into 40 extra deaths.

The SHMI is a standardised measurement calculated as the ratio between observed and expected deaths, therefore it is difficult to interpret changes in level and slope without looking at how crude mortality rates have changed. The same classification of improving and not improving trusts and modelling strategy were used. The coefficients of this model are available in the Appendix Chapter 8, Table 8.6.

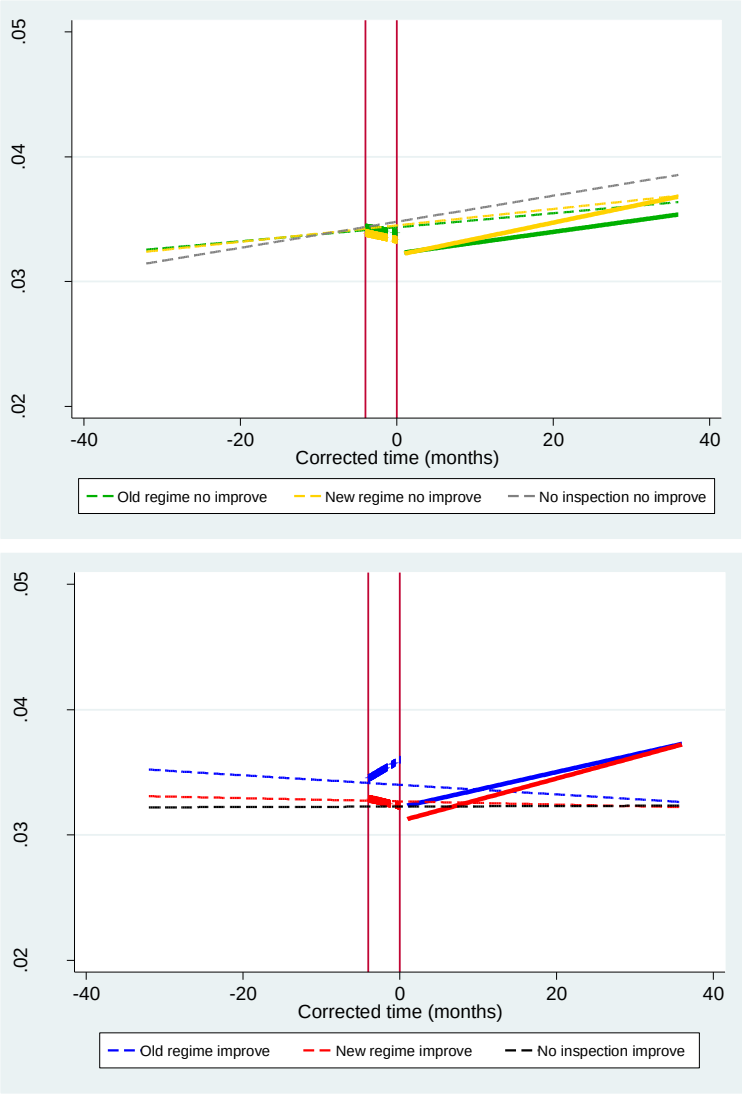


Figure 8.4 Crude mortality rates before the inspection, after the announcement and the inspection by previous performance

In the case of trusts classified as not improving based on the values of SHMI, there was a significant transient decrease of crude mortality rates after the inspection under the old regime (1.7 [1 to 2] fewer deaths per 1,000 patients). Since these changes were not observed in the SHMI, this reduction can be attributed to a decrease of similar magnitude in expected and observed mortality. In the case of the post-inspection trend, in the analysis of SHMI this was going downward, whilst the analysis of crude mortality is going upward. Therefore, the increase in crude mortality would be related to an increase of greater magnitude of expected mortality, which would yield a lowering SHMI.

Crude mortality rates for improving non-inspected trusts remained stable during the observation period; however SHMI was improving, therefore, expected deaths for this group were increasing. For trusts inspected under the old regime, there was a transient non-significant increase of slope for crude mortality rates after the announcement (0.6 [-0.1 to 1] extra deaths per 1,000 patients/month) and a significant step decrease after the inspection (2 [0.9 to 3] fewer deaths per 1,000 patients), which was also observed for the SHMI, consequently the reduction can be attributed to a decrease in observed deaths. The analyses of SHMI and crude mortality rates showed an upward trend after the inspection; therefore, there was an increase in observed deaths, whilst expected deaths remained relatively stable.

8.1.3 Waiting times

8.1.3.1 Accident & Emergency department waiting times

Trusts with improving A&E waiting times were more likely to be specialist trusts (15.6% vs 0.9%, p=0.002) and more likely to have received a rating of “outstanding” or “good” in the latest CQC inspection (50% vs 24%, p=0.008).

Trusts that improved rates of attendances waiting over 4 h in A&E before the inspection and were inspected under the new regime had higher rates at the beginning and improved at a faster pace than those not inspected or inspected under the old regime (Table 8.4). No changes in level were observed after the announcement, but the slope shifted and became steeper for those trusts with improving performance inspected under the new regime (-2.6 [-4.6 to -0.6] fewer attendances waiting over 4 h per 10,000 patients/week vs 9.8 [4 to 15.6] extra attendances waiting over 4 h per 10,000 patients/week). For trusts with improving performance inspected under the new regime, there was a step increase after the inspection and the steep upward trend observed before flattened (Figure 8.5).

Table 8.4 Slopes and level changes before, after announcement and inspections for rates of attendances waiting over 4 h in A&E by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=7,744 Trusts=32	Obs=12,342 Trusts=51	Obs=6,534 Trusts=27	Obs=2,420 Trusts=10	Obs=3,146 Trusts=13	Obs=2,178 Trusts=9
Baseline rates	198.2 (156.8, 250.7)	201.7 (168.9, 241)	201.2 (155.2, 260.9)	313.7 (206.8, 476)	663.3 (462.5, 951.3)	319.1 (203.2, 501)
Pre-inspection slope	0.9 (0.8, 1)*	0.9 (0.8, 1)*	0.9 (0.8, 1.1)*	-0.5 (-1.3, 0.3)*	-2.6 (-4.6, -0.6)*	-0.4 (-1.3, 0.5)*
Level change						
Announcement	-73.9 (-133.4, -14.3)	-24.7 (-77.9, 28.4)	-	0.05 (-57.2, 57.3)	-4.6 (-68.6, 59.3)	-
Inspection	-37.4 (-96.7, 22)*	60.1 (-2.7, 122.9)*	-	23.2 (-43.7, 90.1)	44.8 (-69, 158.7)*	-
Slope						
Announcement	0.1 (-5.5, 5.8)	3.2 (-1.8, 8.3)	-8.2 (-13.8, -2.5)*	1.1 (-4.5, 6.8)	9.8 (4, 15.6)*	-0.2 (-5.2, 4.9)
Post-inspection	2.8 (1.8, 3.9)	1.1 (-0.4, 2.6)	3.3 (2.1, 4.4)*	1.8 (0.5, 3.1)	0.2 (-2.5, 2.9)*	2.6 (1.4, 3.7)

* Significant values at 0.05 level

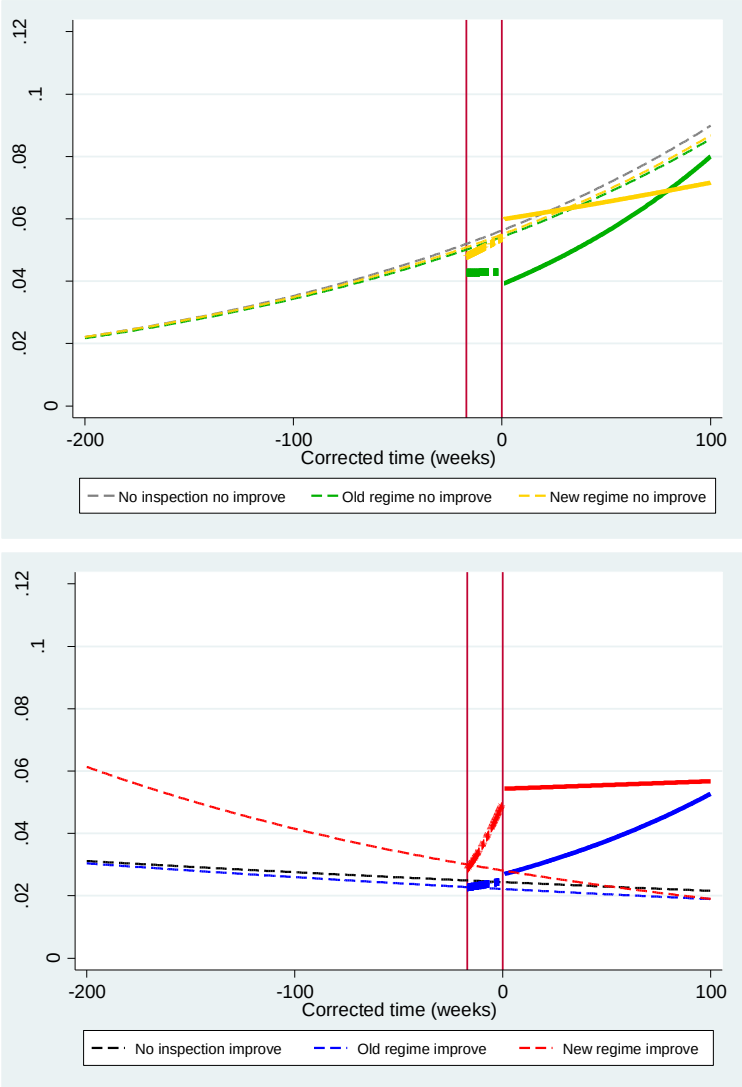


Figure 8.5 Rates of attendances waiting over 4h in A&E before the inspection, after the announcement and the inspection by previous performance

At 12 months after the inspection the change of slope results in a significant increase for trusts with improving performance inspected under the old (176.4 [69.7 to 283.2) attendances waiting over 4 h per 10,000 patients), new regime (326.1 [185.9 to 466.4] attendances waiting over 4 h per 10,000 patients) and for those not inspected (156 [36.5 to 275.6] attendances waiting over 4 h per 10,000 patients). In the case of trusts not improving, the change in slope results in a significant decrease for trusts inspected by the old regime (-362.8 [-616.7 to -108.8] pressure ulcers per 10,000 patients).

8.1.3.2 Consultant-led referral to treatment waiting times (admitted)

The rapid improvement of rates of referrals waiting over 18 weeks during the first two years of implementation of this performance measure meant that 95.5% of acute trusts had improving performance before the inspection. To address this problem, the first 24 months of data were excluded from this analysis and previous performance was estimated using data from August 2009 onwards. Trusts with improving referral to treatment waiting times were similar to those not improving in all the variables analysed (see Appendix Chapter 8, Table 8.8).

Trusts that improved rates of referrals waiting more than 18 weeks before the inspection had higher rates at the beginning and the magnitude of the speed of change was greater compared to those with steady or worsening performance (Table 8.5). In the case of improving trusts that were inspected under the new regime, the announcement produced a step increase of 213 (102.6 to 323.5) extra referrals per 10,000 waiting over 18 weeks (Figure 8.6). For all other trusts, the announcement did not produce a change in level or slope. No changes in level or slope were observed after the inspection (Table 8.5).

Table 8.5 Slopes and level changes before, after announcement and inspections for rates of referrals waiting over 18 weeks by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=1,535 Trusts=31	Obs=2,076 Trusts=40	Obs=1,152 Trusts=24	Obs=810 Trusts=17	Obs=1,362 Trusts=26	Obs=768 Trusts=16
Baseline rates	441.7 (358.5, 544.1)	490.5 (407.8, 590)	487 (384, 617.7)	942.2 (712.3, 1246.3)	1235.5 (985, 1549.6)	1099.6 (821.3, 1472.3)
Pre-inspection slope	4.8 (3.8, 5.9)*	4.4 (3.5, 5.3)*	4.2 (3.1, 5.3)*	-8.7 (-14.6, -2.8)*	-11.1 (-17.1, -5)*	-12.8 (-20.5, -5)*
Level change						
Announcement	-28.1 (-122.8, 66.5)	32.5 (-52.3, 117.2)	-	57.2 (-33, 147.4)	213 (102.6, 323.5)*	-
Inspection	-55.4 (-153.3, 42.5)	29 (-61.5, 119.6)	-	-23.8 (-110.6, 63)	-10.7 (-140.6, 119.1)	-
Slope						
Announcement	13.5 (-38.1, 65.1)	14.8 (-32.3, 61.9)	13.3 (-14.2, 40.7)	-6.5 (-57, 44)	45.5 (-15.4, 106.5)	12.5 (-10, 34.9)
Post-inspection	24.7 (19.3, 30)	26.7 (21.1, 32.2)	22 (16.4, 27.6)	21.1 (15.9, 26.3)	39.5 (31.3, 47.7)	21.5 (16.2, 26.8)

* Significant values at 0.05 level

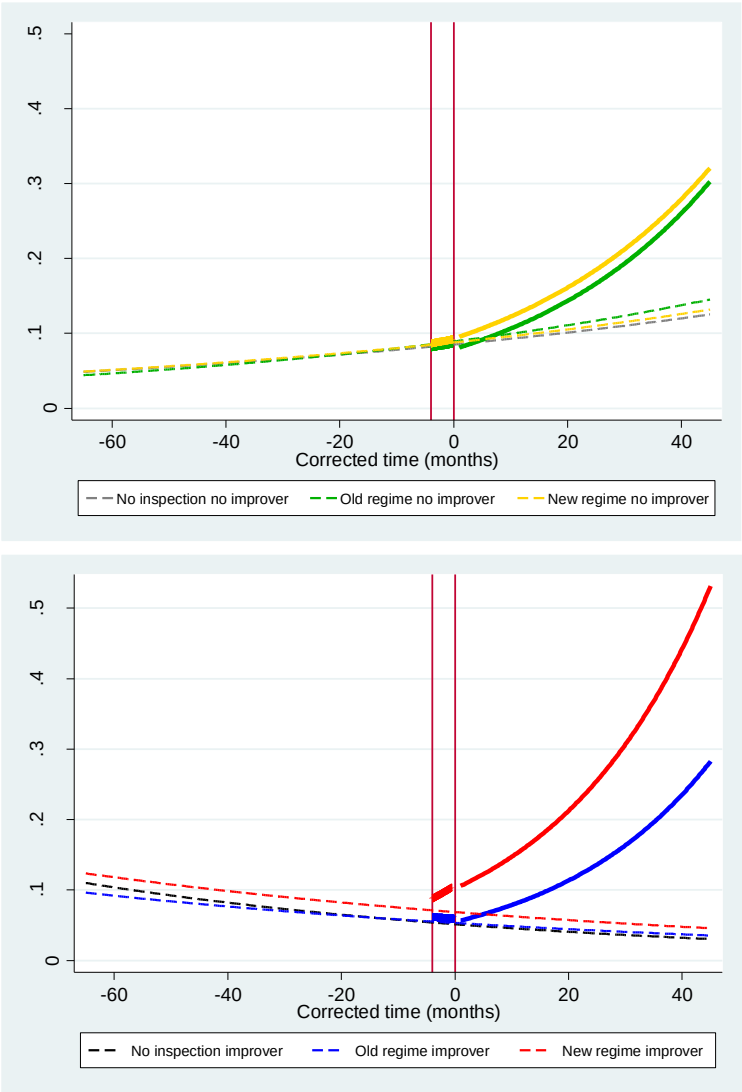


Figure 8.6 Rates of referrals waiting over 18 weeks before the inspection, after the announcement and the inspection by previous performance

If the counterfactual with the actual rates 12 months after the inspection is used, there was a significant increase for trust with improving performance inspected under the old (367 [246.3 to 491.7] referrals per 10,000 patients), new regime (967.2 [778.2 to 1156.2] referrals per 10,000 patients) and those not inspected (389.9 [249.9 to 530] referrals per 10,000 patients). In the case of trusts that were not improving before the inspection, there was an increase for those inspected under the new regime (313.3 [183 to 443.6] referrals per 10,000 patients).

8.1.4 Treatment of patients with dignity and respect

Trusts with improving patients' perception of being treated with dignity and respect were more likely to have Foundation Trust status (71% vs 51%, p=0.01), less likely to be deemed at

"significant risk" by Monitor financial sustainability rating (3% vs 21%, p=0.005) and less likely to receive a Monitor Governance rating of "subject to enforcement action" (13% vs 38%, p=0.005).

Patients' perception of being treated with dignity and respect was similar across groups in 2005, and the magnitude of the slope before the inspection was similar for trusts that improved and those with worsening performance (Table 8.6). No changes in level were observed after the inspection in any of the groups, however, there was an upward shift in the trend for trusts with worsening performance inspected under the old regime (0.07 [-0.008 to 0.14] points), the new regime (0.13 [0.07 to 0.2] and for those not inspected (0.18 [0.09 to, 0.3]). In the case of trusts with improving performance, the rate of improvement improved for those inspected under the old regime (0.07 [0.02 to 0.1] points) (Figure 8.7).

One year after the inspection the change of slope translates into a significant improvement compared to the counterfactual, for those trusts with worsening patients' perception inspected by the old regime (1.44 [0.7 to 2.18] points), the new regime (2.37 (1.8 to 2.89] points) and trusts not inspected (1.19 [0.39 to 1.99] points) (Figure 8.7). For a trust with an adjusted patients' perception of 90 points and if patient-mix and distribution of the scores remain the same (e.g. 80 patients giving a score of 100 points and the remaining 20 patients giving a score of 50 points), one extra point means two more people per 100 patients answered that they always felt treated with dignity and respect.

Table 8.6 Slopes and level changes before, after announcement and inspections for patients' perception of being treated with dignity and respect by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=165 Trusts=15	Obs=319 Trusts=29	Obs=143 Trusts=13	Obs=352 Trusts=32	Obs=396 Trusts=36	Obs=275 Trusts=25
Baseline rates	89.6 (88.3, 90.8)	88.7 (87.8, 89.6)	88.6 (87.3, 89.9)	87.8 (86.9, 88.6)	86 (84.7, 87.2)	88.8 (87.3, 90.4)
Pre-inspection slope	-0.01 (-0.02, -0.004)*	-0.017 (-0.02, -0.01)*	-0.01 (-0.02, -0.005)*	0.017 (0.01, 0.02)*	0.02 (0.01, 0.03)*	0.016 (0.003, 0.03)*
Level change						
Inspection	0.56 (-0.64, 1.75)	0.7 (-0.02, 1.5)	-	-0.4 (-1.2, 0.5)	-0.6 (-1.3, 0.08)	-
Slope						
Post-inspection	0.07 (-0.008, 0.14)*	0.13 (0.07, 0.2)*	0.18 (0.09, 0.3)*	0.07 (0.02, 0.1)*	0.07 (-0.04, 0.2)	-0.06 (-0.2, 0.07)

* Significant values at 0.05 level

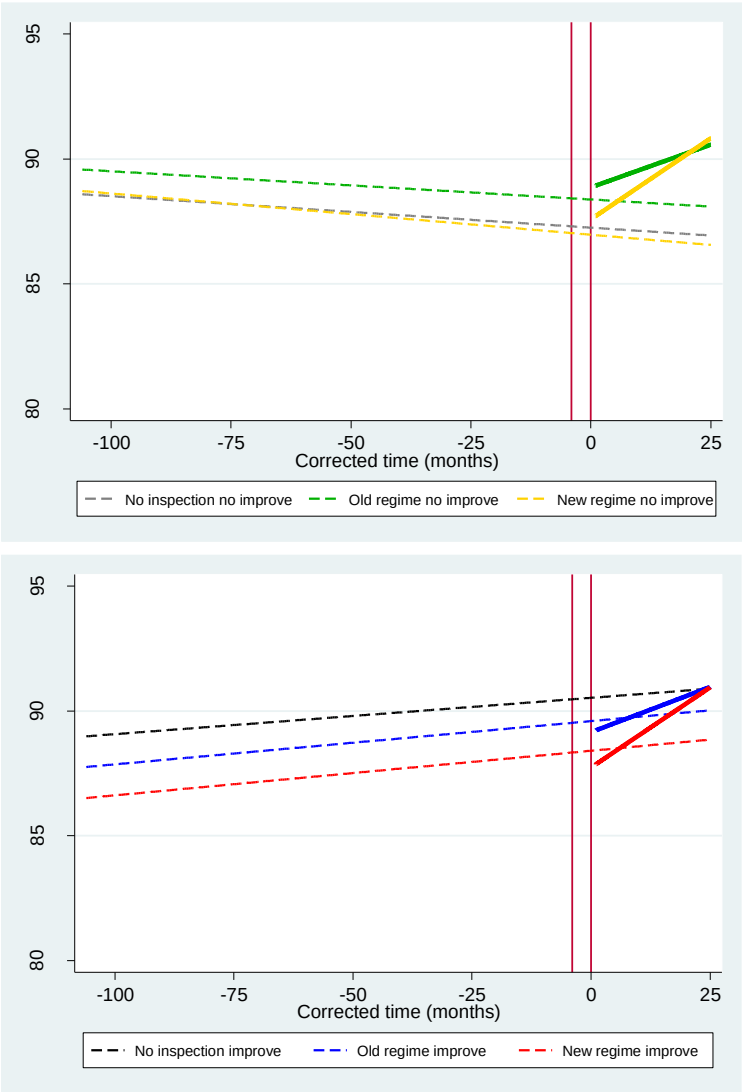


Figure 8.7 Patients' perception of being treated with dignity and respect before the inspection, after the announcement and the inspection by previous performance

8.1.5 Staff leaving acute NHS trusts

Trusts with improving rates of staff leaving were more likely to be located in the South (37% vs 16%, p=0.03) and less likely to be located in the North or London (35% vs 54%, p=0.03). Trusts that improved their rates of staff leaving before the inspection had higher rates than those with steady or worsening performance at the beginning of the time series (Table 8.7). For trusts with improving performance inspected by the old regime, the announcement produced a significant increase of 36.5 (11.3 to 61.7) members of staff leaving the trusts per 10,000 employees. For trusts with worsening performance inspected by the old regime, there were

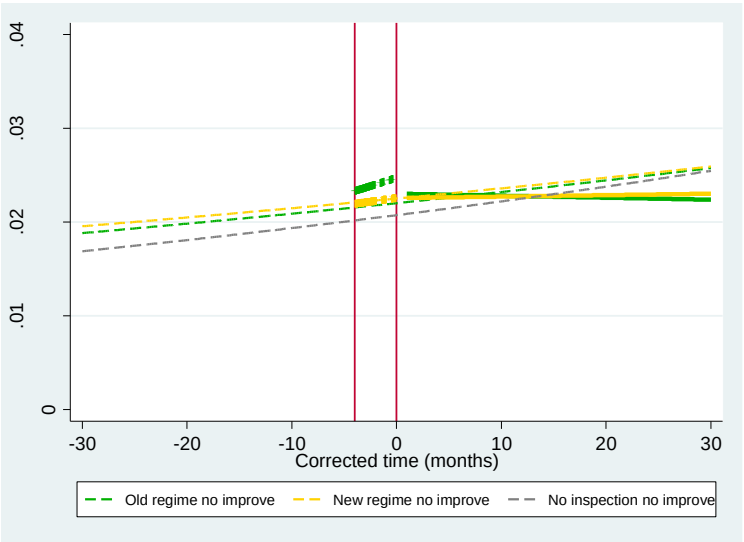
17.4 (34.1 to 0.7) fewer members of staff leaving the trusts per 10,000 employees after the inspection. No other changes in level or slope were observed for the other trusts (Table 8.7).

For trusts with improving rates of staff leaving, the change of slope results one year after the inspection in 44.75 (20.44 to 69.1) extra members of staff leaving for those inspected by the old regime, 31.34 (13.8 to 48.88) extra members of staff leaving for trust inspected by the new regime and 59.86 (33.63 to 86.09) for those not inspected (Figure 8.8).

Table 8.7 Slopes and level changes before, after announcement and inspections for rates of staff leaving NHS trusts by previous performance

	Not improving			Improving		
	Old regime	New regime	No inspection	Old regime	New regime	No inspection
	Obs=1,598 Trusts=34	Obs=1,880 Trusts=40	Obs=1,175 Trusts=25	Obs=611 Trusts=13	Obs=1,175 Trusts=25	Obs=658 Trusts=14
Baseline rates	186.2 (169.1, 204.9)	193.6 (180.5, 207.7)	166.5 (147, 188.4)	232.9 (199.5, 272.1)	221.7 (201.5, 243.9)	241.3 (204.5, 284.8)
Pre-inspection slope	0.9 (0.3, 1.6)*	0.9 (0.5, 1.4)*	1.1 (0.4, 1.9)*	-1.8 (-3.5, -0.2)*	-0.7 (-1.5, 0.1)*	-2 (-3.9, -0.1)*
Level change						
Announcement	21.1 (4.4, 37.8)	0.1 (-14, 14.3)	-	36.5 (11.3, 61.7)*	-10.4 (-26.3, 5.5)	-
Inspection	-17.4 (-34.1, -0.7)*	-0.03 (-14.3, 14.2)	-	11.7 (-10.5, 33.9)	0.5 (-17.7, 18.8)	-
Slope						
Announcement	3.5 (-4.4, 11.4)	1.6 (-5.3, 8.4)	-3.6 (-14.2, 7)	-8 (-20.4, 4.3)	11.5 (4.1, 18.8)	-13.2 (-34.9, 8.6)
Post-inspection	-0.2 (-0.7, 0.2)	0.1 (-0.3, 0.6)	0.02 (-0.4, 0.5)	-0.2 (-0.9, 0.4)	-0.5 (-1.1, 0.07)	-1.1 (-1.8, -0.4)

* Significant values at 0.05 level



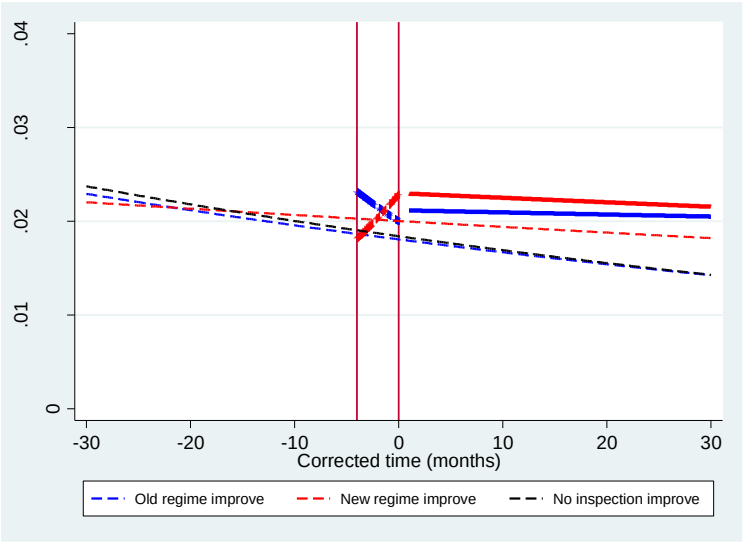


Figure 8.8 Rates of staff leaving NHS trusts before the inspection, after the announcement and the inspection by previous performance

8.2 Summary

In the case of trusts with worsening or stable performance before the inspection, rates of adverse events had no level change after the announcement or inspection under the old regime, but there was a decrease of falls with harm after the new regime inspection. The slope did not change after the announcement or inspection under the new regime, but there was a downward shift of the trend of falls with harm and pressure ulcers after the announcement of the old regime inspection.

Neither the announcement nor the CQC visit influenced the level or trend of the summary hospital mortality index.

For waiting times, the only change observed was a step decrease in attendances waiting over 4 h in A&E after an old regime inspection and a step increase for those inspected under the new regime. No changes were detected for referrals to treatment.

The rate of change of patients' perception of being treated with dignity and respect improved after the inspection for the three groups.

Level or trend of rates of staff leaving NHS trusts were not affected by the announcement or CQC inspection under the new regime; however, after the old regime visit, there was a significant decrease in level.

In the case of trusts with improving performance before the inspection, no level change was seen for adverse events after the announcement of an inspection, but in the case of trusts inspected by the old regime, the improving trend flattened after the announcement for falls with harm and pressure ulcers. Additionally, a step increase of pressure ulcers was observed after the old regime inspection.

Summary Hospital Mortality Index had a decrease immediately after the old regime inspection, but no other changes were observed for both groups inspected. However, those trusts not inspected showed worsening values of SHMI after July 2013.

No change in level or slope of waiting times was observed after the announcement or inspection under the old regime. However, trusts inspected by the new regime exhibited a steep increase in attendances waiting over 4 h in A&E after the announcement, whilst the level worsened and the improving trend flattens after the CQC inspection. In the case of referrals waiting over 18 weeks, there was an increase after the announcement of a new regime inspection. No other changes were observed for this outcome measure.

The old regime CQC visit improved the rate of change of patients' perception of being treated with dignity and respect, which was not observed for trusts not inspected and for those inspected under the new regime.

After the announcement of an old regime inspection, an increase in the rate of staff leaving NHS trusts was observed; however, the same phenomenon was seen in those trusts not inspected. No other changes in level or slope were seen for this indicator.

A summary of these results is shown in Table 8.8.

Table 8.8 Summary table indicating significant changes in the outcome measures analysed

	Pre-inspection slope	Level change		Change of slope	
		Announcement	Inspection	Announcement	Post-inspection
Old regime not improving					
Falls with harm	↑	–	–	↓	–
Pressure Ulcers	↑	–	–	↓	–
SHMI	↑	–	–	–	–
>4 h A&E wait	↑	–	↓	–	–
>18w RTT wait	↑	–	–	–	–
Dignity and respect	↓		–		↑
Leavers	↑	–	↓	–	–
New regime not improving					
Falls with harm	↑	–	↓	–	–
Pressure Ulcers	↑	–	–	–	–
SHMI	↑	–	–	–	–
>4 h A&E wait	↑	–	↑	–	–
>18w RTT wait	↑	–	–	–	–
Dignity and respect	↓		–		↑
Leavers	↑	–	–	–	–
No inspection not improving					
Falls with harm	–	–	–	–	–
Pressure Ulcers	–	↑	–	–	–
SHMI	↑	–	–	–	–
>4 h A&E wait	↑	–	–	↓	↑
>18w RTT wait	↑	–	–	–	–
Dignity and respect	↓		–		↑
Leavers	↑	–	–	–	–
Old regime improving					
Falls with harm	↓	–	–	↑	–
Pressure Ulcers	↓	–	↑	↑	–
SHMI	↓	–	↓	–	–
>4 h A&E wait	↓	–	–	–	–
>18w RTT wait	↓	–	–	–	–
Dignity and respect	↑		–		↑
Leavers	↓	↑	–	–	–
New regime improving					
Falls with harm	↓	–	–	–	–
Pressure Ulcers	↓	–	–	–	–
SHMI	↓	–	–	–	–
>4 h A&E wait	↓	–	↑	↑	↑
>18w RTT wait	↓	↑	–	–	–
Dignity and respect	↑		–		–
Leavers	↓	–	–	–	–
No inspection improving					
Falls with harm	↓	–	–	↑	–
Pressure Ulcers	↓	–	–	–	–
SHMI	↓	–	–	↑	–
>4 h A&E wait	↓	–	–	–	–
>18w RTT wait	↓	–	–	–	–
Dignity and respect	↑		–		–
Leavers	↓	↑	–	–	–

Key: Arrows are placed where a significant effect was observed. Blue arrows signal a positive effect, whilst yellow arrows signal a negative effect. The direction of the arrow indicates whether there was an increase (upwards) or decrease (downwards).

9 Costs of the new regime of CQC inspections

Chapters 6, 7 and 8 reported the findings for the overarching question whether CQC inspections have an effect on selected measures of process of care and clinical outcomes. The overall result was that new or old regime CQC inspections are not associated with changes in the measures selected.

A cost-effectiveness analysis of CQC new regime inspections was planned using adverse events and risk-adjusted mortality as measures of effectiveness; nonetheless, as no effect was detected on these outcomes, it was not possible to estimate cost-effectiveness. Costs associated with any intervention are important because resources are scarce; therefore, only interventions providing value for money should be funded. Contrary to the standards for assessing health technologies, in the case of health policies, the methods for assessing cost-effectiveness are underutilised and underdeveloped (Kristensen et al., 2015). Given the large scale of transformation required for the implementation of system-level health policies, opportunity costs are particularly relevant since the potential health gains forgone by not funding alternative treatment are potentially substantial and widespread (Kristensen et al., 2015).

This chapter presents the findings of the opportunity costs of CQC new regime of inspections for a sample of trusts representing the regions and type of trusts of the English NHS. Additionally, the incremental costs of implementing the new regime of inspections and the average operational cost per inspection for the CQC are presented based on the information publicly available in its annual accounts. Incremental costs were calculated because the CQC was already in operation when the new regime was implemented, having the infrastructure in place for monitoring and inspecting trusts, hence, the extra costs of changing the regime could only be estimated.

9.1 Methods for estimating the incremental cost of the new regime of inspections to the CQC

To obtain the costs borne by the CQC, information about the overall operational expenses, income from fees and income from the government grant-in-aid were retrieved from their annual accounts report from 2009/10 to 2016/17. The increment in operational expenses was calculated to have an estimation of the incremental cost of changing the regime of inspection,

which started to be implemented in the period 2012/13, being officially launched in 2014/15. Information on activities performed (e.g. number of inspections and registrations), staff costs, the proportion of the budget spent on inspections and average costs per inspection were retrieved when available. When costs were only available graphically, data was extracted using WebPlotDigitizer (http://arohatgi.info/WebPlotDigitizer/).

9.1.1 Estimations

A series of failures to act or prevent failures to comply led to a change of regime in 2013 (see Chapter 3). The first changes were set out in the annual account 2012/13 including appointing chief inspectors for each sector, developing the fundamentals standards of care, changing the definition of quality of care, recruiting inspectors with knowledge in particular areas of care and the introduction of a programme to deal with failing acute trusts (Care Quality Commission, 2013a). The incremental costs associated with the increase of inspections performed and the initial changes to the regime of inspections were £16 million.

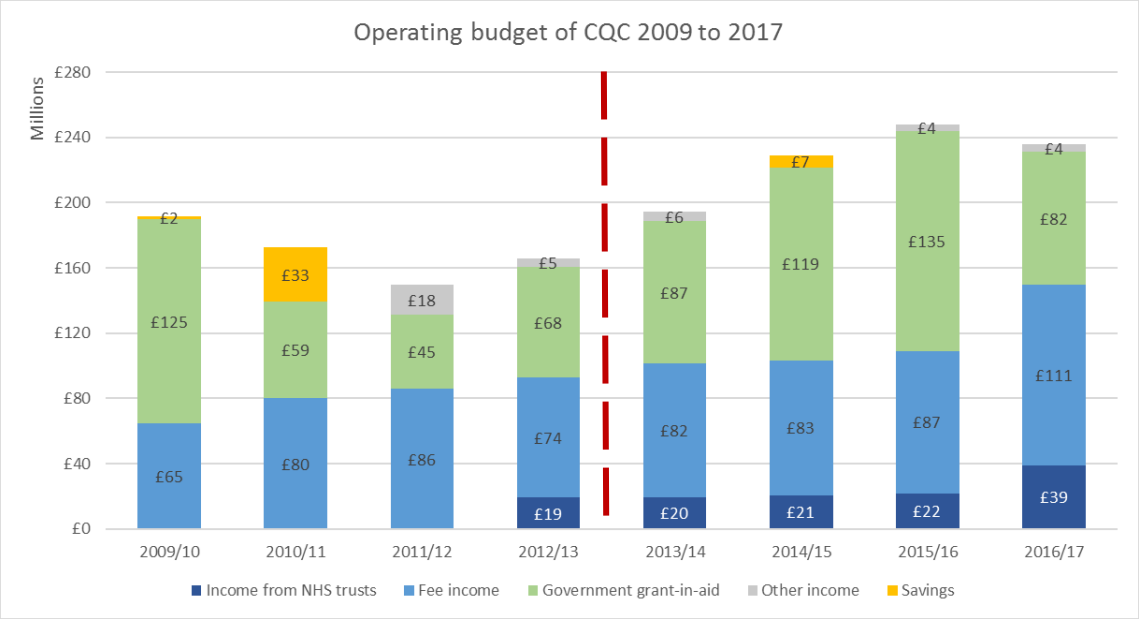


Figure 9.1 Operating budget of the CQC between 2009/10 to 2016/17. The proportion of income coming from NHS trust was only available from 2012/13 onwards

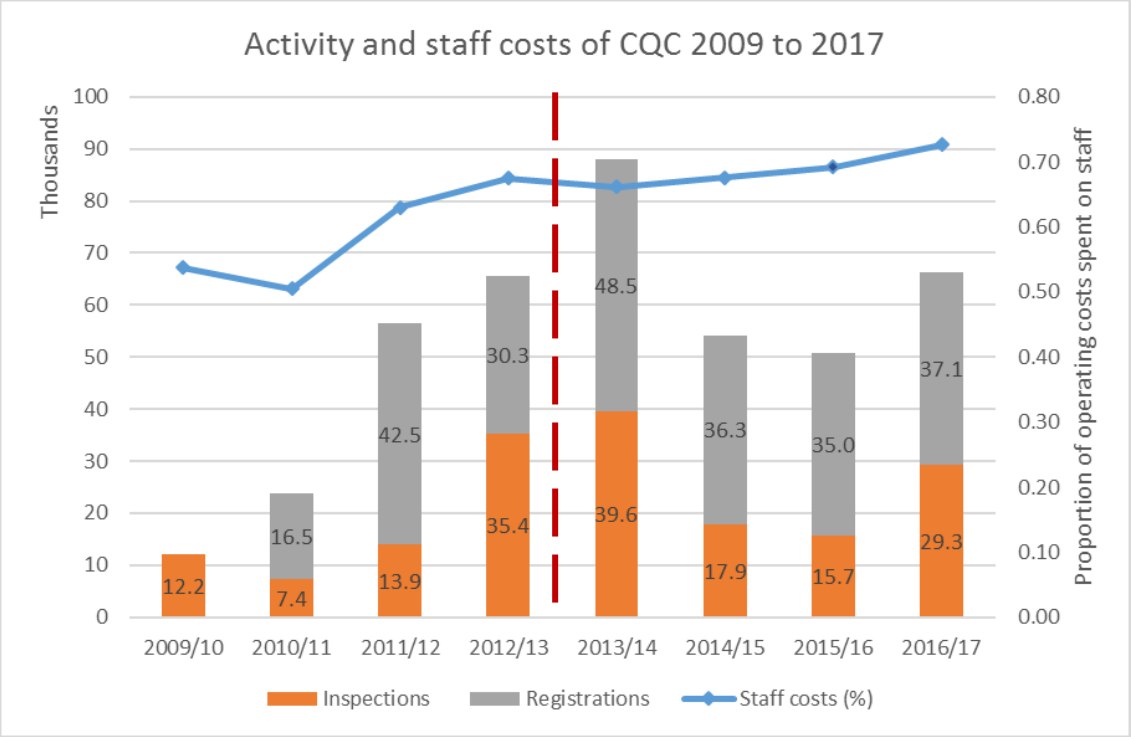


Figure 9.2 Activity and staff costs of the CQC from 2009/10 to 2016/17

The 2013/14 financial year, when the old and new regime of inspections were in operation, had the greatest increase in the number of inspections and registrations performed (Care Quality Commission, 2014a). The new regime of inspections finished the first wave in June 2016; therefore, the incremental cost of implementing this regime was £53 million from April 2013 until the end of March 2016.

The CQC calculates that on average, an inspection under the new regime of the hospital directorate cost £108,581 in the financial year 2015/16 (Care Quality Commission, 2016b) and this cost was reduced to £43,119 in the next year (Care Quality Commission, 2017a) (Table 9.1). During 2015/16 the cost of an inspection of the hospital directorate was reduced from £182,068 during the first quarter to £74,759 in the fourth quarter. The high cost during the first quarter was attributed to the recruitment of new staff needing training, whereas the reduction in the subsequent quarters was attributed to an increase in the number of inspections of independent hospitals, which are smaller and have fewer specialities than NHS trusts (Care Quality Commission, 2016b).

Table 9.1 Average cost per inspection declared by the CQC in its annual reports 2015/16 and 2016/17

	Hospitals directorate	Primary medical services directorate	Adult social care directorate
2015/16	£108,581	£6,641	£4,051
2016/17	£43,119	£4,902	£3,283

The cost per inspection reported by the CQC do not differ greatly from the annual fee paid by the acute hospitals, therefore for the estimation of the cost of an inspection, the CQC fee has been used as a proxy for the costs borne by the regulatory body. The costs borne by the CQC include the development of standards of care and a methodology for their assessment, the salaries of the inspectors and analysts drawing up data packs, and per-diem and accommodation costs of inspectors.

9.2 Methods for costing new regime CQC inspections

To obtain the opportunity cost of a new regime CQC inspection on hospital Trusts, four case studies were initially planned representing the four regions in England. However, after four large trusts from the Midlands declined to participate, it was not possible to approach, recruit, and collect data within the timeframe available in another trust from that region. The locations were chosen considering different sizes of NHS Trusts, Foundation Trust status, governance ratings, number of inspections since 2012, and deprivation index of the main funding Clinical Commissioning Group (CCG). Table 9.2 shows the chosen NHS Trusts for the costing case studies.

Table 9.2 Characteristics of chosen NHS Trusts for case studies

Name	Case study 1	Case study 2	Case study 3	Case study 4
Region	North	South	London	Midlands and East
Size	Medium acute Trust	Small acute Trust	Teaching acute Trust	Large acute Trust
Status	Foundation Trust	Foundation Trust	Foundation Trust	Trust
Number of beds	1100-1200	400-500	1700-1800	700-800
Number of inspections	5	2	4	3

The Health Sciences Research Governance Committee of the University of York reviewed and approved the protocol for this study, including the costs audit tool, in July 2016. The information sheet sent to potential interviewees is available in the Appendix Chapter 9, Figure 9.1. This study did not need approval from an NHS research ethics committee since it only involved members of staff sharing information in a professional capacity, without referring to their views of experiences with CQC inspections.

This empirical research is based largely on methods outlined in Mumford et al. (2015) for collecting costs associated with one inspection cycle. Mumford et al. (2015) performed a mixed methods study to estimate the cost of an accreditation cycle in Australia. Their methods

included stakeholder analysis, survey design, activity-based costing, and review of findings by a panel of experts. Mumford et al. (2015) identified hospitals, the accreditation agency, and agencies developing the programme as the main sources of expenditure. The costs associated with the accreditation agency were used as proxies for the development of standards and its assessment since these were performed by the same agency. To develop the cost audit tool, a team of researchers followed and observed accreditation surveyors during their visits to three hospitals. With this information and through an iterative process, they created the cost audit tool with the activities representing an extra cost. The audit tool was later modified based on the feedback from the accreditation agency staff and surveyors and the research team. The collection of costs was carried out through interviews with key stakeholders to obtain documentary evidence of the costs over a 4-year accreditation cycle. Lastly, they performed a sensitivity analysis with different rates of on-cost multiplier, operating and staffing costs.

For this thesis, the Finance Director of each trust was first contacted by email, where an information sheet with details about the study (see Appendix Chapter 9, Figure 9.1) and the cost audit tool was attached. If the trust was willing to participate, the researcher and the chosen person to provide the costing information arranged a date for a phone call or a face-to-face meeting at least two months in advance. In this way, the trust had enough time to collate the information needed.

In each of these Trusts, a semi-structured interview, which was recorded, was carried out with the finance director, director of quality governance, or equivalent position using the audit tool (Table 9.3). The aim of the interview was to clarify the timeline of the preparation for the inspection and how the estimations were made. The information provided by these key stakeholders was cross-checked with documentary evidence when possible (e.g. schedules for interviews, emails with data requests). The recordings were used as a back-up for the calculations and will be kept until December 2019.

The audit tool was adapted from Mumford et al. (2015) to reflect the reality of CQC inspections and the English NHS. A preliminary version of this tool was piloted in a mental health trust to determine the appropriateness of each item and adapted based on the feedback received.

Table 9.3 Incremental costs audit tool—activity groups and activities (adapted from Mumford et al. (2015))

Type of cost	Activities to be costed
Trust approach (before inspection)	Workshops with board members
	Review of clinical standards and self-assessment by clinical teams to identify areas of improvement
	Drawing up briefing material for staff (Quality unit)

Type of cost	Activities to be costed
Trust approach (before inspection)	Engagement and communication briefings with all staff (Quality unit).
	Attending pre-inspection briefings given by each division (General staff)
	Meetings of each working group to coordinate implementation of remedial changes pre-inspection.
	External consultancy fees.
	Update of all policies organisational wide.
	Environment (e.g. deep cleaning, painting)
	Quality of care (e.g. update of procedures, familiarise staff with specific processes)
Mandatory (before inspection)	Collecting data in response to the CQC's first data request to provider
	Drawing up a report in response to the CQC's first data request to provider
	Collecting and drawing up a report in response to the CQC's second data request to provider
	Reviewing and approving documentation to be sent before the inspection.
	Review and reply to pre-inspection data pack for factual inaccuracies
	Reply to inspection report due to factual inaccuracy
During inspection	Organising meetings between inspection teams and management, staff and/or board
	Introduction to the organisation (day 0)
	Command room
	Extra data requests on-site
	Focus groups and interviews
	Hiring of venues for listening events, meetings with staff and/or quality summit
	ID badges for inspectors, clinical chaperones, boxes for comments, parking fees and any other extra cost
After inspection	Implementation of changes after verbal feedback given by the CQC
	Action plan to improve deficient aspects of care after inspection
	Organising quality summit
	Quality summit
	Implementation of quality improvement initiatives in response to action plan agreed during the quality summit.
	Meetings to monitor improvement
CQC fee	CQC’s annual subscription fee

In the first case study, the interviewee provided an estimation of the average number of hours, number of people, number of times and pay band for those involved in each activity. Given the imprecision of the estimates, which are subject to memory bias, for the following case studies the interviewees were asked to estimate the lowest and highest estimate of:

- Number of hours invested in each activity;
- Number of people, role and pay band of those involved in each activity; and
- Number of times each activity was performed.

To have a better estimate of the costs per hour, these were calculated using two approaches: Agenda for Change average pay bands (NHS Staff Council, 2014, 2015) and Unit Cost of Health and Social Care (UCHSC) for the year of the inspection and then adjusted by the Hospital and Community Health Services (HCHS) index when needed (Curtis and Burns, 2015, 2016). The main difference between these two approaches is that pay bands include the raw estimate of annual pay; whilst unit costs include overheads, payment for annual leave, contributions to national insurance and superannuation. The payment of doctors is not included in the Agenda for Change pay bands; therefore, for activities carried out by doctors, the pay and conditions circular for the year of inspection was used (NHS employers, 2014, 2015), following the assumptions below:

- Consultants: 10 years completed as a consultant on a 2003 contract, 52 working weeks a year and 43.3 hours of work per week.
- Junior doctor: Year 2 foundation training, grade 1 salary, 52 working weeks a year and 40 hours of work per week.

The average pay per hour of work using these methods are summarised in Table 9.4.

Table 9.4 Average rate per hour for healthcare professionals and doctors

	Agenda for Change pay bands			Unit Costs for Health and Social Care			
				Nurses and midwives		Basic pay	
	2014	2015	2016	2015	2016	2015	2016
Average pay band 1	7.49	7.79	7.95			7.68	7.87
Average pay band 2	8.04	8.33	8.50			8.39	8.57
Average pay band 3	9.11	9.24	9.43			9.47	9.56
Average pay band 4	10.48	10.58	10.80	10.34	10.46	10.83	10.91
Average pay band 5	12.50	12.62	12.88	13.21	13.28	13.07	13.14
Average pay band 6	15.29	15.44	15.75	16.37	16.47	16.18	16.29
Average pay band 7	18.18	18.34	18.73	19.66	19.77	19.45	19.58
Average pay band 8A	22.04	22.24	22.71	23.20	23.18	23.12	23.12
Average pay band 8B	26.09	26.34	26.87	27.80	27.66	27.71	27.64
Average pay band 8C	31.20	31.29	31.92	32.79	32.47	33.04	32.75
Average pay band 8D	37.33	37.33	38.08	38.62	38.39	39.72	39.40
Average pay band 9	44.93	44.92	45.83	46.62	45.57	47.62	47.24
Consultant	43.40	43.40	43.83			105	104
Associate specialist	38.75	38.75	39.14			101	101
Foundation Training year 1	11.56	11.56	11.68			29	29
Foundation Training year 2	14.82	14.82	14.90			36	35

In the case of activities carried out by board members, the annual salary was retrieved from the annual accounts of the trust. Salaries are provided in bands of £5,000; therefore, the average of the highest and lowest band were used. For example, if a salary was declared as £110,000-115,000 then the annual salary was £112,500. This number was later divided by 52 working weeks and 37.5 hours per week to obtain the cost per hour. Non-executive directors were assumed to work 7.5 hours per week (i.e. equivalent to four to five days/month).[18]

For simplicity, the narrative description of the costs was performed using the Agenda for Change costing strategy since, proportionally, the results using Unit Cost for Health and Social Care are similar.

9.3 Case studies

After collecting data using the cost audit tool (Table 9.3) through interviews with the director or deputy director of quality governance, these estimations were transformed into a cost per activity and summarised into five domains: preparation for the inspection (Trust approach and mandatory work), during the inspection, after the inspection and the CQC fee. These results are presented below as net costs and as a proportion of the total cost of the inspection for each of the participating trusts.

9.3.1 Case Study 1: Medium acute trust from the North

The cost per activity considering number of people and hours used are presented in Table 9.5.The total expenditure on the inspection calculated for this trust was £357,557 in 2015 prices (Table 9.6), which represents a 0.08% of its operating budget in the financial year 2014/15. The costs associated with the CQC fee represent 55.4% of the expenditure on the inspection. The costs borne by the NHS trust are £159,557. Considering the total costs of the inspection, the greater proportion was spent on preparatory work the trust decided to carry out (22.8%), followed by the opportunity costs associated with the implementation of improvements after the inspection (13.9%). The mandatory preparatory work represents 4.3% of the total cost of the inspection, whilst the on-site visit represents 3.7%. The full details regarding the costing of the activities carried out by this trust are available in the Appendix Chapter 9, Table 9.1. The most expensive single activity performed by this trust was a review of clinical standards and self-assessment to identify areas of improvement, which cost £40,032 using Agenda for Change pay bands and £41,760 using Unit Costs for Health and Social Care. Responding to data requests from the CQC cost approximately £12,291 for this trust using Agenda for Change pay bands.

[18] Number obtained from the profile of non-executive directors published by NHS improvement in https://improvement.nhs.uk/news-alerts/?keywords=&articletype=appointment.

Table 9.5 Details of cost per activity using Agenda for Change pay bands for case study 1

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total
Board level committee	Workshops with board members	1	1.5	15+1	15 directors+8D	£1,415.09
	Discussions regarding:					
	- Action plan to improve deficient aspects of care after inspection	2	37.5	2	8D+8B	£4,756.00
	- Reply to inspection report due to factual inaccuracy	1	4	9	Executive directors	£3,669.23
	- Implementation of quality improvement initiatives in response to action plan agreed during quality summit					£0.00
Management	Collecting data in response to CQC's first data request to provider	12	4	1	8B	£1,252.08
	Drawing up a report in response to CQC's first data request to provider	3	37.5	2	8D+8B	£7,134.00
	Collecting and drawing up a report in response to CQC's second data request to provider	1	37.5	2	8D+8B	£2,378.00
	Review and reply to pre-inspection data pack for factual inaccuracies	1	37.5	1	8B	£978.19
Quality and safety unit	Review of clinical standards and self-assessment by clinical teams to identify areas of improvement	2	7.5	120	8A	£40,032.00
	Engagement and communication briefings with all staff	4	1	100	5	£5,000.00
	Drawing up briefing material for staff	1	15	2	8D+8B	£951.20
General staff	Attending pre-inspection briefings given by each division	12	1	10	8B	£3,130.20
	Hours of extra staff hired to maintain clinical care during inspection	0	0	0	0	£0.00
Working groups	Meetings of each working group to coordinate implementation of remedial changes pre-inspection	0	0	0	0	£0.00
	Organising meetings between inspection teams and management, staff and/or board	1	2.5	3	Clinical director+ matron+ divisional manager	£234.01

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total
Inspection coordinators or managers	Introduction to the organisation (day 0)	2	7.5	3	Chief executive+ medical director+ director of nursing	£4,288.46
	Quality summit	1	4	10	Executive directors+ chair	£3,471.17
During inspection	Focus groups and interviews	1	29	79	8C	£3,802.11
	Command room	4	13	3	8D+8B+7	£4,242.68
	Extra data requests on-site	4	4	1	8B	£417.36
After inspection	Engaging meetings	3	1.5	5	2 directors+ deputy director of operations + Trust board secretary + assistant director of governance	£1,198.90
Other costs	ID badges for inspectors					£75.00
	External consultancy fees					£6,000.00
	CQC's annual subscription fee					£198,000.00
	Hiring of venues for listening events, meetings with staff and/or quality summit					£0.00
	Remedial changes in preparation for inspection that would not have been implemented in a different circumstance					£0.00
	- Update of all policies organisational wide					£5,453.00
	- Environment (e.g. deep cleaning, painting)					£14,500.00
	- Quality of care (i.e. directorates were asked to review serious incidents reports and check recommendations were implemented. Knowing the profile of reported incidents)					£681.63
	- Quality of care (i.e. Organisational risk registers: consistency)					£4,296.50
	Implementation of changes after verbal feedback given by CQC					£40,200.00
Total						£357,556.80

Table 9.6 Summary of the cost of work carried out before, during and after the CQC inspection- case study 1

	Agenda for Change 2014/15	Unit costs for health and social care 2015
Preparation for the inspection (Trust's approach)	£81,459.61	£84,425.75
Preparation for the inspection (mandatory)	£15,411.50	£16,027.40
During inspection	£13,059.63	£14,528.29
After inspection	£49,626.06	£49,898.49
CQC fee	£198,000.00	£198,000.00
Total	£357,556.80	£362,879.93
Adjusted to 2016 prices	£362,314.47	£367,708.42
Approx. operating income	£440 million	£440 million
% operating income	0.081	0.082

9.3.2 Case Study 2: Small acute trust from the South

The cost per activity for the most conservative scenario using pay bands and considering number of people and hours used are presented in Table 9.7. The total expenditure on the inspection calculated for this trust ranged from £169,691 to £256,378 in 2016 prices (Table 9.8), which represents a 0.1 to 0.16% of its operating budget in the fiscal year 2015/16. The costs associated with the CQC fee represent between 30.5% and 46.1% of the expenditure on the inspection. The costs borne by the NHS trust ranged from £91,483 in the most conservative estimation to £178,170 in the highest estimation. Considering the total costs of the inspection, the greater proportion was spent on preparatory work the trust decided to carry out (30.7 to 42.6%), followed by the opportunity costs associated with the implementation of improvements after the inspection (11.1 to 13.2%). The mandatory preparatory work represents 8.5 to 9.5% of the total cost of the inspection, whilst the on-site visit represents 3.7 to 4.2%. The full details regarding the costing of the activities carried out by this trust are available in the Appendix Chapter 9, Table 9.2. The most expensive single activity performed by this trust was responding to data requests after the inspection, which cost between £10,188 and £12,735 using Agenda for Change pay bands and between £10,869 and £13,587 using Unit Costs for Health and Social Care. Responding to data requests from the CQC cost approximately between £15,786 and £24,991 for this trust using Agenda for Change pay bands.

Table 9.7 Details of cost per activity using Agenda for Change pay bands and the lowest estimate provided for case study 2

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total lowest estimate
Board level committee	Workshops with trust board members	4	2	8	7	£3,935.10
	Workshops with non-executive directors	2	2	8	7	£1,324.20
	Workshops with senior management (divisional managers)	3	2	8	8A	£1,067.52
	Discussions regarding: - Action plan to improve deficient aspects of care after inspection (initial set-up)	4	1.5	30	COO+ director of nursing+ 10*band 6 + 10*band 7 + 8*band 8A	£3,633.72
	- Action plan to improve deficient aspects of care after inspection (long term follow-up)	3	1.5	6	Director of nursing+ 2*band 6+ band 7+ band 8A	£726.06
	- Reply to inspection report due to factual inaccuracy	1	33	7	COO+ band 6 + 5 divisional managers (8A)	£5,913.63
	- Implementation of quality improvement initiatives in response to action plan agreed during quality summit	6	1	5	COO or CEO + band 4+ 3*band 7	£1,957.31
Management	Collecting and drawing up a report in response to CQC's first data request to provider	1	7.5	7	8	£3,294.93
	Approval session for first data request	2 to 3	1	4	COO + band 6+ secretary + director communication (8B)	£225.38
	Collecting and drawing up a report in response to CQC's second data request to provider	1	10	12	COO+ 5 divisional managers (8A)+ trust secretary+ clinical quality (6)+ associate director (8A)+ HR+ Info (2*6)	£3,134.79
	Approval session for second data request	4 to 5	1	4	Director operations + secretary + director communication (8B) + clinical quality (6)	£450.75
	Review and reply to pre-inspection data pack for factual inaccuracies	1	3	7	CEO+5 exec directors+ trust secretary	£1,317.97

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total lowest estimate
Quality and safety unit	Self-assessment by clinical teams to identify areas of improvement	16	1	4	8A	£1,423.36
	Drawing up booklets for general staff	1	4	1	8A	£88.96
	Engagement briefings with all staff	29	0.5	10	1	£1,889.65
	Teaching afternoon with medical staff	1	1	20	10 junior Drs + 10 consultants	£679.63
General staff	Attending pre-inspection briefings given by each division	2	1	40	5	£1,009.90
	Hours of extra staff hired to maintain clinical care during inspection					£0.00
Working groups	Meetings of director of nursing (or equivalent) with working groups	50	2	4	3*band 6 + band 8C	£7,760.33
	Review of clinical standards: meetings of the lead of working group with the team	50	1	5	band 2 + 3*band 4 + band 8B	£3,321.31
Inspection coordinators or managers	Organising meetings between inspection teams and management, staff and/or board	2	4	1	4	£84.66
	Introduction to the organisation (day 0)	1	2	6	CEO + executives	£841.96
	Preparation of presentation for day 0	1	4	1	CEO	£517.95
	Quality summit	1	3	14	CEO+ all board members+ council+ CCG+ hospice	£2,358.74
During inspection	Focus groups and interviews	9	1	5	5	£1,860.47
	Command room	3	7	2	8A	£1,124.20
	Extra data requests on-site	3	7	1	6	£324.17
	Daily briefings with chief of inspection	2	0.3	15	Executive team + 9*band 6	£335.95
After inspection	Responding to data requests after the inspection	22	30	1	6	£10,188.20

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total lowest estimate
Other costs	ID badges for inspectors					£100.10
	Cards for comments					£7.95
	External consultancy fees - KPMG					£19,613.00
	External consultancy fees					£9,891.00
	CQC's annual subscription fee					£78,208.00
	Hiring of venues for listening events, meetings with staff and/or quality summit					£1,080.00
	Remedial changes in preparation for inspection that would not have been implemented in a different circumstance					£0.00
	- Update of all policies organisational wide					£0.00
	- Environment (e.g. deep cleaning, painting)					£0.00
	- Quality of care (i.e. directorates were asked to review serious incidents reports and check recommendations were implemented. Knowing the profile of reported incidents)					£0.00
	- Quality of care (i.e. Organisational risk registers: consistency)					£0.00
	Implementation of changes after verbal feedback given by CQC					£0.00[19]
Total						£169,690.85

[19] The interviewee from this trust said changes implemented after verbal feedback had no costs associated since these were minor (e.g. changing where milk was stored).

Table 9.8 Summary of the cost of work carried out before, during and after the CQC inspection- case study 2

	Agenda for Change 2015/16		Unit costs for health and social care 2016	
	Lowest estimate	Highest estimate	Lowest estimate	Highest estimate
Preparation for the inspection (Trust's approach)	£52,003.96	£103,617.65	£53,634.44	£109,217.11
Preparation for the inspection (mandatory)	£14,337.44	£23,438.76	£14,745.72	£24,393.28
During inspection	£6,277.41	£10,341.12	£6,433.23	£10,725.77
After inspection	£18,864.04	£31,205.45	£19,844.87	£33,833.80
CQC fee	£78,208.00	£78,208.00	£78,208.00	£78,208.00
Total	£169,690.85	£246,810.98	£172,866.26	£256,377.96
Approx. operating income	£160 million	£160 million	£160 million	£160 million
% operating income	0.10	0.15	0.11	0.16

9.3.3 Case study 3: Large teaching acute trust from London

The cost per activity for the most conservative scenario using pay bands and considering number of people and hours used are presented in Table 9.9. The total expenditure on the inspection calculated for this trust ranged from £351,100 to £418,136 in 2016 prices (Table 5), which represents a 0.035 to 0.042% of its operating budget in the fiscal year 2015/16. The costs associated with the CQC fee represent between 30.7% and 36.6% of the expenditure on the inspection. The costs borne by the NHS trust ranged from £222,616 in the most conservative estimation to £273,532 in the highest estimation. Considering the total costs of the inspection, the greater proportion was spent on preparatory work the trust decided to carry out (57.7 to 60.8%), followed by the mandatory preparatory work for the inspection (2.4 to 3.1%). The opportunity costs associated with the implementation of improvements after the inspection represents 1.1 to 1.5% of the total cost of the inspection, whilst the on-site visit represents 1.9 to 4.9%. The full details regarding the costing of the activities carried out by this trust are available in the Appendix Chapter 9, Table 9.3. The most expensive single activity performed by this trust was remedial changes in the environment (e.g. deep cleaning or painting), which cost £125,000. The next most expensive activity was reviewing and approving documentation to be sent before the inspection, which cost between £21,377 and £42,754 using Agenda for Change pay bands and between £23,216 and £46,432 using Unit Costs for Health and Social Care. Responding to data requests from the CQC cost approximately between £8,243 and 12,048 or this trust using Agenda for Change pay bands.

Table 9.9 Details of cost per activity using Agenda for Change pay bands and the lowest estimate provided for case study 3

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total lowest estimate
Board level committee	Workshops with board members	4	1	15	Executives +4*NED+ clinical division managers (5) 8D	£3,786.84
	Discussions regarding:					
	-Action plan to improve deficient aspects of care after inspection	8	1	4	3*band 8A + 1*band 9	£1,116.4
	-Reply to inspection report due to factual inaccuracy	10	1	5	2*band 7 + 3*band 8D	£1,486.64
	-Implementation of quality improvement initiatives in response to action plan agreed during quality summit	4	1	2	8A+8D	£238.26
Management	Collecting and drawing up a report in response to CQC's first data request to provider	8	1	15	10*band 8A + 5*band 8D	£3,272.2
	Collecting and drawing up a report in response to CQC's second data request to provider	3	1	15	10*band 7 + 5*band 8D	£1,110.21
	Review and reply to pre-inspection data pack for factual inaccuracies	8	1	11	6*band 7 + 5*band 8D	£2,373.53
	Meetings of director of nursing (or equivalent) with working groups	10	1	9	2*band 8C + 7*band 8D	£3,238.62
Quality and safety unit	Review of clinical standards and self-assessment by clinical teams to identify areas of improvement	64	1	10	7*band 5 + 3*band 8D	£12,821.84
	Engagement and communication briefings with all staff	6	4	20	2*band 1 + 2*band 2 + 2*band 3 +2*band 4 + 2*band 5 +2*band 6 + 2*band 7 +1*band 8A + 1*band 8B +1*band 8C + 3*band 9	£9,104.38
	Reviewing and approving documentation to be sent before the inspection	64	2	6	3*band 7 + 3*band 8D	£21,377.07
General staff	Attending pre-inspection briefings	10	1	20	2*band 1 + 2*band 2 +3*band 3 +3*band 4 +3*band 5 +3*band 6 +2*band 7 +2*band 8A	£2,570.80
	Hours of extra staff hired to maintain clinical care during inspection					

Group in charge	Activities to be costed	Number of times	Number of hours	Number of people	Average payment band	Total lowest estimate
Working groups	Meetings of each working group to coordinate implementation of remedial changes pre-inspection	15	1	3	1*band 2 + 2*band 7	£675.35
Inspection coordinators or managers	Organising meetings between inspection teams and management, staff and/or board	36	1	2	band 8A + 8D	£2,144.34
	Drawing up welcome packs for inspectors	2	6	2	band 4 + 8D	£574.89
	Organising quality summit	1	7	2	band 4 + 8D	£335.36
	Quality Summit	1	3	11	Executives +5*NED	£2,376.41
	Focus groups and interviews	19	1	209	band 3	£3,832.84
Other costs	ID badges for inspectors, clinical chaperones, boxes for comments, parking fees and any other extra cost					£100.00
	External consultancy fees (additional project support costs)					£25,080.00
	CQC's annual subscription fee					£128,484.00
	Hiring of venues for listening events, meetings with staff and/or quality summit					£0.00
	Remedial changes in preparation for inspection that would not have been implemented in a different circumstance					£0.00
	-Staff (e.g. mandatory training)					£0.00
	-Environment (e.g. deep cleaning, painting)					£125,000.00
	-Quality of care (e.g. update of procedures, familiarise staff with specific processes)					£0.00
	Implementation of changes after verbal feedback given by CQC					£0.00[19]
Total						351,099.98

Table 9.10 Summary of the cost of work carried out before, during and after the CQC inspection- case study 3

	Agenda for Change 2015/16		Unit costs for health and social care 2016	
	Lowest estimate	Highest estimate	Lowest estimate	Highest estimate
Preparation for the inspection (Trusts approach)	£203,654.90	£244,350.16	£206,726.80	£249,788.15
Preparation for the inspection (mandatory)	£8,242.58	£12,048.04	£8,911.41	£13,024.06
During inspection	£6,652.08	£11,380.94	£10,160.65	£20,463.62
After inspection	£4,066.43	£5,752.44	£3,935.84	£6,376.52
CQC fee	£128,484.00	£128,484.00	£128,484.00	£128,484.00
Total	£351,099.98	£402,015.59	£358,218.71	£418,136.35
Approx. operating income	£1000 million	£1000 million	£1000 million	£1000 million
% operating income	0.035	0.04	0.036	0.042

9.4 Conclusion

The overall incremental cost of implementing CQC's new regime of inspections for health, social and mental health care organisations is approximately £69 million.

One of the issues that this chapter raises is that the opportunity cost to a hospital for a CQC inspection ought to be assessed in comparison with a baseline position, i.e. that it has effective systems to assure and maintain quality. Updating policies and reviewing the consistency of risk registries should be a routine process in effective systems and not necessarily a cost to the hospital of a CQC inspection. It could be observed during the interviews that this is not always the case. Acute NHS trusts implement several strategies to ensure all staff are prepared for the CQC visit and that the institution can show its best performance. Some of these activities include reviewing clinical standards, performing a self-assessment against the CQC standards, updating policies and risk registries. The implementation of these processes has a cost that ranged between £16,864 for case study 2 and 139,613 for case study 3. Given the small size of the sample, it is not possible to judge whether this is a justifiable expense or not. Although these processes are essential to delivering quality care, it is not clear if they will produce an effect in the long-term. The question remains whether trusts would perform these activities if the CQC were not visiting for an inspection. If this is the main effect of inspection, then it is questionable if they are cost-effective.

The costs collected from the different acute NHS trusts showed that one CQC new regime inspection costs between 0.035 to 0.16% of a hospital's annual operating budget, which is within the range of 0.03 to 0.6% reported for an accreditation visit in Australia for different

sizes of acute hospitals (Mumford et al, 2015). It is noteworthy that Mumford et al. (2015) spread the costs of the accreditation over the 4-year cycle, whilst in this thesis costs were collected for the period starting 4 to 6 months prior the visit up to one year after. It was not possible to collect the costs associated with an old regime inspection since hospitals did not keep records of activities performed three to four years ago.

Collecting information for data requests before, during and after the inspection does not represent a large proportion of the operational budget (i.e. between £8,243 and £24,991, which represents 0.0008% and 0.016% of their operational budget); however, it is an aspect that could be streamlined considering trusts are regularly reporting data to the NHS. This task involves time of very senior managers, and the trust cannot make use of this information until several months later. Consequently, creating a single platform where regulatory agencies can extract information and trusts could use it for quality improvement could help reduce costs and the burden of regulation.

The estimates here presented have some limitations. They are subject to recall bias and depend largely on the quality of the record keeping of the senior management of the hospital. Documentary evidence was requested when available, but this usually involved the focus groups and individual interviews CQC carried out during the on-site visit, number of data requests, and consultancy fees. Time spent in the self-assessment and engagement meeting were broad estimations. Overall, the precision of the costs here presented could be improved.

Inspections may also carry hidden costs. From the point of view of clinicians and managers there is no consensus on the value of inspections. Some clinicians think that inspections impose an extra burden that can have detrimental effect on their practice; whilst managerial staff sometimes perceived inspections as a distraction (Schaefer and Wiig, 2017). Although, it is possible to calculate the opportunity cost of an inspection, it is not possible to establish a causal relationship between the time invested preparing for the inspection and potential detrimental effects on care quality.

Since there is no threshold to establish the cost-effectiveness of system-level health policy, it is difficult to make a judgement regarding whether CQC inspections are good value for money overall. The lack of apparent effect of individual inspections (chapters 6-8), alongside the demonstrable opportunity costs of these inspections casts doubt on their value. However, it should be kept in mind that in the past when inspection regimes did not exist or were light-touch and reliant on desktop monitoring, scandals such as the case of Bristol Royal Infirmary, deaths associated with care by Dr Shipman and poor care in Mid-Staffordshire NHS Foundation Trust happened. If the main effect of inspectorates is simply due to their existence, then it is not possible to isolate the effect of CQC from other quality governance interventions.

10 External inspections and the value for money of the CQC in a complex health system: discussion, findings and suggestions for change and improvement

In this thesis, the evolution of the regulatory environment of the English NHS has been explored, highlighting the theoretical basis of four perspectives for the various models of governance used. Additionally, the effectiveness of external oversight on changing organisational and patient outcomes has been reviewed and the effectiveness of CQC inspection regimens in three different scenarios evaluated (i.e. any inspection, comparing the old and new regime, and accounting for previous performance). Incremental costs of inspections were estimated, and finally, the overarching question of this thesis "do the CQC inspections of acute NHS trusts affect quality of care?" was addressed using a carefully selected suite of measures for care quality.

In this chapter, the findings will be synthesised and explored within the current context of the NHS, the body of evidence available on the effectiveness of regimes similar to CQC inspections, and the theories explored in previous chapters. Additionally, a reflection on the strengths and limitations of the methodological decisions taken is provided. Finally, I offer evidence-based and theoretically informed suggestions for researchers, service evaluators and policymakers (including the CQC) regarding potential strategies for improving the effectiveness and value for money of external inspections and regulation as part of the mixed economy of quality assurance that the NHS and government employ.

10.1 Synthesis and discussion of findings

The effect of CQC inspections was variable, as the overview of reviews suggested it would be. This finding can largely be explained because the health system is a complex adaptive system. This translates into a lack of universal definition of quality (given it is an abstract concept), the combination of several regulatory instruments targeting various aspects of the health system to govern quality, and that the various self-governing subsystems (i.e. wards and teams within hospitals and acute trusts) adapt differently to the demands of the environment. The other factor explaining the lack of effect is that oversight institutions influence quality of care by

their very existence, providing a continuous expectation that they might visit, instead of through on-site inspections alone; however, this could not have been detected in this analysis.

The findings from the different empirical studies carried out as part of this thesis are summarised in Table 10.1 and reviewed using thematic analysis to identify the common themes. Seven main themes that integrate the theoretical aspects of regulation of quality of care and the quantitative findings were identified and are used to organise the discussion of this research.

Table 10.1 Summary of key findings

Chapter	Summary of findings	Theme
2	**Theoretical perspectives on quality and quality governance** Attempts to define an abstract concept such as quality in a complex adaptive system such as healthcare have resulted in multiple definitions and frameworks for measuring quality of care. Consequently, operationalisations are achieved by balancing social, political, and healthcare goals.	Complexity of healthcare quality concept
3	**Governance of quality in the English National Health Service** The NHS has gone through constant change since its creation. The evolution of perspectives on how to govern quality coming from economics and management has led to the implementation of successive reforms for governing the quality of care delivered, creating a crowded regulatory environment with multiple institutions and instruments. The CQC is only one more.	Competing priorities- Crowded regulatory system
	External oversight institutions have competed with other regulatory agencies since their creation; although, some periods of history have given more relevance to the work of the healthcare inspectorates (For instance, during the "targets and terror" that took place between 2000 and 2005). In the current NHS, CQC inspections have become the central means by which to govern the quality of healthcare institutions; however, their ratings are not associated with strong incentives and clear sanctions, which influences their potential effectiveness.	Competing priorities- Macro and meso level context
4	**Overview of reviews of the effectiveness of external oversight** Evidence shows that external oversight (accreditation or external inspections) has mixed effects on changing organisational behaviour and clinical outcomes. These findings were driven by a large body of studies using disease-specific measures to determine effectiveness. When these are removed, the intervention is generally ineffective.	Effectiveness of external inspections
	The findings from an update of the most methodologically rigorous systematic review support the conclusion that the effect of external oversight interventions is mixed, at best. Out of 53 measures assessed, four improved, 31 showed no change and 15 got worse after an accreditation or inspection visit. Mortality and MRSA infection rates were assessed in two studies, showing mixed effects.	
	The myriad outcomes used to measure the effect of external oversight underscores the difficulties of finding adequate, relevant and sensitive indicators to determine the effect of this intervention. The synthesis of seven reviews did not yield a definitive answer regarding the best set of indicators to reflect the overall quality of care at hospital level.	Complexity of healthcare quality concept
6	**Effect of any inspection** Overall, the on-site visit of CQC was not associated with changes of level or trend for any of the process and clinical outcomes measures.	Effectiveness of external inspections

Chapter	Summary of findings	Theme
6	The announcement of a CQC inspection was associated with a step decrease of A&E and RTT waiting times and a temporary improvement of the rate of leavers. This suggests that the pressure of the visit triggers quick improvements with temporary effect.	The effect of anticipatory pressure
	When the effect of the inspection was analysed depending on the performance rating of the trust in 2009, the announcement or the inspection did not affect the level or slope of any of the measures analysed in trusts with the lowest ratings (i.e. weak and fair). However, trusts rated as good had a step increase in the rate of leavers after the inspection; whereas, trusts rated as excellent had a transient increase in falls with harm and a temporary decrease in rates of leavers after the announcement of an inspection.	Differential effect of inspections-performance ratings.
7	**Comparison of the old and new regime of inspections** The old regime on-site visit produced a step decrease of A&E waiting times, whilst new regime inspections were associated with a step increase of A&E waiting times. For rates of leavers, the announcement of an old regime CQC inspection was related to a step increase, whereas the new regime inspection was associated with a step decrease.	Differential effect of inspections-old vs new regime.
	The announcement of a new regime CQC inspection produced a step decrease of falls with harm, whereas RTT waiting times showed a step decrease regardless of the type of inspection.	The effect of anticipatory pressure
8	**Comparison of the old and new regime of inspections accounting for previous performance** It was assumed that performance before the inspection could be a good proxy of improvement culture and capacity to respond to the inspection. Therefore, CQC visits would have the largest impact on trusts with improving performance. However, findings showed the opposite scenario: worsening performance after the inspection in improving trusts, whilst performance improved after the visit in not improving trusts. Except for RTT waiting times and patients' perception that had a similar pattern for all groups. Not improving trusts had better performance in each indicator and the stable trend reflected a floor effect. After the inspection, this upward trend returned to a "normal" low. Conversely, improving trusts were in the extreme of the distribution of worse performance for each indicator; therefore, their probability of improvement was higher. After the inspection, performance tended to stabilise towards the mean.	Culture as mediator of the response to the inspection
	The announcement of an inspection produced detrimental effects on improving trusts on four measures analysed: slower improvement of adverse events after any inspection, a worsening trend for A&E waiting times and a step increase of RTT waiting times after a new regime inspection, whilst rate of leavers had a step increase after an old regime inspection. The effects were mixed for not improving trusts: faster improvement of adverse events after any inspection and a step increase of the rate of leavers after the announcement of an old regime inspection.	The effect of anticipatory pressure
9	**Cost of the new inspection regime** The costs of a new regime CQC inspection, considering opportunity costs borne by acute NHS trusts and the operational costs of an inspection for CQC, ranged from £169,691 to £256,378 for a small trust and from £351,100 to £418,136 for a large trust. If inspections were reviewed as an intervention in isolation and were submitted for review by NICE, the intervention would not be funded. Consequently, the value for money of CQC inspections is questionable.	Value for money

10.1.1 The complexity of the concept of quality in healthcare

Attempts to define an abstract concept such as quality in a complex adaptive system such as healthcare have resulted in multiple definitions and frameworks for measuring quality of care (see Chapter 2). Operationalisation for research, monitoring, or assessment of performance is usually achieved by balancing social, political, and healthcare goals (Pfeffer and Coote, 1991). The myriad of outcomes used to measure the effect of external oversight in previous research reflects the difficulties of identifying adequate, relevant and sensitive indicators representing care quality that can be used to determine the effect of this intervention. The synthesis of seven reviews did not yield a definitive answer regarding the best set of indicators to reflect the overall quality of care at hospital level because most research focused on disease-specific measures. Only six studies reported hospital-level organisational performance (Duckett, 1983, Piontek et al., 2003, Quality assurance project, 2005, Salmon et al., 2003, Thornlow and Merwin, 2009, OPM evaluation team, 2009), but they used 32 different indicators, with three of them repeated in two of these studies: hygiene and sanitation, patient satisfaction, and healthcare-associated infections. The effect of external oversight on these outcomes was not consistent across studies; therefore, there was no option for assessing the effect of inspections.

Based on the findings from the overview of reviews, the CQC definition of care quality was used to select measures that could provide a broad picture of the effect of external inspections. The process of selecting indicators involved the careful analysis and interpretation of CQC documentation and an extensive search of data available (see Chapter 5). Using criteria established a priori, it was sought to balance the validity of the indicators to measure quality of care with pragmatic criteria (i.e. data publicly and freely available). However, using another set of indicators might have yielded different results.

Four recent studies used more indicators and a composite, expert-driven measure of performance to determine the effect of accreditation. Devkaran and O'Farrell (2015) assessed the effect of an accreditation cycle in one hospital using 27 measures of care quality and a composite measure combining 23 of them (Devkaran and O'Farrell, 2014). A research group in Denmark studied the effectiveness of an accreditation scheme on mortality, length of stay, readmission rates, and had a composite measure of 21 indicators for four diseases (Falstie-Jensen et al., 2015a, Bogh et al., 2015, Falstie-Jensen et al., 2015b). Two other studies from this Danish research group assessed the effectiveness of accreditation in a composite measure of 43 processes of care indicators (Bogh et al., 2016, Bogh et al., 2017). Beyond mortality, none of the indicators used to measure quality coincide in these studies. Considering the ubiquity of external oversight in healthcare institutions, how difficult it is to define quality of care, and the

extensive body of literature on the topic, an expert-led and theory-driven definition of relevant hospital-level quality of care indicators to measure when examining the effectiveness of these regimes may be justified. Some potential indicators are emergency admission of patients with long-term conditions, adverse events (such as falls and pressure ulcers), 30-day readmissions, and in-hospital mortality of patients in palliative care. This consensus could enable a better understanding of when, and using which measures, external oversight works.

10.1.2 Competing priorities for acute NHS trusts

10.1.2.1 Crowded regulatory system

In the last 20 years, the NHS has gone through constant reforms, often with the stated aim of improving quality (see Chapter 3). As a consequence, the institutions with regulatory and governing power have developed overlapping responsibilities for performance, resulting in duplication of effort (NHS Confederation, 2013). NHS trusts assert that the definition and the institutions responsible at the national level for finance and access are clear. However, in the case of quality, there are several bodies claiming responsibility for its assurance, whilst the definition and core set of outcomes to measure quality are not clear (NHS Confederation, 2013).

The impact of a crowded regulatory environment is threefold. Firstly, it is more complicated to isolate the effect of CQC inspections over other regulatory institutions. Secondly, mixed messages about trust performance from each agency make understanding and correcting poor performance harder. Thirdly, inspections and repeated and contradictory data requests come with high opportunity costs: making crafting and implementing an action plan for deficient aspects of care harder, whilst reducing any impact of external oversight.

The complexity of the regulatory environment makes it more difficult to establish cause-effect relationships between inspection and improvements in the quality of care (Pollitt, 1995). Sutherland and Leatherman (2006) suggest that inspections catalyse efforts to measure and improve performance before their occurrence; whilst Wan and Connell (2003) propose that external oversight provides recommendations so that health managers can improve care and that inspectorates prevent failure in performance mainly through their existence.

Regardless of the mechanism that explains how inspections might lead to changes in quality of care, it is impossible to disentangle the impact of all historical events happening near the inspection to estimate an unbiased measure of effect. However, common shocks (i.e. economic crises or increases in demand) are accounted for in the longitudinal study design.

In terms of contradictory messages and repeated requests from different regulatory agencies, a report from the NHS Confederation indicates that the health service lacks incentives for reducing the burden of data requests and striving for better regulation (NHS Confederation, 2013). The reason given is that oversight institutions do not bear the costs and NHS providers are the ones who must find ways to streamline the process of answering multiple requests and inspections from regulators (ibid). In addition to the CQC, NHS improvement, and NHS England, professional bodies, the Department of Health and the Cabinet Office's Implementation Unit occasionally request data (NHS Confederation, 2013). Regarding opportunity costs, £1.4 million a year is the average estimated cost associated with finding and reporting nationally mandated data for each trust (NHS Confederation, 2013, Stevens, 2016). For clinical staff, the burden of collecting, reporting, and validating data is comparatively small, however, for managerial and administrative staff it is estimated that it takes between five to 20 hours a week on average (NHS Confederation, 2013).

In January 2017, the CQC and NHS Improvement merged the data collection functions. These two institutions used to collect, analyse, and present information to trusts in different ways, which produced confusion about their meaning regarding performance (Stevens, 2016). Unifying the process might help acute trusts to respond better to inspections by having a more precise picture of their performance and more resources (time) to prepare for it.

10.1.2.2 Macro and meso level context

The health system as a complex adaptive system encompasses several subsystems with blurred limits (The Health Foundation, 2010), which can be organised in levels: macro, meso and micro. Regulation functions as an intervention affecting the whole health system, which is the macro level. Acute NHS trusts are self-governing sub-systems belonging to the meso level. The importance of this difference is that some factors are common to every hospital, whilst others are particular to a region or trust. Consequently, the difference between levels allows making a more detailed analysis of the impact of their features on the effect of inspections.

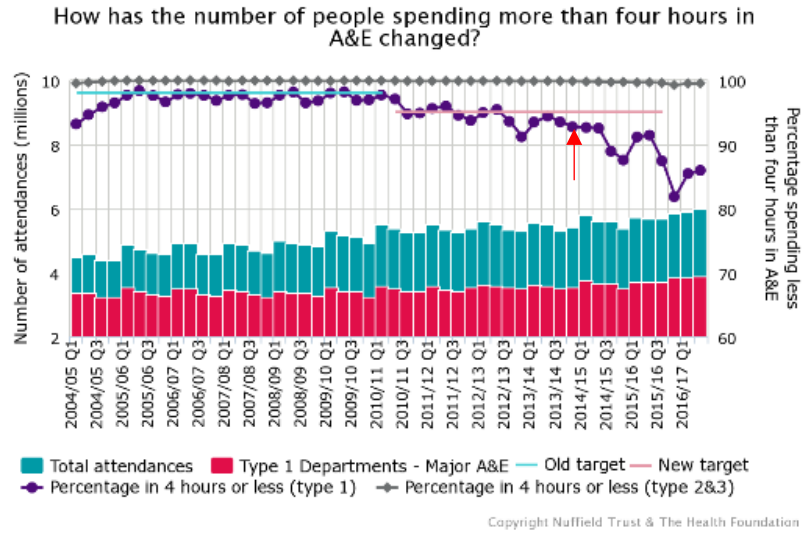
Context, understood as the factors creating the environment where implementation happens (Pfadenhauer et al., 2017), determines the effect of quality improvement initiatives (Kaplan et al., 2010, Øvretveit, 2011). The context where external oversight is implemented affects its potential effectiveness since it is a quality improvement intervention (Walshe, 2003). In the case of the healthcare inspectorates that have existed in the NHS, the quality governance models and contextual factors can be seen to differ.

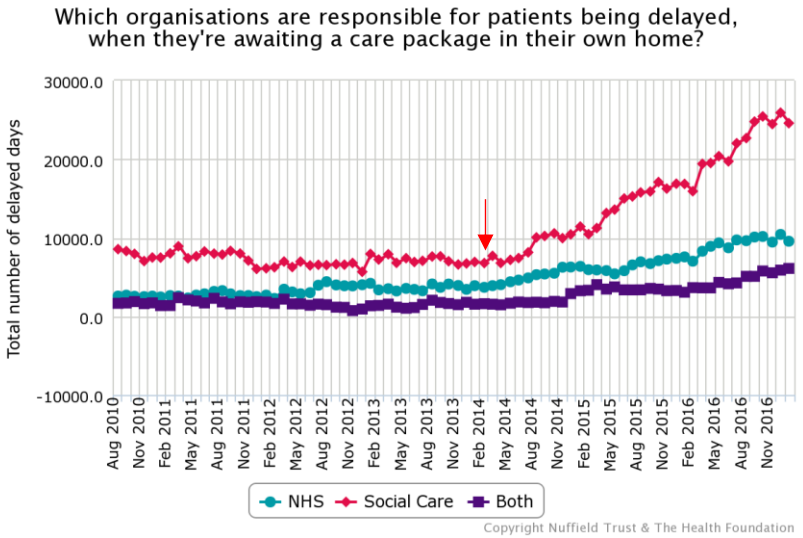
For instance, between 2000 and 2005, the star ratings given to acute NHS trusts after an inspection by the CHI were used as part of the "targets and terror" regime with strong

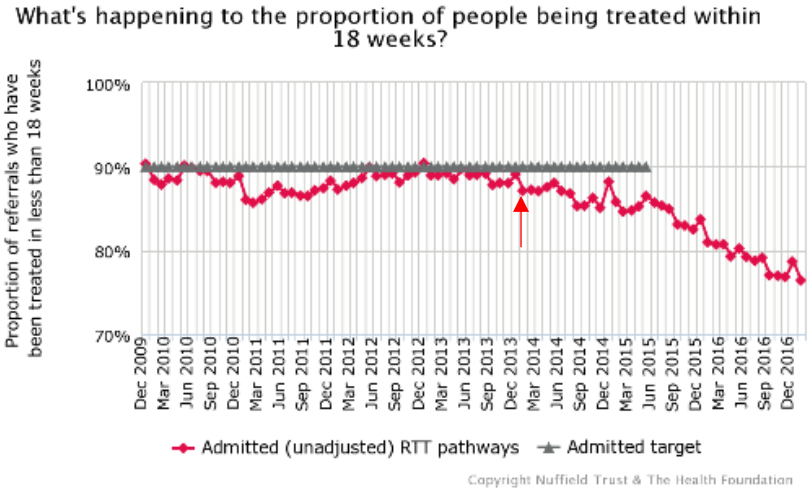
sanctions to Chief Executives if no improvement was shown. Consequently, ratings were associated with powerful incentives and sanctions. Between 2006 and 2009, quality governance was achieved through a "choice and competition" model where the Healthcare Commission (i.e. CHAI) carried out annual checks providing the quality performance information that patients could use to choose a provider, although, in healthcare, users rarely exercise choice (Bevan and Fasolo, 2013). In consequence, during these two periods, external inspections were a necessary element for quality governance, but there were reputational and financial incentives involved to obtain a "good" rating.

In turn, "targets and terror" and "naming and shaming" were effective because there was a common belief that the service needed urgent improvement, incentives and sanctions were aligned with priorities (i.e. a dozen targets that had to be met), and failures were very public. These two models of governance of quality were paired with large increases in spending and workforce size (Mays et al., 2011), which can explain some of the improvements in performance. Additionally, during the first decade of the 21st century, the performance of the NHS needed to move from average to good, where targets and performance management can be effective (Ham, 2014b). However, targets are insufficient when a service needs to move from adequate to excellent (Barber et al., 2008), and where other approaches such as embedding a culture of improvement might work (Ham, 2014b).

The current context where CQC inspections are implemented is very different to the context of other inspection regimes, which may explain the lack of or small effect observed. In contrast to the period between 2000 and 2008, since 2010, the NHS has been going through austerity measures, with minimal growth in spending and falling productivity (Lafond et al., 2017). Data from the Quality Watch (2017) shows that A&E waiting times, RTT waiting times and delays in care have consistently worsened since the last quarter of 2013/14 (i.e. January to March), which is the first financial year NHS providers had an overall deficit (Figure 10.1, arrows signal point when trend shifted). This suggests that NHS providers adapted to a more restricted budget for a couple of years, and then ran out of capacity to adapt to increasing demands on a limited budget, affecting the delivery of quality care.







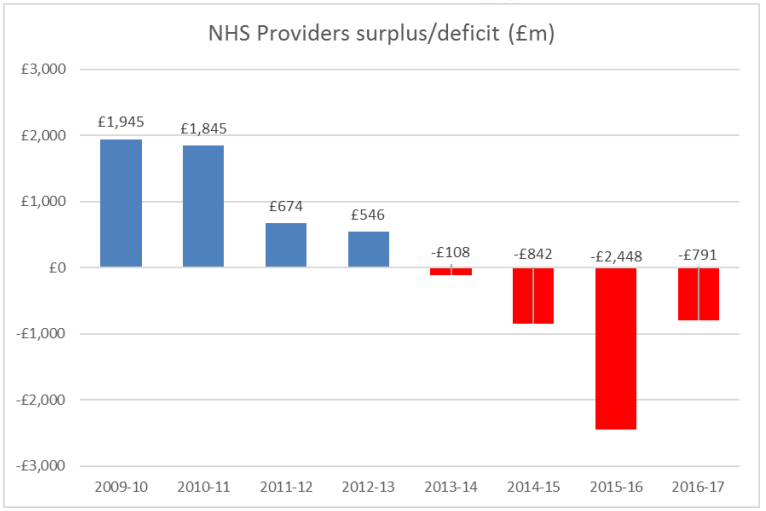


Figure 10.1 Trends in A&E waiting times, patients being delayed, RTT waiting times (QualityWatch, 2017) and NHS providers surplus/deficit (DOH, 2010-2017)

*Arrows signal when the trend shifted.

Another contextual difference is the change of priorities in the service. In the 2000s, the main priority was improving waiting times during a period of relatively generous funding. In 2017, after years of austere funding, challenges include achieving cooperation and integration of providers in a local area to manage a population with more complex care needs (NHS England, 2015b). At the same time providers should strive to deliver 3% efficiency savings per year without compromising quality (NHS England, 2014). Therefore, although targets were effective in improving waiting times in the past, it is unlikely that they will be effective at improving coordination of care. The CQC's endeavour will be to find ways to include value for money, plus integration and continuity of care in its assessments, so they can serve as incentives for the achievement of these goals.

In terms of sanctions, the general deterrence theory (see Chapter 2, section 2.3.4) suggests that the certainty and severity of sanctions are associated with the potential of legal provisions for preventing deviant behaviour (Stafford and Warr, 1993). During the "targets and terror" period, sanctions were certain and severe (see Chapter 3). CQC has strong sanctions available, but their certainty of use is very low due to their potential impact on the population. The strongest sanction that CQC can impose is revoking a providers' license, but this would involve relocating patients and services to the nearest provider; therefore, there is no record of this being used in acute NHS hospitals. Instead, hospitals have been temporarily closed until CQC recommendations can be implemented (Care Quality Commission, 2016d). The second strongest sanction available involves putting a provider into special measures, where the organisation is partnered with another trust to help them improve, an improvement director is appointed and, depending on the capability of the trust's leadership, the management can be replaced. This is, in turn, the most commonly used sanction in extreme cases of non-compliance,[20] but it is not clear how much it deters trusts' board members and senior management from allowing or preventing poor performance.

In summary, the "Inspection state" has four main contextual differences with previous governance of quality models that influence (and hinder) its effectiveness. Firstly, it does not have extra resources to invest in improvements or increasing the workforce. Secondly, the main priority (i.e. delivering efficiency savings without compromising quality) is aligned with some incentives in the system (e.g. NHS Outcomes Framework, Quality Premium and CQUIN); however, CQC inspections and how quality of care is measured are not fully aligned with this

[20] Nineteen acute hospitals were put in special measures during the observation period. Most of them were put in special measures after the Keogh Review (2013). Additionally, 740 health and social care providers were put into special measures in the 2016-17 fiscal year (Care Quality Commission, 2017a).

priority.[21] Thirdly, sanctions are not certain, and failure is not associated with strong public reputational threats. Finally, the overall performance of services needs to go from adequate to good or outstanding, which means that improvements are slower and subtler. As a result, even if CQC inspections were an effective intervention, these contextual factors would interfere with their effect on the measures analysed here. Probably, a different context with financial resources, incentives to achieve an improvement culture (not just efficiency), and the addition of more time could have resulted in CQC inspections being more effective than found in this thesis. Given the contextual factors at play, the findings seem to reflect naturally occurring patterns.

Considering that the preparation for these inspections demands time away from regular duties for clinical and managerial staff (which could negatively affect the quality of care provided), the fact that performance remains unchanged after a CQC inspection could be considered a positive finding. The overall existence of the CQC probably produces general (although unmeasurable and intangible) effects at the macro level, which could not be detected at the meso level (i.e. hospitals).

10.1.3 The effect of anticipatory pressure

CQC inspections comprise four interventions: an announcement, an on-site visit, a Quality Summit and the publication of an inspection report (see Chapter 3). Previous research suggests that inspections have an anticipatory effect (Healthcare Commission, 2008a, Robertson et al., 2017).

The announcement does not involve a direct intervention from the inspectorate. Consequently, its effect depends on board members' leadership and ability to measure, analyse, and interpret soft and hard intelligence about the hospital's performance, thus allowing them to benchmark performance and steer efforts for improvement based on local needs (Joshi and Hines, 2006, Millar et al., 2013). Despite the body of literature suggesting a link between board members' leadership skills and hospital performance, it is not clear how board members' competencies, skill-mix, and capabilities to draw and monitor a quality improvement project influence the anticipatory effect, the rating, and the effect of a CQC inspection.

Six scenarios could explain the effect (or lack of effect) of CQC inspections (and any of their components) (Figure 10.2).

[21] The CQC piloted the assessment of value for money as part of the inspections in 2016 and implemented it in 2017 (Care Quality Commission, 2016b). The evaluation of the coordination and integration of care has been implemented as a pilot since 2017 (Care Quality Commission, 2017b).

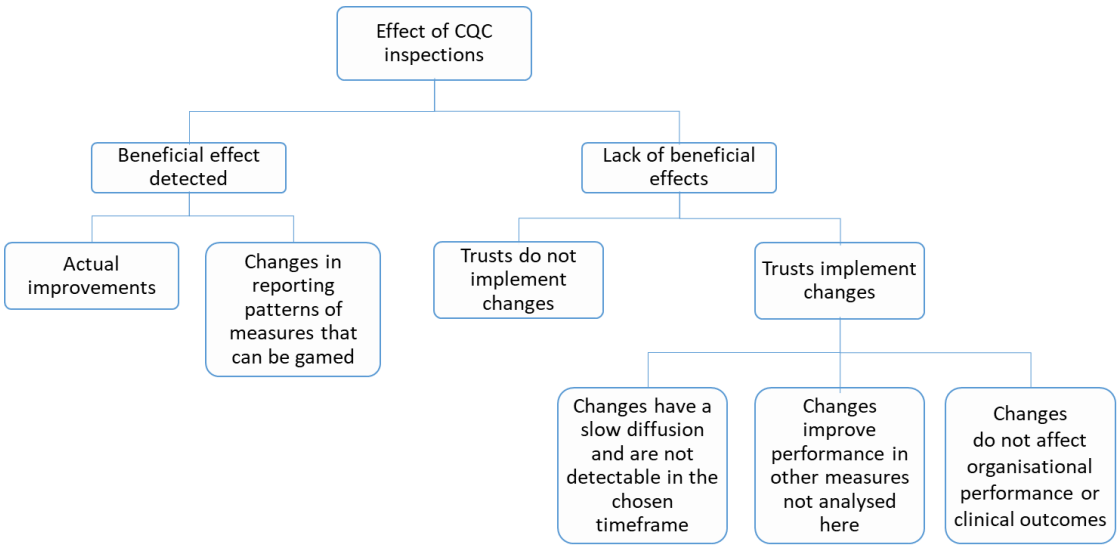


Figure 10.2 Potential options for explaining the effect (or lack) of CQC inspections

Elucidating which of these options explains the observed effects would require another type of research method (see section 10.3). However, evidence assessing the impact of "targets and terror" (Besley et al., 2009, Mason et al., 2012) and external inspections of hospitals' cleanliness in England (Toffolutti et al., 2017) shows that their beneficial effect was a mix of actual improvements and gaming. In the case of external inspections in general, there is no evidence exploring how and when hospitals respond. Consequently, the explanations provided below are largely based on evidence linking the internal features of hospitals and their performance.

The analysis of the effect of any inspection on measures of quality of care serves as an indication of the overall impact of the intervention without factoring in other variables (Shadish et al., 2002). This analysis showed that the only significant effect was a step decrease in A&E and RTT waiting times after the announcement of an inspection. Moreover, the subgroup analysis by 2009 performance rating showed that trusts rated as excellent, good, and fair had a step decrease following the announcement of the inspection for both measures of waiting times.

Two factors could explain the effect of the announcement on waiting times. One is that these measures have been a central component of performance management since 2000. Improving waiting times was a governmental commitment until 2005, they are a right for patients as set out in the NHS Constitution (DOH, 2015b), they are assessed as part of the NHS Outcomes Framework (DOH, 2016b), they are national targets which are priority for hospitals boards (Machell et al., 2010), and CQC includes these two measures as part of the intelligent monitoring tool (Care Quality Commission, 2014c). Another potential explanation is that the NHS modernisation agency worked to support the implementation of innovative strategies to achieve the targets imposed during the "targets and terror" period (Buchanan et al., 2006),

which suggest there is already the capacity and skills in-house for improving waiting times. This finding also highlights that hospitals try to implement quick fixes before an inspection, in particular, for those indicators deemed relevant for the inspection regime (i.e. tunnel vision).

In comparing the effect of the old and new regime of inspections, the step reduction of waiting times after the announcement was significant only for patients waiting more than 18 weeks for a referral to treatment, regardless of the type of inspection. After the visit, all groups exhibited an upward trend. Common events instead of the inspection visit itself (e.g. austerity measures) could explain this pattern. In the case of A&E waiting times, no significant change was observed after the announcement of an old or new regime inspection, suggesting that the type of inspection does not explain the variability in effect observed for A&E waiting times.

Rates of falls with harm had a significant step reduction after the announcement of a new regime visit, but after the inspection, trends were similar for the three groups. The introduction of quality improvement initiatives to reduce adverse events or changes in the reporting patterns of these trusts could explain this transient change. The fact that trusts inspected by the new regime had a worse reporting culture suggests that the second option is more plausible.

The comparison of the old and new regimes of inspection accounting for previous performance showed that the announcement of an inspection produced detrimental effects on improving trusts on the four measures analysed, whereas it had mixed effects on not improving trusts. Table 10.2 summarises the significant changes detected after the announcement of an old or new CQC inspection when accounting for previous performance.

Table 10.2 Summary of significant changes after the announcement of a new and old inspection accounting for previous performance

	Improving			Not improving		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Falls with harm	– ↑ trend	– ↑ trend	– ↑ trend		+ ↓ trend	
Pressure ulcers	– ↑ trend	– ↑ trend	– ↑ trend		+ ↓ trend	
SHMI						
Crude mortality						
A&E waiting times	– ↑ trend					
RTT waiting times	– ↑ level					
Patients' perception of care						
Rate of leavers		– ↑ level			– ↑ level	

For the three groups, the improving trend flattened for both adverse events following the announcement. However, trusts classified as improvers for these two outcomes were more likely to receive a “requires improvement” rating when inspected by the new regime. Moreover, they were more likely to be rated with “significant delivery issues” by Monitor, which could partially explain why improvement slowed down after the inspection. It is equally plausible that the deceleration was produced by a floor effect or an increase in reporting.

After the announcement of a new regime inspection, the improving trend of A&E waiting times shifted upwards (worsened) and there was a step increase in RTT waiting more than 18 weeks. In these two cases, trusts had worse Monitor governance and sustainability ratings, indicating potential financial difficulties. A combination of limited ability to adapt to increasing pressure, diversion of attention of managerial and clinical teams to prepare for the inspection, and contextual elements such as austerity measures could explain this change after the announcement of a resource-intensive inspection.

Rate of leavers increased after the announcement of an old regime inspection. Results are counter-intuitive for trusts with improving performance inspected by the old regime since they are less likely to be in London (with the highest overall rates of leavers), are more likely to be medium size, have Foundation Trust status and be in the Midlands. Additionally, they were more likely to be rated as “good” or “outstanding” by the CQC. The most plausible explanation for this pattern is that 75% of inspections of these trusts occurred between November 2013 and February 2014. Therefore, the announcement period took place between August and October 2013, when rates of leavers are higher every year compared to November-January. Without information about reasons for leaving, any potential explanation would be speculation.

The announcement of an inspection for not improving trusts presented mixed effects. A step increase in rates of leavers was found after the announcement of an old regime inspection; however, this increase was transient. Trusts inspected under the old regime were more likely to have a Monitor sustainability rating of “material risk”, but there was no difference in distribution between improving and not improving trusts. Not improving trusts inspected under the old regime were more likely to have a governance rating of “no evident concerns”, potentially explaining why the increase was only temporary. In the post-inspection period, trends appear similar for all trusts, again suggesting that the contextual factors described above could be linked to the changes observed.

In the case of adverse events, the announcement of an old regime inspection was associated with a downward shift of the slope for falls with harm and pressure ulcers. This group of trusts was more likely to be rated as “good” or “outstanding” after the first new regime inspection, which might reflect a better self-efficacy and safety culture. These two factors relate to achieving goals (Locke and Latham, 2006); therefore, the announcement of the inspection could have triggered the effective implementation of improvement strategies explaining the changes observed.

Overall, it seems that detrimental effects after the announcement of an inspection could be associated with previous financial and governance performance measured by Monitor ratings, and the rating after a new regime inspection since those groups with worse ratings tended to respond more badly to such announcements.

10.1.4 The effectiveness of external inspections

On-site inspections were not significantly associated with changes in measures of quality of care. This mirrors the findings of the review of reviews in Chapter 4. Perhaps, a different approach to synthesizing evidence such as a realist synthesis could yield different results, and help inform when and how institutions respond to external inspections.

Falls with harm and pressure ulcers can be used as proxies for quality of nursing care (Aiken et al., 2016, National Institute For Health And Care Excellence, 2014) since they are nursing-sensitive outcomes (Currie et al., 2005, Butler et al., 2011). Falls with harm, pressure ulcers and patients’ perception of care are associated with staffing levels; however, these measures are affected by both, the quantity and quality of nursing care (Griffiths et al., 2014, Griffiths et al., 2016, Aiken et al., 2016). The relationship between CQC inspections and safe-staffing levels is not clear. Considering the expenditure in agency staff before and after an inspection could help elucidate if trust boards try to improve the quantity and quality of nursing care in preparation for the inspection or afterwards. However, monthly information is not publicly available, and a previous Freedom of Information request was denied because disclosing this data could affect the monitoring functions of NHS Improvement (NHS Improvement, 2016a).

Regarding the sensitivity of these three measures to external inspections, previous evidence is scarce and low quality. A cross-sectional study found that implementing standard safety practices requested by the accreditation agency was associated with lower pressure ulcer rates (Thornlow and Merwin, 2009), whilst, an interrupted time-series study found a significant increase in the level and trend for falls after an accreditation visit (Devkaran and O'Farrell,

2015). In terms of patients' perception of care, an RCT (Salmon et al., 2003) and a prospective cohort study (Quality assurance project, 2005) found no effect on patient satisfaction. The subgroup analysis by 2009 performance rating (see Chapter 6, section 6.2) showed that the behaviour of adverse events and patients' perception of care after an inspection was similar for the four groups (i.e. excellent, good, fair, and weak). In the case of adverse events, the trends converged towards the mean; whilst for patients' perception of care, all trusts showed improvement in the post-inspection period. The latter could be associated with an increase in awareness about treating patients with dignity after the publication of the Francis Inquiry. The patterns observed post-inspection suggest that changes are related to other system-wide underlying processes (e.g. austerity measures and the Francis Inquiry) instead of the on-site CQC visit.

A&E and RTT waiting times were first established as a political commitment to quality that later turned into an issue of legal rights within the NHS Constitution (DOH, 2009). Although improving access was the primary purpose of imposing waiting times targets, later research has shown an association of long waits in A&E with patient outcomes (Guttmann et al., 2011, Day, 2013, Carter et al., 2014). In the case of long waits for elective non-urgent care, evidence suggests that the risk of adverse events and poor outcomes increases with the length of wait for cardiovascular surgery, cholecystectomies, orthopaedic and corrective eye surgery. (Barua et al., 2014, Day, 2013, Sobolev et al., 2003, Oudhoff et al., 2007, Braybrooke et al., 2007, Bailey et al., 2016, Montin et al., 2008, Vergara et al., 2011, Desmeules et al., 2012, Conner-Spady et al., 2007, Hodge et al., 2007). Therefore, given the link between the length of wait for emergency and elective care and quality of care, it was deemed relevant to test the effect of inspections on these measures.

The CQC assess A&E and RTT waiting times as part of intelligent monitoring; however, it is not clear if these two measures were affected by CQC inspections. Research on this topic has explored the relationship between the introduction of targets associated with "naming and shaming" and improvements in waiting times (Besley et al., 2009, Mason et al., 2012); but evidence on the impact of inspections is limited. The results suggest that inspections, regardless of type, are not associated with improvements in waiting times. Post-inspection patterns for A&E and RTT waiting times show a similar worsening trend for both indicators across all trusts (by 2009 performance ratings), which is only significantly different from the counterfactual for A&E waiting times of those rated as fair. This finding can be explained by a higher proportion of trusts with the lowest ratings in Monitor sustainability (i.e. significant or material risk) and governance ratings (i.e. subject to enforcement action or under review) in

this group, indicating that their ability to adapt to an extra burden may be more limited. Further subgroup analyses would be needed to confirm this hypothesis (see section 10.2).

Mortality is a contested measure of quality of care (Park et al., 1990, Pitches et al., 2007, Goodacre et al., 2015, Hogan et al., 2015, Kobewka et al., 2017) due to the low predictive value of risk-adjusted mortality in detecting hospitals providing poor care (Girling et al., 2012). However, recent scandals such as Bristol (Kennedy, 2001) and Mid-Staffordshire (Francis, 2013) had higher than expected mortality rates. Further investigations showed there was a culture of blame that did not learn from mistakes, and which could explain the failure of care (Kennedy, 2001, Francis, 2013). Other scandals such as those involving the care provided by Ledward (Ritchie, 2000) and Paterson (Kennedy, 2013) were not associated with high mortality rates, but they did leave patients with severe damage, whilst investigations revealed similar cultural failures (Ritchie, 2000, Kennedy, 2013). Risk-adjusted mortality should not be used in isolation to judge performance due to its low predictive value, but it can serve to prompt further investigation into the care provided by an organisation. The CQC uses 98 mortality indicators (including risk-adjusted and composite mortality measures) as part of intelligent monitoring to determine what trusts to inspect and when (Care Quality Commission, 2014c); consequently, it was deemed relevant to assessing the impact of the regime.

The relationship between on-site visits and their effect on mortality is not clear. Two of the studies included in the update of the most rigorous systematic review found conflicting evidence on their effect (see Chapter 4). Whilst Devkaran and O'Farrell (2015) found no significant changes in level or trend the month following the accreditation visit, and Towers and Clark (2014) detected a significant decrease in risk-adjusted mortality the month after the accreditation visit ($\beta = -0.045$, $p<0.05$). The most recent evidence regarding the effectiveness of accreditation comes from a research group in Denmark, who found that fully-accredited hospitals had lower risk-adjusted mortality rates than did non-accredited ones (OR [95% CI]: 0.83 [0.72-0.96]) (Falstie-Jensen et al., 2015a).

In the NHS, there is no quantitative assessment of the impact of external inspections on mortality, but Dr Foster (2015) analysed the effect of special measures on the 11 trusts subjected to this regime after the Keogh Review. The overall analysis showed a significant downward shift in the trend after the beginning of special measures (Dr Foster, 2015). Conversely, the findings of this thesis suggest there is no such association after an inspection. One explanation is regression to the mean, where extreme values tend to move towards the mean regardless of any intervention (Barnett et al., 2005). The scope of each intervention could also explain differences in effect. These 11 trusts were mortality outliers and the Keogh Review identified aspects of care contributing to high mortality; therefore, the interventions

implemented targeted areas of care with increased rates of avoidable deaths. The focus of CQC inspections changes depending on the results of intelligent monitoring, consequently, the analysis presented here includes trusts both where mortality is a concern and where it is not, so as to dilute any potential effect.

Staff turnover is associated with quality of care through two interrelated pathways: the work environment and staffing levels. A poor working environment contributes to job dissatisfaction leading to staff turnover (Hellman, 1997, Yin and Yang, 2002, Coomber and Barriball, 2007, Estryn-Behar et al., 2010), whilst low staffing levels can increase work stress and intention to leave (Coomber and Barriball, 2007, Aiken et al., 2002, Gauci Borda and Norman, 1997). Additionally, staffing levels are also related to an increase in adverse events and mortality (Aiken et al., 2008, Aiken et al., 2016, Griffiths et al., 2016). However, this research, focused mainly on nurses, is inconsistent. The CQC uses staff turnover in conjunction with the staff stability index (i.e. the proportion of staff working more than 12 months in the organisation) to reflect the skill-mix and culture in the organisation. Although there is evidence suggesting a link between organisational culture and performance (Jacobs et al., 2013, West et al., 2013, Taylor et al., 2015), the relationship between inspections or accreditation visits and staff turnover had not been explored before.

Rate of leavers was selected to reflect the trusts' capacity to adapt to an additional external demand such as an inspection. The expected result was that trusts with a better culture would have lower overall rates of leavers and the inspections would not affect turnover, or it would do so to a lesser extent. The results of this thesis suggest that overall, the on-site visit is not associated with changes in the rate of leavers. The analysis by performance rating in 2009 showed that the rates of leavers and the trend after the inspection were similar for the four groups. This can have three possible meanings: inspections do not affect turnover, the performance ratings might not be a good indicator of culture, or turnover does not reflect trusts' capacity to adapt. Exploring differential turnover by profession or reasons for leaving a trust in more detail, might help elucidate the most probable cause, but this was outside the scope of this thesis.

One of the difficulties of determining the effect of CQC inspections is that they are complex interventions (Walshe, 2007) that target different areas of care depending on the findings of the intelligent monitoring tool (Care Quality Commission, 2014b). Therefore, it is plausible to consider that in some trusts the measures analysed here exhibited poor performance and the CQC identified them as such, whilst in others the performance for these measures was not poor. This means that the effect might dilute when trusts are analysed together. Additionally, improving these measures is in itself a complex task (see Chapter 2, Figure 2.1), where several

aspects of care have to be addressed to improve one measure. Therefore, trusts could have improved performance in an intermediate variable in the causal path (e.g. working environment that can affect turnover rates) but did not reach any significant difference in terms of the measure itself.

Qualitative research assessing previous inspectorates suggests that inspections serve as a catalyser for improvements that were on hold (Day and Klein, 2004, Sutherland and Leatherman, 2006, Walshe et al., 2014). However, it is not clear how long this effect lasts and if it is enough to produce observable improvements in measures of care quality. The CQC strives to "encourage care services to improve" (Care Quality Commission, 2014b), but this statement can only be true if the catalyst effect translates into better performance and outcomes. Changes in practice based on the best evidence available are not synonymous with improvements (Berwick et al., 2003). The process of successful implementation of improvements requires senior management and a trust board with the abilities to detect aspects of poor care, the skills and knowledge to identify and adapt potential solutions for deficient areas to their context, and the leadership to guide their implementation. Therefore, quality improvement skills of board members could be a future area that CQC could assess.

The CQC produces a detailed report about overall hospital performance following an inspection, which could be another opportunity to influence providers' behaviour. When the CQC has serious concerns about performance, an enforcement action is issued. However, when improvements are requested without formal enforcement hospitals were unclear on how to proceed, the timescale for implementation, their accountability, and the expected standards (Walshe et al., 2014). This suggests that even when the CQC could influence improvements in hospitals after an inspection, unclear instructions may dilute and delay the potential effects, making it difficult to attribute any improvement in the quality of care to a CQC inspection.

The CQC exerts its effect mainly through its existence by creating a constant pressure to maintain standards to avoid regulatory actions and to perform well during an inspection without any additional effort being required. The time available between the announcement and the visit is insufficient for the immediate implementation of interventions to improve the measures analysed in this research (see Appendix Chapter 10, Table 10.1); therefore, the CQC may be viewed as acting as an invisible (but ever present) reminder to meet standards of practice and strive for improvement.

10.1.5 Differential effect of inspections

10.1.5.1 Performance ratings

Table 10.3 Summary of findings for the effect of any inspection by 2009 CQC performance rating

	Poor	Fair	Good	Excellent
Falls with harm				– ↑ level post announcement
Pressure ulcers				
SHMI				
A&E waiting times				
RTT waiting times				
Patients' perception of care				
Rate of leavers			– ↑ level post-inspection (transient)	+ ↓ level post announcement

Some differences in the features of trusts could explain the effect observed. Trusts rated as excellent and good were less likely to be large (21% vs 40%) and to have been under special measures (9% vs 21%), which could be associated with better capacity to respond to inspections than those rated as poor or fair. Additionally, trusts rated as good were more likely to have a lower Monitor sustainability rating and be subject to enforcement actions than trusts rated as excellent. Therefore, the transient increase in the rate of leavers after an inspection could be associated with attempts to retain staff in preparation for the inspection without a long-term strategy to retain an experienced workforce. Conversely, trusts rated as excellent were more likely to receive a good or outstanding CQC rating after a new regime inspection (47% vs 21%); this could reflect a better culture regarding retaining staff, which might have affected the rate of leavers after the announcement. This compounded with the transient increase of falls with harm suggests that this group of trusts invest resources in preparing for an on-site visit, recruiting more staff and, probably, improving reporting patterns for adverse events. It is equally plausible that the increase in falls with harm may be related to staff investing more time in preparatory administrative work instead of contact time with patients affecting negatively on care quality. Determining the causes behind the changes observed would require further research (see section 10.2).

10.1.5.2 Old versus new regime

Table 10.4 Summary of findings for the comparison of effect by type of inspection

	New regime	Old regime	No inspection
Falls with harm			
Pressure ulcers			
SHMI			
A&E waiting times	– ↑ level post inspection	+ ↓ level post inspection	
RTT waiting times			
Patients' perception of care	+ ↑ trend post inspection	+ ↑ trend post inspection	+ ↑ trend post inspection
Rate of leavers	+ ↓ level post announcement	– ↑ level post announcement	

The different effects on A&E waiting times might suggest that old regime inspections could have driven a transient improvement, whilst the new regime inspection might have diverted clinical and managerial attention away from improving practice during the preparatory phase and after the visit. The change could be reflected in A&E waiting times because data is weekly, and trusts might have more control over waiting times than other outcomes. It is equally plausible that changes may indicate a modification in reporting patterns.

In the case of rates of leavers, the differing effect of the announcement could be explained by a higher proportion of trusts within the group inspected by the old regime with a Monitor sustainability rating of material risk. This group might have had difficulties retaining staff, which could explain the step increase. In the case of trusts inspected under the new regime, the step decrease suggests that they were improving retention before the on-site visit. It is noteworthy that 27% of trusts inspected by the new regime were under special measures; therefore, the improvement in rates of leavers could be associated with an increased effort to attract and retain experienced staff.

Consistent with findings from the previous research question, no association was observed between CQC inspections and changes in adverse events, RTT waiting times, risk-adjusted mortality or rates of staff leaving an NHS trust. Conversely, patients' perceptions of being treated with dignity and respect improved in the post-inspection period for all three groups, which was probably associated with recommendations by the Francis Inquiry regarding patients' experience of care (Thorlby et al., 2014). In summary, although the responses to the visit and announcement differed for two indicators depending on the type of inspection received, this seems to reflect selection bias, instead of differential effectiveness of the interventions.

10.1.6 Culture as a mediator of the response to the inspection

Table 10.5 Summary of changes post-inspection for the comparison of old and new regime of inspections accounting for previous performance

	Improving			Not improving		
	New regime	Old regime	No inspection	New regime	Old regime	No inspection
Falls with harm				+ ↓ level		
Pressure ulcers		– ↑ level				
SHMI	– ↑ trend*	– ↑ trend*		+ ↓ trend*	+ ↓ trend*	
Crude mortality		+ ↓ level			+ and – ↓ level and ↑ trend	
A&E waiting times	– ↑ level and trend			– ↑ level	+ ↓ level	
RTT waiting times						
Patients' perception of care		+ ↑ trend		+ ↑ trend	+ ↑ trend	+ ↑ trend
Rate of leavers					+ ↓ level	

*significant one-year after the inspection.

Performance prior to the inspection was considered a proxy for a trust's culture, assuming that improving organisations had the internal capacity and leadership to implement changes of practice. The findings suggest that the opposite was actually true.

The analysis of adverse events considering previous performance showed a similar pattern regarding form and level for all groups following an inspection, suggesting the possibility of regression to the mean. Nonetheless, there were some small statistically significant changes: for trusts with worsening performance a drop in the rate of falls after a new regime inspection was observed; whilst for trusts with improving performance, there was a step increase in rates of pressure ulcers after an old regime inspection.

Although there was a step increase in pressure ulcers after an old regime inspection of improving trusts, this change seems to be a statistical artefact produced by a non-significant decrease during the announcement phase, since a comparison with the counterfactual shows no difference. In the case of the decline in falls with harm after a new regime inspection in not improving trusts, this group had a higher proportion of trusts with significant concerns regarding their reporting culture (57% vs 34% in the other groups), which might imply an

observed change is due to gaming. No other differences were observed that could explain this pattern. After the inspection, the trends for all groups appeared to converge, suggesting a phenomenon of regression to the mean that could be explained by historical events. During the implementation of the NHS ST, the NHS Institute and the National Patient Safety Agency, which supported the initiative, were decommissioned and the CQC restructured (Power et al., 2016). After the ST pilot phase ended in March 2013, providers became responsible for continued reporting and improvement. Efforts expended may conceivably have differed depending on trusts' competing priorities and commitment to patient safety, thus diminishing the national, coordinated effort and explaining the deceleration of the improvement observed previously.

The analysis of risk-adjusted mortality showed that there was a trend shift following the inspection for trusts with improving and worsening performances, which was significantly different from the counterfactual 12 months after the inspection. However, a comparison of the six groups showed no differences among them. When the crude mortality rates were analysed together with the SHMI, a step decrease in mortality was observed for trusts with worsening performance after an old regime inspection, whilst the SHMI remained the same. Therefore, the expected mortality for these trusts had a similar reduction in terms of observed mortality. The post-inspection trend goes downward for SHMI and upward for crude mortality rates, which means that the expected mortality increased more than the observed mortality. In practice, this implies that hospitals classified as not improving for SHMI were receiving patients with poorer health status over time. It could be presumed that this group of hospitals implemented measures to prevent the death of patients with high probabilities of dying, which would explain the decreasing SHMI. Another possible explanation for this pattern is a change in the coding behaviour of patients' comorbidities to increase artificially the probability of dying (e.g. coding more comorbidities or coding conditions with higher weight in the probability of dying).

For trusts with improving performance inspected by the old regime, a significant drop in mortality was observed after the on-site visit, which coincides with a significant decline in SHMI. This change can be attributed to a reduction of observed deaths whilst expected deaths remained stable. In practical terms, this improvement might be associated with the implementation of quality improvement initiatives that have shown positive effects on reducing mortality (Zegers et al., 2016). A qualitative study exploring the real causes of this decrease in mortality would be needed to increase certainty. When post-inspection trends for the six groups are analysed together, they follow a similar pattern that can be explained by regression to the mean.

Trusts with worsening performance in A&E waiting times showed a significant decrease in levels after an old regime inspection and an increase in levels after a new regime inspection. However, the latter represents a statistical artefact explained by a non-significant drop during the announcement phase. Trusts with improving performance in A&E waiting times had an increase in level and slope after the new regime on-site visit. The trends observed for trusts inspected by the new regime are similar regardless of previous performance, which suggests that there might be a common mechanism to explain these changes. The most plausible explanation is a diversion of managerial and clinical attention away from patient care. As mentioned in previous chapters, trusts inspected by the new regime were more likely to be in special measures; have a Monitor sustainability rating of "significant risk"; have a Monitor governance rating of "under review" or "subject to enforcement actions"; and have a reporting culture rating of "poor" or "significant concerns". These trusts seemed to have less capacity to adapt and respond to increasing pressure. Therefore, the new regime inspection could have worsened performance, or it could have improved the accuracy of reporting. Nonetheless, although post-inspection trends are different among groups, at the end of the observation period there are no differences to rates of attendances waiting more than 4 hours in A&E, suggesting that a common shock, such as the delayed effect of austerity measures, could explain the worsening performance.

A significant improvement in the post-inspection slope of patients' perception of being treated with dignity and respect was observed for not improving trusts regardless of the type of inspection they received, whilst for improving trusts, only those inspected under the old regime had a significant improvement in the post-inspection rate of change. The two groups of trusts that did not show any statistically significant improvement (i.e. new regime and not inspected improving) had a higher proportion of trusts with a Monitor financial rating of material or significant risk.[22] Additionally, these were more likely to have a Monitor Governance rating of "subject to enforcement actions",[23] which might indicate more restricted possibilities for investing in improvements, worse working environments affecting patients' experience or lower staff:patient ratios.

In the case of the significant rate drop for leavers after an old regime inspection of not improving trusts, there were no differences observed in the analysed variables among groups to explain this phenomenon. However, this change seems to be a statistical artefact since the

[22] New regime improving 46%, not inspected improving 34% versus new regime not improving 5%, not inspected not improving 13%, old regime not improving 27% and old regime improving 0%.

[23] New regime improving 62%, not inspected improving 50% versus new regime not improving 21%, not inspected not improving 9%, old regime not improving 9% and old regime improving 0%

rate of leavers had a non-significant increase during the announcement phase, and in the post-inspection period, rates appear similar to the counterfactual.

The existing literature suggests that high performing hospitals have a positive organisational culture where innovation and quality improvement initiatives can excel, and performance monitoring is effective (Taylor et al., 2015). Their culture promotes interdisciplinary work and trust, through committed and visible management and a focus on excellence (Taylor et al., 2015). This implies that quality and safety are at the heart of the organisation's goals and mission, therefore, efforts are continuously made to act on data and fix potential problems (ibid). These features can make them respond differently to external inspections and consequently, the effect on quality measures might differ from other organisations. There is evidence suggesting that a critical component to quality improvement is that the organisation has a common, shared vision (West et al. 2013) and that the inspection could be a driver to having one or remembering what that shared vision is.

Given the patterns observed in the data, it seems that high-performing hospitals were those that had stable or worsening performance because they had the lowest overall rates during the observation period (i.e. floor effect), whilst hospitals classified as improving were low-performing because their improvement reflected the possibility of them improving more than their culture. As seen in Chapter 8, trusts with improving performance in clinical outcomes were more likely to be in special measures and less likely to be Foundation Trusts.

It is noteworthy that a myriad of methods exists to identify a high-performing hospital (Taylor et al., 2015). The NHS star ratings (Mannion et al., 2005), risk-adjusted mortality rates (Cherlin et al., 2013), performance over time (Curry et al., 2011) and composite scores of quality (Kramer et al., 2008) are some of the measures previously used to classify high-performing hospitals. Considering hospitals not improving their performance as "high-performing" would be reductionist since it is not possible to infer hospitals' organisational culture based on the previous performance of selected quality indicators. However, it is known that the performance and culture of acute trusts vary at every level and it is common to find "good" and "bad" organisational culture within wards, departments and sites (West et al., 2013). This highlights how complex it is to define high-performance and support the premise that hospitals not improving in the analyses presented might have had a "good" culture that makes them similar to institutions with a positive organisational culture. Qualitative research could help disentangle the relationship between historical performance and the response to an external inspection.Assessing the organisational culture during inspections could be an area that the CQC could explore, and further research could inform if there is a relationship between culture and the effect of an inspection.

10.1.7 Value for money

Although a cost-effectiveness analysis of the new regime inspections was planned, it was not appropriate to calculate the cost per adverse event or death prevented due to these inspections' lack of effectiveness. The costs of a new regime CQC inspection considering the opportunity costs borne by acute NHS trusts and the operational costs of an inspection for CQC ranged from £169,691 to £256,378 for a small trust and from £351,100 to £418,136 for a large trust.

Contrary to the standards used by NICE to determine what interventions to fund in the NHS, when it comes to system-level policies, there is no exhaustive search for high-quality evidence to assess the effectiveness and cost-effectiveness of a given intervention. If we viewed inspections in isolation as an intervention, and these findings regarding the effectiveness of the new regime of CQC inspections were submitted to a review by NICE, the intervention would not be funded. However, the value for money associated with CQC inspections remains a valid question. The work of the CQC involves the development of standards; the registration and monitoring of social, mental, and health care providers; and inspections; therefore, the value of regulatory institutions cannot be judged solely based on the effect of inspections.

Evidence regarding the costs of external inspections or accreditation visits is scant. The cost audit tool used for data collection in this thesis was based on Mumford et al. (2013) who found that hospitals in Australia spent between 0.03% and 0.6% of their annual budget in one accreditation cycle, which is similar to what it was estimated in this research (i.e. between 0.035% and 0.16% of the annual operating budget). In England, a study commissioned by the Healthcare Commission to determine the cost of their inspections for acute NHS trusts found that there was not enough information to calculate the costs because trusts were not keeping a log of the resources spent on preparing for a self-assessment (Healthcare Commission, 2008a).

Some aspects that could help increase the value for money of CQC inspections are the time commitment needed to perform the inspection, costs associated with goal displacement[24] and monitoring how the action plan is carried out to ensure changes translate into improvements. Providers recognise CQC inspections as a form of external review that allow them to confirm and showcase the standards and care quality delivered (NHS Providers, 2017). Indeed, CQC visits may confirm what providers already know about deficient and outstanding areas of care (Walshe et al., 2014, NHS Providers, 2017). However, when NHS providers were asked if the

[24] Duty managers have to stop performing to respond to CQC requirements. It also conveys an opportunity cost associated with using resources to meet consensus raised during the inspection, to the detriment of other interests.

benefits of CQC inspections justified the costs, answers were mixed: 38% agreed, and 38% disagreed. Moreover, providers stated, “the same benefits could be achieved through a more streamlined approach” (NHS Providers, 2017). In comparison, the views of trusts regarding the “annual health check” were more favourable. In that case, 53% (31 of 58 trusts) considered that the assessment of core standards outweighed the costs, 77% (94 of 122 trusts) thought the self-assessment provided assurance to the board, 82% (100 of 122 trusts) mentioned it helped identifying priorities for improvement, and 75% (92 of 122 trusts) claimed it put quality in a central position (Healthcare Commission, 2008a). This implies that trusts are willing to submit to some regulatory burden to ensure quality of care (i.e. compliance is seen as a moral act), but the new regime of CQC inspections between 2013 and 2016 was particularly burdensome.

It is useful to remember that the failure of care by Mid-Staffordshire happened during the time of the annual health check, which was a more light touch approach to regulation (Bevan, 2015); therefore, it was deemed appropriate to switch to a more controlling regime of inspection to prevent more failures and protect the public.

The CQC has already taken actions to reduce the burden of on-site visits and increasing value. In June 2017, the CQC launched a new regime of inspections which is using the trust’s previous rating to determine the frequency of inspection, is focusing on one core service and the well-led domain, and is including an assessment of the trust’s use of resources (Care Quality Commission, 2017c). Future research could examine whether this simpler approach is better value for money than the regime implemented until June 2017.

10.2 Strengths and weaknesses of the thesis

This is the first quantitative study estimating the effect and cost of external inspections of hospitals in England. The design chosen, an interrupted time series with control, is a robust method for assessing the impact of health policies when executing a controlled randomised trial is not possible (Penfold and Zhang, 2013, Shadish et al., 2002, Kontopantelis et al., 2015b). Estimations of the opportunity cost of inspection visits are largely unknown. This thesis provides the first insight into the activities NHS trusts carry out in preparation for an on-site visit and how much they cost. Lack of effectiveness meant that estimating the cost-effectiveness of inspections was unnecessary.

The robustness of the analyses in this thesis relies on the inclusion of a high proportion of acute trusts in England and a long time-series before and after an intervention, improving the validity of the conclusions. The use of two intervention points allows testing for both anticipatory and immediate effects. Additionally, intervention points (i.e. inspection and

announcement) were spread over a 12-month period, reducing confounding related to one specific time point (Shadish et al., 2002). The inclusion of several confounding and intermediate variables into the model improves the confidence in the estimates. The study design chosen can only assess the effect of inspections in isolation, and it does not allow for determination of the overall effectiveness of the CQC, in particular, because it would be difficult to find a good counterfactual for evaluating the effect of a regulatory institution.

A weakness of this thesis is the lack of qualitative information that could shed light on the mechanism of change for CQC inspections. Despite the large body of literature exploring the effect of accreditation or external inspections (see Chapter 4), it remains largely unknown when (regarding temporality and circumstances), how, and why organisations respond to external oversight. This means that most of the potential explanations for the findings are based on theoretical relationships since empirical evidence linking features of organisations and response to inspections is limited.

10.2.1 Data quality

Data quality is a particularly challenging issue for observational comparative effectiveness studies (Hernan, 2011). The main difficulty is that routinely collected data does not always meet reliability and validity requirements for research; therefore, validation studies are often required before making inferences. For this thesis, acute NHS trusts reported all data; however, the requirements and quality checks for submission of the information for each indicator were different.

Falls with harm and pressure ulcers are reported to the NHS safety thermometer (NHS ST), a publicly available dataset, collected nationally, on a monthly basis, using consistent definitions and standards. It provides data on adverse events in real time and allows trusts to act on this information (Power et al., 2012). However, data may be inconsistent due to variable data entry skills, flexible interpretations of operational definitions and variations in patients' case-mix across sites (Power et al., 2014). The interpretation of these measures can vary within hospitals and over time, making it imprecise and at risk of gaming (Power et al., 2014).

There is no published reliability assessment of the falls with harm component of the ST. However, Sari et al. (2006) found that only 56% of falls and 23% of pressure ulcers were reported to the routine system (i.e. NRLS) compared to incidents found in medical records. Whilst this number could have been used as a proxy of the magnitude of underreporting, it was not direct evidence of underreporting to the ST, with later research showing differences in the extent of underreporting to the NRLS and the ST (Smith et al., 2016). In the case of pressure ulcers, a pressure ulcer and wound audit (PUWA) found that 50.6% of pressure ulcers

were reported to the ST, which translates into weighted sensitivity of 48.2% (95% CI 35.4 to 56.7%) (Smith et al., 2016). Although this study provides a nation-wide estimation of underreporting, to factor the impact of reporting behaviours in the model, two pieces of information are needed. One is the variation over time for each trust, and the other is how the announcement and on-site visit affect reporting of adverse events. The lack of this information hinders their inclusion into the model, and validation of the dataset was out of the scope of this thesis.

Given the potential effect of reporting culture on data reliability, two measures were introduced into the model: a score given to assess potential under-reporting of patient safety incidents provided by the National Reporting and Learning System (NRLS) in October 2013, and reporting culture ratings provided by CQC in 2016. In the model for falls with harm, the NRLS score was statistically significant, but their trust type (large, teaching, medium, small, or specialist) better explained between-trust variability. The results of the analyses in groups matched by potential confounders remained the same, providing confidence in the estimations.

Although waiting times are official statistics, audits and research performed during the "targets and terror" period indicate that reported A&E waiting times were overstated in the official statistics since patients and doctors reported longer waiting times (Healthcare Commission, 2008b, Jones and Schimanski, 2010) and the patterns of data suggested gaming (Locker and Mason, 2005, Locker and Mason, 2006, Mason et al., 2012). The lack of more recent audits measuring the extent of gaming and how it changes in relation to an upcoming inspection prevent including this factor into the model, but it is presumed waiting times in A&E are underreported, and gaming would increase prior to a CQC visit.

RTT waiting times are submitted to the database used to determine payment for services (i.e. Secondary Uses Service [SUS]) (NHS England, 2015c); therefore, data quality standards should be higher. However, flexible interpretation of the rules (i.e. clock starts, pause and stops), led to incorrect recording and low comparability of data (National Audit Office, 2014). Recording errors produced a median of 11 days that were under-recorded, with the proportion of correctly timed cases ranging from 13 to 57% in the trusts audited (National Audit Office, 2014). In October 2015, the Department of Health published a new suite of rules to ensure consistent reporting and eliminate the possibility of pausing or suspending the waiting time (DOH, 2015c). This change could be responsible for the increase in the rate of referrals waiting more than 18 weeks observed in the analyses. The lack of information on the accuracy of data at a national level and its relation to the pressure of an upcoming inspection prevent it being

accounted for. Similar to what it is expected for adverse events, trusts may manipulate their RTT waiting times before an on-site CQC visit, but at present, this remains speculation.

Crude mortality rates are highly reliable, but some problems can arise from the reporting of variables for risk adjustment (Clinical Indicators Team, 2017). The main problem with SHMI is that data is not extracted directly from patients' records. Instead, the information is stored in a single database for internal purposes (i.e. Patient Administration System), which is later submitted to the SUS. NHS Digital uses the latter to create HES data (Clinical Indicators Team, 2017). This means that a trained coder has to transform the primary diagnosis and all the comorbidities into ICD-10 codes (ibid). NHS Digital reports that there are some variations between organisations in the accuracy of clinical coding, but these do not affect the SHMI calculation (ibid). Other factors that might affect the indicator such as palliative care are not included due to inconsistency in the coding (HSCIC, 2013b). The data submitted by the providers have to comply with validation rules and go through an audit (Clinical Indicators Team, 2017); therefore, the possibility of manipulating data to the advantage of a trust is low. In practice, variations in clinical coding are translated into higher variability between trusts, reducing the probability of finding statistically significant differences in the effect of inspections among groups, but gaming is expected to be low.

NHS Digital does not recommend using SHMI to determine performance over time because the model for predicted deaths is recalibrated each quarter. This means that the SHMI value will vary depending on how much the performance of a trust changes compared to the variation in the national average (Clinical Indicators Team, 2017). Despite this, SHMI was chosen over HSMR because the latter is more prone to gaming or error via changing the number of patients coded as receiving palliative care (Taylor, 2013). Changes in crude mortality rates can be explained by variations in case-mix over time without reflecting the effort to improve death rates. In turn, SHMI was the best available measure of mortality.

The National NHS Inpatient Survey is the source of information for patients' perception of being treated with dignity and respect. The response rate to this survey has dropped over time from 59% in 2005 to 47% in 2015 (Boyd et al., 2007, Care Quality Commission, 2016a). Most of the data collection occurs in July of the year of the survey, and only small trusts collect information from patients discharged in previous months (Care Quality Commission, 2016a). These two features make data prone to bias (i.e. non-response bias and seasonal effects). These biases could affect the estimations via two scenarios: when the variation year to year makes the estimations of the trajectory invalid and when the magnitude of these biases is differential. The CQC reports response rates for each trust every year; nonetheless, there is no way to know if over time the samples represent variations in perception of care for each trust

or how these changes relate to CQC inspections. The solution to achieving comparability of data, which does not resolve the issue around validity, is to standardise responses by case-mix. This provides a picture of what patients' perception of care would be if all trusts had the same population demographic. The impact of CQC inspections on the representativeness of the responding sample, and therefore, the validity of the responses to the survey, remains unknown.

NHS Digital generates NHS workforce statistics using information trusts report to electronic staff records, where turnover rates are part of the quarterly published official statistics (Electronic Staff Record Programme, 2017). The definitions are standardised through Information Standards Notices to achieve consistent reporting (ibid). Since April 2012, NHS Digital has performed validation checks on the workforce data in ESR, including crosschecking and validation rules (HSCIC, 2013a). The results of this exercise produce a score for each trust with suggestions on how to improve data quality. The areas with more errors are pay bands, job roles, and missing information (NHS Digital, 2017). Since turnover rates are linked to the payment for staff services, it was expected to be accurate, but no formal study validating the dataset was included. The lack of reliability or validity information would affect the estimation presented here if reporting varied close to an inspection. However, manipulation of these statistics does not seem to produce an advantage for acute trusts; therefore, this was deemed unlikely.

10.2.2 Statistical analysis

The estimation of an intervention effect in an interrupted time series is based on a comparison with a counterfactual. In the case of a single time-series, this counterfactual is the trend observed before the intervention. When a control group is added, the counterfactual is constructed in comparison to the pre-inspection pattern and the change seen in the control. In an environment that is under constant change, such as healthcare organisations in the NHS, assuming that the previous pattern observed is a good representation of what would have happened should the inspection not have been conducted, is questionable. Moreover, acute trusts are subject to interventions by other agencies such as NHS Improvement and PLACE assessments (i.e. Patient-Led Assessments of the Care Environment), which can affect the trajectory of the time-series. Since all the organisations received these external interventions at a different time in relation to the inspection, the approach chosen for this thesis was to simplify modelling by ignoring other inspections and assuming that the pre-inspection trend would remain equal post-intervention. A different approach to modelling the counterfactual could have yielded a different picture about the effectiveness of CQC inspections. However, the lack of information regarding the impact of other interventions, and the potential

trajectory for each measure in the absence of an inspection prevented the use of a more complex approach. If the hypothesis that a delayed effect of austerity is responsible for the worsening or flat performance on the measures analysed is true, then, the counterfactual used is too optimistic, and the real effect would be smaller.

The mechanisms leading to changes in the outputs of an inspection are poorly known. Robertson et al. (2017) explain what might trigger a shift in behaviour in organisations waiting for an inspection, but information is lacking about several aspects relevant for modelling. For instance, knowing the speed of diffusion of change (i.e. gradual or abrupt), the length that efforts are sustained, and whether or not the Quality Summit and the publication of the report should be factored in to determine the model's specification. The modelling strategy chosen allows the detection of abrupt and gradual changes; however, it does not take into account the duration of the effect (i.e. permanent or short-term) or the potential impact of the Quality Summit and the publication of the report on quality measures. Two of the difficulties elucidating these three aspects are that they differ for each acute trust and that information on them is rarely available. This thesis did not look into the effect of the Quality Summit and the report, and exploring their impact is worth pursuing in the future. Regarding the duration of the effect, potential differences between the counterfactual and the observed level 12 months following an inspection was tested; however, it is not clear if an inspection can trigger improvements that are sustainable for one year or if those changes are due to other interventions. A process evaluation could help clarify these uncertainties and increase confidence in the estimations of effect.

The findings could also be explained by a statistical phenomenon produced by the point chosen for the interruption. Since to a certain degree, the quality measures selected vary randomly, the segmented regression could have artificially created changes to levels or trends not linked to the implementation of improvements, therefore, making them spurious. Since the changes were small and generally non-significant, performing a sensitivity analysis did not seem justified.

10.2.3 Potential risks of bias

Other events occurring during or around the inspection and which may change the behaviour of NHS trusts and the outcomes measured can produce history bias. One measure taken against this bias was the use of a switching-replication design (Shadish et al., 2002), where intervention points are spread over time. However, during the observation period, at least three historical events occurred that could have influenced the findings. Although they

affected all trusts, the relevance of these events relies on its potential to prevent or be synergetic to the effect of CQC inspections.

Firstly, austerity measures were imposed in June 2010, constraining the NHS budget substantially, particularly towards the end of the time series. This might have affected trusts' ability to maintain safe staffing levels during high demand periods and implement any new quality improvement initiatives. Secondly, the Health and Social Care Act 2012 was fully implemented in April 2013, changing the commissioning structure of the NHS in England. Although only 17 (11%) of the inspections occurred before this date, a reform of this magnitude could have had repercussions several months after its implementation. Any learning effect could effectively plateau, but it is not possible to predict for how long and to what extent the reform could have affected hospitals' performance. Thirdly, there were high profile quality improvement initiatives contemporaneous to the time series (Keogh, 2013, National Advisory Group on the Safety of Patients in England, 2013). All these external factors could have produced a change in managerial and clinical priorities and behaviours that would explain the limited effect detected, without being a direct effect of CQC inspections.

Another potential threat to the validity of the results is that the selection of trusts for the new regime of CQC inspections was not random and significant differences were detected. Trusts selected in the first round of new regime inspections were more likely to be in special measures, have a "poor" or "significant concerns" reporting culture rating and less likely to have Foundation Trust status. Hence, changes to trend in this group could be explained by regression to the mean, modification of reporting behaviour or the regulatory intervention to which they were subjected. The analyses performed in a subsample of acute trusts matched by these three features showed similar patterns, thus increasing the confidence in the reported estimates.

Two other phenomena could modify the effect of CQC inspections: spillover effects and complementary interventions. The spillover effect refers to the impact of an intervention on other measures or groups that were not initially targeted. In this thesis, trusts not inspected and those inspected under the old regime could have modified their behaviour in response to the pressure of being the next in line to receive a new regime inspection. Another potential spillover may occur in relation to quality indicators, where implemented quality improvements initiatives could beneficially impact measures not assessed by this regime. This was one of the arguments to include falls with harm and pressure ulcers as care quality measures; however, the quality of these data affects the validity of these findings (see section 10.2.1).

Complementary interventions are those that affect the same indicators being studied, are implemented in parallel and can have a synergetic effect. For example, interventions promoted by NHS England (e.g. how to improve flow and demand), NHS Improvement (e.g. stop the pressure), foundations (e.g. the point of care patient's experience programme) and institutes (e.g. pursuing perfection of the Institute for Healthcare Improvement) could be responsible for improvements observed without being associated with a CQC inspection. A process evaluation of the implementation of the new regime of inspection could have helped tease out how many of the changes are due to spillover or complementary interventions and how many are attributable to CQC visits; however, this was beyond the scope of this thesis.

10.3 Policy implications and unanswered questions

Four models of quality governance with various degrees of effectiveness have been used in combination throughout the history of the NHS in order to direct efforts for improvement: trust and altruism, choice and competition, targets and terror, and naming and shaming (see Chapter 3). During the review of the NHS services commissioned by Lord Darzi (2008), the findings of three independent organisations emphasised that the way reform was approached had some negative consequences. The constant change had produced organisational instability and interim leadership, targets had driven a culture of compliance and fear of sanctions, there was a divide between clinical professionals and managers, and expectations about commissioning as a driver for improvement were unrealistic (Ham, 2014b). The recommendations of these reports (Institute for Healthcare Improvement, 2008, McGlynn et al., 2008, Joint Commission International, 2008) and other experts (Ham, 2009b) were to engage clinicians on any type of reform, and to invest in fostering and increasing staff capabilities for quality improvement, whilst encouraging a culture of learning.

The current model of quality governance in the NHS, the "inspection state", assumes that board members have the skills and capacity to influence staff behaviour, and in that way, drive improvements and ensure compliance with external standards (Mannion et al., 2015). Another assumption is that the system has enough data about quality of care for allowing regulators, commissioners, and providers to monitor performance.

Although the National Health Service collects information for several national audits on a regular basis, and every acute trust reports a standard set of indicators, the data collected do not always meet the requirement for supporting improvement. For example, clinical staff deem data gathered to respond to regulatory requests of great value, but they suggest there should be a national dataset of performance allowing comparison at the trust, speciality, and clinician levels to enable improvements in clinical care (NHS Confederation, 2013). Another

issue identified was timeliness of information, since trusts receive collated data months after the initial request. Therefore, a shorter turnaround time would increase the value of existing information (NHS Confederation, 2013). Additionally, for clinicians and patients the information available is not easy to access or understand, which hinders its potential impact on quality of care (ibid).

Given these issues, the following are suggested: a single standardised platform where each NHS providers can upload information; the definition of a minimum set of quality indicators that every provider should report; and investment in improving the reliability and validity of regularly collected data. These suggestions could reduce the regulatory burden for providers since regulators could extract information from the aforementioned platform instead of requesting data for monitoring and inspection purposes. Real-time data paired with trained clinicians and senior managers would allow the identification of potential areas for improvement, enabling the creation of action plans to remedy any issue. Moreover, better information systems would impact commissioning, since CCGs could compare the performance of all providers in an area and establish realistic targets for the delivery of services and improvements in quality of care. Finally, the publication of ranked quality performance data has the potential to drive improvements by increasing competition among providers due to reputational threats (Hibbard et al., 2003).

The CQC has the ability to monitor performance and apply enforcement measures to non-compliant trusts. In a sense, constant scrutiny of hospitals' activities and outcomes is already in place, which reinforces the idea that on-site visits could be reduced. The role of the CQC should be to exert a constant pressure on providers so they maintain a minimal standard of care continuously (i.e. quality assurance role), which in the long term could reduce the preparatory burden. In addition, the maintenance of those systems could lead to improvements of care quality over time (i.e. quality improvement role). The oversight strategy of NHS Improvement as financial regulator points to "reducing the reporting burden in order to allow providers to focus on improving quality and efficiency" (NHS Improvement, 2016b). Moreover, since June 2017, the CQC (again) changed the approach to inspections to make them less burdensome. These two examples illustrate the current efforts to improve the use of resources in regulation. The results suggest that the pressure or expectation of a future on-site inspection(s) may influence acute trust behaviour, but this does not lead to positive lasting changes. There may be more efficient uses of NHS resources than the current intensive inspection regime: the appropriate 'dose' of inspection in terms of maximising the efficiency of scrutiny that hospitals receive is unknown.

Bevan and Hood (2006b) suggest that telling institutions exactly how and when their performance will be measured is similar to an open invitation to game the monitoring system (Bevan and Hood, 2006b). Therefore, adding some randomness to oversight (with an associated evaluation) could increase certainty that the observed performance is a fair reflection of real performance.

Over time, there have been several attempts to improve the external oversight system within the NHS: different types of rating systems have been employed, different risk stratification methods used, and a myriad of approaches to on-site visits considered. However, dissonance from everyday work in hospitals remains and with it, a limited ability to influence improvement (NHS Providers, 2017). Strategies that could lead to more effective regulatory schemes include risk stratification tools for prioritising the inspection of worse performers, proportional inspection methods that focus on care areas requiring more attention and the ability to use enforcement actions of differing strengths. The CQC has all these instruments at its disposal, but instead of making the inspection regime more effective, it has turned it into something that is overly burdensome (Limb, 2016).

Oversight institutions have been in use for nearly 20 years within the NHS, each has been criticised and consequently replaced with ever more complex solutions; each promising to remedy the ills of past structures and institutions. If increasing regulation has not paid off, perhaps, it may be time to reduce the administrative burden of the inspections and institutions that prevail. Improving data systems and joint inspections of several regulators (e.g. CQC, NHS Improvement and PLACE assessments), could help reduce the burden of regulation.

One question that remains unanswered relates to identifying the mechanisms explaining how and when inspections work. This could be informed by a realist process evaluation, first exploring the underlying medium level theories that could help understand how inspections work, and then, evaluating the process of preparing for the inspections and what happens afterwards in a selected sample of acute trusts, thus reflecting different contextual factors.

10.4 Conclusion

The findings of this thesis suggest that neither the announcement of or inspections by CQC of acute hospitals are associated with changes in the seven measures of care quality selected. Even when some statistical differences were found, the magnitude of these indicates that they are unlikely to be clinically significant. The patterns observed are more likely to be related to other phenomena such as a lagged effect of austerity measures rather than the intervention of the CQC.

The main contribution of this thesis is as the first rigorous, quantitative assessment of the contribution of external inspections to the quality of care provided by acute hospitals in England. Although such inspections were not associated with improvements in the seven measures selected, this evidence will help build a body of literature to inform future decision-making. It remains unclear, however, if regulation can prevent poor care.

Future research should renew the focus on understanding when, how and why some institutions respond to external inspections, in order to maximise the potential effectiveness of these interventions.

Appendices

Appendix Chapter 2

Table 2.1 Quotes referring to quality in key NHS policy documents from 1948 to 2012

Policy document	Structure	Process	Output	Outcome
Health and social care act 2012	"In discharging the duty under subsection (1) the Secretary of State must, in particular, act with a view to securing continuous improvement in the outcomes that are achieved from the provision of the services. The outcomes relevant for the purposes of subsection (2) include, in particular, outcomes which show— (a) the effectiveness of the services, (b) the safety of the services, and (c) The quality of the experience undergone by patients. (Part 1, section 2 and 3) In paragraph 14R, these same duties must be exercise by clinical commissioning groups "[objectives of trust special administration] (3) The criterion is that ceasing to provide the service under this Act would, in the absence of alternative arrangements for its provision under this Act, be likely to— (a) have a significant adverse impact on the health of persons in need of	"(4) In carrying out the duty under subsection (2) or (3) (standardisation of the specifications of health services), the Board and Monitor must have regard to whether, or to what extent, standardisation is likely to have a significant adverse impact on the provision of health care services for the purposes of the NHS". (section 119) "(1) In exercising its functions NICE must have regard to— (a) the broad balance between the benefits and costs of the provision of health services or of social care in England, (b) the degree of need of persons for health services or social care in England, and (c) The desirability of promoting innovation in the provision of health services or of social care in England." (section 233)	"For the purpose of determining whether to make a payment under subsection (1) and (if so) the amount of the payment, the Board must take into account at least one of the following factors— (a) the quality of relevant services provided during the financial year; (b) any improvement in the quality of relevant services provided during that year (in comparison to [...] previous financial years); (c) the outcomes identified during the financial year as having been achieved from the provision at any time of relevant services; (d) Any improvement in the outcomes identified during that financial year as having been so achieved (in comparison to [...] previous financial years)". (Section 223K, paragraph 2)	"(1) The Board must conduct a performance assessment of each clinical commissioning group in respect of each financial year. (2) A performance assessment is an assessment of how well the clinical commissioning group has discharged its functions during that year. (3) The assessment must, in particular, include an assessment of how well the group has discharged: - Duty as to improvement of quality of services - Duty in relation to quality of primary medical services - Duty as to reducing inequalities - Public involvement and consultation by clinical commissioning groups - Financial duties of clinical commissioning groups: expenditure and use of resources". (Section 14Z16) "(3) In this section a “quality indicator” means a factor by

Policy document	Structure	Process	Output	Outcome
	the service or significantly increase health inequalities, or (b) Cause a failure to prevent or ameliorate either a significant adverse impact on the health of such persons or a significant increase in health inequalities". (section 175, paragraph 3) "Each clinical commissioning group must, in the exercise of its functions, have regard to the need to— (a) reduce inequalities between patients with respect to their ability to access health services, and (b) Reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services". (Section 14T) "The Secretary of State must specify in the mandate— (a) the objectives [...] the Board should seek to achieve in the exercise of its functions [...], and (b) Any requirements that the Secretary of State considers it necessary to impose on the Board for the purpose of ensuring that it	[Referring to the Professional standards authority]"(3) If the Authority is satisfied that a voluntary register meets the accreditation criteria, it may accredit the register. (4) The Authority may carry out periodic reviews of the operation of registers accredited under this section for the purpose of stablishing whether they continue to meet the accreditation criteria. (5) If, on a review under subsection (4), the Authority is satisfied that a voluntary register no longer meets the accreditation criteria, the Authority may remove or suspend, or impose conditions on, the accreditation of the register. (6) The Authority may refuse to accredit a register, or to continue to accredit a register, unless the person who maintains the register pays a fee of such amount as the Authority may determine. (7) The Authority must publish such accreditation criteria as it sets." (section 229, subsection 25G) "(1) The Authority has the following functions—		reference to which performance in the provision of services or care can be measured." (section 268) "The Board must establish and operate systems for collecting and analysing information relating to the safety of the services provided by the health service". (section 13R, paragraph 1) "The Board must give advice and guidance, to such persons as it considers appropriate, for the purpose of maintaining and improving the safety of the services provided by the health service (subsection 4). The Board must monitor the effectiveness of the advice and guidance given by it under subsection (4)". (section 13R, subsection 4-5) "(4) Subsection (5) applies if, having given a notice under subsection (1), the Secretary of State is satisfied that— (a) the bodies concerned have breached or are continuing to

Policy document	Structure	Process	Output	Outcome
	achieves those objectives". Chapter A1, section 13A) "(2) The responsible local authority and each of its partner clinical commissioning groups must prepare a strategy for meeting the needs included in the assessment by the exercise of functions of the authority, the National Health Service Commissioning Board or the clinical commissioning groups ("a joint health and wellbeing strategy")." (Section 193) "(b) where it concludes that any of the matters specified in the reference operate, or may be expected to operate, against the public interest, must specify in the report the effects adverse to the public interest which those matters have or may be expected to have, and (c) Where it concludes that any adverse effects so specified could be remedied or prevented by changes in relation to the matters specified in the reference, must specify in the report changes which could remedy	(a) to promote the interests of users of health care, users of social care in England, users of social work services in England and other members of the public in relation to the performance of voluntary registration functions, (b) to promote best practice in the performance of voluntary registration functions, and (c) To formulate principles of good governance in the performance of voluntary registration functions and to encourage persons who maintain or operate accredited voluntary registers to conform to those principles." (Section 229, subsection 25I) "(1) The relevant commissioner (NHS Board or Secretary of State) may direct NICE to prepare statements of standards in relation to the provision of— (a) NHS services, (b) public health services, or (c) social care in England. (2) In this Part such a statement is referred to as a "quality standard"." (section 234)		breach the duty or, the risk of a breach having materialised, are breaching the duty, and (b) The breach is having a detrimental effect on the performance of the health service (or, where the effect of the breach on the performance of the health service is both beneficial and detrimental, its overall effect is detrimental). (5) The Secretary of State may by order prohibit each body from exercising specified functions or from exercising specified functions in a specified manner, unless the other body concerned agrees in writing that the body may do so." (section 291)

Policy document	Structure	Process	Output	Outcome
	or prevent those effects." (schedule 10 section 6) "(1) Regulations may impose requirements on the National Health Service Commissioning Board and clinical commissioning groups for the purpose of securing that, in commissioning health care services for the purposes of the NHS, they— (a) adhere to good practice in relation to procurement; (b) protect and promote the right of patients to make choices with respect to treatment or other health care services provided for the purposes of the NHS; (c) Do not engage in anti-competitive behaviour which is against the interests of people who use such services". (Section 75) "The Board must make arrangements to secure that individuals to whom the services are being or may be provided are involved (whether by being consulted or provided with information or in other ways)—	"(1) Regulations may confer functions on NICE in relation to the giving of advice or guidance, provision of information or making of recommendations about any matter concerning or connected with the provision of— (a) NHS services, (b) public health services, or (c) social care in England." (section 237) "(5) The regulations may make provision about—(a) the persons who may request or require [functions of NICE], (b) the publication or other dissemination of [functions of NICE] (c) the imposition by NICE of charges for or in connection with [its functions]." (section 237) "(1) The main duty of Monitor in exercising its functions is to protect and promote the interests of people who use health care services by promoting provision of health care services which— (a) is economic, efficient and effective, and (b) Maintains or improves the		

Policy document	Structure	Process	Output	Outcome
	(a) in the planning of the commissioning arrangements by the Board, (b) in the development and consideration of proposals by the Board for changes in the commissioning arrangements where the implementation of the proposals would have an impact on the manner in which the services are delivered to the individuals or the range of health services available to them, and (c) In decisions of the Board affecting the operation of the commissioning arrangements where the implementation of the decisions would (if made) have such an impact. (section 13Q, paragraph 1-2) "Each clinical commissioning group must, in the exercise of its functions, act with a view to enabling patients to make choices with respect to aspects of health services provided to them". (Section 14V) "10A The general duties of the council of governors are— (a) to hold the non-executive directors individually and collectively	quality of the services". (section 62) "(1) The Commission has the following functions in relation to the processing of relevant information— (a) to monitor the practice followed by registered persons in relation to such processing, and (b) To keep the National Health Service Commissioning Board and Monitor informed about the practice being followed by registered persons in relation to such processing. (2) The Commission must, in exercising those functions, seek to improve the practice followed by registered persons in relation to the processing of relevant information". (section 280)		

Policy document	Structure	Process	Output	Outcome
	to account for the performance of the board of directors, and (b) To represent the interests of the members of the corporation as a whole and the interests of the public." (section 151, paragraph 4) "(5) The function in this subsection is to provide the persons mentioned in subsection (6) with information and advice on— (a) the views of people who use health or social care services and of other members of the public on their needs for and experiences of health and social care services, and (b) The views of Local Healthwatch organisations and of other persons on the standard of provision of health and social care services and on whether or how the standard could or should be improved." (section 45A, subsection 5) "(3) Each local authority may make such other arrangements as it considers appropriate for the provision of services in relation to its area providing assistance to individuals in connection with			

Policy document	Structure	Process	Output	Outcome
	complaints relating to the provision of services as part of the health service." (section 185) "(1) Monitor must publish guidance about— (a) compliance with requirements imposed by regulations under section 75; (b) How it intends to exercise powers conferred on it by regulations under that section". (section 78) "Monitor must exercise its functions with a view to enabling health care services provided by the purposes of the NHS to be provided in an integrated way and the provision of health care services is integrated with the provision of health related services or social care services where it considers that this would— (a) improve the quality of the health services (including the outcomes that are achieved from the provision of those services), (b) reduce inequalities between persons with respect to their ability to access those services, or			

Policy document	Structure	Process	Output	Outcome
	(c) Reduce inequalities between persons with respect to the outcomes achieved for them by the provision of those services". (section 62, paragraphs 4-5) The Board must exercise its functions with a view to securing that the health services are provided in an integrated way and the provision of health services is integrated with the provision of health related services or social care services where it considers that this would— (a) improve the quality of the health services (including the outcomes that are achieved from the provision of those services), (b) reduce inequalities between persons with respect to their ability to access those services, or (c) Reduce inequalities between persons with respect to the outcomes achieved for them by the provision of those services. (section 13N, paragraphs 1-2) "(1) A Health and Wellbeing Board must, for the purpose of advancing the health and wellbeing of the			

Policy document	Structure	Process	Output	Outcome
	people in its area, encourage persons who arrange for the provision of any health or social care services in that area to work in an integrated manner." (Section 195)			
High quality care for all 2008	The NHS is as much a social movement as a health service. That is why it is so vital to secure its founding principles and set out the rights and responsibilities of patients, public and staff. An NHS that gives patients and the public more information and choice, works in partnership and has quality of care at its heart. The NHS is there when we need it most. It provides round the clock, compassionate care and comfort. It plays a vital role in ensuring that as many of us as possible can enjoy good health for as long as possible – one of the things that matters most to us and to our family and friends. They were delivered by the dedication and hard work of NHS staff who were determined to improve services for patients and the public.	Over the last 10 years we have improved the basic standards of the NHS. If the challenge 10 years ago was capacity, the challenge today is to drive improvements in the quality of care. We need a more personalised NHS, responsive to each of us as individuals, focused on prevention, better equipped to keep us healthy and capable of giving us real control and real choices over our care and our lives. My team's conversations about quality take place in weekly multidisciplinary meetings rather than in corridors. Together, these changes have meant real improvements for patients. In developing the visions, the NHS has had to face up to significant variations in the quality of care that is provided.	Developing new best practice tariffs focused on areas for improvement. These will pay for best practice rather than average cost, meaning NHS organisations will need to improve to keep up. High quality work is not simply a matter of a good deal for staff and for patients. It is also essential to meeting the productivity challenge: high quality workplaces make best use of the talents of their people, ensuring that their skills are up to date, and their efforts never wasted. The public rightly expect their taxes to be put to best use. For those working in the NHS there is a need to reduce unnecessary bureaucracy, freeing up their time to care for patients, within the resources available. Creating high quality workplaces requires great leadership and good management.	Outcomes have improved as a result: 238,000 lives have been saved in the last 11 years as a result of significant improvements in cancer and heart disease survival rates in particular. NHS South West, for example, has set a goal of matching the longest life expectancy in Europe. From no later than 2010, payments will reward outcomes under the scheme.

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	My career is dedicated to improving continuously the quality of care we provide for patients. This is what inspires me and my professional colleagues, and it has been the guiding principle for this Review. We need to continue the NHS journey of improvements and move from an NHS that has rightly focused on increasing the quantity of care to one that focuses on improving the quality of care. The NHS in the 21st century faces a particular set of challenges, which I would summarise as: rising expectations; demand driven by demographics; the continuing development of our 'information society'; advances in treatments; the changing nature of disease; and changing expectations of the health workplace. These are challenges we cannot avoid. The NHS should anticipate and respond to the challenges of the future. People want a greater degree of control and influence over their health and healthcare. If anything, this is even more important for those who for a variety of reasons find it	Tackling this will be our first priority. The NHS needs to be flexible to respond to the needs of local communities, but people need to be confident that standards are high across the board. Delivering the visions will mean tackling head on those variations in the quality of care and giving patients more information and choice. The message they send is that the programme of reform that has been put in place has been unevenly applied and can go much further. The vision this report sets out is of an NHS that gives patients and the public more information and choice, works in partnership and has quality of care at its heart – quality defined as clinically effective, personal and safe. It will see the NHS deliver high quality care for all users of services in all aspects, not just some. We will raise standards. The visions set out for each NHS region and formed by patients' expectations are ambitious for what the NHS can achieve.	Providing greater choice of GP will mean developing fairer rewards for practices that provide responsive services and attract more patients. Funding will be freed up through reducing the tariff uplift from 2009 to give commissioners dedicated space to pay for improved outcomes. Providers will be rewarded in the first year for submitting data.	

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	harder to seek out services or make themselves heard. Personalising services means making services fi t for everyone's needs, not just those of the people who make the loudest demands. When they need it, all patients want care that is personal to them. The NHS has a responsibility to promote good health as well as tackle illness. Achieving this goal requires the NHS to work in partnership with the many other agencies that also seek to promote health. Much progress on closer working has been made in recent years. In line with my terms of reference, this report focuses on what the NHS can do to improve the prevention of ill health. That includes those people traditionally less likely to seek help or who find themselves discriminated against in some way. The visions published in each NHS region make clear that more support is needed for all people to help them stay healthy and particularly to improve the health of those most in need.	Getting the basics right first time, every time. We will continue to seek improvements in safety and reductions in healthcare associated infections. The Care Quality Commission will have new enforcement powers. There will be national campaigns to make care even safer. • Independent quality standards and clinical priority setting. NICE will be expanded to set and approve more independent quality standards. A new National Quality Board will offer transparent advice to Ministers on what the priorities should be for clinical standard setting by NICE. • For the first time we will systematically measure and publish information about the quality of care from the frontline up. Measures will include patients' own views on the success of their treatment and the quality of their experiences. There will also be measures of safety and clinical outcomes. All registered healthcare providers working for, or on behalf of, the NHS will be required by law to publish 'Quality Accounts' just as they publish financial accounts.		

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	Every primary care trust will commission comprehensive wellbeing and prevention services, in partnership with local authorities, with the services offered personalised to meet the specific needs of their local populations. Our efforts must be focused on six key goals: tackling obesity, reducing alcohol harm, treating drug addiction, reducing smoking rates, improving sexual health and improving mental health. • A Coalition for Better Health, with a set of new voluntary agreements between the Government, private and third sector organisations on actions to improve health outcomes. Focused initially on combatting obesity, the Coalition will be based on agreements to ensure healthier food, to get more people more physically active, and to encourage companies to invest more in the health of their workforce. We will give patients more rights and control over their own health and care. I have heard the need to give patients more information and choice to make the system more responsive to their personal needs.	Making funding for hospitals that treat NHS patients reflect the quality of care that patients receive. For the first time, patients' own assessments of the success of their treatment and the quality of their experiences will have a direct impact on the way hospitals are funded. For senior doctors, the current Clinical Excellence Awards Scheme will be strengthened, to reinforce quality improvement. New awards, and the renewal of existing awards, will become more conditional on clinical activity and quality indicators; and the Scheme will encourage and support clinical leadership of service delivery and innovation. Easy access for NHS staff to information about high quality care. All NHS staff will have access to a new NHS Evidence service where they will be able to get, through a single web-based portal, authoritative clinical and non-clinical evidence and best practice. Measures to ensure continuous improvement in the quality of		

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	High quality care should be as safe and effective as possible, with patients treated with compassion, dignity and respect. As well as clinical quality and safety, quality means care that is personal to each individual. As independent research has shown, the NHS has made good progress over the past decade in improving the overall quality of care for patients. During this period, improvements in quality were focused primarily on waiting times, as basic acceptable standards of access to A&E and secondary care were established, and on staffing levels and physical infrastructure. As this Review has shown, change is most likely to be effective if it is led by clinicians. We will do this by ensuring that: • Medical directors and quality boards feature at regional and national level. These will complement the arrangements at PCT level that are developing as part of the World Class Commissioning programme. • Strategic plans for delivering the visions will be published later this	primary and community care. We have just completed our consultation on proposals to bring all GP practices and dental practices within the scope of the new health and adult social care regulator, the Care Quality Commission. We will foster a pioneering NHS. Throughout my career, in all the clinical teams I have worked in, my colleagues and I have challenged one another to improve the way we provide care for patients. Continuous advances in clinical practice mean the NHS constantly has the opportunity to improve. My review will enable this through: • Introducing new responsibilities, funds and prizes to support and reward innovation. Strategic health authorities will have a new legal duty to promote innovation. New funds and prizes will be available to the local NHS. We will value the work of NHS staff. NHS staff make the difference where it matters most and we have an obligation to patients and the		

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	year by every primary care trust. Change will be based on the five principles I set out earlier this year in Leading Local Change. I have seen that, where change is led by clinicians and based on evidence of improved quality of care, staff who work in the NHS are energised by it and patients and the public more likely to support it. We will empower frontline staff to lead change that improves quality of care for patients. We will provide more integrated services for patients, by piloting new integrated care organisations, bringing together health and social care professionals from a range of organisations – community services, hospitals, local authorities and others, depending on local needs. Enhancing professionalism. There will be investment in new programmes of clinical and board leadership, with clinicians encouraged to be practitioners, partners and leaders in the NHS. We challenge all organisations that do business as part of, or with, the NHS to give clinicians more control over budgets and HR	public to enable them to make best use of their talents. An NHS Constitution will help patients by setting out, for the first time, the extensive set of legal rights they already have in relation to the NHS. It will ensure that decision-making is local where possible and more accountable than it is today, providing clarity and transparency about who takes what decisions on our behalf. The focus on prevention, improved quality and innovation will support the NHS in its drive to ensure the best possible value for money for taxpayers. It is also an excellent opportunity to pursue our duties to promote equality and reduce discrimination under the Equality and Human Rights Act. it must constantly respond to those it serves, changing to continue to live up to the ambition of high quality care. The NHS should be universal, but that does not mean		

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	decisions. Over the past few months, each region of the NHS has published its vision for improving health and healthcare services. These visions are the product of the work more than 2,000 clinicians and other staff in health and social care, who have shown tremendous leadership in creating, shaping and forming the conclusions. In each region, they have met in eight or more groups reflecting different 'pathways of care' – from maternity and newborn care through to end of life care. These groups have considered the best available clinical evidence, worked in partnership with thousands of patients, listened to the needs and aspirations of the public and set out comprehensive and coherent visions for the future. The proposals will allow NHS services everywhere to reflect the needs of their local communities. People and communities across England have different characteristics and different needs. Yet too often, the services they receive are not sufficiently shaped around those characteristics	that it should be uniform. Clear minimum standards and entitlements will exist, but not a one size fits all model. These visions are the start of responding to local needs. They describe an NHS that will work with partner organisations locally to reach out and help people stay healthy, and, when people do need care, provide convenient, high quality care. Services will be found in the community, with family doctors, pharmacies and local partnerships taking a leading role in helping people to stay healthy. In future, the NHS will not be confined to hospitals, health centres or GP surgeries but will be available online and in people's homes, whilst the most specialist care will be concentrated to allow excellence to flourish. The visions have sent a powerful message that the most effective treatments should be available for all NHS patients. Their plans for transforming treatment for heart attack, stroke and major trauma vividly illustrate this. For stroke –		

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	and needs. There is a clear consensus across the service that the NHS must help people to lead independent and fulfilling lives by supporting them to stay healthy. The local NHS wants to work with others to help people stop smoking, to address obesity in children and adults, and to tackle excessive alcohol consumption. In the East of England, for example, patients, the public and staff have set themselves the ambition of reducing the number of smokers in their region by 140,000, from its current level of a million. Each region will continue to improve the quality of access by reducing waiting times for treatment, whilst ensuring that services are available regardless of where a patient lives. All the visions emphasised the need to organise care around the individual, meeting their needs not just clinically, but also in terms of dignity and respect. This report addresses big national themes such as improving quality,	the third largest cause of death and single largest cause of disability in the UK – the clinical evidence clearly demonstrates that the quality of care is greatly improved if stroke is treated in specialist centres. Each region is therefore pushing forward with the development of specialised centres for their populations with access to 24/7 brain imaging and thrombolysis delivered by expert teams. From the vision documents, and from my own visits to every region of the country, the message that improving quality of care is what excites and energises NHS staff has been loud and clear. International evidence shows that we have made great improvements but that there is further to go. Nolte and McKee have found that the NHS made a 21 per cent reduction in premature mortality rates from 1997–98 to 2002–03, compared to a 4 per cent reduction by the US. However, there is much more to do, as our starting point was worse than our international comparators.		

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	leadership and the workforce.25 It focuses on what must be done centrally to support local organisations. It illustrates that the role of the Department of Health is to enable the visions created by the local NHS to become a reality, whilst ensuring that universality, minimum standards and entitlements are retained and strengthened. It sets out how we will back local leaders to deliver for their communities. The drivers for change in healthcare and society are beyond the control of any single organisation. Nor can they be dealt with simply or reactively at national level. This reinforces the case for enabling and encouraging the NHS locally to anticipate and respond proactively to the challenges of the future. The children of the last three decades of the 20th century. These generations are influenced by new technologies that provide unprecedented levels of control, personalisation and connection. They expect not just services that are there when they need them, and treat them how they want them to,	Every region of the NHS has articulated its aspiration for high quality care for their populations. Using clinical expertise, NHS East Midlands will publish standard quality measures allowing patients to compare the performance of different providers. Health practitioners will see a generation with expectations of more tailored treatment received at a time and place convenient to them. As people continue to live longer, they will continue to access services for longer, and are likely to live more of their life with one or more long-term condition. They will make demands that are not just larger but different. They still expect the clinician to lead, but expect a bigger role for themselves in decision-making during their care. It is easier to access information on how to stay healthy than ever before. People are able to quickly and conveniently find information about treatment and diseases in a		

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	but that they can influence and shape for themselves. Better still, they will want services that 'instinctively' respond to them using the sophisticated marketing techniques used by other sectors. The NHS and all of its many partners must respond to this shifting disease burden and provide personalised care for long-term conditions, a goal already set out in the Government's Our health, our care, our say White Paper. We need to make this goal a reality. Providing personalised care should also help us to reduce health inequalities, as the households with the lowest incomes are most likely to contain a member with a long-term condition. Improved technology is enabling patients that would once have been hospitalised to live fulfilling lives in the community, supported by their family doctor and multi-professional community teams. Where patients were once confined to hospital, Wireless and Bluetooth technologies allow their health to be monitored in their own homes. This information helps to prevent	way that was previously impossible. They are able, and want, to engage with others online, sharing information and experiences. They want to do their own research, reflect on what their clinicians have told them and discuss issues from an informed position. The challenge is ensuring that people are able to access reliable information. Evidence shows that clinicians have sometimes been slower in exploiting the potential of new information sources, such as the internet, than others. Healthcare itself is on a journey where the emphasis of care is shifting to extending wellness and improving health. This is making healthcare more complex, with a broader range of interventions possible. In some areas of practice, such as for acute coronary syndrome, this has led to increased standardisation where the evidence shows that following protocols leads to better outcomes		

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	unnecessary hospital admissions. This is better for patients and their carers, delivers improved outcomes, and is a very efficient way of using NHS resources. An even bigger factor in the shift from hospital to home is the up-skilling of a wider range of staff, and the removal of barriers to more independent working in the patient's interest. Healthcare professionals expect the depth of their expertise to be recognised and rewarded, and their skills to be developed and enhanced. They seek personal fulfilment as well as financial reward. They understand the demands of accountability and welcome transparency as a route to achieving true meritocracy. Staff expect a better work/life balance and more respect and regard for pressures on their time beyond those of their profession. The extra capacity in the NHS today gives all of us the opportunity to focus on improving quality. To achieve that we need to: -Help people to stay healthy. -Empower patients.	High quality care is safe, meaning no avoidable healthcare associated infections. This is obviously better for patients and also reduces the need for costly post-infection recovery in hospital. Finally, high quality care involves giving the patient more control over their care, including information to make healthy choices, which will reduce their chances of poor health and dependency on the NHS. The answer to the challenges the NHS faces is therefore to focus on improving the quality of care it provides. This Review is about achieving the highest quality of care for patients and the public. I have heard from patients and staff, and I know from my own experience, that when in the care of the NHS, it is the quality of that care that really matters. People want to know they will receive effective treatment. They want care that is personal to them, and to be shown compassion, dignity and respect by those caring for them. People want to be reassured that they will be safe in		

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	-Provide the most effective treatments. -Keep patients as safe as possible. Locally, the NHS and local authorities are working closely together to improve health and wellbeing, prompted by their legal duty to co-operate in improving outcomes for their populations. It highlighted the rapidly rising risks to long-term health if people are not supported sufficiently early to address issues that stop them from working, with back problems and mental ill health among the most significant. From next year, we will introduce integrated Fit for Work services in primary and community care, bringing together access to musculoskeletal services and psychological therapies for example. This will help people get the support they need to return to appropriate work faster. People referred for secondary or hospital-based care can now choose freely where they receive their treatment. And increasingly, there is better information available for patients about outcomes of care such	the care of the NHS. And whilst most people recognise their health is their responsibility, they also look to the NHS for help. The strategy will describe a vision for primary and community care that builds on these strengths and raises our ambitions. It will focus on making services personal and responsive to all, promoting healthy lives and striving to improve the quality of care provided. Care planning creates packages of care that are personal to the patient. It involves working with professionals who really understand their needs, to agree goals, the services chosen, and how and where to access them. First, we will make payments to hospitals conditional on the quality of care given to patients as well as the volume. A range of quality measures covering safety (including cleanliness and infection rates), clinical outcomes, patient experience and patient's views		

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	as the information at GP-practice level from the Quality and Outcomes Framework. Patients empowered in this way are more likely to take greater responsibility for their own health, and to dedicate their own time, effort and energy to solving their health problems. This partnership is especially important for those with long-term conditions and their carers. We must therefore continue to empower patients with greater choice, better information, and more control and influence. Choice gives patients the power they need in the system, as NHS resources follows patients in the choices they make. Where patients find it difficult to express preferences, it is the role of staff to take steps to ensure that patients can benefit from greater choice. We believe that choice should become a defining feature of the service. A health service without freedom of choice is not personalised. So the right to choice will now be part of the NHS Constitution, ensuring that people become more clearly aware of it.	about the success of their treatment (known as patient reported outcome measures or PROMs) will be used. Whilst all primary care trusts have a legal duty to fund drugs that have been positively appraised by NICE, we recognise that patients and the public are concerned that there remains unexplained variation in the way local decisions are made on the funding of new drugs before the appraisal takes place, or where no guidance is issued. We will take steps to end this so called 'postcode lottery' for new drugs and treatments. Through the NHS Constitution we will make explicit the right of NHS patients everywhere to positively NICE appraised drugs and treatments, where their doctor judges that these would be of benefit. • Quality of care includes quality of caring. This means how personal care is – the compassion, dignity and respect with which patients are treated. It can only be improved by		

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	We want patients to make the right choices for themselves and their families. So we will empower them to make informed choices. The first step towards this vision was taken with the launch of the NHS Choices website, with a variety of limited quality information (such as Healthcare Commission ratings and MRSA rates at an organisation level). The next stage is to empower patients with clear information on the quality of each service offered by every NHS organisation – across all settings of care. The information will be on every aspect of high quality care – on safety such as cleanliness and infection rates, on experiences such as satisfaction, dignity and respect, and on measures of outcomes that include patients' views on the success of treatments. During the Review, patients have told us that they need better information and more help to understand how to access the best care, especially urgent care, when they need it. People need to know the risks and	analysing and understanding patient satisfaction with their own experiences. • Effectiveness of care. This means understanding success rates from different treatments for different conditions. Assessing this will include clinical measures such as mortality or survival rates, complication rates and measures of clinical improvement. Just as important is the effectiveness of care from the patient's own perspective which will be measured through patient-reported outcomes measures (PROMs). • Bring clarity to quality. This means being clear about what high quality care looks like in all specialties and reflecting this in a coherent approach to the setting of standards. • Measure quality. In order to work out how to improve we need to measure and understand exactly what we do. The NHS needs a quality measurement framework at every level. • Publish quality performance. Making data on how well we are doing widely available to staff, patients and the public will help us		

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	have the opportunity to take control of their own healthcare. To help with this, the Department of Health will publish a new Patients' Prospectus by the end of this year to provide patients with long-term conditions the information they need about the choices which should be available to them locally and to enable them to self-care in partnership with health and social care professionals. Enabling increasing numbers of patients to securely see and suggest corrections to a summary of their care records, to receive personalised information about staying healthy, and to upload the results of health checks for their clinician(s) to see. We will increase the influence that patients have over NHS resources. For hospitals, resources already follow the choices that patients make through the Payment by Results system. We will strengthen this by reflecting quality in the payment mechanism and increasing individual control. Give individual patients greater control over the services they receive and the providers from which they	understand variation and best practice and focus on improvement. • Recognise and reward quality. The system should recognise and reward improvement in the quality of care and service. This means ensuring that the right incentives are in place to support quality improvement. • Raise standards. Quality is improved by empowered patients and empowered professionals. There must be a stronger role for clinical leadership and management throughout the NHS. • Safeguard quality. Patients and the public need to be reassured that the NHS everywhere is providing high quality care. Regulation – of professions and of services – has a key role to play in ensuring this is the case. • Stay ahead. New treatments are constantly redefining what high quality care looks like. We must support innovation to foster a pioneering NHS. If everyone, from the hospital Chief Executive to the GP receptionist is primarily focussed on achieving high		

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	receive services Partnership working between the NHS, local authorities and social care partners will help to improve people's health and wellbeing, by organising services around patients, and not people around services. This will lead to a patient-centred and seamless approach. Continuously improving patient safety should be at the top of the healthcare agenda for the 21st century. The injunction to 'do no harm' is one of the defining principles of the clinical professions, and as my Interim Report made clear, safety must be paramount for the NHS. Public trust in the NHS is conditional on our ability to keep patients safe when they are in our care. High quality care is care where patients are in control, have effective access to treatment, are safe and where illnesses are not just treated, but prevented. These are manifestations of high quality care – there is much more to be done to place quality right at the heart of the NHS.	quality care for patients, we will have succeeded. Central initiatives, from fostering innovation to encouraging quality reporting can play their part. However, ultimately if high quality care is to become more than an ideal, we need to free the local NHS to concentrate on quality. We seek to change that not by central control, but by freeing NHS staff and organisations to make the right decisions. Therefore, we will extend and improve existing reforms such as NHS foundation trusts and practice-based commissioning. Through these changes, healthcare professionals will be not just practitioners, but partners and leaders.		

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	If quality is to be at the heart of everything we do, it must be understood from the perspective of patients. Patients pay regard both to clinical outcomes and their experience of the service. They understand that not all treatments are perfect, but they do not accept that the organisation of their care should put them at risk. For these reasons, the Review has found that for the NHS, quality should include Patient safety. Providing high quality care leads to professional pride, and focusing on improving it energises and motivates all NHS staff, clinical and non-clinical alike. I believe we can use that energy and make the achievement of high quality of care an obsession within the NHS. Healthcare is delivered by a team. The team includes clinicians, managerial staff and those in supporting roles. All members of the team are valued. The sense of a shared endeavour – that all of us matter and stand together – was crucial in the inception of the NHS.			

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	We will continue the journey of setting frontline staff, both providers and commissioners, free to use their expertise, creativity and skill to find innovative ways to improve quality of care for patients. • Creating a new accountability. Setting NHS staff free from central control requires a new, stronger accountability that is rooted in the people that the NHS is there to serve. It means the service should look out to patients and the communities they serve not up the line. • Empowering staff. Professionals need to be empowered to make the daily decisions that improve quality of care and we will enable this to happen. • Fostering leadership for quality. All these steps together create the right environment for high quality care to happen, but we need to further develop clinical and managerial leadership.			
A first class service- quality in the new NHS 1998	"High quality care should be a right for every patient in the NHS. […] . Such a National Health Service should guarantee fair access and high quality to patients wherever they live". (paragraph 1.1)	"There are unacceptable variations in performance and practice. The inequalities go beyond the provision of medicines and other treatments. There are inequalities in the way that some proven treatments get introduced to the NHS too slowly	"As a result of participation in national comparative clinical audit, individual hospital doctors will be able to compare their own performance with national averages". (paragraph 3.14)	"The Government will ensure there is accountability for both efficiency and quality throughout the NHS" (paragraph 1.8).

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	"Improving the quality and consistency of NHS services is an important part of improving the overall health of the population and tackling inequalities in both health and access to care". (paragraph 2.2) "Quicker access to services will be brought by reducing hospital waiting lists" (paragraph 1.9) "We will introduce a clinical governance framework that: •modernises and strengthens professional self-regulation and builds on the principles of performance review • strengthens existing systems for quality control, based on clinical standards, evidence based practice and learning the lessons of poor performance". (paragraph 3.11) "Clinical governance will be the process by which each part of the NHS quality assures its clinical decisions. Backed by a new statutory duty of quality it will introduce a	while other unproven treatments can be introduced too quickly. There are inequalities in waiting times for operations; in the time it takes for patients to receive test results; in the number of people given screening tests. There are inequalities in clinical practice – and in clinical outcomes". (paragraph 1.6) "National Service Frameworks will set standards to achieve greater consistency in the availability and quality of services for a range of major care areas and disease groups. The clear aim will be to reduce unacceptable variations in care and standards of treatment, using the best evidence of clinical and cost-effectiveness" (p. 34) "The commission has an important role in working to reduce variations in services across the NHS through its systematic reviews of services, providing feedback into the National Service Frameworks, and its monitoring of uptake if NICE guidance". (p. 66)		"Quicker access to services will be brought by reducing hospital waiting lists" (paragraph 1.9) "National Service Frameworks will include performance measures against which progress will be assessed" (paragraph 2.38) "Strengthening the way in which we assess the performance of the NHS, using measures that are relevant to the standards of care delivered and by making public information on clinical quality". (paragraph 4.2) "Performance Framework [...] focusing on six main areas: • health improvement • fair access to services • effective delivery of appropriate healthcare • efficiency • patient and carer experience and • health outcomes of NHS care". (paragraph 4.49) "The Performance Framework will

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	system of continuous improvement into the operation of the whole NHS". (paragraph 1.16) "We need consistent action locally to ensure that national standards and guidance are reflected in the delivery of services. That action will be guided by a single, robust framework – a new system of clinical governance – to monitor health care quality at a local level. This will be backed up by lifelong learning by staff, through rigorous professional self-regulation and through a new system of external monitoring". (paragraph 3.1) "Clinical governance needs to be underpinned by a culture that values lifelong learning and recognises the key part it plays in improving quality". (paragraph 3.28) "There is much excellent work on which to draw, but too often it is fragmented in its approach and dependent on the enthusiasm of individuals rather than the commitment of whole organisations	"Each National Service Framework will set out where care is best provided and the standard of care that patients should be offered in each setting". (paragraph 2.35) "National Service Frameworks will bring together the best evidence of clinical and cost- effectiveness with the views of service users to determine the best ways of providing particular services". (p. 30) "The NHS has a duty to make the best use of resources and to deliver good value for money. But true value for money includes an assessment of quality and outcomes as well as quantity and cost". (paragraph 4.48) "There is a view that high quality care costs more money. But this fails to recognise that poor quality is itself costly. Operations that need to be re-done, patients who need to		support the drive for higher quality standards by ensuring that performance assessment is focused on the delivery of effective, appropriate and timely health services which meet local needs". (paragraph 4.50) "Each patient is different and treatment must be tailor-made to their specific needs". (paragraph 1.11) "The National Survey of Patient and User Experience will ask those who use the services for their views about clinical quality". (paragraph 1.17) "Introducing a new National Survey of Patient and User Experience to provide systematic and comparable information on patient and user experiences". (paragraph 4.2) "Service failure, from the patient's viewpoint, could trigger a

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	or whole health systems. We want to keep and build on what works, on existing good practice, but most of all on the experience and commitment of NHS staff". (paragraph 5.4) "The point has been made repeatedly to us that achieving meaningful and sustainable quality improvements in the NHS requires a fundamental shift in culture, to focus effort where it is needed and to enable and empower those who work in the NHS to improve quality locally. One of the key challenges is to engage health organisations wholeheartedly, from top to bottom, in developing and delivering a common agenda for quality improvement". (paragraph 5.6) "We want to create a culture in the NHS which celebrates and encourages success and innovation. But this must also be a culture which recognises that if the NHS is to have the confidence to strive for quality there must be scope for acknowledging and learning from past mistakes". (paragraph 5.7)	be re-admitted within weeks or months, infections picked up on wards, unnecessary or inappropriate treatments, complaints and litigation might all be reduced with higher quality care". (paragraph 5.10) "In a National Health Service there must be a guarantee of excellence for all patients". (paragraph 1.5) "Modern professional self-regulation, for example, will play a fuller part in the early identification of possible lapses in clinical quality". (paragraph 1.16) "Doctors with results that fall short of these norms will need to take urgent action to improve their results. Where the outcome has unacceptable mortality or complications, it might be necessary for the clinician to stop performing the procedure. Fellow professionals could provide extra training, supervision and support to correct what had been going wrong. In		Commission investigation". (paragraph 4.35) "We will ask patients about the issues which really matter to them, such as the ease of access to services, how long they have to wait for treatment, and whether they are happy with the quality of information provided about their care. We want to explore patients' views of the efficiency of the medical and technical aspects of their care. We also want to cover areas such as the privacy and dignity of their care, especially with regard to mixed sex accommodation in hospital, as well as the courtesy and helpfulness of staff". (paragraph 4.60) "The NHS Executive Regional Offices will lead in overseeing the implementation of local clinical governance arrangements. The Commission will complement and strengthen these mechanisms, by providing a further external and independent check on local arrangements". (paragraph 4.1)

Policy document	Structure	Process	Output	Outcome
	"There are some crucial elements which are needed to drive change forward: -Excellent leadership: A clear commitment and involvement from the top. Trust Boards and Chief Executives must sign up to the need for change and drive it forward through the whole organisation. Strong leadership is needed by, and from, both clinicians and managers -Involvement of staff: Total involvement of staff in shaping services and planning change, with open communication and collaboration, is one of the best ways in which the NHS can improve patient care -Involvement of patients: Patients provide a uniquely valuable perspective on services, and it is impossible to get the best from a change process without actively involving them". (paragraph 5.21)	appropriate circumstances, the General Medical Council would be involved". (paragraph 3.15) "[Patients] need to be assured that their treatment is up to date and effective, and that it is provided by those whose skills have kept pace with new thinking and new techniques. Where individual health professionals fail to meet the standards set by their profession, when things go wrong, people expect matters to be openly investigated, explanations provided and, where appropriate, action taken to prevent similar problems". (paragraph 3.29) "If the Commission discovers or suspects that there are problems with the performance of individual clinicians, it will refer these to the appropriate professional regulatory body (for example, the General Medical Council) for it to take action". (paragraph 4.31) "The objective is to ensure fair		"Health professionals need to be able to assess the care they give against established clinical standards. This can be done through clinical audit, which allows them to look at what they are doing against agreed standards and, where necessary, make changes to practice". (paragraph 2.18) "Clinical audit involves systematically looking at the procedures used for diagnosis, care and treatment, examining how associated resources are used and investigating the effect care gas on the outcome and quality of life for the patient. Audit is a valuable tool to improve quality of professional care and, ultimately, patient choice" (p. 26)

Policy document	Structure	Process	Output	Outcome
		access to effective, prompt high quality care wherever a patient is treated in the NHS. The Government's intention is to ensure clear national standards for services. These will be supported by consistent, evidence-based guidance to raise quality standards in the NHS". (paragraph 1.10) "Involves setting clear national standards but with responsibility for delivery being taken locally and being backed by consistent monitoring arrangements". (paragraph 1.14) "NICE will produce clear guidance for clinicians about which treatments work best for which patients. It will assess new drugs, treatments and devices for their clinical and cost-effectiveness". (paragraph 1.15) "NICE will reduce duplication of this activity and maximise the use of the academic and professional expertise needed to produce		

Policy document	Structure	Process	Output	Outcome
		credible guidance". (paragraph 2.11) "The Commission for Health Improvement will provide an independent means of guaranteeing quality throughout the NHS. Through a rolling programme of reviews of Trusts and the ability to investigate when things are going wrong [...]. It will have the power to intervene at the Government's request, in a hospital where clinical problems have been identified" (paragraph 1.17) "The Performance Framework will judge how well each part of the NHS is doing to deliver quality services". (ibid) "Establishing a new statutory body, the Commission for Health Improvement, to provide independent scrutiny of local efforts to improve quality and to help address any serious problems". (paragraph 4.2)		

Policy document	Structure	Process	Output	Outcome
		"Recent tragedies demonstrate all too clearly the necessity for supplementing a hospital's internal processes with independent, external, review of clinical quality by the Commission". (paragraph 4.12) "The Commission's reports will not just be about identifying areas for improvement, but will also provide a way of identifying and acknowledging success and good practice, and encouraging its dissemination". (paragraph 4.13) "These components will come together to help assure quality, improve equity of access and tackle unacceptable variations in services. They will support local services in working to improve the quality of services for patients". (paragraph 5.2) "There may be cases where there is an unacceptable delay in putting		

Policy document	Structure	Process	Output	Outcome
		serious problems right, or a persistent failure to act. In such cases, the Secretary of State for Health will be able to ask the Commission to investigate the problem and make recommendations for rapid action. This will usually happen only where there are very serious concerns about the quality of clinical services". (paragraph 4.29)		
The new NHS-modern, dependable 1997	0	"The new Commission will offer an independent guarantee that local systems to monitor, assure and improve clinical quality are in place. It will support local development and 'spot-check' the new arrangements. It will also have the capacity to offer targeted support on request to local organisations facing specific clinical problems" (paragraph 7.13) When performance is not up to the standards, there will be an investigation and if necessary, an intervention: -the NHS executive regional office could be called by the health authority, when an NHS trusts is not delivering according to the health	0	"A new national performance framework, measuring how local services are progressing against their targets, will help shape NHS services to meet the challenge". (paragraph 8.2) "... for the first time in the history of the NHS there will be systematic evidence to enable the health service to measure itself against the aspirations and experience of its users, to compare performance across the country and to look at trends over time. The survey will give patients and their carers a voice in shaping the modern and dependable NHS". (paragraph 8.10)

Policy document	Structure	Process	Output	Outcome
		improvement programme. The regional office can investigate the issue. Also, CHI could be called to investigate on the problem. Primary care groups can change terms of service agreements when a NHS trusts is underperforming. The secretary of State could remove the NHS board (Paragraph 6.2)		
Promoting better health 1987	The committee (on social services) and the government are at one in their firm commitment to [...] continuing to develop comprehensive care of a high standard, available and accessible to all. (paragraph 1.20) "The government will review its minimum standard for premises. FPCs and HBs will continue to be responsible for the inspection of premises, and will be required to apply sanctions […] in respect of inadequate premises" (paragraph 3.51) "Effective team working requires willingness amongst all the team members to co-operate and communicate well, and to adopt a flexible approach which puts the	"… There are wide variations in standards across the country (in FPS), particularly, in inner cities, where too many, often elderly, doctors are operating single-handed practices where group practices would be more effective" (paragraph 3.6). Several factors related to "considerable variations in the quality of general medical services": population served is different in terms of age structure, medical and social needs; standard of premises is often poor; use and development of practice teams is variable; medical services need to be adapted to ethnic minorities sometimes. "The government intends to raise standards nearer to those of the	1.17…"the new financial incentives for doctors and the stronger management role for FPCs and HBs will encourage doctors to provide better service, thus creating a more competitive environment which will itself have the effect of raising standards further." The Government approves the development of private practice, because it serves as an alternative and a comparator of NHS services. Moreover, this would offer more choice to consumers and drive improvement through competition.	"The government sees advantage in practices submitting annual reports to FPCs and HBs about the range of services offered and the workload undertaken in the period of question. This should encourage doctors to focus more clearly on the provision of high-quality, patient-oriented services and the need to plan and set objectives for their development and improvement" (paragraph 3.65) "Monitoring performance: output measures and performance indicators for the Family Practitioner Services will be developed to assist FPCs in their management of these services". The annual reports would help FPCs to monitor the level and quality of services provided (paragraph 10.10)

Policy document	Structure	Process	Output	Outcome
	quality of health provision to the population served above professional status and function" (paragraph 7.9)	best practices" (paragraph 3.6). "Family doctors remuneration system should be develop in order to recognise high standards quite explicitly, probably through the introduction of a 'good practice allowance'. this will be linked to: personal availability to patients; provision of wide range of services, including prevention; ensuring certain services had been provided for an agreed proportion of patients; attendance at recognised post-graduate course" (paragraph 3.22) "Many of the improvements set out earlier (basic practice allowance, compulsory retirement, allowances linked to immunization and health promotion) will not only improve the quality of service to the public but also raise cost-effectiveness" (paragraph 3.59) "…the government has provided resources directly for monitoring the quality and appropriateness of treatment provided and to		1.17…"the consumer will be much better informed about the services offered by local practices and will be able to choose the one that best suits his or her needs". 2.6 "the Government is prepared to invest substantial extra resources in FPS to develop positive health promotion activities, raise standards and make the services more sensitive to the need so the consumer"

Policy document	Structure	Process	Output	Outcome
		encourage continuing education through: - the dental reference services, which routinely examine a sample of patients to ensure that all necessary treatment has been provided and to the proper standard; - the dental estimates boards, which monitor the treatment dentists provide; - funds for dentists' postgraduate training" (paragraph 4.25) FPCs should use independent medical advisers to encourage good practice in the referral of patients to hospital (paragraph 3.62)		
Griffiths report 1983	"They (managers) are concerned with levels of service, quality of product, meeting budgets, cost improvement, productivity, motivating and rewarding staff, research and development, and the long term viability of the undertaking" (general observations, paragraph 1). "Rarely are precise management objectives set; there is little measurement of health output; clinical evaluation of particular	"policy for performance appraisal and career development operates, from the Unit to the centre, to meet both the aspirations of staff and the management needs of the service" (paragraph 9.3)	This approach should prompt some measurement of output in terms of patient care, and should ensure that the time at present spent by doctors in meetings, committees, etc., will be reduced and employed more purposefully. (paragraph 8.2)	The role of the Health Services Supervisory Board would be to strengthen existing arrangements for the oversight of the NHS. It would be concerned with: a. determination of purpose, objectives and direction for the Health Service; b. approval of the overall budget and resource allocations; c. strategic decisions; d. receiving reports on performance and other evaluations from within the Health Service.

Policy document	Structure	Process	Output	Outcome
	practices is by no means common and economic evaluation of those practices extremely rare" (paragraph 2). "Ascertain how well the service is being delivered at local level by obtaining the experience and perceptions of patients and the community" (paragraph 13.1). "The driving force behind our advice is the concern to secure the best deal for patients and the community health within available resources; the best value for the taxpayer; and the best motivation for staff". (general observations, paragraph 3) "Sufficient management impression must be created at all levels that the centre is passionately concerned with the quality of care and delivery of services at local level" (recommendations, paragraph 12). "The most important development to be achieved is one of morale and			

Policy document	Structure	Process	Output	Outcome
	attitudes: this will be done by the line management leadership and the perceived professional competence of the Personnel Director and an injection of enthusiasm and pride in the quality of personnel service provided". (personnel, paragraph 24)			
NHS reorganisation act 1973	"the rights of members of Councils to enter and inspect premises controlled by Area Health Authorities" (paragraph 9 subsection 4)	Commissioner may investigate- (a) an alleged failure in a service provided by a relevant body ; or (b) an alleged failure of a relevant body to provide a service which it was a function of the body to provide ; or (c) any other action taken by or on behalf of a relevant body, in a case where a complaint is duly made by or on behalf of any person that he has sustained injustice or hardship in consequence of the failure or in consequence of maladministration connected with the other action. (Paragraph 34 subsection 3). Paragraph 35 refers to patients' complaints about a service	0	0
Cogwheel report 1968	"recommendations for changes which the Working Party believes would lead to considerable improvement in the organisation and therefore in the overall quality of clinical work in hospitals"	Clinical practice and opinion differ in a variety of situations are the treatment of varicose veins and after-care in meniscectomy; tonsillectomy; and fenestration. (paragraph 51)	0	“Medical advisory committees could valuably undertake periodic discussion of a systematic review and statistical analysis of the clinical work of all departments in the hospital, thus helping to maintain a high standard" (Paragraph 24).

Policy document	Structure	Process	Output	Outcome
				"If the results of the work of all departments were regularly reviewed and where practicable subjected to statistical analysis and brought before the full committee at its periodical meetings, discussion of the results would, in the Minister's view, assist all the staff in achieving and maintaining a high standard of clinical work". (appendix 2)
Porritt report 1962	It proposes the unification, under one administrative body, of services under supervision of executive councils, personal health services, public health services and school health services.	0	0	0
Guillebaud committee 1956	0	"If the test of “adequacy” were that the Service should be able to meet every demand which is justifiable on medical grounds, then the Service is clearly inadequate now, and very considerable additional expenditure (both capital and current) would be required to make it so" (paragraph 94)	"The rise in the cost of the Service between 1948 and 1954, when expressed in real terms (i.e., at constant prices), was quite small; while many of the services provided were substantially expanded during this period". (Paragraph 110).	0
Collings survey on general practice 1950	"In most cases, waiting rooms are too small, cold, and generally inhospitable"	0	0	0

Policy document	Structure	Process	Output	Outcome
	"Consulting rooms vary greatly in size and furnishing" With better organisation, the same volume of work could be handled at a higher level and adequate safety and comfort to the patient "Causes unnecessary inconvenience; expense, and sometimes danger to patients who have to travel to the nearest hospital".			
NHS act 1946	Comprehensive health service to secure improvement of physical and mental health, and the prevention, diagnosis and treatment of illness" "to provide or secure effective provision of services"	A tribunal, for the purpose of inquiring into cases presented by the executive council or any other person that continued inclusion of an independent contractor would be prejudicial to the efficiency of the services in question. (part IV, paragraph 42, pag 39)	0	0
National Health Service 1944	The government wanted to ensure provision of treatment and care for all matters related to health within the best facilities available, regardless ability to pay with the aim "to reduce ill-health and promoting good health in all its citizens"	"Double purpose of bringing to notice defects of organisation or management and, what is equally important, of enabling individual hospitals to be kept in touch with the latest practice and ideas."	0	0

Policy document	Structure	Process	Output	Outcome
	"that their getting these [best treatment] shall not depend on whether they can pay for them, or on any other factor irrelevant to the real need" "Reform in this field is not a matter of making good what is bad, but of making better what is good already"			
Beveridge report 1942	A National Health Service will provide medical treatment for all citizens (Paragraph 19, section xi)	0	0	0

Appendix Chapter 3

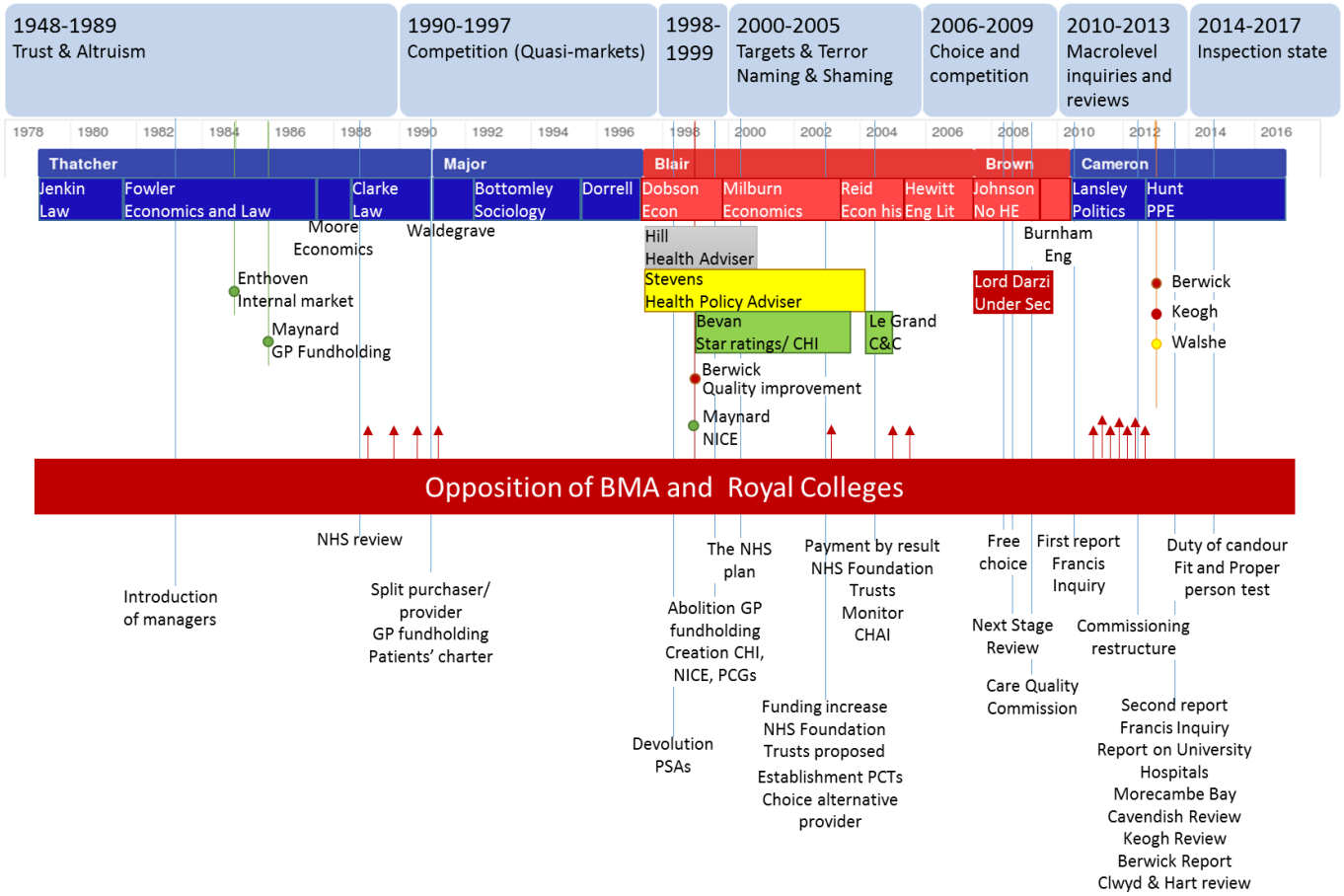

Figure 3.1 Timeline of Prime ministers, Health secretaries, main proponents of reforms and key changes in the last 40 years of the NHS.

Key: Blue-Conservative/Coalition government. Red-Labour government. Grey-Background on education. Yellow- Background on management. Green- Background on Economics. Dark Red- Background on Medicine

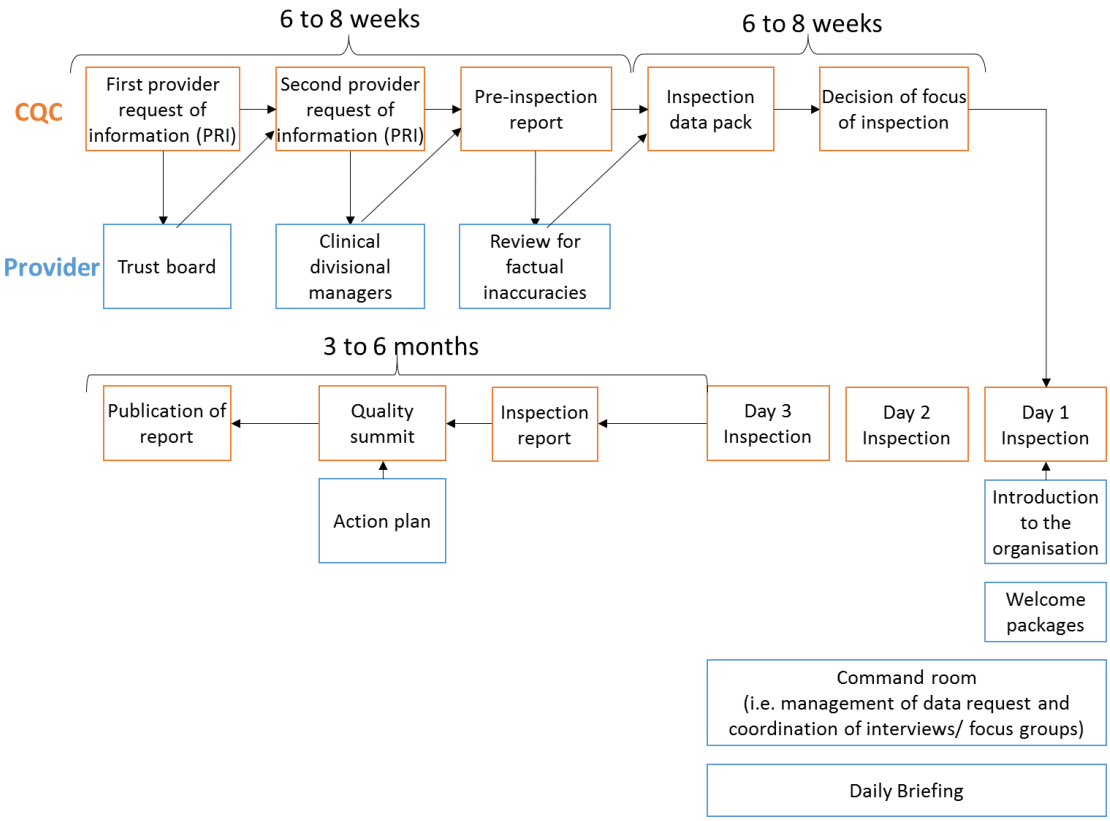

Figure 3.2 Scheme of a CQC comprehensive inspection of acute NHS trusts

Appendix Chapter 4

4.1 Search Strategies

The Cochrane Library, Issue 7, July 2015 (CDSR, DARE, CENTRAL)

1 MeSH descriptor: [Health Facilities] explode all trees

2 (hospital or hospitals or (health near/2 care)):ti,ab

3 1 or 2

4 MeSH descriptor: [Peer Review, Health Care] this term only

5 MeSH descriptor: [Benchmarking] this term only

6 MeSH descriptor: [Accreditation] explode all trees

7 MeSH descriptor: [Management Audit] explode all trees

8 MeSH descriptor: [Clinical Audit] explode all trees

9 7 or 8

10 ("organisation* raid*" or "organization* raid*"):ti,ab

11 ((external* near/5 accreditation) or (external* near/5 accredited) or (external* near/5 peer review) or (external* near/5 inspection) or (external* near/5 inspected) or (external* near/5 regulation) or (external* near/5 regulated) or (external* near/5 certified) or (external* near/5 certification) or (external* near/5 benchmark*) or (external* near/5 measured) or (external* near/5 measurement) or (external* near/5 (audit or audits or auditing)) or (external* near/5 evaluation) or (external* near/5 evaluated) or (external* near/5 assessment) or (external* near/5 assessed) or (external* near/5 monitored) or (external* near/5 visitation) or (external* near/5 surveillance)):ti,ab

12 4 or 5 or 6 or 9 or 10 or 11

13 st.fs.

14 (standards or standard or performance or criterion or criteria or indicator* or "clinical competence" or compliance or "clinical improvement" or "quality improvement" or "organisation* development" or "organization* development" or "health care regulation"):ti,ab

15 13 or 14

16 3 and 13 and 15 - Publication Year from 2011 to 2015

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present

1 exp Health Facilities/

2 (hospital or hospitals or (health adj2 care)).tw.

3 or/1-2

4 Peer Review, Health Care/

5 Benchmarking/

6 exp Accreditation/

7 exp Management Audit/ or exp Clinical Audit/

8 (organi?ation$ adj raid$).tw.

9 (external$ adj5 (accreditation or accredited or peer review or inspection or inspected or regulation or regulated or certified or certification or benchmark$ or measured or measurement or evaluation or evaluated or audit or audits or auditing or assessment or assessed or monitored or visitation or surveillance or (control adj program$))).tw.

10 or/4-9

11 st.fs.

12 (standards or standard or performance or criterion or criteria or indicator$ or (clinical adj competence) or compliance or (clinical adj improvement) or (quality adj improvement) or (organi?ation$ adj development) or (health adj care adj regulation)).tw.

13 or/11-12

14 randomized controlled trial.pt.

15 random$.tw.

16 intervention$.tw.

17 control$.tw.

18 evaluat$.tw.

19 controlled before-after studies/ or interrupted time series analysis/

20 14 or 15 or 16 or 17 or 18 or 19

21 Animals/

22 Humans/

23 21 not (21 and 22)

24 20 not 23

25 3 and 10 and 13 and 24

26 "audit and feedback".mp.

27 25 not 26

28 limit 27 to yr="2011 -Current"

Embase 1974 to 2015 August 13

1 *health care facility/

2 (hospital or hospitals or (health adj2 care)).tw.

3 or/1-2

4 "peer review"/

5 Clinical audit/

6 (organi?ation$ adj raid$).tw.

7 (external$ adj5 (accreditation or accredited or peer review or inspection or inspected or regulation or regulated or certified or certification or audit or audits or auditing or benchmark$ or measured or measurement or evaluation or evaluated or assessment or assessed or monitored or visitation or surveillance or (control adj program$))).tw.

8 exp accreditation/

9 or/4-8

10 (standards or standard or performance or criterion or criteria or indicator$ or (clinical adj competence) or compliance or (clinical adj improvement) or (quality adj improvement) or (organi?ation$ adj development) or (health adj care adj regulation)).tw.

11 3 and 9 and 10

12 randomized controlled trial/

13 (randomised or randomized).tw.

14 experiment$.tw.

15 (time adj series).tw.

16 (pre test or pretest or post test or posttest).tw.

17 impact.tw.

18 intervention?.tw.

19 chang$.tw.

20 evaluat$.tw.

21 effect?.tw.

22 compar$.tw.

23 or/12-22

24 nonhuman/

25 23 not 24

26 11 and 25

27 limit 26 to yr="2011 -Current"

Web of Knowledge (SCI, SSCI, Conference Proceedings)

1 TS=(((external* SAME audit) or (external* SAME accreditation) or (external* SAME accredited) or (external* SAME peer review) or (external* SAME inspection) or (external* SAME inspected) or (external* SAME regulation) or (external* SAME regulated) or (external* SAME certified) or (external* SAME certification) or (external* SAME benchmark*) or (external* SAME measured) or (external* SAME measurement) or (external* SAME evaluation) or (external* SAME evaluated) or (external* SAME assessment) or (external* SAME assessed) or (external* SAME monitored) or (external* SAME visitation) or (external* SAME surveillance)))

2 TS=(standards or standard or performance or criterion or criteria or indicator* or "clinical competence" or compliance or "clinical improvement" or “quality improvement" or "organisation* development" or "organization* development" or "health care regulation")

3 TS=(randomi?ed or experiment* or impact* or intervention* or evaluat* or effect* or comparative or "time series")

4 TS=(random* SAME allocat*) or TS=(random* SAME assign*) or TS=(controlled SAME trial*) or TS=(controlled SAME study)

5 4 OR 3

6 TS=(hospital or hospitals or (health NEAR care))

7 6 AND 5 AND 2 AND 1 - Timespan=2011-2015

PsycINFO 2002 to February Week 4 2018

1 (randomi?ed or experiment* or impact* or intervention* or evaluat* or effect* or comparative or pre test or pretest or posttest or post test).tw.

2 ((time adj2 series) or (random* adj2 allocat*) or (random* adj2 assign*) or (controlled adj2 trial*) or (controlled adj2 study) or (clinical adj2 trial*) or (clinical adj2 study)).tw.

3 1 or 2

4 (hospital or hospitals or (health adj2 care)).tw.

5 Peer Evaluation/

6 Hospital Accreditation/

7 Clinical audits/

8 (organi?ation* adj raid*).tw.

9 (external$ adj5 (accreditation or accredited or peer review or inspection or inspected or regulation or regulated or certified or certification or benchmark$ or measured or measurement or evaluation or evaluated or assessment or assessed or audit or audits or auditing or monitored or visitation or surveillance or (control adj program$))).tw.

10 5 or 6 or 7 or 8 or 9

11 (standards or standard or performance or criterion or criteria or indicator$ or (clinical adj competence) or compliance or (clinical adj improvement) or (quality adj improvement) or (organi?ation* adj development) or (health adj care adj regulation)).tw.

12 4 and 10 and 11

13 3 and 12

14 limit 13 to yr="2011 -Current"

HMIC Health Management Information Consortium 1979 to January 2018

1 exp Health Services/

2 exp Health Buildings/

3 (hospital or hospitals or (health adj2 care)).tw.

4 1 or 2 or 3

5 Peer Review/

6 Benchmarking/

7 exp Accreditation/

8 exp Clinical audit/ or exp Management audit/

9 (organi?ation* adj raid*).tw.

10 (external$ adj5 (accreditation or accredited or peer review or inspection or inspected or regulation or regulated or certified or certification or benchmark$ or measured or measurement or evaluation or evaluated or assessment or assessed or audit or audits or auditing or monitored or visitation or surveillance or (control adj program$))).tw.

11 5 or 6 or 7 or 8 or 9 or 10

12 (standards or standard or performance or criterion or criteria or indicator$ or (clinical adj competence) or compliance or (clinical adj improvement) or (quality adj improvement) or (organi?ation* adj development) or (health adj care adj regulation)).tw.

13 4 and 11 and 12

14 (randomi?ed or experiment* or impact* or intervention* or evaluat* or effect* or comparative or pre test or pretest or posttest or post test).tw.

15 ((time adj2 series) or (random* adj2 allocat*) or (random* adj2 assign*) or (controlled adj2 trial*) or (controlled adj2 study) or (clinical adj2 trial*) or (clinical adj2 study)).tw.

16 14 or 15

17 13 and 16

18 limit 17 to yr="2011 -Current"

CINAHL Plus, EBSCO

S21 (S13 AND S20) OR (S17 AND S20)

S20 S18 OR S19

S19 TI (control* or random* or experiment or time series or impact or intervention? or evaluat* or effect?) or AB (control* or random* or experiment or time series or impact or intervention? or evaluat* or effect?)

S18 (MH “Clinical Trials+”) or (MH “Comparative Studies”) or (MH “Pretest-Posttest Design”) or (MH “Quasi-Experimental Studies+”)

S17 S14 OR S15 OR S16

S16 (MH “Quality Assurance+/ST”) or (MH “Clinical Indicators/ST”) or (MH “Clinical Competence+/ST”)

S15 (MH “Peer Review+/ST”) or (MH “Benchmarking/ST”) or (MH “Accreditation+/ST”)

S14 (MH “Outcome Assessment/ST”) or (MH “Process Assessment (Health Care)+/ST”)

S13 S3 AND S11 AND S12

S12 TI (standards or standard or performance or criterion or criteria or indicator* or “clinical competence” or compliance or “clinical improvement” or “quality improvement” or “organisation* development” or “organization* development” or “health care regulation”) or AB (standards or standard or performance or criterion or criteria or indicator* or “clinical competence” or compliance or “clinical improvement” or “quality improvement” or “organisation* development” or “organization* development” or “health care regulation”)

S11 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10

S10 TI ("care quality commission" or "commission for health care improvement" or "Commission for health care audit and inspection" or "healthcare commission") OR AB ("care quality commission" or "commission for health care improvement" or "Commission for health care audit and inspection" or "healthcare commission")

S9 TI ((external* N5 accreditation) or (external* N5 accredited) or (external* N5 peer review) or (external* N5 inspection) or (external* N5 inspected) or (external* N5 regulation) or (external* N5 regulated) or (external* N5 certified) or (external* N5 certification) or (external* N5 benchmark*) or (external* N5 measured) or (external* N5 measurement) or (external* N5 evaluation) or (external* N5 evaluated) or (external*N5 assessment) or (external* N5 assessed) or (external* N5 monitored or (external* N5 visitation) or (external* N5 surveillance) or (external* N5 audit) or (external* N5 audits) or (external* N5 auditing)) OR AB ((external* N5 accreditation) or (external* N5 accredited) or (external* N5 peer review) or (external* N5 inspection) or (external* N5 inspected) or (external* N5 regulation) or (external* N5 regulated) or (external* N5 certified) or (external* N5 certification) or (external* N5 benchmark*) or (external* N5 measured) or (external* N5 measurement) or (external* N5 evaluation) or

(external* N5 evaluated) or (external* N5 assessment) or (external* N5 assessed) or (external* N5 monitored) or (external* N5 visitation) or (external* N5 surveillance) or (external* N5 audit) or (external* N5 audits) or (external* N5 auditing))

S8 TI (organization* raid* or organisation* raid*) or AB (organization* raid* or organisation* raid*)

S7 (MH "Nursing Audit")

S6 (MH "Accreditation+")

S5 (MH "Benchmarking")

S4 (MH "Peer Review")

S3 (S1 OR S2)

S2 TI (hospital or hospitals or (health N2 care)) or AB (hospital or hospitals or (health N2 care))

S1 (MH “Health Facilities+”)

Table 4.1 Primary studies according to pairwise comparisons of interventions

	Accredited institutions	After accreditation	High performance in accreditation
Non-accredited institutions	Sekimoto et al. (2008), Weeks et al. (2007), Casey et al. (2006), Salmon et al. (2003), Duckett (1983), Simons et al. (2002), Suñol et al. (2009), Barker et al. (2002), Landon et al. (2006), Chandra et al. (2009), Pasquale et al. (2001), Lutfiyya et al. (2009), Quality assurance project (2005), Chen et al. (2003), Longo et al. (2007), Ross et al. (2008)		
Before accreditation		Piontek et al. (2003), Stradling et al. (2007), OPM evaluation team (2009)	
Low performance in accreditation			Williams et al. (2005)
Association quality measures and outcomes	Thornlow and Merwin (2009)		

Table 4.2 Individual primary studies included and their relationships with eligible systematic reviews

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
Salmon et al (2003)	Randomised controlled trial	x	x	x	x	x	x	x
Piontek et al (2003)	Interrupted time-series		x					x
OPM report (2009)	Interrupted time-series			x				
D'Aunno et al (2002)	Time-series study					x		
Williams et al (2005)	Time-series study						x	
Stradling et al (2007)	Time-series study		x			x		
Weeks et al (2007)	Time-series study					x		
Pollack et al (2008)	Time-series study				x			
Barker et al (2002)	Prospective Cohort				x	x	x	x
Quality Assurance Project (2005)	Prospective Cohort					x		
Duckett (1983)	Retrospective Cohort				x	x		
Pasquale et al (2001)	Retrospective Cohort				x			

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
Van Such et al (2006)	Retrospective Cohort						x	
Ross et al (2008)	Retrospective Cohort				x	x		
Silver et al (2004)	Before and after study with control						x	
Snyder et al (2005)	Before and after study with control						x	
Tan et al (2004)	Before and after study				x	x		
Frasco et al (2005)	Before and after study				x			
Juul et al (2005)	Before and after study				x	x		
Al Tehewy et al (2009)	Before and after study				x	x		
Hadley et al (1988)	Cross-sectional analytical				x	x	x	x
McGurrin et al (1991)	Cross-sectional analytical							x
Verstraete et al (1998)	Cross-sectional analytical					x		
Beaulieu et al (2002)	Cross-sectional analytical				x	x	x	x

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
Grachek (2002)	Cross-sectional analytical					x		
Simons et al (2002)	Cross-sectional analytical				x		x	x
Sierpinska et al (2002a, b ,c)	Cross-sectional analytical					x		
Bruneau et al (2003)*	Cross-sectional analytical					x		
Chen et al (2003)	Cross-sectional analytical				x		x	x
Peterson et al (2003)	Cross-sectional analytical						x	
Borenstein et al (2004)	Cross-sectional analytical						x	
Brown et al (2004)	Cross-sectional analytical				x			
Lau et al (2004)	Cross-sectional analytical					x		
Brannigan et al (2004)	Cross-sectional analytical					x		
Casey et al (2005)	Cross-sectional analytical					x		
Grasso et al (2005)	Cross-sectional analytical						x	
Lemark et al (2005)	Cross-sectional analytical					x		

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
Williams et al (2006)	Cross-sectional analytical						x	
Landon et al (2006)	Cross-sectional analytical					x		
Partha-Sarathy et al (2006)	Cross-sectional analytical				x			
Longo et al (2007)	Cross-sectional analytical					x		
Muñoz et al (2007)*	Cross-sectional analytical					x		
Niska et al (2007a,b)	Cross-sectional analytical					x		
Braun et al (2008)	Cross-sectional analytical					x		
Menachemi et al (2008)	Cross-sectional analytical				x	x		
Sekimoto et al (2008)	Cross-sectional analytical				x	x		
Chandra et al (2009)	Cross-sectional analytical				x	x		
Lutfiyya et al (2009)	Cross-sectional analytical					x		
Suñol et al (2009)	Cross-sectional analytical					x		
Thornlow and Merwin (2009)	Cross-sectional analytical		x					

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
Mazmanian et al (1993)	Cross-sectional study				x	x	x	
Fairbrother et al (2000)	Cross-sectional study					x		
Gough et al (2000)	Cross-sectional study					x		
Gross et al (2000)	Cross-sectional study						x	
Griffith et al (2002)	Cross-sectional study				x		x	x
Daucort et al (2003)	Cross-sectional study						x	
Government Audit Office (2004)	Cross-sectional study							x
Heuer (2004)	Cross-sectional study							x
Miller et al (2005)	Cross-sectional study				x		x	x
Bruneau et al (2006)*	Cross-sectional study					x		
Oh et al (2006)	Cross-sectional study				x			
Wells et al (2007)	Cross-sectional study				x	x		
Wineman et al (2007)	Cross-sectional study					x		

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
El-Jardali et al (2008)	Cross-sectional study					x		
Quimbo et al (2008)	Cross-sectional study				x			
Dédale (2009)*	Cross-sectional study					x		
Sheaham et al (1999)	Descriptive study						x	
Collopy et al (2000a)	Descriptive study						x	
Collopy et al (2000b)	Descriptive study						x	
Bukonda et al (2002)	Descriptive study				x	x		
ANAES (2003)*	Descriptive study					x		
Abdelmounène et al (2006)*	Descriptive study					x		
Gabriele et al (2006)	Descriptive study						x	
Office of Inspector General (1999)	Multi-methods study							x
Benson et al (2004)	Multi-methods study					x		x
Day et al (2004)	Multi-methods study							x

	Study design	Brubakk et al (2015) n=1	Greenfield et al (2012) n=4	Flodgren et al (2011, 2016) n=2	Alkhenizan and Shaw (2011) n=26	Matrix Knowledge Group (2010) n=56	Greenfield and Braithwaite (2008) n=23	Sutherland and Leatherman (2006) n=16
Douguet et al (2005)*	Multi-methods study					x		
Beaumont (2008)*	Multi-methods study					x		
Berthelier (2002)*	Qualitative study					x		
Grenade et al (2002)	Qualitative study					x		
Devers et al (2004)	Qualitative study							x
Pomey et al (2004)*	Qualitative study					x		
Pham et al (2006)	Qualitative study					x		
Doyle et al (2008)	Qualitative study					x		
Lancaster et al (2010)	Qualitative study					x		
Pomey et al (2010)	Qualitative study					x		
Scrivens (1995)	Book					x		

*Studies in French

Table 4.3 List of excluded reviews and reasons for exclusion

Excluded studies	Reasons for exclusion
Al-Awa et al, 2011	Lack of inclusion/exclusion criteria defined a priori.
Cerqueira, 2006	The search strategy is not replicable.
Hinchcliff et al, 2012	Meta-synthesis of themes commonly mentioned in healthcare accreditation research.
Kilsdonk et al, 2015	Focus on organisational processes during accreditation or peer-review.
Petit Dit Dariel and Regnaux, 2015	Accreditation programme assesses working environment for nurses, instead of process of care more generally.
Mumford et al, 2013	Search strategy is not replicable.
Ng et al, 2013	No relevant outcomes reported. SWOT (strengths, weaknesses, opportunities and threats) analysis of the literature on accreditation.
Nicklin, 2015	Lack of inclusion/exclusion criteria defined a priori.
Vist et al, 2014	Duplicate of Brubakk et al (2015) systematic review. Manuscript in Norwegian.

Table 4.4 Description of primary studies included in the seven reviews of the overview of reviews

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Salmon et al (2003)	Randomised controlled trial	18 hospitals	Acute hospitals in KwaZulu-Natal, South Africa	To assess the effects of an accreditation program on public hospitals' processes and outcomes in a developing country setting.	COHSASA accreditation process, which starts with a self-assessment against standards, then the implementation of a continuous quality improvement programme and the last phase is the audit to determine accreditation status	Hospitals in waiting list
Piontek et al (2003)	Interrupted time-series	7811 patients admitted with diagnosis of trauma	Level II trauma centre at a community hospital, USA	To compare the impact of trauma patient outcomes before and after Level II American College of Surgeons (ACS) verification was received in a not-for-profit community hospital.	Trauma patients admitted between March 1993 and November 2001. The centre was certified in July 1998	Coronary artery bypass graft surgery at the same hospital and trauma patients in a non-ACS hospital
OPM report (2009)	Interrupted time-series	168 acute trusts (2009)	Acute trusts in the English NHS, United Kingdom	To assess the effect of the external inspection of compliance with Code of practice on MRSA infection rates	5 quarters before external inspection by the Healthcare Commission	8 quarters after external inspection
D'Aunno et al (2002)	Time-series study	1988 (n=172), 1990 (n=140), 1995 (n=116), 2000 (n=150)	Outpatient methadone facilities, USA	To examine changes in the last 12 years on methadone doses provision and to identify factors associated with variation in programme performance.	Patient's ethnic group Ownership status Accreditation status Region	

Author	Outcomes	Level of analysis	Results
Salmon et al (2003)	Overall compliance with accreditation standards (28 service elements) Compliance with critical criteria (19 generic service elements) 8 quality indicators: Nurse perceptions of clinical quality, participation and teamwork Patient satisfaction Medication education Medical record accessibility and accuracy Medical record completeness Completeness of peri-operative notes Completeness and accuracy of ward stock medicine labelling Hospital sanitation	Patient level	Intervention group improved average overall compliance from 48 to 78%, control remained in 43%. The compliance with critical criteria in the intervention group improved from 38% to 76%, whilst for the control group there was no change (37% baseline vs 38% follow-up) Mean effect for each quality indicator: overall nurses' perception of care 6% (p<0.03) patients' satisfaction 2% (p=0.48) medication education 1.7% (p>0.05) Accessibility of medical records 3% (p>0.05) Discharge and admission record completeness 6% (p>0.05) Completeness peri-operative notes -1.9% (p>0.05) Medicine labelling 12% (p>0.05) Hospital sanitation -2.4% (p>0.05)
Piontek et al (2003)	Length of stay Mortality Total hospitalisation cost Intensive care unit cost Payment and key labour cost Ventilator use Prevalence of complication Readmission to the hospital within 31 days	Patient level	In the external control, length of stay (1.146 vs 1.340), cost (0.968 vs 1.167) and readmission (-0.015 vs 0.043) ratios (observed to expected) increased between pre-certification and post-certification period. Mortality remained similar. In the internal control, there were no differences in length of stay and mortality, but cost increased (0.755 vs 0.937). In the exposed group, length of stay (1.122 vs 1.014), mortality (-0.007 vs -0.019), cost (1.147 vs 1.097) and readmission (-0.046 vs -0.052) ratios decreased.
OPM report (2009)	MRSA infection rates	Trust level	Non-significant decrease, mean (CI) cases at 3 months 100 (-221 to 21.5)
D'Aunno et al (2002)	Accreditation status and % of patients receiving 40, 60 and 80mg/day of methadone	Patient level	Patients treated in JCAHO accredited units in 1988 were less likely to receive doses <40mg/day, <60mg/day and <80mg/day. The coefficients (95% CI) were -4.84 (-9.6 to -0.04; p=0.05), -4.8 (-9.7 to 0.09; p=0.05) and -4.5 (-8.6 to -0.3; p=0.04) for doses of 40, 60 and 80 mg/day, respectively. In 2000, the direction of the result remained constant, but the magnitude increased for <60mg/day and <80 mg/day, although for <40mg/day was no longer significant. The coefficients (95% CI) were -4.5 (-9.25 to 0.3; p=0.07), -10.45 (-18.6 to -2.31; p=0.01) and -12.75 (-21.9 to -3.6; p=0.01) for doses of 40, 60 and 80 mg/day, respectively.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Williams et al (2005)	Time-series study	3087 hospitals	JCAHO accredited acute care medical-surgical hospitals, USA	To examine JCAHO accredited hospitals' performance on 18 standardised indicators of quality of care for acute myocardial infarction, pneumonia and heart failure.	High level of performance on 18 indicators at baseline (Third quarter 2002)	Low level of performance at baseline
Stradling et al (2007)	Time-series study	1161 stroke admissions	Acute hospital, USA	To examine the effect of JCAHO stroke centre certification and related changes on delivery of stroke care at one institution	1.5 years after JCAHO stroke centre certification	2.5 years previous JCAHO certification

Author	Outcomes	Level of analysis	Results
Williams et al (2005)	18 standardised indicators of the quality of care: **Acute myocardial infarctio**n Aspirin within 24 hours after admission Aspirin prescribed at discharge ACE inhibitor prescribed at discharge for patients with left ventricular systolic dysfunction Smoking-cessation counselling or advice Beta-blocker within 24 hours after admission Beta-blocker prescribed at discharge Mean time from arrival to thrombolysis Mean time from arrival to PCI Inpatient death **Heart failure** Discharge instructions regarding medications, diet, weight, worsening of symptoms, follow-up, and activity Assessment of left ventricular function ACE inhibitor prescribed at discharge for patient with left ventricular systolic dysfunction Smoking-cessation counselling or advice **Pneumonia** Oxygenation assessment within 24 hours after admission Pneumococcal screening, vaccination, or both by discharge Blood cultures collected before initiation of antibiotic therapy Smoking-cessation counselling or advice Mean time from arrival to initial antibiotic administration	Patient Level	15 measures showed improvement over time. Absolute changes from 2002 to 2004 were: Acute myocardial infarction Aspirin at admission: 3%, p=0.002 Aspirin at discharge: 3%, p <0.001 ACE inhibitor for LV systolic dysfunction: 5%, p <0.001 Smoking cessation counselling: 19%, p <0.001 Beta-blocker at admission: 7%, p<0.001 Beta-blocker at discharge: 6%, p <0.001 Mean time to thrombolysis: -8 min, p=0.53 Mean time to PCI: -113 min, p <0.001 Inpatient death: -1%, p=0.58 Heart failure Discharge instructions: 26%, p<0.001 Assessment of LV function: 7%, p <0.001 ACE inhibitor for LV systolic dysfunction: 4%, p=0.005 Smoking-cessation counselling: 32%, p<0.001 Pneumonia Oxygenation assessment: 4%, p <0.001 Pneumococcal vaccination: 22%, p <0.001 Blood cultures: <1%, p= 0.31 Smoking-cessation counselling: 33%, p <0.001 Mean time to initiation of antibiotics: -39 min, p<0.001 The rate of improvement was greater for hospitals with a low level of performance at baseline compared to hospitals with an average and high level of performance in all measures, but time to thrombolysis.
Stradling et al (2007)	Stroke admission Deep vein thrombosis prophylaxis Lipid profile testing	Patient Level	The proportion of individuals receiving DVT prophylaxis (80% before vs 98% after, p<0.0001) and lipid profile testing (71% before vs 86% after, p<0.0001) increased, whilst admission rate remained similar after certification for patients with ischemic stroke. Admission rates for all types of stroke increased by 36% after certification (from 64 to 87 cases per quarter, p<0.005). Mainly driven by an increase in admission of patients with intracerebral haemorrhage (from 14 to 32 cases per quarter, p <0.0001).

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Weeks et al (2007)	Time-series study	3446 hospitals	Hospitals assessed by JCAHO and with information in AHA data set, USA	To examine the relationship between JCAHO accreditation status, scores and process of care and surgical outcomes	JCAHO accreditation	Non-accredited hospitals

Author	Outcomes	Level of analysis	Results
Weeks et al (2007)	**Acute Myocardial Infarction** ACE-I for left ventricular systolic dysfunction Aspirin at arrival Aspirin at discharge ß-blocker at arrival ß-blocker at discharge PTCA within 90 minutes of arrival Smoking cessation advice/counselling **Heart Failure** ACE-I for left ventricular systolic dysfunction Assessment of left ventricular function Discharge instructions Smoking cessation advice/counselling **Pneumonia** Blood culture before 1st antibiotic Initial antibiotic timing Oxygenation assessment Pneumococcal vaccination Smoking cessation advice/counselling **Mortality in 1999, 2000 and 2001 for** Abdominal aortic aneurysm repair Aortic valve replacement Coronary artery bypass graft Carotid endarterectomy Colectomy Cystectomy Esophagectomy Gastrectomy Lower extremity bypass Lung lobectomy Mitral valve replacement Nephrectomy Pancreatectomy Pneumonectomy	Patient level	Significant differences in level of performance (weighted mean) between JCAHO accredited and non-accredited hospitals for: aspirin at arrival (94.3 vs 93.5, p=0.02), aspirin at discharge (94.1 vs 92.9, p=0.01), assessment of left ventricular function (86.3 vs 82.3, p<0.001), initial antibiotic timing (69 vs 71.8, p<0.001) and oxygenation assessment (98.4 vs 97.7, p=0.003). Odds of death in 2001 comparing non-accredited vs accredited hospitals for Abdominal aortic aneurysm repair: 0.70 (0.60 – 0.83), p<0.001 Aortic valve replacement: 0.71 (0.62 – 0.81), p<0.001 Coronary artery bypass graft: 0.86 (0.81 – 0.91), p<0.001 Carotid endarterectomy: 0.87 (0.81 – 0.94), p<0.001 Colectomy: 0.87 (0.81 – 0.95), p<0.001 Cystectomy: 0.49 (0.33 – 0.72), p<0.001 Esophagectomy: 0.00 (0.00 – 0.23), p<0.001 Gastrectomy: 0.73 (0.52 – 1.01), p<0.05 Lower extremity bypass: 0.76 (0.69 – 0.84), p<0.001 Lung lobectomy: 0.49 (0.40 – 0.59), p<0.001 Mitral valve replacement: 0.46 (0.36 – 0.59), p<0.001 Nephrectomy: 0.97 (0.80 – 1.19) Pancreatectomy: 0.33 (0.16 – 0.66), p<0.001 Pneumonectomy: 0.66 (0.34 – 1.26)

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Pollack et al (2008)	Time-series study	1988 (n=172), 1990 (n=140), 1995 (n=116), 2000 (n=150), 2005 (n=146).	Outpatient methadone treatment facilities, USA	To examine the extent to which U.S. methadone maintenance facilities meet established standards for minimum dosages, 1988–2005.	Ethnic group receiving care Staff characteristics Ownership status Accreditation status Region Managed care Harm reduction/HIV prevention	
Snyder et al (2005)	Before-and-after study with control	Medical records for 5 clinical areas: atrial fibrillation (n=9003), acute myocardial infarction (n=8041), heart failure (n=9278), pneumonia (n=8598) and stroke (n=8509)	Acute care hospitals from Maryland, New York, Nevada, Utah, Washington and District of Columbia, USA	To explore whether the quality of hospital care for Medicare beneficiaries improves more in hospitals that voluntarily participate with Medicare's QIOs compared with nonparticipating hospitals.	Actively participating: either used the information to track quality improvement efforts or implemented system changes. Four other definitions of "active participation": - Hospitals only using data to track performance - Hospitals only implementing system changes - Hospitals doing both - Hospitals not participating at all	
Barker et al (2002)	Prospective Cohort	36 institutions	JCAHO accredited and non-accredited hospitals and skilled nursing facilities in Georgia and Colorado, USA	To identify the prevalence of medication errors (doses administered differently than ordered)	JCAHO accredited hospitals	Non-accredited hospitals and skilled nursing facilities

Author	Outcomes	Level of analysis	Results
Pollack et al (2008)	Percentage of patients receiving <40, <60 and <80mg/day of methadone	Facility level	Patients treated in JCAHO accredited facilities were more likely to receive higher doses. The coefficients were -2.848, -4.079 and -4.643 for doses <40, <60 and <80 mg/day, respectively
Snyder et al (2005)	15 quality indicators **Atrial fibrillation** Warfarin prescribed Acute myocardial infarction Administration of aspirin within 24 h of admission Aspirin prescribed at discharge Administration of beta-blocker within 24 h of admission Beta-Blocker prescribed at discharge ACE inhibitor prescribed at discharge for patients with LVEF <40% Smoking cessation counselling given during hospitalisation **Heart failure** Evaluation of ejection fraction and ACE inhibitor prescribed at discharge for patients with LVEF <40% **Pneumonia** Antibiotic within 8 h of arrival at hospital Antibiotic consistent with current recommendations Blood culture drawn (if done) before antibiotic given Patient screened for or given influenza vaccine Patient screened for or given pneumococcal vaccine **Stroke** Antithrombotic prescribed at discharge for patients with acute stroke or transient ischemic attack Avoidance of sub lingual Nifedipine for patients with acute stroke	Patient level	Non-participating hospitals had fewer beds and a higher proportion was for-profit. At baseline non-participating hospitals performed better in prescription of warfarin for AF (OR 0.75 [CI 95% 0.6 to 0.94]) and prescription of beta-blocker at discharge for AMI (0.56 [0.33 to 0.98]). Participating hospital performed better in smoking counselling during hospitalisation for AMI (2.28 [1.37 to 3.8]), screening for or given influenza vaccine (1.70 [1.23 to 2.36]) and pneumococcal vaccine (1.93 [1.46 to 2.54]). At follow-up participating hospitals performed better in evaluation of ejection fraction and ACE-I prescription at discharge for patient with systolic dysfunction for heart failure (1.27 [1.06 to 1.53]), antibiotic administration within 8 hrs of arrival at hospital (1.3 [1.04 to 1.61]), screening for or given influenza vaccine (2.51 [1.9 to 3.33]) and pneumococcal vaccine (3.61 [2.92 to 4.45]). When change from baseline was compared between the two groups, only screening for or given pneumococcal vaccine was significant (1.58 [1.15 to 2.18])
Barker et al (2002)	Medication errors during 50 medication administration per shift site: Unauthorised drug, extra drug, wrong dose, omission, wrong route, wrong form, wrong technique and wrong time	Facility level	Overall, 19% (605/3216) of doses were in error. JCAHO accredited hospital did not have a significantly different rate of errors compared to non-accredited hospitals or skilled nursing facilities. The most frequent errors were: 43% wrong time, 30% omission, 17% wrong dose and 4% unauthorised drug.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Quality Assurance Project (2005)	Prospective Cohort	26 hospitals	District, mission and general hospitals, Zambia	To evaluate the impact of the Zambia accreditation programme on various indicators of the quality of healthcare and health outcomes in the participating hospitals.	Hospitals participating in the accreditation programme	Hospitals non-participating in the accreditation programme.
Duckett (1983)	Retrospective Cohort	23 hospitals	Large, small, rural and urban hospitals in New South Wales, Australia	To determine the impact of a hospital accreditation programme in New South Wales, Australia	Hospitals surveyed by the accreditation programme between 1978 and 1980.	Hospitals to be surveyed and not applying to be surveyed in the same period of time

Author	Outcomes	Level of analysis	Results
Quality Assurance Project (2005)	Overall compliance with accreditation standards 8 indicators of quality of care: -Hospital death rate within two days of admission divided by rate of all hospital deaths -Cesarian section (C-section) infection rate -Availability of emergency drugs -Availability of essential drugs -Availability of lab tests -Hygiene and sanitation -Nurse satisfaction -Patient satisfaction.	Patient level	Compliance with accreditation standards in exposed group change from 36% in 1998-99 to 48% in 2000-01. In the unexposed group, the compliance in 2000-01 was 18% (p=0.018) Compliance with 8 indicators. Unexposed vs exposed Deaths<2 days: 38% vs 48% C-section infection: 53% vs 67% Emergency drugs: 42% vs 52% Essential drugs: 75% vs 76% Lab tests availability: 93% vs 85% Sanitation: 60% vs 73% Nurse satisfaction: 54% vs 56% Patient satisfaction: 63% vs 62% High performing hospitals were larger (number of beds and admissions) and had a higher patient-to-nurse ratio.
Duckett (1983)	Six areas considered indicators of overall performance of hospitals: -Administration and management -Medical staff organisation -Review systems -Organisation of nursing services -Physical facility and safety -Hospital role definition and planning.	Patient level	Administration and management: more informal communication in the hospital not applying to accreditation. Surveyed and to be surveyed hospitals had more systematic processes to make decisions and prioritise actions. Medical staff organisation: surveyed hospitals had a better organisation of medical staff, which was reflected by meetings more often and more delegation to department chairs. Review systems: surveyed and to be surveyed hospitals had better or a greater number of review systems than hospitals not applying to accreditation. Organisation of nursing services: The accreditation was seen as an opportunity to update or create documentation and review procedures. The representation of nurses in committees was increased. This change was not observed in the hospital not applying to accreditation. Physical facility and safety: All types of hospitals made changes related to fire and physical hazards. To be surveyed hospitals had a higher incidence of preventive actions than surveyed hospitals. On the other hand, surveyed hospitals had more safety inspections than the other two types of hospitals. Hospital role definition and planning: role definition was more common for surveyed and to surveyed hospitals compared to not applying hospitals. However, accreditation had no effect on hospital planning according to the needs of the community.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Pasquale et al (2001)	Retrospective Cohort	24 accredited trauma centres (88728 patients)	Information from 1992 to 1996 from Trauma centres in Pennsylvania, USA	To evaluate the impact of five trauma centre characteristics on survival outcome in nine serious injury categories.	Level of accreditation (I or II) by American College of Surgeons Volume of trauma admissions In-house trauma surgeon Surgical residency programme On-site medical school	
Van Such et al (2006)	Retrospective Cohort	782 patients with heart failure	One tertiary hospital in Minnesota, USA	To determine whether documentation of compliance with any or all of the six required discharge instructions is correlated with readmissions to hospital or mortality.	Compliance with six written instructions for patients with heart failure Activity Weight Diet Discharge medications Follow-up appointment Worsening symptoms	
Ross et al (2008)	Retrospective Cohort	4197 hospitals	Hospitals reporting core measures for AMI during 2005, USA	To determine whether hospitals accredited by the Society of Chest Pain Centers (SCPC) hospitals are associated with better performance regarding Centers for Medicare and Medicaid Services (CMS) core measures for acute myocardial infarction (AMI) than non-accredited hospitals.	Accreditation by Society of Chest Pain Centres	Non-accredited by Society of Chest Pain Centres

Author	Outcomes	Level of analysis	Results
Pasquale et al (2001)	Survival in nine selected serious injuries defined as A Severity Characterization of Trauma (ASCOT) <0.5 Injuries of Head, Neck, Chest, Brain, Lung, Liver, Spleen, Aorta and Vena Cava	Patient level	Level I and II of accreditation had higher than predicted survival in six (head, neck, chest, brain, lung and spleen) out of nine serious injuries. High volume of trauma admissions was associated with higher than predicted survival for seven (head, neck, chest, brain, lung, spleen and aorta) out of nine serious injuries, whilst for low volume, survival was higher for only three injuries. Centres with in-house trauma surgeon had higher than expected survival for four serious injuries (head, brain, lung and spleen), and centres without in-house trauma surgeon had higher survival for six injuries (head, neck, chest, brain, lung and spleen). The presence of surgical residency was associated with higher than predicted survival for six serious injuries (head, neck, chest, brain, lung and spleen) and five for centres without surgical residency (chest, brain, lung, spleen and aorta). Having an on-site medical school related to seven (head, neck, chest, brain, lung, spleen and aorta) higher than expected survival rates and six (head, neck, chest, brain, lung and spleen) in the case of not having a medical school on-site. Low-volume was a significant risk factor for death for head, chest, brain and lung injuries.
Van Such et al (2006)	Mortality and readmissions	Patient level	Only 68% of patients received all the discharge instructions. There was no association between survival and receiving all discharge instructions. At 9 month after discharge, 37% and 41% of patients were readmitted for heart failure or any cause, respectively. Patients receiving all instruction were less likely to be readmitted for heart failure (p=0.003) or any other cause (p=0.035)
Ross et al (2008)	Core measures AMI: Aspirin administration at hospital arrival Aspirin administration at discharge Beta-blocker administration at arrival Beta-blocker administration at discharge Percutaneous coronary intervention < 120 minutes after arrival Fibrinolytic therapy < 30 minutes after arrival ACE-I or angiotensin receptor blocker administration for left Ventricular systolic dysfunction Smoking cessation counselling on discharge.	Patient level	The rate of percutaneous coronary intervention was higher in accredited hospitals (92.8% vs 80.8%), whilst it was lower for fibrinolysis (7.2% vs 19.2%) In the unadjusted analysis, for seven out of eight core measures the level of compliance was higher for accredited hospitals, except for fibrinolytic administration. These results were robust when adjusted by hospital characteristics (e.g. number of hospital beds, type of ownership, JCAHO accreditation, teaching hospital status, urban location, total patient days, and region of the country).

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Tan et al (2004)	Before and after study	1997 (n=10207), 2001 (n=12519)	Cytology service at National University Hospital, Singapore	To identify changes in the quality indices of our cervicovaginal cytology service preceding and following laboratory accreditation by the College of American Pathologists in 2000.	Data from 2001 after accreditation by College of American Pathologists.	Data from 1997 before accreditation
Frasco et al (2005)	Before and after study	1082 patients undergoing surgery	Post-anaesthesia care unit (PACU) of Mayo Clinic, USA	To assess the effects of the JCAHO pain initiative in our institution.	Mandatory use of 11-point scale to assess pain intensity after surgery in PACU	Period before January 2002
Juul et al (2005)	Before and after study	51 surgical and anaesthetic units	Acute care hospitals in Copenhagen, Denmark	To examine the availability and quality of clinical guidelines on perioperative diabetes care in hospital units before and after a randomised clinical trial (RCT) and international accreditation.	JCAHO accreditation in early 2002	

Author	Outcomes	Level of analysis	Results
Tan et al (2004)	Positive predictive value (PPV) of low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL) and positive cytology to diagnose cervical intraepithelial neoplasia.	Patient level	The PPV of LSIL increased from 68% in 1997 to 78% in 2001. The PPV of HSIL decreased from 94% in 1997 to 85% in 2001. The overall PPV for positive cytology increased from 82% in 1997 to 87% in 2001. None of these differences was statistically significant.
Frasco et al (2005)	Amount of opioids used in PACU Opioid-induced side effects (nausea and vomiting requiring treatment and naloxone used for respiratory depression) PACU discharge time	Patient level	Overall opiates use increased (p=0.001) due to increased use in PACU. Postoperative use of opioids increased for all diagnostic related groups except for back surgery. Nausea and vomiting treatment decreased between 2000 and 2002 (31.2% vs 27.5%), but prophylactic treatment increased in the same period (53.2% vs 73.8%). Naloxone used for respiratory depression did not change between 2000 and 2002. Length of stay in PACU decreased between 2000 and 2002 (105.6 vs 97.9 min, respectively)
Juul et al (2005)	Availability and quality of clinical guidelines for perioperative diabetic care	Facility level	At baseline, a higher proportion of units that were accredited during the period (63%, 17/27) had clinical guidelines compared to those non-accredited (29%, 7/24). At the completion of the follow-up, the accredited units with clinical guidelines increased by 33%, whilst for non-accredited units the increase was 21%. Quality of clinical guidelines measured by the systematic development scale, improved more in the accredited units (median[range]: 2 [0-8] to 9 [0-9]) than the non-accredited ones (0 [0-6] to 2 [0-7])

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Al Tehewy et al (2009)	Before and after study	60 non-governmental health units	Primary healthcare units, Egypt	To determine the effect of accreditation of non-governmental organisations' health units on patient satisfaction and provider satisfaction and the output of accreditation on compliance to some accreditation standards	Accreditation	
Hadley et al (1988)	Cross-sectional analytical	216 state psychiatric hospitals	Psychiatric hospitals, USA	To determine whether accreditation by JCAHO or certification by the Health Care Financing Administration (HCFA) were related to seven hospital characteristics reflecting quality of care (1984 data)	JCAHO accreditation HCFA accreditation Accredited by JCAHO and HCFA Non-accredited by JCAHO or HCFA	

Author	Outcomes	Level of analysis	Results
Al Tehewy et al (2009)	Patient satisfaction Provider satisfaction Compliance with selected standards: Clean toilets Functioning toilets Appropriate furniture Alarm system Incineration contract Maintenance contract Complaints box Announced patient rights Analysed patient satisfaction questionnaire (at least once) Analysed provider satisfaction questionnaire (at least once) Presence of record room Presence of records Presence of guidelines Presence of emergency drug list ≥50% of records with recorded two visits (for hypertension) ≥50% of records with recorded two visits (for diabetes) ≥50% of records with recorded two visits (for antenatal care) Waste segregation Proper sharp disposal Presence of three sterilised sets Employee health file	Patient level	For patient satisfaction, accredited health units had higher mean scores in all aspects assessed compared to non-accredited health units: Unit staff (90.6 vs 83.2), cleanliness (81.3 vs 71.9), waiting area (85.7 vs 73.8), waiting time (75.2 vs 67.8) and overall (90.4 vs 79.5). For provider satisfaction, accredited units only performed better in the mean overall score (81 vs 73) compared to non-accredited units. For all the selected standards, compliance was better in accredited units than non-accredited units, with the exception of more than 50% of antenatal care records with two visits recorded, and the presence of three sterilised sets, which had similar compliance.
Hadley et al (1988)	Average cost per patient Per diem bed cost Total staff hours per patient Clinical staff hours per patient % staff hours provided by medical staff Bed turnover % beds occupied	Facility level	Average cost per patient (R^2=0.38), per diem bed cost (R^2=0.39), percent of staff hours provided by medical staff (R^2=0.46) and bed turnover (R^2=0.49) were better explained by accreditation status. Additionally, higher costs were associated with percent of patient care provided by medical staff (r=0.72).

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
McGurrin et al (1991)	Cross-sectional analytical	216 state psychiatric hospitals	Psychiatric hospitals, USA	To determine the proportion of JCAHO /HCFA accredited hospitals that maintained their status and proportion of non-accredited hospitals that gained accreditation between 1984 and 1986	JCAHO accreditation HCFA accreditation Full accreditation by JCAHO and HCFA Non-accredited by JCAHO or HCFA	
Verstraete et al (1998)	Cross-sectional analytical	77 medical laboratory technologists in 1995 and 24 in 1996	2 medical laboratories in Belgium and one in Netherlands	To determine attitudes of laboratory personnel towards accreditation	Beltest accreditation in Belgium or CCKL-accreditation in Netherlands	
Beaulieu et al (2002)	Cross-sectional analytical	630 health plans	Health plans provided by health maintenance organisation, USA	To determine the characteristics of plans that have submitted to accreditation review, the performance of accredited plans on quality indicators and the impact of accreditation on enrolment.	National Committee on Quality Assurance (NCQA) accreditation status of health plans: Accredited Denied	Non-accredited compared to accredited Denied compared to fully accredited

Author	Outcomes	Level of analysis	Results
McGurrin et al (1991)	Change of status Average cost per patient Per diem bed cost Total staff hours per patient Clinical staff hours per patient % staff hours provided by medical staff Bed turnover % beds occupied	Facility level	Only two out of 178 hospitals accredited by JCAHO or HCFA or both in 1984 lost their status by 1986. Seven out of 55 hospitals that were accredited by one agency in 1984, gained full accreditation by 1986. Five out of 38 hospitals non-accredited by JCAHO or HCFA in 1984 gained full accreditation by 1986. Average cost per patient and per diem bed cost increased for all groups between 1984 and 1986; however, clinical staff hours per patient, percentage of staff hours provided by medical staff, bed turnover, and percentage of beds occupied remained stable between 1984 and 1986. The difference in performance between non-accredited and accredited hospitals remained over time.
Verstraete et al (1998)	Change in quality after accreditation Working preference between accredited and non-accredited laboratory Workload in accredited laboratories Advantages of working in an accredited laboratory Disadvantages of working in an accredited laboratory	Patient level	88% of lab technologists considered that workload is higher or much higher in accredited laboratories. In relation to how quality changed after accreditation, 43% indicated that quality remained the same and 45% replied that it improved. 24 laboratory technologists answered the survey in 1995 and 1996. In relation to advantages of working in an accredited laboratory, there was a significant increase in respondents saying that accreditation improved documentation of all manipulations, increased confidence about procedures, knowledge of analyses, and quality. In relation to disadvantages of accreditation, there was a significant decrease in respondents considering that job was less motivating and there was a discrepancy between reality and what accreditation assesses. Additionally, there was a significant increase in respondents indicating more interest in formalities than in actual results.
Beaulieu et al (2002)	Characteristics of health plans Mean performance on nine HEDIS (Health Plan and Employer Data Information Set) measures Seven patient-reported ratings (quality and satisfaction). Health plan enrolment	Health plan	Accredited plans were more likely to be older, larger in terms of enrolment, federally qualified, affiliated with a national managed care firm (NMCF), and of a mixed model type. Also, they were more likely to offer a point of service (POS) and Medicare managed care products. Fully-accredited plans were more likely to be older and belong to a national managed care. Accredited plans performed modestly better in seven out of nine HEDIS measures: childhood immunization (68.3 vs 61.8), adolescent immunizations (57 vs 51.3), breast (72.4 vs 68.2) and cervical cancer screening (72.6 vs 69.4), prenatal care (86 vs 81.4), diabetic eye exam (41.1 vs 35) and follow-up after hospitalization for mental illness (74.4 vs 70.4). Fully accredited plans performed better in two out of nine HEDIS measures: beta-blocker treatment (67 vs 55.5) and Follow-up after hospitalisation for mental illness (77.2 vs 70.2). Accredited plans performed slightly better in one out of eight patient-reported ratings: overall satisfaction (18.3 vs 16.8). Non-accredited plans performed better in two patient-reported rating: quality of care (86.9 vs 88.5) and choice of specialist (74 vs 76). Health plan enrolment was positively associated with accreditation only for 1994-95 (beta=0.064) and 1995-96 (beta=0.072)

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Simons et al (2002)	Cross-sectional analytical	3 trauma centres	Large, university-affiliated regional centres in British Columbia, Canada	To examine outcomes within a single regional trauma system after the designation of trauma centres and to compare outcomes in the one accredited centre to the non-accredited centres.	Designated accredited trauma centre Designated non-accredited trauma centres	
Chen et al (2003)	Cross-sectional analytical	134579 patients with AMI	Acute care hospitals, USA	To assess whether JCAHO hospital accreditation is associated with the use of guideline-recommended therapies and clinical outcomes.	JCAHO accreditation status Commendation Accredited Accredited with recommendations Conditional Not surveyed	
Borenstein et al (2004)	Cross-sectional analytical	79 quality improvement activities within 50 organisations	Managed care organisations, USA	To determine differences in performance rates between organisations with and without quality improvement activities.	Organisations with or without "similarly targeted" activities. *"similarly targeted" when the aim of quality improvement activity was similar to a quality performance score	

Author	Outcomes	Level of analysis	Results
Simons et al (2002)	Actual mortality compared to predicted mortality by Trauma Injury Severity Score. Sub-group analysis by patients, transfer patients, penetrating trauma and hip fractures rates.	Patient level	Hospital A (accredited) had better survival than hospitals B and C (odds ratio: 2.06 A vs B and 1.47 A vs C) When outcomes were compared to the Major Trauma Outcome Study, hospital A performed above the norm, whilst hospitals B and C had lower performance.
Chen et al (2003)	Use of aspirin or beta-blockers within 48 hrs of admission Aspirin or beta-blockers anytime during hospitalisation Acute reperfusion therapy (thrombolytic agents or primary angioplasty) within six hours of admission risk-standardised 30-day mortality	Patient level	Non-surveyed hospitals were more likely to be rural, non-teaching, publicly-owned and smaller-volume centres. Surveyed hospitals with higher accreditation level were more likely to be urban and larger-volume centres. Performance measured as percent of ideal candidates receiving therapy was worse in not surveyed hospitals compared to surveyed hospitals: aspirin on admission (51.8 vs 54.5), aspirin during hospitalisation (81.4 vs 85.5), beta-blockers on admission (43.1 vs 48.5), beta-blockers during hospitalisation (52.6 vs 60.5) and reperfusion (61.8 vs 67.5). Risk-standardised 30-day mortality was higher (20.4%) in not surveyed than surveyed hospitals (18.4%). Variability of performance across JCAHO accreditation status categories indicates that accreditation is not a good reflection of quality of care for patients with AMI
Borenstein et al (2004)	Performance score in effectiveness-of-care categories: Comprehensive diabetes care Breast cancer screening Childhood immunizations Adolescent immunizations Cervical cancer screening Beta-blocker therapy after myocardial infarction Check-up after delivery Follow-up after hospitalisation for mental illness Prenatal care in the first trimester Advice on smoking cessation Asthma medication management Antidepressant medication management	Facility level	For only 8 out of 12 effectiveness-of-care measures there were organisations with "similarly targeted" activities. Performance scores for these measures were better for five categories: adolescent immunisations, breast cancer screening, comprehensive diabetes care, cervical cancer screening, check-ups after delivery, and follow-up after hospitalisation for mental illness. Results were significant for the latest three categories (mean difference [95% confidence interval]: 6.4 [3.5 to 9.2], 6.6 [1.9 to 11.2] and 21.1 [14.5 to 27.7])

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Brown et al (2004)	Cross-sectional analytical	174 asymptomatic patients with suspicion of stenosis of carotid artery	Ultrasound laboratories in tertiary care community hospitals, USA	To evaluate the reliability of carotid duplex ultrasound scanning performed by non-accredited vascular laboratories and to assess the clinical effect on patient management.	Accredited vs non-accredited laboratories by the Intersocietal Commission for Accreditation of Vascular Laboratories	
Lau et al (2004)	Cross-sectional analytical	3372 nursing home residents	Nursing homes, USA	To estimate the scope of potentially inappropriate medication prescriptions (PIRx) among elderly residents in U.S. nursing homes (NHs), and to examine associated resident and facility characteristics.	Resident characteristics (age, sex, race, marital status, number of living children, education, and poverty status) Facility characteristics (organisational structure, nurse staffing levels, JCAHO accreditation status, high-level technological services and geographical location) Resident and facility characteristics	
Brannigan et al (2004)	Cross-sectional analytical	144 interviews and surveys	Adolescent substance abuse treatment programmes, USA	To conduct the first systematic evaluation of the quality of highly regarded adolescent substance abuse treatment programs in the United States.	Programme characteristics -Region -Age of programme -Programme setting -Multilevel services -Programme approach -Accreditation (Joint Commission on the Accreditation of Healthcare organisations, Commission on the accreditation of rehabilitation facilities or council on accreditation)	

Author	Outcomes	Level of analysis	Results
Brown et al (2004)	Agreement between accredited and non-accredited laboratories about severity of stenosis Effect of ultrasound result on clinical management.	Patient level	There was agreement about the severity of stenosis in 49% (171/348) of the vessels examined. In 88 patients (104 vessels) the degree of stenosis was overestimated in the non-accredited laboratory. None of these patients underwent surgery. In 19 patients (19 vessels) the degree of stenosis was underestimated in the non-accredited laboratory. The accredited laboratory finding agreed with the angiography in 5 patients. All 19 patients underwent surgery.
Lau et al (2004)	Potentially inappropriate medication prescriptions -Inappropriate drug choice -Excess dosage -Drug-disease interaction	Patient level	50% of nursing home residents received at least one PIRx during 1996. 40% of PIRx were inappropriate drug choice. Accreditation status was protective of PIRx when the model was adjusted for facility characteristics (OR[95% CI]: 0.78 [0.61-0.99]), and resident and facility characteristics (0.7 [0.54-0.92])
Brannigan et al (2004)	9 key elements Assessment and matching Comprehensive, integrated approach Family involvement Development Appropriateness Engaging and retaining Qualified staff Gender and cultural competence Continuing care Treatment outcomes	Programme level	Top-quartile programmes were more likely to have been implemented more than 20 years ago (54.3% vs 29% in middle 50% vs 37.5% in bottom quartile; $p<0.05$). Additionally, they were more likely to use multidimensional family therapy (25.7% vs 8.7% vs 10%; $p<0.05$) compared to the middle 50% and bottom quartile. 19 programmes (13%) had more than 30 points (45 maximum possible) and 64 (44%) programmes had less than 22 points. Accredited institutions were not better than non-accredited ones in any of the 9 key elements.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Casey et al (2005)	Cross-sectional analytical	387 hospitals	Small rural hospitals, USA	To assess the capacity of small rural hospitals to implement medication safety practices, with a particular focus on pharmacist staffing and the availability of technology.	Hospital size Case mix JCAHO accreditation System membership Type of ownership Financial status Rural adjacency Registered nurse staffing Medication or patient safety committee with active participation of a pharmacist	
Grasso et al (2005)	Cross-sectional analytical	31 medical records	State psychiatric hospital in Maine, USA	To compare the sensitivity of medication error detection resulting from independent audit with hospital's usual self-reporting process for errors and with the JCAHO, CMS, and Maine Department for Health and Human Services (DHHS) licensing surveys.	Medication error rates according to -JCAHO licensing standards -CMS licensing standards -Maine DHHS licensing standards -Augusta Mental Health Institute (AMHI) study	

Author	Outcomes	Level of analysis	Results
Casey et al (2005)	Pharmacists full-time equivalents (FTEs) Use of computer for clinical purposes Implementation of four medication safety practices: list of "do not use", policy for using two patient identifiers for administering medication, a list of "high-alert" drugs, and a policy for checking high-alert medications dosage by two health professionals.	Facility level	46% of hospitals had 1.0 or less FTE pharmacists. Pharmacist staffing levels were significantly associated with the active participation of a pharmacist on medication and patient safety committees ($p<0.001$). Amount of pharmacist staffing was positively associated with inpatient days in hospital unit ($p<0.0001$), inpatient day in nursing home ($p<0.001$), Medicare case mix index ($p<0.0001$), JCAHO accreditation ($p<0.0001$), net other income ($p<0.001$) and net operating margin ($p<0.001$). Additionally, it was negatively associated with for-profit ownership ($p<0.01$). 45% of hospitals had a pharmacy computed being used for clinical purposes. The use of pharmacy computer for clinical purposes was positively associated with inpatient days in hospital unit ($p<0.0001$), JCAHO accreditation ($p<0.001$), net other income ($p<0.001$) and net operating margin ($p<0.05$). Drug protocols were more commonly implemented for emergency medications, anticoagulants and insulin. Protocols for chemotherapy were implemented in 46% of hospitals, whilst protocols for pre-surgical antibiotics were implemented in 58%. 49% of hospitals had implemented the four medication safety practices. Three variables were positively associated with their implementation: JCAHO accreditation ($p<0.0001$), active participation of a pharmacist in patient/medication safety committee ($p<0.001$), and net operating margin ($p<0.05$).
Grasso et al (2005)	Rates of medication errors	Patient level	JCAHO survey gave a score of 89 (one third of hospitals surveyed obtained this score) due to deficiencies in the initial assessment, pathology and clinical laboratory services, medication use, strategic planning, staff orientation, training and education, and assessing staff competency. CMS survey found deficiencies in the documentation of social services, psychiatric evaluation, and treatment plans. Maine DHHS survey found deficiencies in Medical/professional staff bylaws. AHMI study found that self-report was significantly lower than medication errors found through independent audit: 9 errors over two months compared to 2194 errors

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Lemark et al (2005)	Cross-sectional analytical	1995 (n=678) 1999-2000 (n=745)	Substance abuse treatment programmes surveyed by the National Drug Abuse Treatment System Survey (NDATSS), USA	To examine whether and how various organisational and environmental forces influence staffing in outpatient substance abuse treatment programs.	Percentage of revenues covered by managed care Managed care stringency Professional qualifications of staff JCAHO accreditation Hospital affiliation Mental health centre affiliation Ownership Methadone treatment unit Percentage of clients unemployed Percentage of clients with dual diagnoses Percentage of clients with previous treatment	
Williams et al (2006)	Cross-sectional analytical	30 hospitals	JCAHO accredited hospitals, USA	To investigate the reliability of self-reported standardised performance indicators introduced by the Joint Commission on Accreditation of Healthcare Organizations in July 2002	Self-report of standardised performance indicators by hospital Re-abstraction of standardised performance indicators by JCAHO	

Author	Outcomes	Level of analysis	Results
Lemark et al (2005)	Number of treatment staff hours per client Active client caseload	Patient level	The average staff hours per patient per week was 2.66 and an average number of active patients per treatment staff was 32. JCAHO accredited (beta=0.36, p<0.01) and mental health centre-affiliated units (beta=0.55, p<0.05) provided more staff hours per patients. Percentage of revenues covered by managed care (beta=-0.002, p<0.05), private not-for-profit (beta=-0.12, p<0.01) and private for-profit units (beta=-0.22, p<0.001) were negatively associated with active caseload. Conversely, professional qualifications of staff (beta=0.003, p<0.01), mental health centre affiliation (beta=0.2, p<0.01) and methadone treatment units (beta=0.44, p<0.001) were positively associated with active caseload. Units with a higher percentage of unemployed (beta= -0.002, p<0.05) patients had a lower active caseload.
Williams et al (2006)	61 individual elements grouped into 5 categories: -Global elements (9 indicators) -Acute myocardial infarction elements (22 indicators) -Heart failure elements (13 indicators) -Pneumonia elements (16 indicators) -Pregnancy elements (1 indicator)	Patient level	The weighted average agreement for data elements was 91.9%. In the case of binary data, the overall weighted agreement was 0.68. When indicators rates were calculated again using original and re-abstracted data, the mean difference was 4.8%. For eight indicators, there was a statistically significant difference in the symmetry (i.e. differences in inclusion, exclusion, numerator and denominator): aspirin at arrival, aspirin prescribed at discharge, beta-blocker at arrival, discharge instructions, left ventricular (LF) function assessment, smoking cessation advice for heart failure, oxygenation assessment, and smoking cessation advice for pneumonia.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Landon et al (2006)	Cross-sectional analytical	4059 hospitals	Acute hospitals reporting to JCAHO and/or CMS, USA	To determine the quality of care in US hospitals for three common conditions (AMI, heart failure and pneumonia) and hospitals characteristics associated with high-quality performance	Hospital type Region JCAHO accreditation Teaching status Metropolitan Statistical Area size Number of beds Medicare discharges per admission Medicaid discharges per admission Technology index Registered nurse per adjusted inpatient day Licensed practical nurse per adjusted inpatient day	

Author	Outcomes	Level of analysis	Results
Landon et al (2006)	Acute Myocardial Infarction -Aspirin at arrival -Aspirin prescribed at discharge -ACE inhibitor for LVSD -Adult smoking cessation advice/counselling -Beta-Blocker prescribed at discharge -Beta-Blocker at arrival -Thrombolysis within 30 min of arrival -PTCA within 90 min of arrival Congestive Heart Failure -Discharge instructions -LVF assessment -ACE inhibitor for LVSD -Adult smoking cessation advice/counselling Pneumonia -Oxygenation assessment -Pneumococcal vaccination -Blood culture before the first antibiotic -Adult smoking cessation advice/counselling -Paediatric smoking cessation advice/counselling -Initial antibiotic timing Two composite measures: -"Opportunity" score for each disease -Measures that crosscut multiple conditions identified through factor analysis.	Patient level	75.9% of these recommended practices were delivered to hospitalised patients. The lowest performance was for the administration of thrombolytic therapy within 30 min of arrival (mean [interquartile range]: 0.36 [0-0.67]), whilst the highest was for assessment of blood oxygenation for patients with pneumonia (0.98 [0.98-1]). The mean (interquartile range) overall performance for each disease was: AMI 0.85 (0.81-0.95), CHF 0.64 (0.52-0.74), and pneumonia 0.88 (0.75-0.92). Factor analysis revealed two common factors for the three diseases: Factor 1 was treatment and diagnosis including aspirin at arrival and at discharge for AMI, Beta-blocker at arrival and discharge for AMI, ACE inhibitor for LVSD, and assessment of LVF for CHF; Factor 2 was counselling and prevention including smoking cessation advice for the three diseases, pneumococcal vaccination for pneumonia, and discharge instructions for CHF. For-profit and public/municipal hospitals consistently performed worse in both composite measures than not-for profit hospitals. In contrast, federal/military hospitals performed better than not-for-profit hospitals. JCAHO accredited hospitals also performed consistently better than non-accredited hospitals. A higher number of registered nurses hours (above 4.77) was associated with better performance in both composite scores. Similarly, a higher technology index was associated with better performance in both composite measures.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Partha-Sarathy et al (2006)	Cross-sectional analytical	632 patients with Obstructive Sleep Apnoea	Sleep centres, USA	To study the effect of American Academy of Sleep Medicine (AASM) accreditation of sleep centres and sleep-medicine certification of physicians on the management of patients with obstructive sleep apnoea (OSA).	Accreditation of centre and certification of physician. Accreditation of centre or certification of physician. Neither centre was accredited nor physician was certified	
Longo et al (2007)	Cross-sectional analytical	107 hospitals	Acute hospitals in Utah and Missouri, USA	To examine characteristics of hospitals with extensive patient safety systems and those that have made more in implementing these systems over time	Hospital bed-size (large hospital>100 beds) Management type Rural location JCAHO accreditation status	

Author	Outcomes	Level of analysis	Results
Partha-Sarathy et al (2006)	Adherence to positive airway pressure (PAP) therapy Timeliness of the initiation of PAP therapy Patients' perceptions about education received Overall satisfaction with care received from physicians and centres	Patient level	78% of 632 respondents had been prescribed the use of a PAP device. 444 patients were aware of the certification/accreditation status of their centre and physician. 5% of patients (16 out of 307) being cared for a certified physician and an accredited centre had discontinued the use of the PAP device. Whilst 7% of patients (7 out of 99) being treated in either an accredited centre or by a certified physician had discontinued the use of the PAP device. In the case of patients treated in non-accredited centres by a noncertified physician, the drop-out proportion was 21% (8 out of 38). Lack of centre accreditation or physician certification (OR [95% CI]: 1.86 [1.08-3.20]) and severity of nasal congestion (1.57 [1.03-2.41]) increased the odds of discontinuing use of the PAP device. Conversely, patient's risk perception and education (0.47 [0.23-0.93]), medication for nasal congestion (0.28 [0.1-0.81]), and having health insurance (0.19 [0.05-0.77]) decreased the odds of discontinuing use of the PAP device. When accreditation/certification status was entered into the model with patients' education, accreditation/ certification was no longer significant; therefore, the effect of accreditation might be mediated by the approach to educate patients.
Longo et al (2007)	Seven latent variables: -Computerised physician order entry (CPOE) systems -Specific patient safety policies -Use of data in patient safety programmes -Drug storage, administration and safety procedures -Manner of handling adverse event/error reporting -Prevention policies -Root-cause analysis	Facility level	The summary score for the seven latent variables was significantly higher in both surveys for larger hospitals (p=0.007 survey 1 and p=0.04 survey 2); rural hospitals (p=0.02 survey 1 and p=0.03 survey 2); and JCAHO accredited (p<0.0001 survey 1 and p=0.0007 survey 2). Significant differences between first and second survey were found for larger hospitals (p=0.03); nongovernment not-for-profit hospitals (p<0.0001); and urban hospitals (p=0.03). Additionally, a significant difference in change of summary score was found between state/local government and non-governmental not-for-profit hospitals (p=0.047); and JCAHO accredited and non-accredited (p=0.01). The effect of accreditation remained significant when results were adjusted for survey 1 results (p=0.03)

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Niska et al (2007a)	Cross-sectional analytical	739 hospitals	Acute hospitals participating the National Hospital Ambulatory Medical Care Survey (NHAMCS), USA	To determine which hospital characteristics are associated with preparedness for terrorism and natural disaster in the areas of emergency response planning and availability of equipment and specialised care units.	Residency programme Medical school affiliation Hospital size Ownership Location in urban or rural area Accreditation by JCAHO.	
Niska et al (2007b)	Cross-sectional analytical	739 hospitals	Acute hospitals participating the National Hospital Ambulatory Medical Care Survey (NHAMCS), USA	To determine which hospital characteristics are associated with providing terrorism preparedness training to clinical staff.	Teaching hospital status Residency programme Medical school affiliation Hospital size Ownership Location in urban or rural area Geographic region JCAHO accreditation	

Author	Outcomes	Level of analysis	Results
Niska et al (2007a)	Revision of emergency plan after September 11, 2001 Types of incidents addressed in the plan: biological, chemical, nuclear-radiological, explosive-incendiary, and natural disaster incidents 10 components of emergency plan: -Integration into community-wide planning -Cooperative planning with other health care facilities -Memoranda of understanding with outlying hospitals to accept in-patients during a disaster -Alternate care sites -Cancellation of elective procedures and admissions -Conversion of post-anaesthesia unit to augment intensive care -Activation of decommissioned wards -Utilization of nonclinical space for medical purposes -Antibiotic and supply stockpiles -Coordinated supply-chain management of pharmaceuticals and other supplies.	Facility level	92% of hospitals revised their emergency plans after September 11, 2001. JCAHO accreditation was not significantly associated with revising the emergency plan, but accredited hospitals were more likely to have plans for natural disasters and four types of terrorism incidents. JCAHO accredited hospitals included more components in their emergency plan (mean [95% CI]: 6.3 [6 to 6.5] vs 3.8 [3 to 4.5]). JCAHO accredited hospitals were significantly more likely to include all the components of the emergency plan, except for utilisation of nonclinical space for medical purposes (mean [95% CI]: 62.6 [57.1 to 67.8] vs 47.9 [33.3 to 62.8]). JCAHO accredited hospitals had a significantly higher mean number of mechanical ventilators, personal protective suits, negative pressure isolation rooms, critical care beds, and decontamination showers for mass casualties episodes.
Niska et al (2007b)	Staff received special training since September 11, 2001, in terrorism response Staff have received training in the identification, diagnosis and treatment of smallpox, anthrax, plague, botulism, tularaemia, viral haemorrhagic fever, viral encephalitis, chemical exposures, and nuclear-radiological exposures. Key personnel had been trained in the implementation of a formal hospital incident command system.	Facility level	88.4% of registered nurses, 75.1% of attending physicians and 39% of residents had received training in terrorism response. JCAHO accredited hospitals were more likely to have trained their staff than non-accredited hospitals in terrorism response. Additionally, they were more likely to have trained staff in the identification, diagnosis and management of smallpox, anthrax, plague, botulism, tularaemia, haemorrhagic fever, viral encephalitis, chemical and radiological exposure. There was no significant difference between JCAHO accredited and non-accredited hospital in the percentage of key personnel receiving training in the implementation of a command system.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Braun et al (2008)	Cross-sectional analytical	290 health centres	Health centres with support from the Bureau of Primary Health Care (BPHC), USA	To examine quality-related activities in Health Resources Services Administration (HRSA)/BPHC-supported Health centres (HCs)	Location Size: small (1-35 full time equivalents[FTEs]), medium (36-129 FTEs) and large (>129 FTEs) Accreditation status	
Menachemi et al (2008)	Cross-sectional analytical	720,472 patients treated in 364 facilities	Ambulatory surgical centres (ASC) in Florida, USA	To compare quality outcomes of accredited ASCs operating in Florida with those of non-accredited facilities.	ASC accredited by JCAHO ASC accredited by Accreditation association for ambulatory health care (AAAHC) ASC non-accredited	

Author	Outcomes	Level of analysis	Results
Braun et al (2008)	Four topic areas (1) resources and activities related to infection control, risk management, QI, and environment of care; (2) follow-up and tracking of diagnostic studies; (3) staff training and education; (4) provider credentialing, privileging, and performance evaluations.	Facility level	The reported mean FTEs dedicated to infection control by accredited hospitals was higher than non-accredited ones (0.8 vs 0.5, p<0.05). Larger HCs as well as accredited HCs reported higher mean FTEs dedicated to risk management (small 0.7, medium 0.7, large 1.2, p<0.05. Accredited 1.1 vs non-accredited 0.7, p<0.05); quality improvement (small 0.9, medium 1.1, large 1.8, p<0.01. Accredited 1.5 vs non-accredited 1.1, p<0.05); environmental safety (small 0.6, medium 1.0, large 1.3, p<0.05. Accredited 1.4 vs non-accredited 0.7, p<0.01). A greater proportion of accredited compared to non-accredited hospitals reported having a consistent follow-up method for mammographies with a referral (88.9% vs 78.3%, p<0.05) and report immediately to a provider critical values of laboratory exams (87.3% vs 77.2%, p<0.05). A greater proportion of accredited compared to non-accredited hospitals reported to have trained more than 75% of clinical staff on emergency preparedness (58.7% vs 41.3%), quality improvement (55.6% vs 37.5%), risk management/patient safety(57% vs 35.8%), and pain management (49.1% vs 18.2%). Additionally, a greater proportion of accredited compared to non-accredited hospitals reported to have trained more than 75% of staff conducting laboratory tests on methods for identifying the correct patient (91.5% vs 52.7%), response to managing patient who have passed out (67% vs 44%), and response to needle stick/sharp injury (94.1% vs 75.1%). A greater proportion of accredited compared to non-accredited hospitals used 14 out of 22 measures related to credentialing, privileging and job performance. Using multiple regression and controlling for size and location, accreditation was significant for the frequency of auditing of clinical records, the frequency of use of credentialing methods, the frequency of providers review and the percentage of staff receiving training.
Menachemi et al (2008)	Risk-adjusted 7-day and 30-day unexpected hospitalisations controlled for facility volume of procedure and patient demographic characteristics including gender, race, age, insurance type and severity of illness. These outcomes were calculated for the five most common procedures i.e. colonoscopy, cataract removal, upper gastroendoscopy, arthroscopy and prostate biopsy.	Patient level	For raw 7-day and 30-day unexpected hospitalisation rates, there were no differences for the most common procedures, except for colonoscopy, where the 30-day raw rate was lower for JCAHO accredited compared to AAAHC accredited and non-accredited ASCs (1.83 vs 1.96 vs 2.00, p-value=0.01). When controlling for procedure volume and patients demographic, this result was still significant. JCAHO accredited ASCs had lower 7-day and 30-day unexpected hospitalisations for colonoscopy (OR: 0.89, p-value<0.05 and 0.9, P-value<0.01; respectively) compared to non-accredited facilities.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Sekimoto et al (2008)	Cross-sectional analytical	460 acute hospitals	Acute teaching hospitals, Japan	To characterise the situation of hospital infection control (IC) programs and activities and assess the impact of accreditation and other factors on hospital infection control performance.	Japan Council for Quality Health Care (JCQHC) accredited in 2004 and 2005 JCQHC newly accredited (2005) JCQHC non-accredited in 2004 and 2005	
Chandra et al (2009)	Cross-sectional analytical	33,238 patients	Hospitals treating acute coronary syndrome participating in CRUSADE study, USA	To evaluate the association between Society of Chest Pain Centres (SCPC) accreditation and adherence to the American College of Cardiology/ American Heart Association (ACC/AHA) evidence-based guidelines for non–ST-segment elevation myocardial infarction (NSTEMI).	SCPC accreditation	

Author	Outcomes	Level of analysis	Results
Sekimoto et al (2008)	Infrastructure for infection control activities: -Organization of IC provision and IC team (ICT) -Presence of IC doctors (ICDs) and IC nurses (ICNs) -Time allocated for IC activities by IC practitioners. Activities and practices of infection control -Surveillance -Standard precautions -Isolation precautions (including patient isolation practices) -Needle-stick prevention programs -Hospital food hygiene -Medical waste management -Catheter-related IC -Sterilization -Antimicrobial therapy use and regulation -IC in operating theatres and intensive care units (ICUs)	Facility level	There was no significant difference in infrastructure for infection control activities according to accreditation status. In the case of newly accredited and accredited hospitals, the hours of ICNs increased significantly between 2004 and 2005. There was no difference in overall score for IC activities according to accreditation status. For newly and accredited hospitals there was a significant increase between 2004 and 2005 in surveillance (mean [standard deviation (Poulsen et al.)]: 1.3[2.7] and 0.5[2.3], $p<0.05$) and anti-microbial therapy (mean [SD]: 0.9 [2.4] and 0.8 [2.5]). For non-accredited and accredited hospitals there was a significant increase between 2004 and 2005 in isolation precautions (mean [SD]: 0.7 [1.5] and 0.4 [1.2], $p<0.05$), IC for operating theatre/ICU (mean [SD]: 1.4 [2.1] and 0.7 [1.8]), and IC without evidence (mean [SD]: 0.3 [1.5] and 0.6 [1.5]). Medical waste management, catheter-related IC and sterilisation had a significant increased between 2004 and 2005 for accredited hospitals (mean [SD]: 0.5 [3.3], 0.5 [1.9] and 0.5 [1.8], $p<0.05$) Using multiple linear regression, accreditation was associated with 2.8 higher overall score in 2004 and 3.2 in 2005. When the change in overall score was used as dependent variable, accreditation in 2005 was associated with 2.0 greater increase, whilst accreditation in 2004 was associated with -2.0 change in score. When newly accredited and no change in accreditation status hospitals are compared, newly accredited hospitals had a 2.6 points greater increase in overall score.
Chandra et al (2009)	-ECG within 10 min of ED presentation -Aspirin -Beta-blocker -Unfractionated or low-weight heparin -Glycoprotein IIb/IIIa inhibitors within 24 hrs -In-hospital mortality -Postadmission infarction	Patient level	In an adjusted model, patients treated in SCPC accredited hospitals were more likely to receive acute aspirin and beta blocker compared to patients treated in non-accredited hospitals (OR [95% Confidence Interval]: 1.73 [1.06 to 2.83] and 1.68 [1.04 to 2.7]). There were no differences in the use of unfractionated or low-weight heparin, glycoprotein IIb/IIIa inhibitors within 24 hrs and ECG within 10 min of ED presentation. In an adjusted analysis of clinical outcomes, there were no differences in mortality, reinfarction, cardiogenic shock, ischemic stroke, haemorrhagic stroke, congestive heart failure, or overall major bleeding episodes.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Lutfiyya et al (2009)	Cross-sectional analytical	218290 patients in 730 hospitals	Rural critical access hospitals reporting to Hospital Compare, USA	To determine whether quality measures used in the US Centres for Medicare and Medicaid Services Hospital Compare database differed for critical access hospitals based on Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation status.	JCAHO accreditation	
Suñol et al (2009)	Cross-sectional analytical	389 acute hospitals	Acute hospitals in Belgium, Czech Republic, France, Ireland, Poland, Spain, Netherlands and United Kingdom.	To explore the association between the implementation of quality improvement strategies in hospitals and hospitals' success in meeting defined quality requirements that are considered intermediate outputs of the care process for AMI, appendicitis and deliveries.	Seven strategies for quality improvement: Accreditation Organisational quality management programmes Audit and internal assessment of clinical standards Patient safety systems Clinical practice guidelines Performance indicators Systems for obtaining patients' views	

Author	Outcomes	Level of analysis	Results
Lutfiyya et al (2009)	**Acute Myocardial infarction (AMI)** - Aspirin at arrival - Aspirin at discharge - Beta-Blocker at arrival - Beta-Blocker at discharge **Heart failure** - ACE inhibitor for LVSD. - Left ventricular function assessment - Comprehensive discharge instructions - Smoking cessation **Pneumonia** - Pneumococcal vaccination status - Initial antibiotic received within 4 h of hospital arrival - Oxygenation assessment - Smoking cessation - Appropriate initial antibiotic selection - Blood culture performed before first antibiotic received **Surgical infection prevention** - Prophylactic antibiotic 1 h prior to surgical incision - Prophylactic antibiotics discontinued 24 h after surgery	Patient level	Accredited hospital had a significantly higher performance for four out of 16 quality indicators: percent of patients given aspirin at arrival for AMI (90% vs 87.1%), percent of patients with heart failure receiving ACE inhibitors for LVSD (81.8% vs 77%) and smoking cessation advice (71% vs 60%), and percent of patients with pneumonia that received smoking cessation advice (68.2% vs 62.1%). The likelihood for accredited hospitals to have an above average performance was significantly better for six quality indicators: percent of patients receiving aspirin at arrival (OR [95% CI]: 1.39 [1.10–1.75]), percent of patients given ACE inhibitor for LVSD (1.29 [1.02–1.62]), percent of patients with left ventricular function assessment (1.50 [1.19–1.89]), percent of patients given comprehensive discharge instructions (1.65 [1.31–2.08]), percent of patients aged 65 and older who were screened for pneumococcal vaccine status and administered the vaccine prior to discharge, if indicated (1.96 [1.56–2.46]) and percent of patients given appropriate initial antibiotic selection (1.56 [1.24–1.97]). Accredited hospitals were more likely to be in the top half for the overall measure of quality (1.39 [1.09-1.76]).
Suñol et al (2009)	Four categories of intermediate outputs: Clinical Safety Patient-centeredness Cross-border patient-centeredness	Facility level	There was a significant correlation between the different internal quality improvement strategies at hospital level, explaining between 6 to 32% of the variance. Given the association between the different strategies, they were combined into one latent strategy index, which was used as a proxy. There was a significant correlation between the different intermediate outputs at hospital level, explaining between 6 to 33% of the variance. These outputs were also combined into a single latent output index, being used as a proxy. The strategies more frequently associated with outputs at a ward level were patient safety, performance indicators and clinical guidelines. The correlation between the latent strategy and latent output indexes at a ward level was 0.76 ($p<0.01$). Voluntary and government accreditation were significantly correlated to clinical outputs at medical wards and safety outputs. Global output was significantly higher in hospitals with a higher maturity index (a measure of how advanced quality improvement strategies were in the PDSA cycle) ($p<0.001$).

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Thornlow et al (2009)	Cross-sectional analytical	115 hospitals	Acute hospitals, USA	To examine the relationship between patient safety practices, as measured by accreditation standards, and patient safety outcomes as measured by hospital rates of infections, decubitus ulcers, postoperative respiratory failure, and failure to rescue.	Teaching status Ownership Hospital size Location (rural or urban) Nurse staffing levels Utilisation of safety practices (comprising four subscores: surveillance capacity, assessing patients' needs, care procedures and measuring processes)	
Mazmanian et al (1993)	Cross-sectional study	252 facilities	Head injury rehabilitation facilities, USA	To describe cognitive rehabilitation services, education and training in Commission on Accreditation of Rehabilitation Facilities (CARF) and non-CARF facilities	CARF Accreditation	
Fairbrother et al (2000)	Cross-sectional study	88 managerial staff	Recently EQuIP surveyed 600-bed hospital, Australia	To describe the views from hospital personnel about the EQuIP survey, survey week and overall views of the process	EQuIP accreditation survey	

Author	Outcomes	Level of analysis	Results
Thornlow et al (2009)	Patient safety indicators: - Healthcare-associated infections -Decubitus ulcers -Postoperative respiratory failure -Failure to rescue.	Patient level	JCAHO accreditation scores were not associated with patient safety indicators. Risk adjusted rates were: healthcare-associated infections (1.8 cases per 1000 discharges), postoperative respiratory failure (9.8 cases per 1000 elective surgical discharges) decubitus ulcers (21.5 incidences per 1000 discharges), failure to rescue or death (133.9 cases per 1000 discharges with potentially preventable complications). Larger hospitals had higher rates of healthcare-associated infections (Beta: 0.30, $p<0.05$) and postoperative respiratory failure than smaller hospitals (Beta: 0.36, $p<0.05$) in univariate and multivariate analyses. Higher rates of decubitus ulcers were associated with poorer performance in care procedures practices subscore (Beta: 0.27, $p<0.01$) and higher rates of healthcare-associated infections with poorer performance in assessing patients' needs practices subscore (Beta: 0.25, $p<0.05$)
Mazmanian et al (1993)	Education and training options Direct costs for staff training Learning needs of clinical staff Cognitive rehabilitation therapy practice	Facility level	
Fairbrother et al (2000)	Preparing for EQuIP survey week EQuIP survey week Overall views on EQuIP accreditation	Individual level	In relation to personnel views about the preparation work before EQuIP, 47% thought the workbook format was easy to use, 45% considered the self-assessment process satisfactory, 48% found the compliance rating helpful, 67% found the individual standards comprehensible, 63% considered standards to be relevant for their departments and 69% expressed that workload associated with future surveys will be less. However, 60% observed that activities were foregone in order to complete EQuIP preparation. Some of these activities comprised planned quality improvement activities, patient care time lost, departmental planning activities and continuing education activities. On average, staff estimated 6.7 hours per week of work during the six months preceding the survey. 51% was satisfied with the face-to-face meeting process during the survey week. Those not satisfied stated as reasons that process was too superficial and did not account for actual evidence presented by the team. 58% thought the overall rating reflected their department's performance. The staff that did not agree since they perceived that the overall rating lost granularity of performance across the hospital. 86% were satisfied with the hospital's facilitation of EQuIP accreditation, but only 45% thought the accreditation process was worthwhile. Among the reasons against accreditation staff mentioned: lack of evidence on the impact of the process on patient care, magnitude in terms of time and paper work and how this could negatively impact patient care, and usefulness of the process.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Gough et al (2000)	Cross-sectional study	93 laboratories	CPA accredited laboratories, United Kingdom	To ascertain whether the users of CPA (Clinical Pathology Accreditation) find the whole procedure helpful and think that it should continue	CPA process	
Griffith et al (2002)	Cross-sectional study	7 non-federal hospitals	Non-federal hospitals, USA	To examine the relationship of outcomes measures generated from Medicare data to Joint Commission accreditation measures for hospitals.	Overall evaluation score	
Government Audit Office (2004)	Cross-sectional study	500 hospitals	JCAHO accredited hospitals, USA	To examine the extent to which JCAHO's pre-2004 hospital accreditation process identified deficiencies in Medicare Conditions of Participation (COPs) that were identified by state survey agencies	State agency and JCAHO found no deficiencies State agency and JCAHO found same deficiencies JCAHO found more deficiencies than state agency State agency found more deficiencies than JCAHO	

Author	Outcomes	Level of analysis	Results
Gough et al (2000)	General impressions about the process Training policies Customer viewpoint Inspection and report Policies and procedures Value for money Suggestions to CPA	Facility level	The response rate was 64%. 71% of respondents agreed that CPA improved lab service delivery, 78% said that lab focus had shifted towards quality, but only 51% thought it had led to structured training and 86% thought training budget had not increased. 62% expressed that CPA was informative, 71% that has changed policies or procedures and 54% that had improved safety and health. 60% considered the accreditation process as a proof of compliance with national standards, whilst a 49% ascertained the excessive paperwork and bureaucracy as a disadvantage. 40% suggested as a way to improve CPA's work to generate consistent standards and have permanent, trained inspectorates.
Griffith et al (2002)	Solucient scores: -Cash flow margin -Asset turnover -Mortality index -Complications index -Cost per case -Length of stay -Outpatient activity Performance areas according to JCAHO accreditation system	Facility level	Overall evaluation scores (OES) ranged from 74 to 100 (possible scores from 0 to 100) and only 15% of cases scored under 87.5. The OES was associated with the mean performance area score (r=-0.9). Out of the 45 performance areas, 10 areas were identified as the most influential on OES: managing staff requests (beta=–0.732); design of new services (beta=–0.724); relevant policies (beta=–0.717); use of comparative information (beta=–0.653); patient and family education (beta=–0.641); measurement of processes and outcomes (beta=–0.639); initial assessment procedures (beta=–0.606); governance (beta=–0.606); and strategic planning (beta=–0.577). The four least influential performance areas were: pathology and clinical laboratory services (beta=–0.269); needs assessment for specific patient populations (beta=–0.180); operative procedures (beta=–0.124); and rehabilitation care (beta=–0.099). There was no association between the individual Solucient scores and the OES, except for mortality (r=-0.085, p=0.02) and percent of patient revenue (r=-0.09, p=0.015).
Government Audit Office (2004)	Rate of hospitals with serious deficiencies according to COPs Number of serious deficiencies according to COPs	Facility level	In the validation surveys run by state agencies designated by CMS (Centres for Medicare and Medicaid Services) during 2000 to 2002, serious deficiencies in compliance with COPs were found in 31%(157 hospitals), of which JCAHO failed to identify them in 78% (123 hospitals) of cases. When single serious deficiencies were analysed, JCAHO failed to identify 69% of them. In only 34 hospitals (6.8%), state agencies and JCAHO detected serious deficiencies. The most common deficiencies not identified by JCAHO fell into the categories of physical environment (36%), nursing services (4%), infection control (3.7%), patient's rights (3.7%) and pharmaceutical services (3.7%)

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Heuer (2004)	Cross-sectional study	41 hospitals	Acute, 200-plus bed, not-for-profit hospitals in New Jersey and Pennsylvania, USA	To determine the association between patient satisfaction and overall accreditation score	Overall JCAHO accreditation score Score for the following categories: -Nutrition -Patient's rights -Medical staff -Patient/family education -Initial assessment -Social environment -Design of environment -Continuity of care	
Miller et al (2005)	Cross-sectional study	2450 hospitals	Acute hospitals surveyed by JCAHO between 1997 and 1999, USA	To examine the association between the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation scores and the Agency for Healthcare Research Quality's (AHRQ) Inpatient Quality Indicators (IQIs) and Patient Safety Indicators (PSIs).	Performance in 15 Inpatient Quality Indicators Performance in 18 Patient Safety Indicators	

Author	Outcomes	Level of analysis	Results
Heuer (2004)	Overall patient satisfaction rating Patients' satisfaction in following categories: -Meals -Personal issues -Physician -Explanation of tests/treatments -Admission -Visitors and family -Room -Discharge	Facility level	No association was found between overall JCAHO accreditation scores and overall patient satisfaction scores. The results were consistent for percentile ranking of patient satisfaction. No significant association was found between JCAHO scores for selected categories and patient satisfaction scores for the equivalent categories. Using multivariable regression analysis, no relationship was found between scores on different patient satisfaction categories and the overall accreditation score. Likewise, there was no relationship between overall patient satisfaction score and scores for different accreditation assessment categories.
Miller et al (2005)	JCAHO final overall evaluation score Accreditation decision	Facility level	Most hospitals obtained a score between 90 and 100 for the final overall evaluation score (FOES). Regression analysis showed that none of the IQIs was associated with the FOES. Factor analysis revealed three factors explaining most of IQIs variability: Factor 1 included post procedural mortality rates; Factor 2 included caesarian section and vaginal delivery after C-section rates, and Factor 3 included mortality rates after hip replacement and rates of laparoscopic cholecystectomy. There was no relationship between these component factors and FOES. Worse rates in postoperative respiratory failure (p=0.003) and technical difficulty with care (p=0.004) were associated with lower FOES. Conversely, higher rates of iatrogenic pneumothorax (p=0.03) and obstetrical trauma (p=0.04) were related to higher FOES. Factor analysis of PSIs resulted in three factors explaining most of the variability: Factor 1 involved postoperative adverse events, Factor 2 involved obstetric trauma, and Factor 3 involved procedural technical complications. Only factor 1 was associated with FOES (p=0.02). Analyses of association between individual JCAHO elements performance score and IQIs/PSIs found no significant association.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Oh et al (2006)	Cross-sectional study	85 hospitals	Acute hospitals with more than 300 beds, Korea.	To assess the infrastructure and essential activities of ISCPs in the Republic of Korea.		
Wells et al (2007)	Cross-sectional study	2000 (n=571) 2005 (n=566)	Outpatient substance abuse treatment unit, USA	To examine to what extent common forms of outpatient substance abuse treatment organisation licensure and accreditation are associated with desirable treatment practices	Features of the centre: Ownership status, affiliation to a hospital or mental health centre, methadone treatment provision and number of patients. Features of clients: Employment status, HIV positive, dual diagnosis and ethnic group.	
Wineman et al (2007)	Cross-sectional study	307 health centres	Health centres, USA	To gain a baseline understanding of existing health centre linkages to community emergency preparedness and response systems and to identify factors that were associated with strong linkages.	Urban location High user volume Large number of service delivery sites Joint Commission accreditation Experience responding to an actual disaster High perceived risk for hazards or threats	

Author	Outcomes	Level of analysis	Results
Oh et al (2006)	Characteristics of Infection Control Doctors (ICD) and Nurses (ICN) Essential activities of Infection Surveillance and Control Programmes (ISCP)	Facility level	There was a significant difference between inpatients wards and intensive care units in the use of paper towels ($p=0.001$), antiseptics ($p=0.004$), and waterless antiseptics ($p<0.001$). 86% of hospitals had an ICD and 98% had an ICN. All hospitals had an infection control committee. There was an increase of newly employed ICNs between 1994 and 1996 and then decrease until 1998. In 2000, it steadily increased again until 2003. There was a significant increase of Intensity of surveillance over time, which is explained by an increase in very active and moderately active approaches since 1997. Authors claim that introduction of medical accreditation in 1995 and change of regulation in 2002 were drivers for the change in infection control systems.
Wells et al (2007)	-Staff-to-client ratio -Treatment comprehensiveness: Physical examinations, Routine medical care, Mental health care, Individual therapy course, Group therapy course, Employment counselling. -Treatment sufficiency: Treatment duration, After-treatment plans	Patient level	Coefficients for JCAHO accreditation for: Staff-to-client ratio: -0.19, $p>0.05$ Physical examinations: 0.57, $p<0.01$ Routine medical care: 0.27, $p>0.05$ Mental health care: 0.51, $p<0.05$ Individual therapy course: -0.14, $p>0.05$ Group therapy course: 0.27, $p>0.05$ Employment counselling: -0.29, $p>0.05$ Treatment duration: -0.28, $p<0.05$ After-treatment plans: 0.52, $p<0.05$
Wineman et al (2007)	Health centre completion of a collaborative hazard Vulnerability analysis with community responders Documentation of the health centre's role in the community Emergency response plan Health centre participation in community-wide exercises.	Facility level	The response rate was 34% (307/890). Respondents were more likely to be JCAHO accredited (42% vs 31%), be located in a rural area (38% vs 31%) and be high user volume (44% vs 32%). Accreditation was associated with having a radio to communicate with the community during a response, to have received extra funds for emergency preparation, to have staff involved in the preparation of the community for emergencies and that have received training in appropriate laboratory techniques. Additionally, accreditation was associated with having a designated contact person that the community emergency manager could reach at any time and having staff aware of the emergency operation plan.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
El-Jardali et al (2008)	Cross-sectional study	1048 registered nurses from 59 hospitals	Accredited hospitals, Lebanon	To assess the perceived impact of accreditation on quality of care through the lens of health care professionals, specifically nurses.	Leadership Commitment and support Strategic quality planning Quality management Human resource utilisation Use of data Accreditation Hospital bed-size	
Quimbo et al (2008)	Cross-sectional study	30 hospitals	Paediatric Hospitals, Philippines	To examine the effectiveness of accreditation by a national health insurance programme to ensure or promote the quality of inpatient, paediatric care.	Public provider Private provider PhilHealth accreditation Incentives payments Physician characteristics (age, sex, specialisation, and type of practice)	

Author	Outcomes	Level of analysis	Results
El-Jardali et al (2008)	Quality results	Individual Level	The response rate was 75.5%. There was an association between quality results and benefits of accreditation, indicating that nurses perceived there was a positive impact on quality. Additionally, there was a significant difference in the perception of nurses on the association between strategic quality planning, education and training, rewards and recognition, quality management, and use of data with accreditation, when small vs large and medium vs large hospitals were compared, with large hospitals having the lowest scores. Predictors of a better perception of benefits of accreditation were leadership, commitment and support (beta: 0.18, p<0.001); use of data (beta: 0.39, 0<0.001); quality management (beta for medium hospitals: 0.4, p=0.004); staff involvement (beta for small hospitals: 0.26, p<0.001); and hospital size (beta medium vs small: -0.15, p=0.02; beta large vs small: -0.27, p<0.001).
Quimbo et al (2008)	Quality of care in five specific clinical domains for diarrhoea, pneumonia and skin condition: -History taking -Physical examination -Ordering tests -Making a diagnosis -Treatment plan	Individual level	61% of physician surveyed worked in public institutions. 66% were accredited and 64% of them had received payment by PhilHealth. The average score of the vignettes was 54 points (possible scores from 0 to 100). In all models, younger doctors provided a better quality of care measured by their score in the vignettes. In the case of doctors working privately, accreditation and receiving payment were associated with better quality of care. On average, receiving payment would add 8 points to their score, whilst accreditation added 6 points. In the case of doctors working in public institutions, when they do not receive payments, accreditation has a significant effect on vignette score, but when they are not accredited, receiving payments had a significant effect on quality of care.

Author	Study Design	Setting	Aim	Intervention/ exposure	Outcomes	Level of analysis	Results
Collopy et al (2000a)	Descriptive study	Acute hospitals, Australia	To describe the development and implementation of the Care Evaluation Programme as part of accreditation in Australia	Clinical performance measures of the Care Evaluation Programme	1. Indicator development 2. Indicator role in accreditation 3. Data validation 4. Effectiveness of the indicators 5. Responses to a particular set of indicators 6. Examples of detailed responses 7. Future directions	Programme level	1. The development of each indicator set involved a literature search, drafting, field testing, confirmation and dissemination. Professional colleges were the main responsible for this process. After submission of data, the organisation would receive a report with their performance compared to similar organisations. 2. Since 1997, when a revised programme of accreditation (EQuIP) was implemented, the reporting of performance on the indicators every 6-month was made mandatory. The uptake of indicators increased since they were included in the accreditation programme. The main reason was the on-site visits to verify clinical performance. 3. Initially, when a healthcare organisation did not meet data requirements, this information was excluded from the aggregated figures. But, when more institutions were reporting, inconsistencies had less influence on the overall figures. 4. Organisations reported to the accreditation programme on their performance for each indicator and actions taken after the monitoring. The reporting of actions has steadily increased over time. 5. Organisations have reported that the introduction of indicators has helped to improve care. 6. For example, one hospital had above average hospital acquired bacteraemia rates. This led to a revision of procedures related to cleaning the insertion site. The rate was reduced (0.72% vs 0.3%) after one year. 7. The 250 indicators will be reduced in number to a core set of measures that are more valuable and responsive. Success of the programme is attributed to two factors: involvement of clinicians in the development of indicators and "soft" policy of the Australian Council on Healthcare Standards (i.e. educational rather than punitive approach)

Author	Study Design	Setting	Aim	Intervention/ exposure	Outcomes	Level of analysis	Results
Collopy et al (2000b)	Descriptive study	Acute hospitals, Australia	To describe the development and implementation of the Australian Council on Healthcare Standards Care Evaluation Programme during its first 10 years	Clinical performance measures of the Care Evaluation Programme	1. Indicator development 2. Growth of indicator programme 3. Validity, reliability and reproducibility 4. Indicators influence on clinical practice 5. Review process 6. Promotion 7. Future directions	Programme level	1. Indicators were developed by medical colleges using three criteria: availability of data from healthcare organisations, clinical relevance, and the measure was achievable. 2. The first set comprised 10 hospital-wide medical indicators. By 2000, there were 200 different indicators organised in 18 sets. 3. Content validity was ensured by involving providers in their development. The number of providers reporting information retrospectively has decreased and the increase in the number of institutions reporting data makes less relevant the impact of any inaccuracy of information. 4. There was a significant difference between 1997 and 1998 for those organisations taking actions to reduce unplanned readmissions, whilst those organisation who did not have a stable rate of unplanned readmissions. 5. Every two years indicators are reviewed by medical colleges using qualitative and quantitative information provided by healthcare organisations. This leads to refinement of the indicator or exclusion from a given set. 6. The indicators are being used by France and New Zealand. The involvement of provider in their development has made them unique and appealing. 7. Future directions are the development of multidisciplinary indicators, the inclusion of intermediate and long term outcomes, and the reduction of the number of indicators.

Author	Study Design	Sample size/ Setting	Aim	Outcomes	Level of analysis	Results
Bukonda et al (2003)	Descriptive study	79 Acute care hospitals, Zambia	To document the development of the Zambia Hospital Accreditation Program from 1997 onwards.	Major milestones 1. Recognising need to improve quality and choosing accreditation to address need 2. Choosing the appropriate accreditation configuration and adapting it to the country 3. Setting up the formal structure to advise, operate, and manage the accreditation program 4. Developing and testing standards, and agreeing on the survey process 5. Recruiting, hiring, and training surveyors 6. Conducting educational campaigns and surveys 7. Refining rules, policies, and procedures for accreditation 8. Developing the accreditation database format 9. Conducting accreditation decision surveys 10. Interpreting survey data and making accreditation decisions	Programme level	1. A health reform aiming to increase access to quality healthcare together with help from USAID impulse the establishment of an accreditation programme as a quality improvement strategy. 2. The chosen configuration was an integrated approach, where an accreditation council (comprising the general public, professional organisations and the government) was going to be in charge of the accreditation programme. 3. The central board of health chose members for the accreditation programme. It had an executive committee and three subcommittees, who were in charge of: standards development, training of surveyors and accreditation outcome decision-making. 4. The first set of standards was developed with healthcare professionals and community representatives taking into consideration the problematic areas at that time and key functions of healthcare facilities. The ZHAC visited the US to learn from the process implemented by JCAHO. 5. Representatives who visited the US conducted the training. Organisation represented in ZHAC nominated surveyors depending on their experience. 6. The standards were piloted during educational surveys, where the hospital would be surveyed without receiving an accreditation outcome. 7. The results from the educational surveys were used to determine decision-making rules for accreditation. 4 out of 10 points were need for each functional area and 6 out of 10 for four critical areas, in order to obtain 'basic' accreditation 8. A decision algorithm and a scoring form were developed to achieve consistency. 9. 12 hospitals received full accreditation surveys during the period. All of them gained accreditation status. 10. The greatest difficulty was drawing up the reports since hospitals were expecting more than just the accreditation decision. Hospitals also expressed their need for assistance to meet the standards.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Gabriele et al (2006)	Descriptive study	133 cases treated in one radiotherapy unit	Acute hospital, Italy	To analyse the practical feasibility and efficacy of the quality indicators elaborated by the National Health Service study group in a radiotherapy unit.	Baseline measurements for quality improvement initiative in a radiotherapy unit	
Office of Inspector General (1999)	Multi-methods study	HCFA database, survey to state and certification agencies, observation of 7 accreditation surveys and one certification survey	Health Care Financing Administration (HCFA), USA	To provide a summary and recommendations based on our assessment of the external review of hospitals that participate in Medicare.	The role of Joint commission and state agencies in overseeing hospitals and of HCFA reviewing the work performed by these bodies.	

Author	Outcomes	Level of analysis	Results
Gabriele et al (2006)	The level of achievement in 8 indicators: 1. Number of staff members/patients treated per year 2. Waiting list 3. Case-history accuracy 4. Multidisciplinary approach in the study of clinical cases/total number of cases 5. Number of CT treatment plans/overall treatments 6. Number of fields performed per fraction/overall treatment fraction 7. Number of treatments verified by portal imaging/overall treatments 8. Patient satisfaction verified by questionnaires filled	Facility level	The reference number of staff/patient ratio was 19 professionals over 1293 patients. The mean (SD) overall waiting time was 54.6 (25.2) days. In relation to the case-history accuracy, the centre had an 80% of conformance with the standard. Treatment was multidisciplinary for 100% of head and neck cancers and 70% for gastrointestinal cancer, however, for breast cancer only reached 50%. The mean (SD) number of CT treatment plans was 1.6 (0.9) per patient. The mean (SD) number of fields performed per day and per patient was 3.5 (1.7). On average (SD), each patient received 16.7 (10) portal images during the whole treatment. An 89.8% of patients were very satisfied with the staff.
Office of Inspector General (1999)	Strengths and deficiencies of the Joint Commission accreditation system, the certification by state agencies and overseeing capacity of HCFA.	Programme level	Nine main findings: 1. Accreditation surveys serve as a driver to improve care and patient-safety 2. State agency investigations serve as an opportunity for responding to complaints and adverse events. 3. Malpractice and substandard care are unlikely to be detected by JCAHO surveys. 4. Non-accredited hospitals are not routinely inspected by state agencies 5. Hospital review systems are moving toward a more collegial way of oversight. JCAHO is leading this movement. 6. A more regulatory approach is being used by state agencies 7. Using a more collegial approach could jeopardise patient protection systems currently in place. 8. HCFA, which is supposed to oversee the work of JCAHO and states agencies, does not obtain information on their performance, or provide thorough feedback to them. 9. Limited use of public disclosure as a mechanism to hold accountable JCAHO and states agencies. Recommendations -HCFA should hold fully accountable for the external review of hospitals performance to JCAHO and state agencies -HCFA should determine the periodicity of certification surveys of non-accredited hospitals.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Benson et al (2004)	Multi-methods study	30 NHS trusts	Acute trusts in the English NHS, United Kingdom	To measure specific changes and improvements in patient care resulting from Commission for Health Improvement regulatory attention.	Clinical governance review by CHI in the last 12 months and follow-up review	

Author	Outcomes	Level of analysis	Results
Benson et al (2004)	For each clinical governance review report, information was collected about: Key area of action, scale and content of change proposed, measurability of changes proposed, key area for action was acknowledged and addressed on action plan, timescale for change, scale and content of proposed actions, routinely collected data available to monitor progress of action plan, categorise progress of change and potential barriers. Additionally, data about validity of recommendation according to the trusts was sought, in terms of how recently the concern was raised, extent that change has happened and if change was driven by CHI's recommendation Four case studies exploring general impressions about CHI review; action plan implementation and development; the contribution of CHI review to change; and learning that was drawn from the experience.	Trust level	Clinical governance report varied in content, depth of content, presentation and design. It is not clear to what extent this variation reflects of the context in each NHS trust. Interviewees found recommendations appropriate for the local issues. 90% of NHS trusts agreed with key areas of action (KAA) recommendations, whilst 25% of PCTs and 40% of SHAs do not know if KAA were adequate. Additionally, interviewees commented that the process of collecting information was very labour intensive, the focus of the review should be on patient experience and the expertise of the reviewers was patchy. Actions plans from NHS trusts also varied greatly in content, depth, structure and design, reflecting the level of engagement of each institution with CHI's review. The inexplicit way KAA were presented led to some of them (5%) not being addressed by NHS trusts. When the progress of KAA was assessed against available data, for 31% of KAA it was not possible to determine the level of progress. For the rest of KAA, 15% had been fully implemented, 30% mainly implemented and 12% showed no implementation. KAAs in the area of strategic capacity were more likely to be implemented (60% mainly or fully implemented) compared to clinical effectiveness (27% mainly or fully implemented). The format of CHI/strategic health authority reviews of progress also varied in format and content. The level of implementation of a KAA was associated with being addressed in detail in the action plan, change being measurable, reasonable timescale for implementation, documentation of progress and NHS trust performance rating (stars). NHS trusts reported that a 77% of changes identified in KAA were raised once or more times before. Additionally, 50% of trusts attributed the change in KAA to CHI's review

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Day et al (2004)	Multi-methods study	25 NHS trusts	Acute trusts in the English NHS, United Kingdom	To identify and analyse the challenges faced by CHI and the way it responded, and to draw out some implications for the future.	Clinical governance review by CHI	

Author	Outcomes	Level of analysis	Results
Day et al (2004)	CHI's methodology was assessed in practice through three main streams: - How adequate is the conceptual framework provided by the seven pillars of clinical governance to the reviews. - How consistent were the reviews to assess performance (i.e. assessment of same aspects of performance, weighting and interpretation of evidence is similar, and presentation of finding allows comparison). - How reviews relate to the score awarded and how to interpret them.	Trust level	The main role of CHI was to report on the systems of clinical governance of NHS trusts. To achieve this role, CHI divided clinical governance into seven pillars: risk assessment, clinical audit, staffing and management, education and training, clinical effectiveness, use of information, and patient involvement. The rationale for these pillars was a mix of common sense and theory. Only the last one (i.e. patient involvement) does not fit in the model since it considers that patient should be involved in the planning of services and in decision-making about their own treatment, which are desirable components of quality of care, but they do not equate clinical governance. Culture and leadership are essential features of good clinical governance, however, they were not included in the pillars, instead, CHI added an additional area of "strategic capacity to develop and implement CG" to assess these features. The review reports are consistent regarding the aspects that are assessed since CHI sends in advance a questionnaire to each NHS trust with the information required. The strategy to weigh the evidence and decide to report on an issue is standardised; however, the characteristics of the NHS trusts cannot fully explain the differences observed in the review reports. For example, for control of infections and bed sores, some reports comment on both, whilst other do not refer to them. Some reports compare performance to the national average or similar trusts, whilst others describe trends over time. The composition of review teams seems to influence the issues that are raised, which raised the question whether the absence of comments on an issue is due to absence of problems or absence of adequate expertise. CHI had a scoring system on a one-to-four-point scale for each of the seven pillars guided by an assessment matrix. The level of compliance and the extent the activity was present across the organisation were considered in the scoring. CHI's overall score is used to assign the "star rating" in the annual review report. Four points in one of the pillars was rarely seen and the best performing trusts received around 18-20 points. This could imply that clinical governance has not been fully implemented; hospitals deliver high quality of care, but their clinical governance systems could be improved or methodology cannot fully capture the variations in performance of clinical governance systems. Moreover, the score does not relate to the narrative in the reports.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Devers et al (2004)	Qualitative study	87 interviews with leaders and 226 with employers	Large hospitals in twelve metropolitan areas, USA	To describe hospital systems' and freestanding hospitals' patient-safety initiatives; their progress toward implementing them; and the relative roles that professionalism, regulation, and markets play in stimulating progress.	Role of regulation, professionalism and market forces	
Lancaster et al (2010)	Qualitative study	3 senior health executives	Hospitals, Australia	To explore how surveying benefits accreditation surveyors and the organisations in which they are regularly employed.	Surveyors for the Australian Council on Healthcare Standards	

Author	Outcomes	Level of analysis	Results
Devers et al (2004)	Hospitals' patient-safety initiatives	Facility level	Interviews showed that major patient-safety initiatives were driven by JCAHO requirements. In 188 occasions these initiatives could be mapped to JCAHO policies or requirements, which can be grouped into three main categories: sentinel events, patient-safety standards and patient-safety goals. The level of implementation for 13 of 15 initiatives was either partially implemented or fully implemented in some hospital areas. Only a bar-code system for patients, medications and staff; and computerised physician order entry were under discussion. When health plans companies were asked about these initiatives, they were not aware of the requirement or level of implementation of them. Besides JCAHO, 14 other organisations were mentioned by hospital respondents: private purchasers, professional associations, federal agencies, public-private partnerships and institutions working on quality improvement. Among the facilitators to implementing patient-safety initiatives, respondents mentioned: Medicare participation requires JCAHO accreditation, publication of "To Err is Human", the Leapfrog Group, and ongoing research and peer education. Among the barriers, respondents mentioned: absence of incentives in local markets to improve patient safety, costs of implementation, Information Technology (IT) infrastructure, the commitment of physicians to implement patient safety initiatives, loss of professional autonomy and income of physicians, and malpractice liability concerns. In terms of the impact of patient-safety initiatives on hospitals, respondents thought that the publication from the IOM had increased attention, efforts and accountability for patient-safety improvement. The impact on patients was unclear. Data on medical errors were not usually reported or were non-existent, therefore current efforts to improve reporting had led to an increase in rates of reported medical errors.
Lancaster et al (2010)	Perceptions about organisational understanding of quality Value of the experience and skills gained from surveying Perception about the reward of being a surveyor Perception of the utility of the experience and skills gained as a surveyor in their professional roles.	Individual level	Main benefits could be categorised into 4 groups: Exposure to new methods and innovation in healthcare Engagement in ongoing learning Gaining expertise to improve quality of care in their own institutions Translating experience as surveyors into improvement of processes of care and enhancement of public health in other institutions

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Comparison
Pham et al (2006)	Qualitative study	111 interviews with hospital association leaders, managers and staff from 36 hospitals	Hospitals participating in the Community Tracking Study (CTS), USA	To examine the interaction between different quality reporting programmes and their impact on operations at hospitals	Quality reporting programmes (i.e. Public reporting, private benchmarking or incentives) categorised according to 6 features: -Sponsorship -Programme type -Mandatory or voluntary -Incentives -Quality improvement support -Inclusion of clinical outcomes measures	

Author	Outcomes	Level of analysis	Results
Pham et al (2006)	-Institutional support and attitudes -Specific clinical conditions -Response to incentives -Adequacy of resources -Feedback and accountability mechanisms -Adoption and modification of quality improvement activities	Facility Level	The 36 hospitals participating reported data to the CMS and JCAHO. Additionally, other 36 quality reporting programmes were mentioned. On average, hospitals reported data to 3.3 programmes (range 1 to 7). Quality improvement had turned into a priority for hospital leadership due to its link with payments, JCAHO accreditation and public benchmarking. This had been translated into practice in several ways: QI activities explicitly included in strategic planning; regular commitment from senior managers to review performance data; introduction of quality performance-based incentives; management more open to releasing resources for quality improvement; and more leadership from senior managers with front-line staff. Quality officers argued that reporting programmes were limiting the aspects of quality of care that the hospital focuses on, shifting resources and attention away from other clinical areas. Reporting to CMS and JCAHO were seen as incentives for participation due to their mandatory nature, impacting on the use of resources which had been redirected to improve the care of JCAHO and CMS core conditions. Initiatives coming from institutions working on healthcare improvement or professional associations were also seen as incentives to focus on specific conditions. For instance, the Institute for Healthcare Improvement (IHI) had published a "ventilator bundle" to prevent ventilator-associated pneumonia, which included a set of concrete evidence-based actions that could be implemented for improvement. There was a general consensus that performance measurement and improvement increased costs. In some hospitals, staff had been relocated to collect performance data, whilst in others, the responsibilities had been added to existing staff. Performance reporting had impacted the frequency of data review. A third of hospitals were reviewing information monthly in order to give rapid feedback to staff or perform root-cause analysis. Dissemination of performance data has also changed. These reports were frequently reviewed by board members along with clinical staff in order to drive improvement. Staff had been restructured into multidisciplinary teams to track and improve overall performance and for those condition included in CMS and JCAHO data reporting. There were mixed responses about the extent to which quality performance reporting had impacted quality improvement initiatives in their hospitals. Those reporting no impact stated that hospitals had been active before the implementation of performance reporting programmes. The proponents of a moderate impact pointed out the uptake of bundles of quality improvement for Chronic Heart Failure (CHF). Hospitals' leaders believed that performance reporting had changed staff ability and willingness to address deficiencies of care.

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure	Outcomes	Level of analysis
Pomey et al (2010)	Qualitative study	5 Healthcare Organisations	Accredited healthcare organisations, Canada	To evaluate how the accreditation process helps introduce organisational changes that enhance the quality and safety of care.	Five case studies selected based on Geographical location Organisational structure Time participating in accreditation	Conceptual framework analysed the following aspects: -General environment -Fundamentals -Strategies -Leadership and competencies -Conceptualisation/ philosophy	Facility Level

Author	Results
Pomey et al (2010)	Case 1: New regional health authority created from the merger of several organisations without experience in accreditation. There was strong leadership at all level of management. The most substantial changes occurred during the self-assessment phase. Accreditation was used to integrate different function into a single entity, as an opportunity for individuals to meet and start working together, and to involve community member in decision-making. The fact that the institution was expected to implement changes served as catalyser to improve problematic areas. At the management level, accreditation drove the creation of an information management strategy, a performance appraisal process, and a director of education and human resources. Case 2: New healthcare organisation was created from the merger of three institutions, all of them with experience in accreditation. Management open to listening to proposals from any member of staff and employees felt responsible for creating quality initiatives. The inclusion of physician with knowledge in administration and leadership helped to be recognised as a leader in certain areas such patient safety and quality. During the self-assessment phase, members of staff from the different institutions had to learn to work together toward a common goal. Accreditation itself served as a means to merge not just the institutions, but the culture. Most changes occurred after receiving the accreditation report, which was focused on group practices, centralising rehabilitation services and communicating better with the community. Case 3: Hospital accredited for many years. It had been put under guardianship in two consecutive years. This supervision led to the implementation of a new governance policy and as a consequence, a performance improvement committee. The quality director was recognised by his leadership abilities and knowledge. Self-assessment and visit did not lead to any changes. After receiving the report, this was not seen as a driver for improvement, rather an invitation to analyse potential changes to meet mandatory requirements. Among the initiatives implemented were strategies to encourage leadership, emphasis on staff retention and adoption of an accountability framework. Case 4: Hospital accredited for many years. Strong leadership from the chief executive. Quality improvement activities were a regular part of the institution, having someone in charge of matters related to risks, preventable events, complaints and quality. Organisational culture was open to change, with very active members in the board of directors and strong communication with their community. Accreditation was seen as an opportunity to prioritise those initiatives that were aligned with recommendations by the accrediting body. A consultancy firm helped them to organise the process. Using the previous report, they mapped changes required against changes implemented. The organisation passed the accreditation. CEO appreciated the recommendations since they were an instrument to emphasise the need for improvement initiatives. Case 5: New regional health authority. Pre-merger institutions had experience in accreditation. The merger was driven by financial pressures. The institution had been recognised as a top employer due to its management of human resources. It provided continuing education opportunities to its staff and encouraged physicians to participate in decision-making. Director of quality improvement and the risk manager were recognised as very visible within the organisation and leaders in their fields. The research department was in charge of the accreditation process, which was seen as an opportunity to share experiences from the different healthcare organisations, now merged into one. Accreditation was a driver to implement changes that had been long overdue. The report was seen as a morale booster since it allowed staff to compare their performance against others in the country. The institution created an ethics committee, improved patients' health records, and implemented a coordinated corporate quality improvement initiative after receiving the accreditation report.

Table 4.5 Descriptive information of missing studies and articles in French

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure
Sierpinska et al (2002a, b ,c)	Cross-sectional analytical	560 physician and nurses	21 hospitals (4 accredited and 17 non-accredited), Poland	To determine professionals' knowledge of the requirements to obtain a Quality Certificate, perceptions about management of therapeutic teams, and the relationship between perception of competence and scope of duties, authorization and responsibility among members of therapeutic teams	Quality certificate in Poland versus non-accredited hospitals
Bruneau et al (2003)	Cross-sectional analytical	900 healthcare professionals	Acute care, France	To determine the perceptions of healthcare professional about the impact of accreditation	Accreditation by ANAES
Muñoz et al (2007)	Cross-sectional analytical	4977 healthcare professionals	Healthcare organisations, France	To describe the working conditions of healthcare professionals in accredited and non-accredited institutions in France	Accreditation level
Bruneau et (2006)	Cross-sectional study			To determine the perceptions of directors, doctors and care personnel about effect of accreditation	Accreditation by ANAES
Dédale (2009)	Cross-sectional study	1575 healthcare organisations	Acute hospitals, regional health offices, regional managers of health and social care offices and risk management support structures, France	To determine characteristics of risk management programmes in hospitals in France and barriers and facilitators to their implementation.	Accreditation
ANAES (2003)	Descriptive study	Annual report of activity	Acute care hospitals, France	To describe progress made between 2002 and 2003 by the accreditation agency in France	Accreditation
Abdelmounène et al (2006)	Descriptive study	100 hospitals	Acute care hospitals, France	To describe the level of implementation of recommendations received by hospitals during the first wave of accreditation, when they received a second visit	Accreditation by ANAES

Author	Study Design	Sample size	Setting	Aim	Intervention/ exposure
Douguet et al (2005)	Multi-methods study	24 structured interview and a questionnaire	Acute hospitals, France	To describe perceptions of healthcare professional about accreditation and its impact on quality of care and on the organisation	Accreditation by ANAES
Beaumont (2008)	Multi-methods study	Case study	Acute hospital, Saudi Arabia	To determine capacity building in a hospital and to describe knowledge about quality improvement	
Berthelier (2002)	Qualitative study	Observation and semi-structured interviews	Nephrology units, France	To describe the perceptions of healthcare professionals working in nephrology units about the accreditation process	Accreditation of nephrology units
Grenade et al (2002)	Qualitative study	45 interviews with stakeholders from facilities, organisations, and peak bodies	Accredited residential care in Western Australia	To explored issues relating to the basic philosophy and principles underlying the accreditation, the implementation process, the accreditation standards, and the overall impact on providers.	Accreditation programme of residential aged care facilities
Pomey et al (2004)	Qualitative study	One case study	University Hospital, France	To assess the impact of the self-assessment phase of accreditation on organisational change	One case study using semi-structured interviews, document analysis and standardised questionnaire and non-systematic observation.
Doyle et al (2008)	Qualitative study	3 Healthcare Organisations	Accredited hospitals, Ireland	Consequences and perceptions about accreditation process, critical success factors, professional groups involvement and costs associated	Three case studies using in-depth interviews, focus groups, surveys and walk of facilities: -One teaching hospital -One rural non-teaching hospital -One private not-for-profit hospital

Table 4.6 Summary of numeric results for all studies included in the overview of reviews

Accredited vs non-accredited									
Disease-specific organisational performance AMI	Unit of analysis	sample size		Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
		exposed	control						
Time-series									
Weeks et al. (2007) -compliance after intervention									
ACE-I for left ventricular systolic dysfunction	Patients	43930	5511	78.4	14.8	78.7	15.9		0.7
Aspirin at arrival	Patients	167064	23782	94.3	5.6	93.5	7.4		0.02
Aspirin at discharge	Patients	183801	23413	94.1	7.9	92.9	9.8		0.01
ß-blocker at arrival	Patients	147181	20819	88.8	10.1	87.9	12.6		0.1
ß-blocker at discharge	Patients	184527	23411	91.4	8.8	90.7	10.7		0.1
PTCA within 90 minutes of arrival	Patients	3015	427	38.1	22.6	41.2	24.4		0.5
Smoking cessation advice/counselling	Patients	24330	3144	83.3	18.7	84	18.4		0.6
Thrombolytic agent within 30 minutes of arrival	Patients	1032	210	38.7	28.8	44.8	33.2		0.2
Retrospective cohort									
Ross et al. (2008) - odds ratio									
Aspirin at hospital arrival	Patients	37758	317514	1.16				(1.09–1.23)	0.0001
Aspirin at discharge	Patients	30570	263277	1.13				(1.07–1.18)	0.0001
Beta-blocker at arrival	Patients	6850	39014	1.37				(1.29–1.46)	0.0001
Beta-blocker at discharge	Patients	528	9277	1.3				(1.07–1.59)	0.0001
PCI < 120 minutes after arrival	Patients	54625	329150	1.17				(1.11–1.23)	0.0001
Fibrinolytic therapy < 30 minutes after arrival	Patients	55418	339832	1.13				(1.08–1.19)	0.0001
ACE-I or angiotensin receptor blocker administration for Left Ventricular systolic dysfunction	Patients	12920	85213	1.11				(1.05–1.17)	0.0001
Smoking cessation counselling on discharge.	Patients	20651	106875	1.54				(1.44–1.65)	0.0001

Accredited vs non-accredited								
Disease-specific organisational performance AMI	Unit of analysis	sample size exposed	 control	Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
Cross-sectional analytical								
Chen et al. (2003)								
Use of aspirin within 48 hrs of admission, n	Patients	124182	10328	36074		2868			
Beta-blockers within 48 hrs of admission, n	Patients	124182	10328	37905		3035			
Acute reperfusion therapy (thrombolytic agents or primary angioplasty) within six hours of admission, n	Patients	124182	10328	8550		606			
Chandra et al. (2009) - Odds ratio								
ECG within 10 min of ED presentation	Facilities	3059	30179	1.28				(0.98-1.67)	
Aspirin	Facilities	3059	30179	1.73				(1.06-2.83)	
Beta-blocker	Facilities	3059	30179	1.68				(1.04-2.70)	
Unfractionated or low-weight heparin	Facilities	3059	30179	1.12				(0.74-1.70)	
Glycoprotein IIb/IIIa inhibitors within 24 hrs	Facilities	3059	30179	1.3				(0.93-1.80)	
Landon et al. (2006)								
Opportunity score, odds ratio	Facilities	3893	166	1.32				(1.26-1.37)	
Lutfiyya et al. (2009)								
Aspirin at arrival, n	Patients	1306	2909	1138		2618			
Aspirin at discharge, n	Patients	638	1480	549		1258			
Beta-Blocker at arrival, n	Patients	1176	2670	960		2107			
Beta-Blocker at discharge, n	Patients	648	1552	559		1315			

Disease-specific organisational performance Pneumonia	Unit of analysis	sample size exposed	 control	Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
Time-series									
Weeks et al. (2007) - Compliance after intervention									
Blood culture before 1st antibiotic	Patients	109209	14450	82.5	9.9	82.9	10		0.5
Initial antibiotic timing	Patients	410328	63884	69	11.8	71.8	12.4		<0.001
Oxygenation assessment	Patients	422229	65288	98.4	4	97.7	5.5		0.003
Pneumococcal vaccination	Patients	226663	35532	43.4	25.7	42.7	26		0.5
Smoking cessation advice/counselling	Patients	27743	3788	63.9	27.6	63.1	27		0.6
Cross-sectional analytical									
Landon et al. (2006)									
Opportunity score	Facilities	3893	166	1.18				(1.16-1.20)	
Lutfiyya et al. (2009)									
Pneumococcal vaccination status, n	Patients	8578	16131	5490		10469			
Initial antibiotic received within 4 h of hospital arrival, n	Patients	10675	18703	8892		15916			
Oxygenation assessment, n	Patients	13299	23947	13179		23755			
Smoking cessation, n	Patients	2611	4453	1781		2765			
Appropriate initial antibiotic selection, n	Patients	10255	18007	8091		13901			
Blood culture performed before first antibiotic received, n	Patients	9117	14998	7604		12403			

Disease-specific organisational performance Heart failure	Unit of analysis	sample size exposed	 control	Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
Time-series									
Weeks et al. (2007) - Compliance after intervention									
ACE-I for left ventricular systolic dysfunction	Patients	130020	17618	75.5	13.5	74.6	14.5		0.2
Assessment of left ventricular function	Patients	385801	57601	86.3	11.4	82.3	17.1		<0.001
Discharge instructions	Patients	120953	16699	48.4	28.5	46.4	27.4		0.2
Smoking cessation advice/counselling	Patients	24087	3414	68.2	27.2	66.6	26.4		0.3
Cross-sectional analytical									
Landon et al. (2006)									
Opportunity score, odds ratio	Facilities	3893	166	1.43				(1.39-1.47)	
Lutfiyya et al. (2009)									
ACE inhibitor for LVSD, n	Patients	1786	2733	1461		2104			
Left ventricular function assessment, n	Patients	7386	12499	5274		8487			
Comprehensive discharge instructions, n	Patients	5240	8295	2720		4197			
Smoking cessation, n	Patients	997	1547	708		928			
Surgical infection prevention									
Cross-sectional analytical									
Lutfiyya et al. (2009)									
Prophylactic antibiotic 1 h prior to surgical incision, n	Patients	2358	5080	1724		3693			
Prophylactic antibiotics discontinued 24 h after surgery, n	Patients	2153	4763	1514		3520			

Hospital-level organisational performance	Unit of analysis	sample size		Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
		exposed	control						
RCT									
Salmon et al									
Overall compliance with accreditation standards, %	Facilities	10	10	30		0		(23 - 37)	0.001
Overall nurses' perception of care, mean difference	Facilities	10	10	1.5	5.1	-4.2	6.7	(0.6 - 10.9)	0.031
Patients' satisfaction, mean difference	Facilities	10	10	4.6	5	3.1	4.6	(-2.8 - 15.8)	0.484
Medical education, mean difference	Facilities	10	10	0.2	4.7	-1.5	3.9	(-2.5 - 5.9)	0.395
Accessibility of medical records, mean difference	Facilities	10	10	-7.9	9.4	-11	9.6	(-6.1 - 12.2)	0.492
Discharge and admission record completeness, mean difference	Facilities	10	10	2	7.7	-3.7	7.4	(-1.4 - 12.9)	0.114
Completeness peri-operative notes, mean difference	Facilities	10	10	2.5	5.5	4.4	6.5	(-8.4 - 4.3)	0.489
Medicine labelling, mean difference	Facilities	10	10	15.8	19.3	4	22	(-3.1 - 26.7)	0.112
Hospital sanitation, mean difference	Facilities	10	10	3.1	12.4	5.5	9.3	(-5.7 - 12)	0.641
Interrupted time series									
Piontek et al. (2003) - 1 -Expected value									
Length of stay (internal control)	Patients	1952	342	-0.11	0.75	-0.02	0.27		
Length of stay (external control)	Patients	1952	2144	-0.11	0.75	0.19	1.19		
Cost (internal control)	Patients	1952	342	-0.05	0.31	0.18	0.35		
Cost (external control)	Patients	1952	2144	-0.05	0.31	0.20	1.23		
Prospective cohort									
Barker et al. (2002)									
Medication errors, n	Doses	1481	284	1247		228			
Quality assurance project (2005)									
C-section infection, %	Facilities	4	4	33		36			
Emergency drugs, %	Facilities	4	4	58		45			
Essential drugs, %	Facilities	4	4	77		77			

Hospital-level organisational performance	Unit of analysis	sample size		Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
		exposed	control						
Lab tests availability, %	Facilities	4	4	9		97			
Sanitation, %	Facilities	4	4	79		62			
Nurse satisfaction, %	Facilities	4	4	54		53			
Patient satisfaction, %	Facilities	4	4	59		55			
Cross-sectional analytical									
Sekimoto et al. (2008)									
Organization of IC provision and IC team (ICT), n	Facilities	211	93	188		71			
Presence of IC doctors (ICDs) and IC nurses (ICNs), compliance	Facilities	211	93	41.9	38.5	32	36.5		
Time allocated for IC activities by IC practitioners, compliance	Facilities	211	93	14.4	17.7	16.5	21.1		
Surveillance, compliance	Facilities	211	93	0.5	2.3	0.5	2.5		
Standard precautions, compliance	Facilities	211	93	0.2	3.5	0.2	4		
Isolation precautions (including patient isolation practices), compliance	Facilities	211	93	0.4	1.2	0.7	1.5		
Needle-stick prevention programs, compliance	Facilities	211	93	0.1	1.3	0.2	1.8		
Hospital food hygiene, compliance	Facilities	211	93	0.1	1.9	0.4	2.1		
Medical waste management, compliance	Facilities	211	93	0.5	3.3	0.6	3.2		
Catheter-related IC, compliance	Facilities	211	93	0.5	1.9	0.3	2.1		
Sterilization, compliance	Facilities	211	93	0.5	1.8	0.2	1.9		
Antimicrobial therapy use and regulation, compliance	Facilities	211	93	0.8	2.5	0.9	2.4		
IC in operating theatres and intensive care units (ICUs), compliance	Facilities	211	93	0.7	1.8	0.4	2.1		

Patients' outcomes	Unit of analysis	sample size exposed	sample size control	Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
Time-series									
Weeks et al. (2007) – odds ratio									
Mortality for Abdominal aortic aneurysm repair	Patients	?	?	0.7				(0.60 – 0.83)	<0.001
Mortality for Aortic valve replacement	Patients	?	?	0.71				(0.62 – 0.81)	<0.002
Mortality for Coronary artery bypass graft	Patients	?	?	0.86				(0.81 – 0.91)	<0.003
Mortality for Carotid endarterectomy	Patients	?	?	0.87				(0.81 – 0.94)	<0.004
Mortality for Colectomy	Patients	?	?	0.87				(0.81 – 0.95)	<0.005
Mortality for Cystectomy	Patients	?	?	0.49				(0.33 – 0.72)	<0.006
Mortality for Esophagectomy	Patients	?	?	0.01				(0.00 – 0.23)	<0.007
Mortality for Gastrectomy	Patients	?	?	0.73				(0.52 – 1.01)	<0.008
Mortality for Lower extremity bypass	Patients	?	?	0.76				(0.69 – 0.84)	<0.009
Mortality for Lung lobectomy	Patients	?	?	0.49				(0.40 – 0.59)	<0.010
Mortality for Mitral valve replacement	Patients	?	?	0.46				(0.36 – 0.59)	<0.011
Mortality for Nephrectomy	Patients	?	?	0.97				(0.80 – 1.19)	
Mortality for Pancreatectomy	Patients	?	?	0.33				(0.16 – 0.66)	<0.001
Mortality for Pneumonectomy	Patients	?	?	0.66				(0.34 – 1.26)	
Interrupted time series									
Piontek et al. (2003) - 1 -expected value									
Mortality (internal control)	Patients	1952	342	-0.012	0.12	-0.002	0.02		
Mortality (external control)	Patients	1952	2144	-0.012	0.12	-0.004	0.07		
Readmission within 30 days (external control)	Patients	1952	2144	-0.006	0.31	0.058	0.41		
Prospective cohort									
Quality assurance project (2005)									
Mortality within two days of admission, %	Facilities	4	4	49		62			

Patients' outcomes	Unit of analysis	sample size exposed	sample size control	Measure of effect	SD	Measure of effect	SD	95 % CI	p-value
Retrospective cohort									
Pasquale et al. (2001)				%obs	%exp	%obs	%exp		
Survival for injuries of Head	Facilities	171	418	68	58	68	57		
Survival for injuries of Neck	Facilities	113	481	76	65	87	79		
Survival for injuries of Chest	Facilities	223	456	80	72	80	70		
Survival for injuries of Brain	Facilities	748	1553	80	73	84	71		
Survival for injuries of Lung	Facilities	2048	3304	83	75	79	68		
Survival for injuries of Liver	Facilities	214	652	61	62	70	69		
Survival for injuries of Spleen	Facilities	403	817	79	74	85	76		
Survival for injuries of Aorta	Facilities	118	272	36	34	39	33		
Survival for injuries of Vena Cava	Facilities	46	205	28	39	48	62		
Cross-sectional analytical									
Simons et al. (2002)									
Observed vs predicted mortality	Facilities	16473	5542	2.06					<0.001
Chen et al. (2003)									
Risk-standardised 30-day AMI mortality	Patients	124182	10328	22849		2107			
Chandra et al. (2009)									
In-hospital AMI mortality	Facilities	3059	30179	1.07				(0.80-1.42)	
Post-admission infarction	Facilities	3059	30179	0.7				(0.36-1.38)	

High vs low performing								
Disease-specific organisational performance								
Time-series	Unit of analysis	intervention			control			p-value
AMI		n	before	after	n	before	after	
Williams et al. (2005)								
Aspirin within 24 hours after admission, n	Facilities	351	351	337	351	274	326	
Aspirin prescribed at discharge, n	Facilities	351	351	323	351	232	302	
ACE inhibitor at discharge for left ventricular systolic dysfunction, n	Facilities	351	351	291	351	126	260	
Smoking-cessation counselling or advice, n	Facilities	351	344	298	351	25	239	
Beta-blocker within 24 hours after admission, n	Facilities	351	351	326	351	214	302	
Beta-blocker prescribed at discharge, n	Facilities	351	351	326	351	207	298	
Mean time from arrival to thrombolysis, min	Facilities	315	24	49	315	138	63	0.03
Mean time from arrival to PCI, min	Facilities	172	92	196	172	881	340	0.33
Pneumonia								
Oxygenation assessment within 24 hours after admission, n	Facilities	426	426	421	426	349	413	
Pneumococcal screening, vaccination, or both by discharge, n	Facilities	426	285	281	426	0	149	
Blood cultures collected before initiation of antibiotic therapy, n	Facilities	426	417	357	426	268	328	
Smoking-cessation counselling or advice, n	Facilities	426	340	315	426	4	243	
Mean time from arrival to initial antibiotic administration, min	Facilities	426	159	190	426	380	254	0.001
Heart failure								
Discharge instructions , n	Facilities	466	340	340	466	5	196	
Assessment of left ventricular function, n	Facilities	466	452	433	466	233	336	
ACE inhibitor at discharge for left ventricular systolic dysfunction, n	Facilities	466	457	391	466	196	326	
Smoking-cessation counselling or advice, n	Facilities	466	405	377	466	9	294	

Before and after accreditation								
Hospital-level organisational performance	Unit of analysis	intervention			control			p-value
Interrupted time series		n	Measure of effect	Variability (SD or CI)	n	Measure of effect	Variability (SD or CI)	
Piontek et al. (2003)								
ICU costs, US dollars	Patients	3973	1,664	91	3835	1370	62	
Labour costs, US dollars	Patients	3973	4,520	25	3835	2005	17.4	
Ventilator use >96 hrs, n	Patients	3973	290		3835	364		0.0001
OPM report (2009)								
MRSA infection rates, mean difference (95% CI)	Trusts	168	24.27	-10.4 to 58.9				0.147
Time-series								
Stradling et al. (2007)								
Stroke admission, %	Patients	1161	87%		?	64%		0.005
Deep vein thrombosis prophylaxis,%	Patients	1161	86%		?	71%		0.0001
Lipid profile testing,%	Patients	1161	98%		?	80%		0.0001
Patients' outcomes								
Interrupted time series								
Piontek et al. (2003)								
Complications, n	Patients	3973	56		3835	42		0.317

Table 4.7 Summary of outcome measures with negative results by type of measure and interventions being compared

	Disease-specific organisational performance	Hospital-level organisational performance	Patients' outcomes	Overall effect within intervention
Accredited versus non-accredited institutions	1/53 outcomes from six studies included in four reviews	4/46 outcomes from eight studies included in seven reviews	0/28 outcomes from six studies included in four reviews	5/127 (3.9%) 16 studies 7 reviews
High versus low performance in accreditation	0/17 outcomes from one study included in one review		0/1 outcomes from one study included in one review	0/18 (0%) 1 study 1 review
Before and after accreditation	0/3 outcomes from one study included in two reviews	3/6 outcomes from two studies included in three reviews	0/3 outcomes from one study included in two reviews	3/12 (25%) 3 studies 4 reviews
Association quality measures and outcomes		0/4 outcomes from one study included in one review		0/4 (0%) 1 study 1 review
Overall effect within outcomes	1/73 (1.4%) 8 studies 5 reviews	7/56 (12.5%) 11 studies 7 reviews	0/32 (0%) 8 studies 5 reviews	8/161 (5%) 21 studies

Table 4.8 Summary of effect of accreditation on measures of organisational performance and health outcomes

Measure	Trend		Change month after accreditation
	Before accreditation	After accreditation	
Initial medical assessment done within 24 h of admission	No effect	No effect	No effect
Initial nursing assessment within 24 h of admission	No effect	No effect	No effect
Percentage of pain assessments completed per month	No effect	No effect	No effect
Percentage of completed pain reassessments per month	Improvement	Decline	No effect
Monitor the timeliness of complete blood count as routine lab results	Improvement	Decline	No effect
The turnaround time of troponin lab results	No effect	Improvement	No effect
Completion of the surgical invasive procedure consent	Improvement	Decline	Decline
Percentage of operating room (OR) cancellation of elective surgery	No effect	No effect	No effect
Unplanned return to OR within 48 h	No effect	No effect	No effect
Reported medication errors	No effect	No effect	Improvement
Percentage of completed anaesthesia, moderate and deep sedation consents	Improvement	Decline	Decline
Percentage of completed modified Aldrete scores (pre, post, discharge)	Improvement	Decline	Decline
Percentage of completed pre-anaesthesia assessments	No effect	No effect	No effect
Percentage of completed anaesthesia care plans	Improvement	Decline	Decline
Percentage of completed assessments of patients receiving anaesthesia	No effect	No effect	No effect
Effective communication of risks, benefits and alternatives of anaesthesia to patients	Improvement	Decline	Decline
Percentage of typed post-operative report completed within 48 h	Improvement	Decline	No effect
Hospital acquired methicillin-resistant Staphylococcus aureus rate	Improvement	Decline	Decline
Healthcare associated infection hospital-wide	No effect	No effect	No effect
Surgical site infection rate	No effect	No effect	No effect
Mortality rate	No effect	No effect	No effect
Compliance with surgical site marking	Improvement	No effect	Decline
Compliance with the time-out procedure	Improvement	Decline	Decline
Screening for patient fall risk	Improvement	No effect	Decline
Overall hospital hand hygiene compliance rate	No effect	No effect	No effect
Patient fall rate	No effect	Decline	Decline
Fall risk assessment and reassessment	Improvement	Decline	No effect

Table 4.9 Detailed characteristics of included studies in update of systematic review

Devkaran and O'Farrell (2015) and Devkaran and O'Farrell (2014)	
Methods	**Study design:** ITS study **Data:** A selection of measures of clinical quality routinely used by the accreditation agency was selected to determine the impact of the intervention. Data were collected monthly for a 4-year period, including one year pre-accreditation (2009) and three post intervention (2010, 2011 and 2012). A random sample of 12,000 patients' records served as the data source. This represented a 24% of the monthly census. A total of 324,000 observations/data points were used for the model.
Participants	**Recipients:** Al-Noor hospital in Abu Dhabi. **Characteristics of included hospital:** Private, 150-bed, multispecialty, acute care hospital. Annual inpatient census is 15,000. **Country:** United Arabic Emirates **Targeted behaviours:** see outcomes
Interventions	**Description of intervention:** Joint Commission International (JCI) accreditation process comprises several consecutive steps: The first phase is characterised by the implementation of new standards. JCI recommends developing an internal structure, composed of teams and leaders, to facilitate coordination of all the activities needed to prepare for accreditation. A steering committee of team leaders coordinates the preparation. As JCI requires a number of mandatory policies and procedures, a document review is initiated. JCI recommends as a next step, to perform a Baseline Assessment/Gap analysis in order to compare current processes and compliance with the expectations of the standards. Additionally, the collection and analysis of baseline quality data are compared with the requirements of the quality monitoring standards. The process includes: (1) analysing compliance with the JCI standards; (2) developing an action plan to address deficiencies; (3) implementation of new processes and data collection targeting compliance to standards; (4) conducting an organisation-wide training programme and (5) Allocation of required resources. 3–6 months prior to the accreditation survey, a mock survey is performed. The findings lead to a review of existing gaps and the staff work on closing these within the short time frame. JCI Accreditation requires submission of a 4-month record of compliance measures prior to the accreditation survey. The process ends with the final accreditation survey, granting accreditation status. **Type of external standard:** Joint Commission International's standards. Indicators from 10 out of 14 chapters were selected. These measures reflect important dimensions of quality, including patient assessment, surgical procedures, anaesthesia and sedation use, medication errors, infection control and patient safety. **Who developed the standards:** The quality measures were selected by a panel of experts consisting of clinical auditors, doctors, quality and patient safety leaders based on: (1) interpretability, enabling clear conclusions to be drawn on the level of compliance with JCI standards and thus accreditation impact; (2) consistency in terms of high values indicating better quality; (3) direct correlation with a specific JCI standard and relation to an important dimension of quality and (4) applicability, as all measures should apply to all patients in the hospital irrespective of disease condition or specialty. **Voluntary or Mandatory review:** Voluntary **Universally or targeted review:** Universal

Interventions	**Who performed the review:** Joint Commission International (non-governmental and non-for-profit organisation). **Purpose and focus of the review:** The goal of the survey is to evaluate care, organisational processes and to provide education with the objective of promoting continual improvement for the organisation under survey. **Timing:** **Frequency and number of inspections:** One survey every three years. Three months before the final accreditation survey, a mock survey was performed **Duration of inspection:** Not specified.		
Outcomes	Some outcome measures were transformed so an increase on its value represent an improvement in clinical quality (e.g. mortality rates, healthcare associated infection rates) **Results:**		
		Change in level (95% CI)	Change in slope (95% CI)
	Patient assessment and laboratory safety measures		
	Initial medical assessment done within 24 h of admission:	−4.54 (−16.33, 7.25) p=0.44	−0.99 (−3.63, 1.65) p= 0.45
	Initial nursing assessment within 24 h of admission	1.24 (−1.63, 4.11) p= 0.38	-0.18 (-0.60, 0.24) p= 0.39
	Percentage of pain assessments completed per month	−4.00 (−12.10, 4.10) p=0.33	-0.02 (-1.82, 1.77) p= 0.98
	Percentage of completed pain reassessments per month	−13.91 (−32.37, 4.56) p= 0.14	-7.28 (-10.00, -4.56) p< 0.001
	Hours for complete blood count as routine lab result	0.34 (0.13, 0.54) p= 0.52	0.34 (0.04, 0.64) p< 0.001
	Turnaround time of troponin lab results (in minutes)	−0.43 (−2.99, 2.13) p= 0.74	−0.60 (−1.02, −0.18) p= 0.01
	Surgical Procedures, medication error use and near-misses		
	Completion of the surgical invasive procedure consent	-2.70 (-4.76, -0.63) p= 0.01	-1.18 (-1.72, -0.64) p= 0.01
	Percentage of operating room (OR) cancellation of elective surgery (transformed)	-0.36 (-4.66, 3.95) p= 0.87	0.32 (-0.31, 0.95) p= 0.31
	Unplanned return to OR within 48 h (transformed)	-0.05 (-0.30, 0.20) p= 0.69	0.01 (−0.03, 0.04) p= 0.63
	Reported medication errors (transformed)	-0.04 (-0.06, -0.01) p< 0.001	-0.001 (-0.01, 0.00) p= 0.18
	Anaesthesia and sedation use		
	Percentage of completed anaesthesia, moderate and deep sedation consents	−15.42 (−23.38, −7.45) p< 0.001	-4.95 (-6.12, -3.78) p< 0.001
	Percentage of completed modified Aldrete scores (pre, post, discharge)	−7.17 (−12.11, −2.23) p= 0.01	−7.30 (−8.49, −6.11) p< 0.001
	Percentage of completed pre-anaesthesia assessments	0.97 (−4.86, 6.80) p= 0.74	−0.84 (−1.98, 0.30) p= 0.14

	Percentage of completed anaesthesia care plans	-11.68 (-20.04, -3.31) p= 0.01	−2.48 (−4.07, −0.88) p< 0.001
	Percentage of completed assessments of patients receiving anaesthesia	−6.17 (−14.37, 2.03) p= 0.14	−0.02 (−1.90, 1.87) p= 0.98
	Effective communication of risks, benefits and alternatives of anaesthesia to patients	−12.83 (−21.63, −4.03) p= 0.01	−3.64 (−4.94, −2.35) p< 0.001
	Infection control, content and use of patient records.		
	Hospital acquired methicillin-resistant Staphylococcus aureus rate	1.41 (0.09, 2.72) p= 0.04	0.70 (0.31, 1.10) p= 0.001
	Healthcare associated infections at hospital level	0.25 (-0.81, 1.32) p= 0.63	0.08 (-0.08, 0.23) p= 0.33
	Surgical site infection rate	-0.05 (-0.29, 0.18) p= 0.64	0.001 (-0.03, 0.04) p= 0.81
	Percentage of typed post-operative report completed within 48 h	4.33 (-4.98, 13.64) p= 0.35	-1.85 (-3.22, -0.48) p= 0.01
	Mortality rate (transformed)	-0.01 (-0.16, 0.14) p= 0.90	-0.02 (-0.04, 0.01) p= 0.15
	International patient safety goals		
	Compliance with surgical site marking	0.79 (−4.37, 5.94) p= 0.76	−5.26 (-6.19, −4.34) p< 0.001
	Compliance with the time-out procedure	−14.89 (−21.30, −8.49) p< 0.001	−7.36 (−8.64, −6.08) p< 0.001
	Screening for patient fall risk	0.21 (−2.46, 2.89) p= 0.87	−0.67 (−1.07, −0.28) p< 0.001
	Overall hospital hand hygiene compliance rate	0.14 (−0.43, 0.71) p= 0.62	−0.02 (−0.11, 0.06) p= 0.62
	Patient fall rate	1.71 (1.04, 2.38) p< 0.001	0.11 (0.00, 0.230) p= 0.06
	Fall risk assessment and reassessment	−1.67 (−6.29, 2.96) p= 0.47	−4.26 (−5.30, −3.22) p< 0.001
	Mean Composite score (It includes only 23 measures)	-3.95 (-6.39, -1.51) p< 0.001	−2.16 (−2.52, −1.80) p< 0.001
Towers and Clark (2014)			
Methods	**Study design:** ITS design **Data:** 10 years (1999-2008) of hospital discharge information was retrieved for 58 hospitals in New Jersey from the healthcare cost and utilization project state inpatient database. From the public-facing Joint Commission website, documentation for each site visit of the Joint Commission was obtained. For each year, risk-adjusted mortality data for 7 months was retrieved: 3 months before and after the accreditation visit and for the month of the visit. Additionally, system affiliation, technological status and if the visit was announced or not, were used to perform subgroup analyses. Annual admission rates and membership to the Council of Teaching Hospitals and Health Systems were used as proxies of hospital characteristics.		

Participants	**Recipients:** 58 hospitals in New Jersey, United States of America. **Characteristics of included hospitals:** Non-specialist and non-paediatric acute hospitals. **Country:** United States of America **Targeted behaviour:** Risk-adjusted mortality
Interventions	**Description of intervention:** Joint Commission on Accreditation of Healthcare Organizations (JCAHO) scheme. **Type of external standard:** JCAHO's standards. **Who developed the standards:** JCAHO. **Voluntary or Mandatory review:** Mandatory **Universally or targeted review:** Universal **Who performed the review:** JCAHO (non-governmental organisation). **Purpose and focus of the review:** The Joint Commission explicitly pursues a mission devoted to the overall quality and safety of patient care. Whilst many of the standards inform a host of practices that may not be obviously tied to mortality, their collective adoption is clearly aimed at reducing the risk of harm and unnecessary death by improving the integrity and effectiveness of care delivery practices. **Timing:** **Frequency and number of inspections:** Every three years. **Duration of inspection:** Not specified
Outcomes	**Results:** There was a statistically significant decrease in risk-adjusted mortality in the month after the site visit (β= -0.0454, p<0.05). System affiliation and technological status were significantly associated with risk adjusted mortality rates during the study period (β=0.048, p<0.05 and β=-0.039, p<0.05; respectively). An analysis including interaction terms for these two variables revealed that the cyclical decrease in risk-adjusted mortality was driven by hospitals with low technological status (β= -0.096, p<0.01). High-technological status hospitals had a lower risk-adjusted mortality rate over time (β= -0.045, p<0.05). The cyclical effect observed in the month after the site visit remained significant after the introduction of the variable "unannounced" (β=-0.0454, p<0.05).

Bogh et al. (2015)	
Methods	**Study design:** Controlled before and after study **Data:** Data regularly reported to disease-specific national registries
Participants	**Recipients:** 6 accredited and 27 non-accredited hospitals in Denmark **Characteristics of included hospitals:** Public, non-specialist, acute hospitals. **Country:** Denmark **Targeted behaviours:** 21 measures of processes of care for stroke, heart failure, perforated and bleeding ulcers. An opportunity-based composite score was calculated based on the individual processes of care for each disease area. The opportunity-based composite score reflects the number of times the patients received a process according to guidelines, divided by the number of patients who were eligible for this process. Second, an all-or-none score was calculated, which reflects the proportion of patients who received 100% of the recommended processes of care.

<table>
<tr><td>Interventions</td><td colspan="4">Description of intervention:
Hospitals were divided into two groups based on their accreditation status through the study period. In 2002, 2005, 2008 and 2011 five hospitals were accredited by the Joint Commission International (JCI), whilst four hospitals in 2004 were accredited by the Health Quality Service (HQS).

Type of external standard: The performance measures were identified by national expert panels taking into account the strength of evidence, the multidisciplinary efforts involved in patient care and the feasibility of collecting the data in routine clinical settings. If relevant, a time limit was defined for the individual performance measures to capture the timeliness of the interventions. Each registry developed standard descriptions on how hospitals should report data and set a deadline for when data should be registered. Data from each registry was used for an annual report, which was used to evaluate disease-specific quality of care within and between hospitals.

Who developed the standards: Danish Healthcare Quality Programme
Voluntary or Mandatory review: Voluntary
Universally or targeted review: Universal
Who performed the review: Governmental institution and The Joint Commission International.

Purpose and focus of the review: The accreditation programme targeted quality improvements within the entire hospitals organization, including improvement of process of care. Accredited hospitals were specifically assessed on their work with data collection and data analysis in order to evaluate their compliance with clinical guidelines

Timing:
Frequency and number of inspections: One visit every three years
Duration of inspection:Visit is announced 6 months in advance. Duration of visit is not stated.</td></tr>
<tr><td>Outcomes</td><td colspan="4">Results:</td></tr>
<tr><td></td><td></td><td>Accredited</td><td>Non-accredited</td><td>Absolute difference</td></tr>
<tr><td></td><td></td><td>(95% CI)</td><td>(95% CI)</td><td>(95% CI)</td></tr>
<tr><td></td><td colspan="4">Opportunity-based composite score</td></tr>
<tr><td></td><td>Stroke</td><td>13.8 (9.7 to 17.8)</td><td>9.8 (4.6 to 15.1)</td><td>3.9 (−1.4 to 9.2)</td></tr>
<tr><td></td><td>Heart failure</td><td>16.8 (11.5 to 22.5)</td><td>8.7 (−5.9 to 23.3)</td><td>8.3 (−3.3 to 19.9)</td></tr>
<tr><td></td><td>Perforated Ulcer</td><td>7.1 (−1.3 to 15.6)</td><td>10.2 (−20.4 to 40.8)</td><td>−3.0 (−23.5 to 17.4)</td></tr>
<tr><td></td><td>Bleeding Ulcer</td><td>−0.3 (−2.3 to 1.7)</td><td>−0.1 (−4.8 to 4.7)</td><td>−0.2 (−3.7 to 3.3)</td></tr>
<tr><td></td><td>Overall</td><td>13.7 (10.6 to 16.8)</td><td>9.9 (5.4: 14.4)</td><td>3.8 (0.8 to 8.3)</td></tr>
<tr><td></td><td colspan="4">All-or-none</td></tr>
<tr><td></td><td>Stroke</td><td>9.9 (3.9 to 16.0)</td><td>6.4 (−4.8 to 17.7)</td><td>3.6 (−3.8 to 10.9)</td></tr>
<tr><td></td><td>Heart failure</td><td>9.7 (5.4 to 14.1)</td><td>4.3 (−1.8 to 10.4)</td><td>5.4 (−0.1 to 14.4)</td></tr>
<tr><td></td><td>Perforated Ulcer</td><td>12.3 (0.4 to 24.2)</td><td>12.4 (−19.3 to 44.1)</td><td>−0.1 (−22.6 to 22.4)</td></tr>
<tr><td></td><td>Bleeding Ulcer</td><td>−3.6 (−7.9 to −0.3)</td><td>−5.2 (−11.7 to 1.3)</td><td>1.6 (−1.8 to 8.2)</td></tr>
<tr><td></td><td>Overall</td><td>9.4 (5.0 to 13.9)</td><td>6.3 (−0.6 to 13.2)</td><td>3.2 (−3.6: 9.9)</td></tr>
</table>

Bogh et al. (2016)	
Methods	**Study design:** ITS study **Data:** Data regularly reported to disease-specific national registries From November 1st, 2008 to December 31st, 2013.
Participants	**Recipients:** 25 hospitals in Denmark **Characteristics of included hospitals:** Public, non-specialist, acute hospitals. **Country:** Denmark **Targeted behaviours:** 43 different process performance measures were included covering six conditions: stroke, heart failure, ulcer, diabetes, breast cancer and lung cancer.
Interventions	**Description of intervention:** All public hospitals in Denmark were obliged to implement The Danish Healthcare Quality Programme (in Danish: Den Danske Kvalitetsmodel (DDKM)). The first version was launched in August 2009; the first hospital was accredited in May 2010 and the last in June 2012. The agency responsible for DDKM recommended that every hospital perform an internal survey 6 months before the external survey, in order to identify areas for improvements and to prepare for the announced on-site survey. A team comprising peer reviewers performed the on-site survey, with the main task to evaluate to what extent the hospital met the predefined standards. The surveyors used methodologies including interviews with staff and patients and reviews of local guidelines. The evaluation was documented in a report used by an independent Accreditation Award Committee to award the hospitals a level of accreditation. Because the report identify strengths and areas for improvement, it was used by the hospital to continue the cycle of quality improvement. **Type of external standard:** The first version of the programme consisted of 104 standards grouped in three categories: organizational, general patient pathway and disease-specific standards. The standards incorporated the four steps in the plan-do-check-act cycle, a management method used for control and continuous improvement of processes. Each standard incorporated a number of indicators used to guide the hospitals to meet the standard. Documentation was required when performance against the disease-specific standards failed to reach the expected quality level. If a hospital reached a satisfactory level of quality, this level had to be maintained as a minimum, and no further action was required. Diseases included in the disease-specific standards were selected according to their incidence/prevalence, severity and the complexity of patient care services. Ultimately the aim was to ensure high quality of care. In addition to the disease-specific standards, DDKM also include general standards that require policies related to clinical guidelines, documentation and monitoring and quality improvement at an organizational level. **Who developed the standards:** Danish Healthcare Quality Programme (DDKM) **Voluntary or Mandatory review:** Mandatory **Universally or targeted review:** Universal **Who performed the review:** DDKM (governmental institution). **Purpose and focus of the review:** DDKM's aim was to create a framework for continuous quality improvement, to document and make the quality of healthcare transparent and to prevent errors that cause death and lower quality of life. **Timing:** **Frequency and number of inspections:** One visit every three years **Duration of inspection:** Visit is announced 6 months in advance. Duration of visit is not stated.

Outcomes	**Results:**			
		Pre-accreditation	During accreditation	Post-accreditation
		(95% CI)	(95% CI)	(95% CI)
	All hospitals (probability of meeting standards)			
	Level	3.5 (2.8 to 4.4) (78%)	–	–
	Trend	1.007 (1.005 to 1.008)	–	–
	Change in trend	–	1.002 (0.997 to 1.006)	0.99 (0.988 to 0.999)
	Subgroup analysis of hospitals not meeting standards pre-accreditation			
	Level	2.2 (1.9 to 2.54) (68%)	–	–
	Trend	1.005 (1.003 to 1.006)	–	–
	Change in trend	–	1.007 (1.002 to 1.013)	0.992 (0.984 to 0.995)

Bogh et al. (2017)

Methods	**Study design:** ITS study **Data:** Data regularly reported to disease-specific national registries From November 1st, 2008 to December 31st, 2013.
Participants	**Recipients:** 25 hospitals in Denmark **Characteristics of included hospitals:** Public, non-specialist, acute hospitals. **Country:** Denmark **Targeted behaviours:** 43 different process performance measures were included for six different conditions: stroke, heart failure, ulcer, diabetes, breast cancer and lung cancer.
Interventions	**Description of intervention:** A team of surveyors conducted on-site surveys to judge the compliance of each hospital according to a set of standards. Their judgements were documented in reports that the independent Accreditation Award Committee then used to award levels of accreditation to hospitals. The reports identified hospitals' strengths and areas for improvement and were used by hospitals in the cycle of quality improvement. In preparation for accreditation, it was recommended that hospitals conduct an internal survey 6 months before the on-site survey. **Type of external standard:** The accreditation standard incorporates the four steps of the plan-do-check-act cycle to encourage systematic quality development. The DDKM comprises 104 standards that can be grouped into three categories: (i) organizational; (ii) general patient pathway and (iii) disease-specific standards. In addition to the requirement that staff work in accordance with clinical guidelines that reflect the recommendations of national clinical guidelines, the disease-specific standards require hospitals to report data on pre-defined processes of care for each of the six conditions. If a hospital fails to reach a pre-defined target value, the accreditation standards require the hospital to complete specific action plans to improve performance. If a satisfactory level of quality is obtained, the (minimum) level must be maintained and no further action is required. **Who developed the standards:** Danish Healthcare Quality Programme (DDKM) **Voluntary or Mandatory review:** Mandatory **Universally or targeted review:** Universal **Who performed the review:** DDKM (governmental institution).

Interventions	**Purpose and focus of the review:** DDKM's aim was to create a framework for continuous quality improvement, to document and make the quality of healthcare transparent and to prevent errors that cause death and lower quality of life. **Timing:** **Frequency and number of inspections:** One visit every three years **Duration of inspection:** Visit is announced 6 months in advance. Duration of visit is not stated.				
Outcomes	**Results:**				
		Pre-accreditation		During accreditation	Post-accreditation
		Level	Trend	Change in trend	Change in trend
		(95% CI)	(95% CI)	(95% CI)	(95% CI)
	All hospitals (probability of meeting standards)				
	Stroke	2.24 (1.91–2.63) [69%]	**1.007** (1.005 -1.009)	**1.004** (1.002–1.007)	1.000 (0.993–1.006)
	Heart failure	2.05 (1.75–2.39) [67%]	**1.003** (1.002–1.004)	**0.996** (0.994–0.999)	**1.003** (1.000–1.006)
	Breast cancer	4.32 (2.86–6.88) [81%]	**1.008** (1.004–1.011)	**0.991** (0.984–0.997)	1.006 (0.999–1.014)
	Lung cancer	1.84 (1.64–2.43) [65%]	**1.003** (1.001–1.006)	1.007 (0.995–1.019)	0.991 (0.977–1.004)
	Ulcer	0.83 (0.75–0.90) [45%]	1.000 (0.999–1.001)	1.003 (0.999–1.008)	0.997 (0.992–1.001)
	Diabetes	7.21 (4.83–10.76) [88%]	**1.009** (1.006–1.013)	1.010 (0.994–1.026)	0.984 (0.967–1.002)
	Subgroup analysis of hospitals not meeting standards pre-accreditation				
	Stroke	1.90 (1.62–2.24) [66%]	**1.007** (1.005–1.008)	0.999 (0.993–1.005)	0.998 (0.991–1.005)
	Heart failure	0.81 (0.58–1.14) [44%]	**1.002** (1.000–1.003)	1.001 (0.997–1.005)	1.001 (0.997–1.005)
	Breast cancer	3.06 (1.69–5.56) [75%]	**1.007** (1.002–1.012)	0.997 (0.989–1.005)	0.999 (0.990–1.008)
	Lung cancer	1.70 (1.41–2.05) [63%]	**1.003** (1.001–1.004)	1.008 (0.995–1.022)	0.995 (0.980–1.010)
	Ulcer	0.38 (0.30–0.62) [28%]	1.000 (0.999–1.002)	1.006 (1.000–1.012)	0.994 (0.988–1.000)
	Diabetes	3.42 (2.08–5.62) [77%]	**1.009** (1.003–1.014)	**1.024** (1.007–1.040)	**0.974** (0.954–0.994)

Table 4.10 List of excluded primary studies and reasons for exclusion

Excluded studies	Reason for exclusion
Abilleira et al, 2012	The intervention was the implementation of a Clinical Practice Guideline and periodic audits- no inspection. In this article, they compared results from two audits.
Adam et al, 2012	Review of literature.
Ahn and Ahn, 2014	Accreditation in education.
Al Awa et al, 2011	Insufficient data points - Four data points were analysed (1 pre, two during and 1 post-accreditation) using ANOVA.
Al Awa et al, 2011	Cross sectional study - perception of quality of care of nursing staff.
Al-Awa et al, 2012	Cross sectional study.
Al-Sughayir, 2016	Comparison before and after.
Al-Sughayir, 2017	Comparison before and after.
Alberts et al, 2013	Observational study - Three data points were compared.
Arani et al, 2014	Cross sectional study.
Babich, 2015	Qualitative study.
Barnett et al, 2017	The model was specified to detect a step change between non-survey and survey week. It does not report secular trends to be considered an interrupted time-series.
Boivin et al, 2011	No assessment of the impact on clinical outcomes. Outcome was the agreement of priorities between patients and clinicians.
Bonacci and Balado, 2015	No assessment of impact.
Caldana et al, 2015	Validation of the Quality Improvement Implementation Survey in Brazil. No assessment of impact.
Carpenter et al, 2011	No assessment of impact.
DeLellis and Ozcan, 2013	Cross sectional study.
Petit Dit Dariel and Regnaux, 2015	Review of literature.
Edwards, 2013	Cross sectional study - intervention does not qualify (compliance with quality improvement programme).
Ergasti and Consolante, 2011	The intervention was performance monitoring.
Falstie-Jensen et al, 2015	Cross sectional study. It pools and compares length of stay and mortality between accredited and non-accredited hospitals during three years.
Falstie-Jensen et al, 2017	Cross sectional study. It compares outcomes of hospitals by compliance in consetive accreditation cycles.
Falstie-Jensen et al, 2017	Cross sectional study. It compares mesasures of hospital care acording to accreditation status.
Ferreira et al, 2013	No intervention.
Flodgren et al, 2011	Review of literature.
Ghaemmaghami, 2012	Cross sectional study.
Greenfield et al, 2012	Cross sectional study - it compares two methods of surveying hospitals.
Greenfield et al, 2012	Review of literature.

Excluded studies	Reason for exclusion
Greenfield et al, 2014	Cross sectional study.
Greenfield et al, 2016	Insufficient information. Abstract from a conference proceeding.
Grigoroudis et al, 2012	No intervention.
Halasa et al, 2015	Insufficient data points – Retrospective difference-in-difference analysis of four hospitals in Jordan. Only one point before the intervention. The assumption of parallel paths was not met.
Hysong et al, 2011	Intervention includes only performance monitoring- no inspection.
Hysong et al, 2012	Qualitative study.
Jaafaripooyan, 2014	Qualitative study.
Jaafaripooyan, 2011	Qualitative study.
Jaber, 2014	Cross sectional study - perception about accreditation was asked of nurses.
Kalodimos, 2017	No assessment of impact.
Lam et al, 2016	Cross sectional study. It analyses the changes in organisational culture before and after accreditation.
Mosadeghrad et al, 2017	No assessment of impact.
Mumford et al, 2013	Review of literature.
Mumford et al, 2015	Cross sectional study. It looks at the association between bacteraemia and accreditation score.
Ng et al, 2013	Review of literature.
Nomura et al, 2016	Before and after study.
Ramjee et al, 2016	Insufficient information. Abstract from a conference proceeding.
Renzi et al, 2012	Intervention was public reporting of hospital performance.
Schmaltz et al, 2011	Cross sectional study - relationships between accreditation status and hospital performance.
Shahian et al, 2012	Intervention includes performance monitoring- no inspection. It compares level of compliance with standards and mortality for three diagnoses.
Stausberg and Berghof, 2014	No intervention.
Tabrizi and Gharibi, 2011	Review of literature.
Telem et al, 2015	Cross sectional study. It compares unaccredited and accredited hospitals.
Yildiz and Kaya, 2014	Cross sectional study - perception about accreditation was asked of nurses.

Appendix Chapter 5

Table 5.1 Analysis for the five domains of CQC definition of quality

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Safe-Key Line of Enquiry S1: Record on safety					
1 Safety performance over time	Safety	Never events incidents	"The Trust had 9 Never Events between November 2013 and January 2015. 8 of the 9 Never Events were for wrong site surgery"		
		Emergency readmissions with an overnight stay within 30 days of discharge following an elective spell at the Trust			
		Emergency readmissions with an overnight stay within 30 days of discharge following an emergency spell at the Trust			
		From the time you first arrived at the A&E department, how long did you wait before being examined by a doctor or nurse?			
2 Safety performance compared to other	Safety	Death in low risk groups (Dr Foster)	Peer reviews report raised serious concerns about the Trust's ability to deliver a safe service, and raised questions about management capability		

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
3	Staff aware of their responsibility to report incidents	Safety	Potential under-reporting of patient safety incidents resulting in death or severe harm		Incident reporting was embraced by staff throughout the organisation. Where some staff groups had low levels of incident reporting, such as doctors, work had been carried to increase their reporting with good results, which demonstrated the continuous improvement culture and accountability amongst all staff groups	Any example of a serious incident or avoidable harm should trigger an examination by the Care Quality Commission of how that was addressed by the provider and a requirement for the Trust concerned to demonstrate that the learning to be derived has been successfully implemented.
			Consistency of reporting to the National Reporting and Learning System (NRLS)			
4	Existence of safety goals and performance against them					
Safe-Key Line of Enquiry S2: Lessons learnt and improvements made after adverse events						
1	Users are informed about incidents and receive and apology	Duty of candour	Proportion of reported patient safety incidents that are harmful	The Trust had 42 new Serious Incidents (SI's) reported from April 2014 to January 2015.		Candour – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it
			Potential under-reporting of patient safety incidents	We reviewed a number of Serious Incidents and there was limited assurance that the duty of candour had been upheld. One incident we reviewed occurred in December 2013 the report was completed in November 2014		A statutory obligation should be imposed to observe a duty of candour: On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
			and the intention to liaise with the family had not taken place in March 2015.		to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request
2 Reviews of incidents. Staff and users are involved in them	Duty of candour	The proportion of staff who stated that the incident reporting procedure was fair and effective	Some staff told us that they did not have the time to report incidents and were not encouraged to report incidents and were not aware of any improvements as a result of learning from incidents.	A safety culture was a priority for staff at all levels and embedded throughout the Trust. Staff were empowered to be part of improvements.	
			"However evidence of learning was limited, actions were not always timely and evident and staff spoken with were not always aware of incidents within their service, within their Clinical Academic Group (CAG) or within the hospital. Learning across the organisation was not apparent"	The Trust had carried out some 'look back' exercises as a team approach to review notes and look for areas of improvement to patient care, with any concerns identified shared with patients in an open and transparent manner.	
3 How lessons are learnt after incidents	Good governance		Feedback to staff on reported incidents to allow learning so that services could improve did not routinely occur, lessons learnt were not always known or widely shared	Learning and improvements from incidents was seen throughout the majority of the organisation with many levels of staff able to describe an improvement to patient care.	
4 How actions are shared to other teams or services.	Good governance				

	Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Safe-Key Line of Enquiry S3: Reliable safety systems, processes and practices.						
1	Staff aware of safety processes, systems and practices	Safety	Dealing timeously with (CAS) safety alerts indicators			There was a gap in safety monitoring that required a means of measuring safety.
2	Staff receive effective mandatory safety training		The proportion of staff receiving health and safety training in last 12 months	Ward staff had not received any training in care of the dying patient for at least three years. We were told by the palliative care team they intended to roll out end of life training once the care planning documentation to replace the Liverpool Care Pathway had been implemented.	Statutory and mandatory training levels were good and where they fell below the Trust expectation there were clear plans in place to make improvements.	
3	Implementation of safety processes is monitored and improved	Safety, Good governance	Proportion of admitted patients risk assessed for VTE			
4	Adults and children are safeguarded from abuse. Staff adhere to safeguarding policies	Safeguarding from abuse			Staff were trained in safeguarding and there were appropriate processes for safeguarding patients against abuse.	
5	Standards of hygiene and cleanliness maintained	Safety	Patient-Led Assessment of the Care Environment		The standard of cleanliness, infection control and hygiene was good and staff were consistently	

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
		"Thinking about your stay in hospital, how clean were the toilets and bathrooms you used?"		seen adhering to infection control policies and procedures	
6 Systems to prevent and avoid healthcare associated infections	Safety	Incidence of Clostridium Difficile	The Trust was exceeding its maximum trajectory for 2014/15 clostridium difficile and reported 79 cases (post 72 hours) in February 2015 against a full year trajectory of less than 71 cases.	There was a system for robust monitoring of cleanliness and infection control to ensure standards were being met	
		Incidence of MRSA	The Trust also reported 10 patients with MRSA bacteraemia (48 hours post admission) from April 2014 to January 2015, against a last year outturn of 11 cases of MRSA bacteraemia, there is zero tolerance as this is recognised as a hospital acquired infection		
7 Maintenance and use of facilities prevent harm	Premises and equipment		We identified non-compliance with theatre ventilation on the Whipps Cross site as it was not adequately monitored or maintained.		

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
8	Maintenance and use of equipment avoid harm	Premises and equipment		The Trust could not assure us that the work which was taking place [It services] was having the required impact and when the issue would be resolved. Staff at the Trust did not know when they would be able to recommence monitoring in line with the national requirements. The Trust had not reported since August 2014.	There was sufficient equipment to ensure staff were able to carry out their duties and there was a robust system for maintaining equipment	
9	Safety arrangement to manage waste and clinical specimens	Safety				
10	Safety arrangement for management of medications	Safety		There were concerns related to both storage and administration of medicines. There was no consistency in the use of opioids, no policy and no guidance with some wards using morphine and others diamorphine.	Medicines management was good throughout the organisation and learning was embedded in response to medication errors.	
11	Safe management of care records (i.e. records are accurate, complete, legible,	Safety	Data Quality of Trust Returns to the HSCIC	Record keeping was a significant issue across all three sites and an area of concern that we had previously identified in 2013 when we last inspected.	Records were well maintained and documentation was completed comprehensively ensuring patient records were up	

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
up to date and stored securely)	Good governance		Improvements were needed to ensure accurate records were maintained and that there were suitable prompts for staff to follow to ensure all patient needs had been met and recorded.	to date, including completion of risk assessments	
Safe-Key Line of Enquiry S4: Assessment of risks for users					
1 Planning of staff levels and skill mix to provide safe care	Safety, Staffing	Composite risk rating of ESR items relating to staff support/ supervision	Staffing levels in some areas were significantly below the recommended standards and did not provide consistently safe care	Nursing staffing levels and skill mix in Paediatrics (services for children) require improvement.	An unacceptable delay in addressing the issue of shortage of skilled nursing staff.
		Composite risk rating of ESR items relating to ratio: Staff vs. bed occupancy			
2 Comparison between planned and actual staffing level			The majority of staff told us staffing was a significant problem and recognised the impact of inadequate staffing levels on maintaining patient safety	Nurse staffing levels were mostly sufficient and where there were vacancies, the Trust monitored the risk through a tool used on each ward consistently	Savings in staff costs were being made in an organisation which was already identified as having serious problems in delivering a service of adequate quality, and complying with minimum standards.
3 Arrangements to use bank, agency and locum staff avoid harm.	Safety		There was a high use of temporary staff however the data being presented to the Trust board did not clearly illustrate this	Where bank or agency nurses were used there was a robust induction checklist, which included introduction to the use of the MET score	
	Fit and proper staff		The processes that should be in place to ensure temporary staff are supported were not sufficient across the Trust despite the high use of temporary staff.		

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
4	Risk assessment and management plans in line with national guidance	Safety, Good governance		The Trust recognised that three patients died following a fall while in hospital in December 2013, April 2014 and in January 2015 the board papers state that the falls documentation is still under review to standardise the paper work and the risk assessment tool used across all sites.	There was a system in place to assess deteriorating patients, known as the Medical Emergency Team (MET) score, which was a tool developed by the Trust. Evidence demonstrated good compliance with completion and appropriate escalation action when required.	
5	Identification and respond to patients' change in risk assessment	Safety			Ensure paediatric staff have the necessary skills to identify and manage the deteriorating child.	
6	Arrangement for handovers and shift changes avoid harm					
Safe-Key Line of Enquiry S5: Anticipation and planning of potential risks						
1	Adjustment of services planning according to potential risks (e.g. seasonal fluctuations)	Safety	"Proportion of ambulance journeys where the ambulance vehicle remained at hospital for more than 60 minutes"			
2	Arrangement to respond to emergencies. Frequency of their review.	Safety				

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
3	Assessment of the impact of changes to the service on safety	Safety				
			CQC's National Customer Service Centre (NCSC) safeguarding concerns			
Effective-Key Line of Enquiry E1: Assessment and treatment of patients according to evidence-based guidance						
1	Use of relevant and current evidence-based guidance to deliver treatment and services	Staffing	Maternity outlier alert: Emergency Caesarean sections	The use of national clinical guidelines was not evident in the majority of services, two examples were the delivery of end of life care and care provided to children. National guidance for the care and treatment of critically ill patients was not always followed.	Evidence-based care was fundamental to the policies and procedures used throughout the organisation, with a commitment to continuously improve outcomes for patients. Guidelines and polices included evidence-based guidance and national recommendations	
			Puerperal sepsis and other puerperal infections within 42 days of delivery			
			Maternal non-elective readmissions within 42 days of delivery			
			Neonatal non-elective readmissions within 28 days of delivery	The application of early warning systems to assist staff in the early recognition of a deteriorating patient was varied and its use inconsistent across the Trust		
			Emergency readmissions with an overnight stay within 30 days of discharge following an elective spell at the Trust			
			Emergency readmissions with an overnight stay within 30 days of discharge following an emergency spell at the Trust			

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
2	Delivery and planning of care and assessment of needs in line with evidence-based guidance	Staffing	Maternity outlier alert: Elective Caesarean sections			
			9 Best Practice standards hip fracture			
			Patients receiving all secondary prevention medications they were eligible for			
3	Care and treatment decisions made avoiding discrimination	Dignity and respect				
4	Assessment of nutrition and hydration needs	Food and drink		The management of patients nutritional and hydration needs varied	Nutrition and hydration of patients was managed effectively and staff were clear in ensuring this aspect of care was delivered according to individual needs	
5	Assessment and management of pain		"Do you think the hospital staff did everything they could to help control your pain?"		Management of pain was good and patient feedback was consistent with this evidence	
6	Use of technology and equipment to enhance delivery of care					
7	Rights protected of people subject to the Mental Health Act	Safeguarding from abuse				

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Effective-Key Line of Enquiry E2: Monitoring of patients' outcomes and performance compared to other services					
1 Routinely collection of outcomes of care and treatment	Good governance	PROMs Groin hernia repair			Why did the regulatory bodies not act sooner to investigate a Trust whose mortality rates had been significantly higher than the average since 2003 and whose record in dealing with serious complaints was so poor?
		PROMs - Hip Replacement			
2 Achievement of intended outcomes		PROMs - Knee Replacement			
3 Comparison of patients' outcomes to those in similar services and their change over time		Summary Hospital Mortality Indicator (SHMI)	Patient outcomes were at or better than the national average across most medical and surgical specialties at The Royal London Hospital and were similar to or below the performance of other hospitals on the other sites inspected.	Clinical outcomes were consistently in line with or better than the national average. Where the Trust had recognised themselves as needing to improve outcome data, such as orthopaedics, there was innovative multidisciplinary team working to assess the concerns identified and take necessary steps to improve outcomes to a position to being better than the national average	
		Composite of Hospital Standardised Mortality Ratio indicators			
		In-hospital mortality - Cardiological conditions and procedures			
		Cerebrovascular conditions			
		Dermatological conditions			
		Endocrinological conditions			
		Gastroenterological and hepatological conditions and procedures			
		Genito-urinary conditions			
		Haematological conditions			
		Infectious diseases			
		Conditions associated with mental health			

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
		Musculo-skeletal conditions			
		Nephrological conditions			
		Neurological conditions			
		Paediatric, congenital disorders and perinatal mortality			
		Respiratory conditions			
		Vascular conditions and procedures			
4 Participation in research, trials, audits and benchmarking		9 Best Practice standards hip fracture Overall team-centred level for key stroke unit indicators	Audits carried out to check compliance with the World Health Organisation (WHO) surgical safety check list were remarkably low - less than 1% of patients notes who had undergone surgery were audited		
5 Use of outcomes information to make improvements		Patients receiving all secondary prevention medications they were eligible for	No proactive monitoring of quality and metrics to ensure that quality was being maintained as well as improvements being aspired to.		
6 Staff involved in monitoring and improvement of outcomes	Good governance				There needs to be a relentless focus on the patient's interests and the obligation to keep patients safe and protected from substandard care.

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Effective-Key Line of Enquiry E3: Skills, knowledge and experience of staff						
1	Staff with right qualifications, skills, knowledge and experience	Safety, Staffing	Composite risk rating of ESR items relating to staff registration		Staff competence and continuous development was evident in the Trust	Not only to inadequate staffing levels, but poor leadership, recruitment and training. Healthcare employers recruiting nursing staff, whether qualified or unqualified, should assess candidates' values, attitudes and behaviours towards the well-being of patients and their basic care needs, and care providers should be required to do so by commissioning and regulatory requirements.
2	Process to identify staff learning needs	Staffing	The proportion of staff reported receiving support from immediate managers			
3	Appropriate training for staff	Staffing	Staff turnover rate			
4	Opportunities for staff to develop	Staffing	Composite risk rating of ESR items relating to staff stability			
5	Arrangements for supporting and managing staff	Staffing	Composite risk rating of ESR items relating to staff support/ supervision			
6	Identification of poor or variable staff performance	Staffing	The proportion of staff who were appraised in last 12 months			

	Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Effective-Key Line of Enquiry E4: Coordinated work of staff, teams and services						
1	All necessary staff involved in assessing, planning and delivering care	Staffing			Staff throughout the organisation were committed to multidisciplinary working and recognised the value of each other's role in delivering high quality care. Multidisciplinary meetings were consistently carried out with a clear commitment to working collaboratively to improve care through innovations, improvements in pathways, improvements in teamwork and more efficient ways of working	
2	Coordination of different teams to deliver care	Safety		The CAG structure facilitated multidisciplinary working across sites but it relied on effective communication and strong working relationships.		
3	When patients are transferred, staff work together to assess and plan ongoing care	Safety				
4	Discharge at an appropriate time of the day, relevant teams informed and care plan in place					
Effective-Key Line of Enquiry E5: Information that staff needs is available						
1	Information needed to deliver care is available in a timely manner					

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
2	During transfers of patients, information is shared appropriately					
3	Support of information management system to staff to deliver care					
Effective-Key Line of Enquiry E6: Consent to care sought according to legislation						
1	Staff aware of consent and decision-making requirements for Children and people with restricted mental capacity	Consent		Most staff lacked an understanding of the Mental Capacity Act 2005 and Deprivation of Liberty Safeguards (DoLs) and how it applied to their roles		
2	Support to patients for decision making	Patient-centred care				
3	Place and time of assessment of mental capacity to consent	Consent				
4	'Best Interest' decisions when patients' mental capacity is restricted					

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
5	Monitoring and improvement of consent seeking process	Consent				
6	Staff aware of lawful and unlawful restraint practices	Safeguarding from abuse				
7	Monitoring of use of restraint of people with restricted mental capacity	Safeguarding from abuse				
Caring- Key Line of Enquiry C1: Treatment of people with kindness, dignity, respect and compassion						
1	Staff understand and respect people's personal needs	Person-centred care	Overall... (I had a very poor/good experience)	Patients were not always offered cultural and religious support they wished to receive.	Where patients had specific needs staff demonstrated a commitment to deliver care that met the individual requirements.	
2	Staff take time to interact in a respectful and considerate way	Fit and proper staff				While the theme of the recommendations will be a need for a greater cohesion and unity of culture throughout the healthcare system,[...] by engagement of every single person serving patients in contributing to a safer, committed and compassionate and caring service
3	Staff have an encouraging, sensitive and supportive attitude	Fit and proper staff	"Did you find someone on the hospital staff to talk to about your worries and fears?" "Did hospital staff tell you who to contact if you were worried about your condition or treatment after		Patients were empowered to be part of their ongoing care and feedback from patients during the inspection was consistently excellent.	

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
		you left the A&E Department?"			
		"Were you (and/or your partner) left alone by midwives or doctors at a time when it worried you?"		There was a clear motivation from staff to offer kind and compassionate care, where patients' views were considered and acted upon	Patients must be the first priority in all of what the NHS does by ensuring that, within available resources, they receive effective care from caring, compassionate and committed staff, working within a common culture, and protected from avoidable harm and any deprivation of their basic rights.
		"If you were feeling distressed while you were in the A&E Department, did a member of staff help to reassure you?"			
4 Staff raise concerns about disrespectful behaviour	Fit and proper staff				
5 Staff respect dignity and privacy of patients	Dignity and respect	Patient-Led Assessment of the Care Environment	We observed staff holding discussions about patients' conditions and care plans in communal areas on wards and in some outpatient areas.	Treating patients with dignity and respect, as well as valuing them as individuals was evident throughout the organisation and fundamentally part of the culture	The knowledge and skills framework should be reviewed with a view to giving explicit recognition to nurses' commitment to patient care and the priority that should be accorded to dignity and respect in the acquisition of leadership skills.
		"Overall, did you feel you were treated with respect and dignity while you were in the hospital?"			
		"Overall, did you feel you were treated with respect and dignity while you were in the A&E Department?"			
		"Thinking about your care during labour and birth, were you treated with respect and dignity?"			

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
6	Staff respond in a compassionate and timely manner to patients in pain		"Do you think the hospital staff did everything they could to help control your pain?" "During your labour, were you able to move around and choose the position that made you most comfortable?"	At the listening events, most people told us they were dissatisfied with the care provided by the Trust. However, during our inspection most patients and relatives were satisfied with the care and support they received and felt that staff listened to them and were compassionate		
7	Staff respect confidentiality	Dignity and respect				
Caring- Key Line of Enquiry C2: Patients and their next of kin are involved in care						
1	Staff communicate with patients in a way they can understand	Person-centred care		Patients told us they understood the care and treatment they were offered or had received. However results of the National Cancer Patient Experience Survey 2013 suggested that patients did not always feel fully involved in decisions about their care and treatment, or were given full information regarding potential side effects, test results or choice of treatment. The Trust performed in the bottom 20% of 50 out of 64 questions		
2	Staff allow patients who need additional support to access it	Person-centred care	"Did you get enough help from staff to eat your meals?			
3	Staff make sure patients can find or ask for further information	Person-centred care	"Thinking about the care you received in hospital after the birth of your baby, were you given the information or explanations you needed?"			

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
4 Patients are routinely involved in planning and decision-making	Person-centred care	"Were you involved as much as you wanted to be in decisions about your care and treatment?"			
Caring- Key Line of Enquiry C3: Support to patients to cope emotionally					
1 Staff understand the impact of treatment on patients' wellbeing		"Do you feel you got enough emotional support from hospital staff during your stay?"			
2 Patients receive appropriate and timely support to cope emotionally		At the very start of your labour, did you feel that you were given appropriate advice and support when you contacted a midwife or the hospital"	Psychological support was not routinely available to patients.		
3 Provision of emotional support and information to next of kin					
4 Patients are empowered and supported to manage their own care	Dignity and respect			There was a culture of innovative approach to meeting patients' individual needs and staff were reported to 'go out of their way' to meet patients' needs. For example, patients reaching the end of life were involved in planning their wishes and staff were committed to meeting these and overcoming obstacles.	

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
5 People is enabled to keep contact with their social network	Dignity and respect				
		Inpatient Friends and Family Test			
		"If you needed attention, were you able to get a member of medical or nursing staff to help you?"			
		"Did you have confidence and Trust in the doctors treating you?"			
		"Did you have confidence and Trust in the nurses treating you?"			
		Did the staff treating and examining you introduce themselves?			
Responsive- Key Line of Enquiry R1: Planning of services to meet people's needs					
1 Use of information on local population needs to plan and deliver care	Person-centred care		There was limited evidence to demonstrate that information about the local population's needs was used to inform the planning and delivery of services.	Meeting people's individual needs were a significant focus when services were developed and patient's views were actively sought through groups in the	There are a wide range of routes through which patients and the public can feed comments into health services and hold them to account.

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
			Senior staff were unaware of their local population make up. There were over 200 different languages spoken in the local population and the 'top 5' were not consistently known and services were not planned for	community, constituency meetings and other forums to ensure developments captured the wishes and needs of their population	However, in the case of Stafford, these routes have been largely ineffective and received little support or guidance.
2 Involvement of commissioners in planning services	Person-centred care				Commissioners of services, as the paying party for services they contract from providers, must ensure that those services are well provided and are provided safely. The commissioner is entitled to and should, wherever it is possible to do so, apply a fundamental safety and quality standard in respect of each item of service it is commissioning.
3 Services reflect the needs of the population. They ensure flexibility, choice and continuity of care			The services provided did not reflect the needs of the population served and did not ensure flexibility, choice and continuity of care	As pathways were reviewed and redesigned, there was a commitment to ensure that patients were able to receive care closer to their home where possible.	
4 Method to identify when services do not meet needs of the population	Person-centred care				Patients surveys contained disturbing indicators that all was not well from long before the intervention of the HCC

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
5 Facilities appropriate for the services	Premises and equipment	"Were you given enough privacy when being examined or treated?"			
Responsive- Key Line of Enquiry R2: Services consider needs of different people					
1 Planning of services take account of the needs of different populations	Person-centred care			The Trust demonstrated a culture that strived to meet the needs of patients through service development and using innovative thinking during planning	
2 Delivery of services take account of the needs of different populations	Person-centred care		Information was only provided in English, and not in the language of the predominant population served by the hospitals.		
3 Planning, delivery and coordination of services for people with complex needs	Person-centred care		The Trust had provided dementia training for 3,130 of its 15,000 staff (21 %) between April 2014 - March 2015. This meant the Trust had not achieved the recommendations of the National Dementia Strategy published in 2009.	The Trust proactively took steps to meet the individual needs of different and vulnerable groups of people that used their services.	
4 Adjustments to enable access and use to people with disabilities					

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
5 Service engagement with patients in vulnerable circumstances			Patients nearing the end of their life were not always identified, and their needs therefore were not always assessed and met.		
Responsive- Key Line of Enquiry R3: Timely access to care and treatment					
1 Timely access to initial assessment, diagnosis or urgent treatment	Safety	Overall team-centred level for key stroke unit indicators		The Trust has consistently met the referral to treatment targets for the previous two years; it has consistently achieved the A&E four-hour target and has met the cancer waiting times target. There were examples of pathway redesign and innovation to achieve this, such as the extended theatre sessions to increase theatre productivity	In 2004, the Commission for Health Improvement (CHI) re-rated the Trust, and it went from a three star Trust to zero stars. [...] factors likely to have been behind this: failure to meet targets for elective surgery, outpatient waiting times, cancer waiting times and financial performance.
		A&E waiting times more than 4 hours	The emergency departments were not meeting the national 4 hour waiting time target		
		Composite monthly Referral to Treatment (RTT) waiting times	Some patients were experiencing delays of more than 18 weeks from referral to treatment (RTT). The Trust had suspended reporting activity to the department of health and had started a recovery plan		
		Patients waiting over 6 weeks for a diagnostic test			
		Proportion of patients receiving their first definitive treatment for cancer within two months (62 days) of GP or dentist urgent referral for suspected cancer			

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
		Proportion of patients receiving their first definitive treatment for cancer within two months (62 days) of urgent referral from the national screening service			
		Proportion of patients receiving their first definitive treatment within one month (31 days) of a decision to treat (as a proxy for diagnosis) for cancer			
2 Access to care at a convenient time		The ratio of the total number of days delayed to the total number of occupied beds over the quarter (3 months), where the delay is attributable to the NHS	Capacity issues within the hospital led to a high proportion of medical "outliers" (patients on wards that were not the correct specialty for their needs). The result of this was that patients were being moved from ward to ward on more than one occasion, this impacted on their treatment, delayed their stay in hospital and were on occasion transferred late at night.		
3 Actions to minimise waiting times for treatment		A&E waiting times more than 4 hours	Bed occupancy was very high, the average between April and December 2014 was 95%. This meant patients were not always cared for in the appropriate environment and the high occupancy impacted on the flow of patients through the hospitals.		
		Composite monthly Referral to Treatment (RTT) waiting times			

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
4 Patients' with most urgent needs are prioritised	Safety		Patients well enough to leave hospital experienced significant delays in being discharged for a variety of reasons and some because of documentation needing to be completed		
5 Appointments system is easy to use			Many patients experienced delays in their treatment as a result of the poor implementation of the new IT system.		
6 Cancellation of treatment when absolutely necessary. Cancellations are explained and rebooked.		Proportion of patients not treated within 28 days of last minute cancellation due to non-clinical reason Proportion of patients whose operation was cancelled	Some patients had their surgery cancelled on multiple occasions due to a lack of beds, We observed patients with cancer having their surgery cancelled while on inspection in November 2014		
7 Services run on time. Disruptions are informed.					
Responsive- Key Line of Enquiry R4: Response to concerns and complaints					
1 Awareness about process for raising awareness or complaint	Complaints				

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
2 System for complaints is easy to use. People receive help and support if needed.	Complaints				Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
					The lack of complaints from the public may well have been due to the lack of profile each organisation has. Both the public and professionals may also be deterred from referring cases by the apparent complexity of the process and the time taken to resolve cases.
3 Effective and confidential treatment of complaints	Complaints	If you raised a concern during labour and birth, did you feel that it was taken seriously?	Complaints were not always managed in a timely or appropriate manner.	Complaints were effectively managed with clear processes in place, which included the CEO and Director of Nursing (occasionally referred to as Chief Nurse) reading all complaints that involved patient care	
			There was no central team for managing complaints - complaints were managed locally within the CAG structure. Time frames were not being met and CAG leads had been spoken with.		There were inadequate processes for dealing with complaints and serious untoward incidents (SUIs). Staff and patient surveys continually gave signs of dissatisfaction with the way the Trust was run, and yet no effective action was taken and the Board lacked an awareness of the reality of the care being provided to patients
			The Trust received 231 formal complaints in January 2015 of which 157 (68%) were acknowledged within three working days. Also only 38% of complaints were responded to within the negotiated time frame in January		Complaints, their source, their handling and their outcome provide an insight into the effectiveness of an

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
					organisation's ability to uphold both the fundamental standards and the culture of caring.
4 Outcome of the complaint is explained to the individual. Openness about process to deal with complaints	Complaints				Patients raising concerns about their care are entitled to: have the matter dealt with as a complaint unless they do not wish it; identification of their expectations; prompt and thorough processing; sensitive, responsive and accurate communication; effective and implemented learning; and proper and effective communication of the complaint to those responsible for providing the care.
5 Lessons learned from complaints. Lessons are shared with others	Complaints			There was a commitment and accountability from staff throughout the organisation to learn from complaints and make improvements where necessary	Complaints were not given a high enough priority in identifying issues and learning lessons. Patients, clinicians and the public need to be at the heart of the health service and the decisions being made.
		Share your experience negative comments			It is service users, including visitors and families, who are likely to be the first to witness poor outcomes or the warning

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
		Patient opinion – negative comments			signs that standards are slipping. It is here that a more specific focus by local inspectors on complaints, allowing perhaps for contact with complainants, would be of great assistance.
		NHS Choices negative comments			The Care Quality Commission should ensure as a matter of urgency that it has reliable access to all useful complaints information relevant to assessment of compliance with fundamental standards, and should actively seek this information out, probably via its local relationship managers.
		CQC complaints			
		Provider complaints			
Well-led- Key Line of Enquiry W1: Clear vision and strategy to deliver quality of care					
1 Quality and safety top priorities in the vision and values	Good governance	Proportion of Health Care Workers (HCW) with direct patient care that have been vaccinated against seasonal influenza	We were not provided with the strategy that detailed the merger objectives and the short, medium and long term plan for the future of the organisation.	The drive for high quality patient-centred care was evident through the combination of the leadership at all levels, with the governance process and the open and transparent culture being used to drive improvements	The Trust lacked a sufficient sense of collective responsibility or engagement for ensuring that quality care was delivered at every level.
		Q2 Monitor/TDA framework: Is the board sufficiently aware of potential risks to the quality, sustainability and delivery of current and future services?	The board members interviewed did not share an agreed strategy or vision for the organisation as a whole other than an aim to be financial viable which was proving a challenge at the time of inspection. Individual board members had different visions.		There must be no tolerance of substandard care; frontline staff must be empowered with responsibility and freedom to act in this way under strong and stable leadership in stable organisations.

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
	Statement of purpose		Lack of strategy for the following aspect of care: nursing, estates, IT, children services or quality.	The positive approach to leadership and shared vision and strategy among staff engendered a culture of patient-centred care with a clear shared purpose, which motivated staff to drive improvements	Foster a common culture shared by all in the service of putting the patient first
			In November 2013 we judged the Trust to not be meeting 15 CQC standards. In the last 12 months the Trust board papers did not demonstrate that the Trust had achieved or had plans to achieve compliance with the regulatory standards to protect patients from harm.		The negative aspects of culture in the system were identified as including: A lack of openness to criticism; A lack of consideration for patients; Defensiveness; Looking inwards not outwards; Secrecy; Misplaced assumptions about the judgements and actions of others; An acceptance of poor standards; and A failure to put the patient first in everything that is done.
2 Robust and realistic strategy for achieving priorities		Q1 Monitor/TDA framework: Does the board have a credible strategy to provide high quality, sustainable services to patients and is there a robust plan to deliver?	They told us they had discussed the strategy but there was nothing written to confirm what the short, medium and long term strategy was. They went on to confirm that they could not monitor it as they had no process to do so. They told us there were limited metrics to assess the effectiveness of the CAGs and believed the information being received at the Quality Assurance Committee and at the Trust board provided adequate assurance.		

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
3	Development process for vision, values and strategy			The medical director took a paper detailing the strategic plan for end of life care to the Trust board in January 2015. This paper referred to the removal of the LCP which took place nationally in July 2013. It was confirmed at the board meeting that the strategic plan had not been through a structured engagement process and had not included engagement with patients, this supported findings on inspection that end of life care was inadequate.		
4	Staff awareness of vision and values				Staff were aligned with the Trust's vision and values "committed to excellence; working together; facing the future" and they were evidently embedded throughout the Trust underpinning fundamental behaviours	
5	Staff awareness of strategy and their role					
6	Monitoring of delivery of the strategy	Good governance				

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Well-led- Key Line of Enquiry W2: Governance framework sets clear responsibilities and management of quality, performance and risks					
1 Effective governance framework to deliver the strategy	Good governance	Q6 Monitor/TDA framework: Are there clear roles and accountabilities in relation to board governance (including quality governance)?	At this inspection we found the CAG structure was still not embedded and site-specific management had not been developed. A clear process for board to ward governance and engagement was not evident.		The Royal College of Surgeons reached critical conclusions about the operation and management of the Trust's surgical department, which it described as "dysfunctional".
2 Staff understand their roles and accountability					All the required elements of governance should be brought together into one comprehensive standard. This should require not only evidence of a working system but also a demonstration that it is being used to good effect.
3 Management of working arrangement with third parties					
4 Regular review of governance framework	Good governance				
5 Holistic understanding of performance	Good governance	Q7 Monitor/TDA framework: Are there clearly defined, well-understood processes for escalating and resolving issues and managing performance?	An example of poor governance with no ownership was a patient who had their surgery cancelled on five occasions and neither the Surgical and Cancer CAG leads nor the Hospital Director and Hospital Matron were aware. Children's services sat across		The focus of the system resulted in a number of organisations failing to place quality of care and patients at the heart of their work. Finances and targets were often given priority without considering the impact on the quality of care.

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
			three CAG's and we heard of a range of developments within children's services however this was compromised with no one known as the lead.		The Trust prioritised its finances and its FT application over its quality of care, and failed to put patients at the centre of its work
					A culture focused on doing the system's business – not that of the patients
					An institutional culture which ascribed more weight to positive information about the service than to information capable of implying cause for concern
6 Comprehensive assurance system and service performance measures	Good governance	Q9 Monitor/TDA framework: Is appropriate information on organisational and operational performance being analysed and challenged?	Senior staff did not always have the information they needed to have oversight of the services they led.	There was evidence that governance structures were embedded throughout the Trust and that the processes were reliable, such as incident reporting where staff demonstrated knowledge of improvements being made as a consequence	Too great a degree of tolerance of poor standards and of risk to patients
7 Effective arrangement to ensure information is accurate, valid, reliable, timely and relevant.	Good governance	Data Quality of Trust Returns to the HSCIC			Deficiencies in the Trust's risk management and assurance systems and made serious criticisms which called into question the accuracy and reliability of the Trust's compliance with standards.

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
			Q10 Monitor/TDA framework: Is the board assured of the robustness of information?			Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
8	Systematic programme of clinical and internal audit	Good governance				
9	Arrangements for managing risks, issues and mitigating actions	Safety		The systems and processes of assurance was variable with some services lacking any formal, effective oversight. Risk registers were poorly applied in some clinical areas which led to some risks not being identified, recorded and managed or escalated.		
10	Alignment between recorded risks and users' opinion about risks					

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
Well-led- Key Line of Enquiry W3: Leadership and culture					
1 Skills, knowledge, experience and integrity of leaders	Fit and proper person: director	Q3 Monitor/TDA framework: Does the board have the skills and capability to lead the organisation?	The Director of Human Resources advised us that the Medical Director and the Director of Corporate Affairs were responsible for the implementation of the Duty of Candour legislation and the Fit and Proper Person Requirements which came into effect on 27 November 2014. At the January 2015 board meeting the new legislations were discussed, however the appropriate steps to ensure compliance and on-going monitoring were not yet in place.	The executive team were cohesive yet challenging to ensure patients were at the centre of their work.	It is clear that a staff nurse's report in 2007 made a serious and substantial allegation about the leadership of A&E. This was not resolved by Trust management.
2 Capacity, capability and experience of leaders					A leadership staff college or training system, whether centralised or regional, should be created to: provide common professional training in management and leadership to potential senior staff; promote healthcare leadership and management as a profession; administer an accreditation scheme to enhance eligibility for consideration for such roles; promote and research best leadership practice in healthcare.
3 Understanding of challenges to good quality of care	Good governance		The Trust board were not aware of significant issues on specific sites, due to the lack of site-specific management and information. At the time of inspection the board was receiving Trust wide data which did not detail the level of issues and concerns we identified on specific sites and when we spoke with both executives and non-executive directors the detail was not evident when looking at Trust wide data.		The fact that it might be typical of what happened elsewhere is cause for increased concern not reassurance. It is an argument which evidences a culture of habituation and passivity in the face of issues which may indicate real suffering.

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
			When we explored this local triumvirate they did not to have accountability and responsibility and had to refer to the CAGs. The relationships and responsibilities between site specific leaders and CAG leadership team were confused.		As a result of poor leadership and staffing policies, a completely inadequate standard of nursing was offered on some wards in Stafford. It failed to tackle an insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities
4 Leaders visible and approachable		The proportion of staff reporting good communication between senior management and staff	The majority of staff did not know the executives leading the Trust nor were they familiar with the leaders of the CAGs despite this structure being in place since October 2012. Staff told us that the executive team were not visible however several staff told us they received the chief executive's weekly email message.	There was a recognised visibility of leadership and excellent engagement with governors and the public through constituency meetings held monthly.	Ward managers should work alongside staff as a role model and mentor, developing clinical competencies and leadership skills within the team and ensuring that the caring culture expected of professional staff is being consistently maintained and upheld.
5 Appreciative, supportive relationships among staff are encouraged		The proportion of staff who would recommend the Trust as a place to work or receive treatment	On the last inspection, November 2013 we identified a culture of bullying and harassment, in response to this the Trust commissioned an independent review by Duncan Lewis that found: • Unreasonable management:	There was a strong sense of support and alignment between clinicians and managers with a clear sense of accountability among staff at all levels.	The previous reports are clear that the following existed: a culture of fear in which staff did not feel able to report concerns; a culture of secrecy in which the Trust board shut itself off from what was happening in its hospital and ignored its

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		Composite indicator: NHS staff survey questions relating to abuse from other staff	mainly associated with negative behaviour from line managers and other managers. • Incivility and disrespect: mainly associated with behaviours from work colleagues and from line managers, but can also include patients and the relatives of patients. • Approximately 75-80% of the respondents indicated that most of the 26 ill-treatment behaviours were still occurring within the last three months.		patients; and a culture of bullying, which prevented people from doing their jobs properly
6 Staff feel respected and valued			Indeed staff gave examples of not being valued or recognised. We spoke with a number of temporary staff and also staff who were actively trying to leave the Trust		
7 Management of behaviour inconsistent with vision and values	Fit and proper staff				
8 Culture centred on needs and experience of service users	Person-centred care	"Overall..." (I had a very poor/good experience)			

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
9 Culture encourage candour, openness and honesty	Good governance	The proportion of staff who would recommend the Trust as a place to work or receive treatment Composite risk rating of ESR items relating to staff sickness rates	Risks were apparent across the Trust and staff commitment to reporting and escalating concerns varied considerably. Some staff told us they had actively been told not to report incidents other staff told us they did not report because there was no action taken.	The culture throughout the Trust was open and transparent with a clear sense of pride among all staff groups	Ensure openness, transparency and candour throughout the system about matters of concern
				An open and transparent approach with patients was evident, with 'look back' exercises carried out and subsequent sharing of information with patients or relatives.	Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful.
			We were provided with some examples that the non-executive directors on their walk rounds had identified concerns that they had previously not been aware of. The reasons for the Trust having a back-log of 100 open SIs and complaints for months and in some cases complaints never answered were unknown.		The NHS Constitution should be revised to reflect the changes recommended with regard to a duty of openness, transparency and candour, and all organisations should review their contracts of employment, policies and guidance to ensure that, where relevant, they expressly include and are consistent with above principles and these recommendations.
		Q4 Monitor/TDA framework: Does the board shape an open, transparent and quality-focused culture?	Morale was low. Some staff were reluctant to speak with the inspection team, when staff did some did not want the inspection team to record the discussions for fear of repercussions.		A failure to tackle challenges to the building up of a positive culture, in nursing in particular but also within the medical profession

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
			The 2013 NHS Staff Survey for the Trust as a whole had work related stress at 44%, the joint highest rate in the country for an acute Trust. Only 32% recommend it as a place to work, which is third lowest in the country.		The Trust was an organisation that lacked insight and awareness of the reality of the care being provided to patients. It was generally defensive in its reaction to criticism and lacked openness with patients, the public and external agencies.
10 Emphasis on promoting safety and wellbeing of staff		Composite risk rating of ESR items relating to staff stability Staff turnover rate	Staffing was a key challenge across all services and the environment was not conducive to recruitment and retention and the sustainability of services. There were a number of vacant managerial posts and interim staff in post making it difficult for staff to be well-led.		Healthcare providers should be encouraged by incentives to develop and deploy reliable and transparent measures of the cultural health of front-line nursing workplaces and teams, which build on the experience and feedback of nursing staff using a robust methodology, such as the "cultural barometer".
11 Teams work collaboratively and share responsibility to deliver good quality of care					
Well-led- Key Line of Enquiry W4: Engagement and involvement of users and staff					
1 People's views and experience are gathered and acted on	Person-centred care	"Overall..." (I had a very poor/good experience) Inpatient Friends and Family Test		There was a sense of mutual support and passion to deliver patient-centred care amongst all staff groups at all levels	It is a significant part of the Stafford story that patients and relatives felt excluded from

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
2	Engagement and involvement of users in decision-making	Person-centred care	NHS England Inpatients response rate from Friends and Family Test			effective participation in the patients' care.
3	Staff's views are reflected in the planning and delivery of care				There was a genuine sense of a flattened hierarchy and culture that ensured all staff views were captured amongst all groups and at all levels	
4	Strategy to prioritise participation and involvement of users and staff		GMC National Training Survey – Trainee's overall satisfaction	Staff described their passion and commitment to the community they served and to their immediate colleagues. Staff did not however speak of vision, strategy and leadership and feeling valued by senior colleagues		
			Q8 Monitor/TDA framework: Does the board actively engage patients, staff, governors and other key stakeholders on quality, operational and financial performance?			
			GMC Enhanced monitoring	In the 2014 NHS Staff survey, the engagement score for the Trust was 3.61 which is in the worst 20% when compared with other acute Trusts of a similar type.		The General Medical Council should in the course of its review of its standards and regulatory process ensure that the system of medical training and education maintains as its first priority the safety of patients.

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
5 Leaders and staff understand value of staff raising concerns. Appropriate actions are taken	Good governance	CQC National Customer Service Centre qualified Whistleblowing alerts		There was a commitment and accountability from staff throughout the organisation to learn from complaints and make improvements where necessary	Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon
Well-led- Key Line of Enquiry W5: Continuous improvement and sustainability					
1 Assessment of impact of changes on quality and sustainability	Good governance	Monitor - Continuity of service rating		The strategy and vision for the Trust, which included the potential acquisition of another provider, demonstrated robust analysis and proactive approach to ensure sustainability and pathways of care (including hyperacute services), whilst remaining realistic regarding the potential challenges that may be encountered.	
2 Examples of financial pressures compromising quality of care	Good governance		Senior staff were trialling the Multidisciplinary Action Training in Crises and Human Factors initiative (MATCH).This was a framework within which Never Events and Serious Incidents could be discussed in an environment characterised by		I have no doubt that the economies imposed by the Trust Board, year after year, had a profound effect on the organisation's ability to deliver a safe and effective service.

Prompts		Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
				mutual respect and in which lessons learnt could be quickly introduced without damaging personal relationships. It was reported that initial results had been very promising. However, staff reported that whilst there had previously been plans to introduce this across the Trust, the financial pressures the Trust faced may put this on hold.		No effective consideration was given to the potential effects of cost savings and staff cuts on patient safety and quality
3	Efforts for continuous learning, improvement and innovation	Good governance	The proportion of staff reported receiving support from immediate managers	We found the financial position of the Trust impacted on the volume of innovation, improvement and sustainability initiatives for the services.	Innovation and continuous improvement was fundamental to the culture at the Trust and there was evidence that innovation among all staff groups and at all levels was encouraged	
4	Focus on continuous improvement of quality of care	Good governance	Q5 Monitor/TDA framework: Does the board help support continuous learning and development across the organisation?			
5	Recognition and reward of improvements and innovations	Good governance				
6	Proactive use of information to improve care	Good governance			There was evidence of a proactive and systematic approach to improve outcomes, improve	The Trust's culture was one of self-promotion rather than critical analysis and openness.

Prompts	Fundamental standards	Intelligent monitoring	Trust put into special measures (Barts Health NHS trust)	Trust rated as outstanding (Frimley Park Hospital NHS FT)	Francis Report
				patient experience, drive efficiency and productivity; including work with other stakeholders where appropriate to continuously improve patient care.	The absence of such a system [clinical governance] meant that the leadership of the Trust was bound to be blind to many concerns which it took the HCC to uncover by its investigation.
		Monitor risk rating for governance			
		NHS Trust Development Authority risk rating for governance			

Key to the table | Performance indicators relevant for more than one KLOE | Monitor's assessment of governance | Breach of compliance leads to immediate enforcement actions

Appendix Chapter 6

Table 6.1 Descriptive information for each acute NHS trust in England (n=155)

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
1	Aintree University Hospital NHS Foundation Trust	REM	Yes	Medium acute Trust	North	South Sefton	2	3	3
2	Airedale NHS Foundation Trust	RCF	Yes	Small acute trust	North	Airedale Wharfedale and Craven	1	2	3
3	Alder Hey Children's NHS Foundation Trust	RBS	Yes	Acute specialist trust	North	NHS England North	2	2	6
4	Ashford and St Peter's Hospitals NHS Foundation Trust	RTK	Yes	Medium acute Trust	South	North West	2	2	4
5	Barking, Havering and Redbridge University Hospitals NHS Trust	RF4	No	Large acute trust	London	Havering	3	3	4
6	Barnsley Hospital NHS Foundation Trust	RFF	Yes	Small acute trust	North	Barnsley	1	1	3
7	Barts Health NHS Trust	R1H	No	Large acute trust	London	Tower Hamlets	8	14	7
8	Basildon and Thurrock University Hospitals NHS Foundation Trust	RDD	Yes	Medium acute Trust	Midlands and East	Basildon and Brentwood	2	2	5
9	Bedford Hospital NHS Trust	RC1	No	Small acute trust	Midlands and East	Bedfordshire	1	1	6
10	Birmingham Children's Hospital NHS Foundation Trust	RQ3	Yes	Acute specialist trust	Midlands and East	NHS England Midlands and East	1	2	4
11	Birmingham Women's NHS Foundation Trust	RLU	Yes	Acute specialist trust	Midlands and East	NHS England Midlands and East	1	1	3
12	Blackpool Teaching Hospitals NHS Foundation Trust	RXL	Yes	Large acute trust	North	Blackpool	5	12	2
13	Bolton NHS Foundation Trust	RMC	Yes	Medium acute Trust	North	Bolton	4	7	4

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
14	Bradford Teaching Hospitals NHS Foundation Trust	RAE	Yes	Large acute trust	North	Bradford Districts	2	6	6
15	Brighton and Sussex University Hospitals NHS Trust	RXH	No	Acute teaching trust	South	Brighton and Hove	6	8	7
16	Buckinghamshire Healthcare NHS Trust	RXQ	No	Medium acute Trust	South	Aylesbury Vale	3	9	5
17	Burton Hospitals NHS Foundation Trust	RJF	Yes	Small acute trust	Midlands and East	East Staffordshire	3	3	5
18	Calderdale and Huddersfield NHS Foundation Trust	RWY	Yes	Large acute trust	North	Calderdale	2	5	5
19	Cambridge University Hospitals NHS Foundation Trust	RGT	Yes	Acute teaching trust	Midlands and East	Cambridgeshire and Peterborough	6	13	2
20	Central Manchester University Hospitals NHS Foundation Trust	RW3	Yes	Acute teaching trust	North	Central Manchester	6	23	6
21	Chelsea and Westminster Hospital NHS Foundation Trust	RQM	Yes	Acute teaching trust	London	West London	2	2	4
22	Chesterfield Royal Hospital NHS Foundation Trust	RFS	Yes	Medium acute Trust	Midlands and East	North Derbyshire	1	2	4
23	City Hospitals Sunderland NHS Foundation Trust	RLN	Yes	Large acute trust	North	Sunderland	8	9	3
24	Colchester Hospital University NHS Foundation Trust	RDE	Yes	Medium acute Trust	Midlands and East	North East Essex	2	2	1
25	Countess Of Chester Hospital NHS Foundation Trust	RJR	Yes	Medium acute Trust	North	Western Cheshire	2	2	1
26	County Durham and Darlington NHS Foundation Trust	RXP	Yes	Large acute trust	North	Durham Dales, Sedgefield & Easington	5	11	6
27	Croydon Health Services NHS Trust	RJ6	No	Medium acute Trust	London	Croydon	2	3	3

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
28	Dartford and Gravesham NHS Trust	RN7	No	Small acute trust	South	Dartford Gravesham and Swanley	2	5	2
29	Derby Teaching Hospitals NHS Foundation Trust	RTG	Yes	Large acute trust	Midlands and East	Southern Derbyshire	2	2	4
30	Doncaster and Bassetlaw Hospitals NHS Foundation Trust	RP5	Yes	Large acute trust	North	Doncaster	4	4	2
31	Dorset County Hospital NHS Foundation Trust	RBD	Yes	Small acute trust	South	Dorset	7	7	1
32	East and North Hertfordshire NHS Trust	RWH	No	Large acute trust	Midlands and East	East and North Hertfordshire	4	6	2
33	East Cheshire NHS Trust	RJN	No	Small acute trust	North	Eastern Cheshire	3	4	2
34	East Kent Hospitals University NHS Foundation Trust	RVV	Yes	Large acute trust	South	East Kent	5	5	4
35	East Lancashire Hospitals NHS Trust	RXR	No	Large acute trust	North	East Lancashire	7	7	4
36	East Sussex Healthcare NHS Trust	RXC	No	Large acute trust	South	Eastbourne, Hailsham and Seaford	7	20	4
37	Epsom and St Helier University Hospitals NHS Trust	RVR	No	Large acute trust	London	Sutton	6	6	3
38	Frimley Health NHS Foundation Trust	RDU	Yes	Medium acute Trust	South	North East Hampshire And Farnham	3	6	3
39	Gateshead Health NHS Foundation Trust	RR7	Yes	Medium acute Trust	North	Gateshead	2	5	2
40	George Eliot Hospital NHS Trust	RLT	No	Small acute trust	Midlands and East	North Warwickshire	1	1	3
41	Gloucestershire Hospitals NHS Foundation Trust	RTE	Yes	Large acute trust	South	Gloucestershire	8	8	4
42	Great Ormond Street Hospital for Children NHS Foundation Trust	RP4	Yes	Acute specialist trust	London	NHS England London	1	1	2

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
43	Great Western Hospitals NHS Foundation Trust	RN3	Yes	Medium acute Trust	South	Swindon	5	5	4
44	Guy's and St Thomas' NHS Foundation Trust	RJ1	Yes	Acute teaching trust	London	Lambeth	6	10	4
45	Hampshire Hospitals NHS Foundation Trust	RN5	Yes	Medium acute Trust	South	West Hampshire	3	3	3
46	Harrogate and District NHS Foundation Trust	RCD	Yes	Small acute trust	North	Harrogate and Rural District	3	3	1
47	Heart Of England NHS Foundation Trust	RR1	Yes	Large acute trust	Midlands and East	Birmingham Crosscity	7	8	6
48	Hinchingbrooke Health Care NHS Trust	RQQ	No	Small acute trust	Midlands and East	Cambridgeshire and Peterborough	1	2	3
49	Homerton University Hospital NHS Foundation Trust	RQX	Yes	Small acute trust	London	City and Hackney	1	2	4
50	Hull and East Yorkshire Hospitals NHS Trust	RWA	No	Large acute trust	North	Hull	2	5	6
51	Imperial College Healthcare NHS Trust	RYJ	No	Acute teaching trust	London	Hammersmith & Fulham	5	12	5
52	Ipswich Hospital NHS Trust	RGQ	No	Medium acute Trust	Midlands and East	Ipswich and East Suffolk	1	6	3
53	Isle of Wight NHS Trust	R1F	No	Small acute trust	South	Isle of Wight	5	10	2
54	James Paget University Hospitals NHS Foundation Trust	RGP	Yes	Medium acute Trust	Midlands and East	Great Yarmouth and Waveney	2	3	4
55	Kettering General Hospital NHS Foundation Trust	RNQ	Yes	Small acute trust	Midlands and East	Nene	1	1	5
56	King's College Hospital NHS Foundation Trust	RJZ	Yes	Acute teaching trust	London	Bromley	4	12	2
57	Kingston Hospital NHS Foundation Trust	RAX	Yes	Medium acute Trust	London	Kingston	1	1	3

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
58	Lancashire Teaching Hospitals NHS Foundation Trust	RXN	Yes	Large acute trust	North	Greater Preston	4	6	4
59	Leeds Teaching Hospitals NHS Trust	RR8	No	Acute teaching trust	North	NHS England North/Leeds West	6	6	6
60	Lewisham and Greenwich NHS Trust	RJ2	No	Medium acute Trust	London	Bexley	6	11	3
61	Liverpool Heart and Chest NHS Foundation Trust	RBQ	Yes	Acute specialist trust	North	NHS England North	1	1	4
62	Liverpool Women's NHS Foundation Trust	REP	Yes	Acute specialist trust	North	Liverpool	2	2	5
63	London North West Healthcare NHS Trust	R1K	No	Large acute trust	London	Ealing and Brent	6	7	10
64	Luton and Dunstable University Hospital NHS Foundation Trust	RC9	Yes	Medium acute Trust	Midlands and East	Luton	3	4	2
65	Maidstone and Tunbridge Wells NHS Trust	RWF	No	Large acute trust	South	West Kent	2	2	6
66	Medway NHS Foundation Trust	RPA	Yes	Medium acute Trust	South	Medway	1	1	7
67	Mid Cheshire Hospitals NHS Foundation Trust	RBT	Yes	Small acute trust	North	South Cheshire	1	3	4
68	Mid Essex Hospital Services NHS Trust	RQ8	No	Medium acute Trust	Midlands and East	Mid Essex	3	5	7
69	The Mid Yorkshire Hospitals NHS Trust	RXF	No	Large acute trust	North	Wakefield	3	7	6
70	Milton Keynes University Hospital NHS Foundation Trust	RD8	Yes	Small acute trust	Midlands and East	Milton Keynes	1	1	3
71	Moorfields Eye Hospital NHS Foundation Trust	RP6	Yes	Acute specialist trust	London	NHS England London	6	10	2
72	Norfolk and Norwich University Hospitals NHS Foundation Trust	RM1	Yes	Acute teaching trust	Midlands and East	North Norfolk	2	3	5

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
73	North Bristol NHS Trust	RVJ	No	Large acute trust	South	South Gloucestershire	3	5	7
74	North Cumbria University Hospitals NHS Trust	RNL	No	Medium acute Trust	North	Cumbria	3	3	6
75	North Middlesex University Hospital NHS Trust	RAP	No	Medium acute Trust	London	Enfield	2	2	5
76	North Tees and Hartlepool NHS Foundation Trust	RVW	Yes	Medium acute Trust	North	Hartlepool and Stockton-on-Tees	3	3	2
77	Northampton General Hospital NHS Trust	RNS	No	Medium acute Trust	Midlands and East	Nene	4	4	2
78	Northern Devon Healthcare NHS Trust	RBZ	No	Small acute trust	South	Northern Eastern and Western Devon	22	25	7
79	Northern Lincolnshire and Goole NHS Foundation Trust	RJL	Yes	Large acute trust	North	North Lincolnshire	3	5	3
80	Northumbria Healthcare NHS Foundation Trust	RTF	Yes	Large acute trust	North	North Tyneside and Northumberland	11	13	2
81	Nottingham University Hospitals NHS Trust	RX1	No	Acute teaching trust	Midlands and East	Nottingham City	3	4	3
82	Oxford University Hospitals NHS Trust	RTH	No	Acute teaching trust	South	NHS England Midlands and East/Oxfordshire	7	7	2
83	Papworth Hospital NHS Foundation Trust	RGM	Yes	Acute specialist trust	Midlands and East	NHS England Midlands and East	1	1	2
84	The Pennine Acute Hospitals NHS Trust	RW6	No	Large acute trust	North	Heywood, Middleton & Rochdale	6	7	8
85	Peterborough and Stamford Hospitals NHS Foundation Trust	RGN	Yes	Medium acute Trust	Midlands and East	Cambridgeshire and Peterborough	2	2	4
86	Plymouth Hospitals NHS Trust	RK9	No	Large acute trust	South	Northern Eastern and Western Devon	8	12	4
87	Poole Hospital NHS Foundation Trust	RD3	Yes	Medium acute Trust	South	Dorset	1	1	4

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
88	Portsmouth Hospitals NHS Trust	RHU	No	Large acute trust	South	Portsmouth	4	4	4
89	Queen Victoria Hospital NHS Foundation Trust	RPC	Yes	Acute specialist trust	South	NHS England South	1	1	3
90	The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust	RL1	No	Acute specialist trust	Midlands and East	Shropshire County	2	2	3
91	Royal Berkshire NHS Foundation Trust	RHW	Yes	Large acute trust	South	Berkshire West Federation	4	5	1
92	Royal Brompton and Harefield NHS Foundation Trust	RT3	Yes	Acute specialist trust	London	NHS England London	2	2	3
93	Royal Cornwall Hospitals NHS Trust	REF	No	Large acute trust	South	Kernow	4	5	6
94	Royal Devon and Exeter NHS Foundation Trust	RH8	Yes	Acute teaching trust	South	North East West Devon	9	12	4
95	Royal Free London NHS Foundation Trust	RAL	Yes	Acute teaching trust	London	Barnet	8	11	4
96	Royal Liverpool and Broadgreen University Hospitals NHS Trust	RQ6	No	Acute teaching trust	North	Liverpool	2	3	4
97	Royal National Orthopaedic Hospital NHS Trust	RAN	No	Acute specialist trust	London	NHS England Midlands and East	2	2	3
98	Royal Surrey County NHS Foundation Trust	RA2	Yes	Medium acute Trust	South	Guildford and Waverley	1	1	2
99	Royal United Hospitals Bath NHS Foundation Trust	RD1	Yes	Medium acute Trust	South	Wiltshire	7	7	4
100	Salford Royal NHS Foundation Trust	RM3	Yes	Acute teaching trust	North	Salford	1	1	3
101	Salisbury NHS Foundation Trust	RNZ	Yes	Small acute trust	South	Wiltshire	1	1	3
102	Sandwell and West Birmingham Hospitals NHS Trust	RXK	No	Large acute trust	Midlands and East	Sandwell and West Birmingham	4	6	3

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
103	Sheffield Children's NHS Foundation Trust	RCU	Yes	Acute specialist trust	North	Sheffield	1	1	2
104	Sheffield Teaching Hospitals NHS Foundation Trust	RHQ	Yes	Acute teaching trust	North	NHS England North/Sheffield	5	16	4
105	Sherwood Forest Hospitals NHS Foundation Trust	RK5	Yes	Medium acute Trust	Midlands and East	Mid Nottinghamshire	2	4	5
106	Shrewsbury and Telford Hospital NHS Trust	RXW	No	Large acute trust	Midlands and East	Shropshire	5	6	3
107	South Devon Healthcare NHS Foundation Trust	RA9	Yes	Medium acute Trust	South	South Devon and Torbay	11	17	3
108	South Tees Hospitals NHS Foundation Trust	RTR	Yes	Large acute trust	North	South Tees	8	10	7
109	South Tyneside NHS Foundation Trust	RE9	Yes	Small acute trust	North	South Tyneside	4	16	3
110	South Warwickshire NHS Foundation Trust	RJC	Yes	Small acute trust	Midlands and East	South Warwickshire	4	6	2
111	Southend University Hospital NHS Foundation Trust	RAJ	Yes	Medium acute Trust	Midlands and East	Southend	1	1	5
112	Southport and Ormskirk Hospital NHS Trust	RVY	No	Medium acute Trust	North	Southport & Formby	2	3	3
113	St George's University Hospitals NHS Foundation Trust	RJ7	Yes	Acute teaching trust	London	Wandsworth	4	6	3
114	St Helens and Knowsley Hospitals NHS Trust	RBN	No	Medium acute Trust	North	St Helens	2	2	5
115	Stockport NHS Foundation Trust	RWJ	Yes	Medium acute Trust	North	Stockport	1	1	3
116	Surrey and Sussex Healthcare NHS Trust	RTP	No	Medium acute Trust	South	Crawley	2	2	2
117	Tameside Hospital NHS Foundation Trust	RMP	Yes	Small acute trust	North	Tameside and Glossop	1	1	5

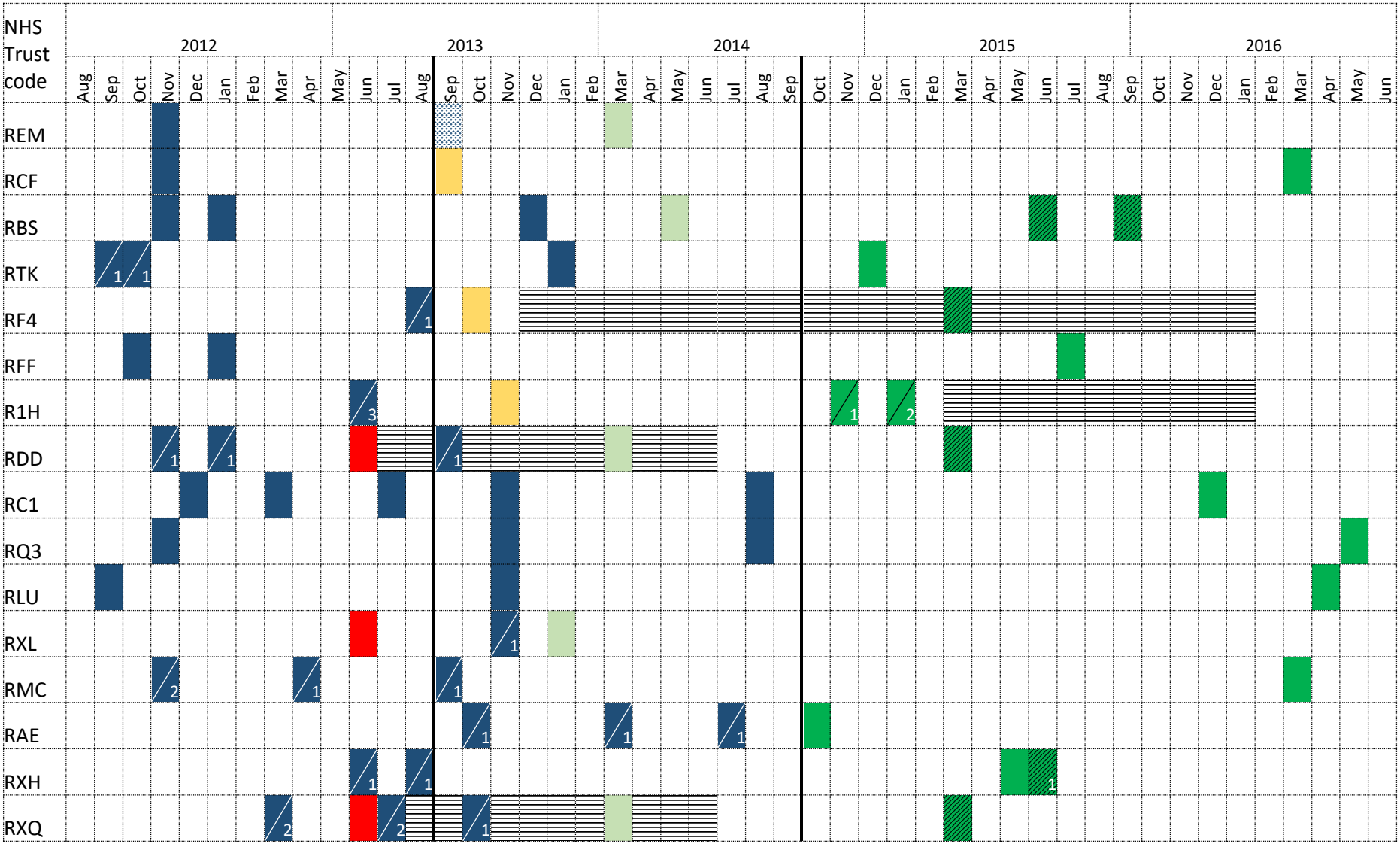
Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
118	Taunton and Somerset NHS Foundation Trust	RBA	Yes	Medium acute Trust	South	Somerset	5	5	3
119	The Christie NHS Foundation Trust	RBV	Yes	Acute specialist trust	North	NHS England North	1	1	3
120	The Clatterbridge Cancer Centre NHS Foundation Trust	REN	Yes	Acute specialist trust	North	NHS England North	1	1	2
121	The Dudley Group NHS Foundation Trust	RNA	Yes	Medium acute Trust	Midlands and East	Dudley	2	2	3
122	The Hillingdon Hospitals NHS Foundation Trust	RAS	Yes	Medium acute Trust	London	Hillingdon	2	7	4
123	The Newcastle Upon Tyne Hospitals NHS Foundation Trust	RTD	Yes	Acute teaching trust	North	Newcastle West	4	6	1
124	The Princess Alexandra Hospital NHS Trust	RQW	No	Medium acute Trust	Midlands and East	East and North Hertfordshire	4	4	2
125	The Queen Elizabeth Hospital, King's Lynn. NHS Foundation Trust	RCX	Yes	Small acute trust	Midlands and East	West Norfolk	1	1	5
126	The Rotherham NHS Foundation Trust	RFR	Yes	Medium acute Trust	North	Rotherham	1	1	2
127	The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	RDZ	Yes	Medium acute Trust	South	Dorset	2	2	4
128	The Royal Marsden NHS Foundation Trust	RPY	Yes	Acute specialist trust	London	NHS England London	2	5	2
129	The Royal Orthopaedic Hospital NHS Foundation Trust	RRJ	Yes	Acute specialist trust	Midlands and East	Birmingham CrossCity	1	1	6
130	The Royal Wolverhampton NHS Trust	RL4	No	Large acute trust	Midlands and East	Wolverhampton	2	5	3
131	The Walton Centre NHS Foundation Trust	RET	Yes	Acute specialist trust	North	NHS England North	1	1	3

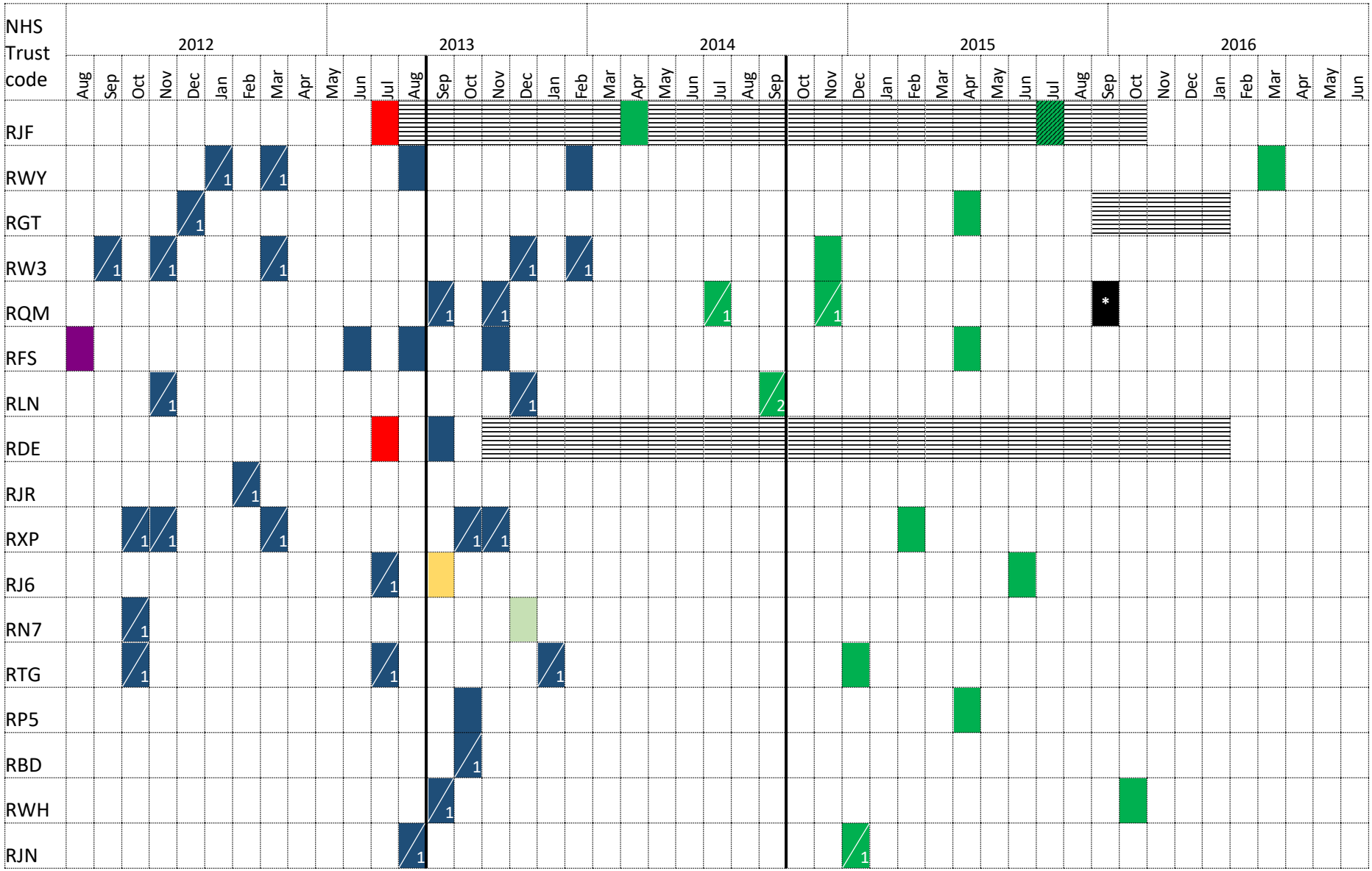
Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
132	The Whittington Hospital NHS Trust	RKE	No	Medium acute Trust	London	Islington	1	1	5
133	United Lincolnshire Hospitals NHS Trust	RWD	No	Large acute trust	Midlands and East	Lincolnshire East	6	7	6
134	University College London Hospitals NHS Foundation Trust	RRV	Yes	Acute teaching trust	London	Camden	7	8	5
135	University Hospital Birmingham NHS Foundation Trust	RRK	Yes	Acute teaching trust	Midlands and East	NHS England Midlands and East	1	1	4
136	University Hospital Of South Manchester NHS Foundation Trust	RM2	Yes	Acute teaching trust	North	South Manchester	3	7	2
137	University Hospital Southampton NHS Foundation Trust	RHM	Yes	Acute teaching trust	South	NHS England South/West Hampshire	4	5	4
138	University Hospitals Bristol NHS Foundation Trust	RA7	Yes	Acute teaching trust	South	NHS England South/Bristol	9	9	5
139	University Hospitals Coventry and Warwickshire NHS Trust	RKB	No	Acute teaching trust	Midlands and East	Coventry and Rugby	2	2	4
140	University Hospitals Of Leicester NHS Trust	RWE	No	Acute teaching trust	Midlands and East	Leicester City	7	20	5
141	University Hospitals Of Morecambe Bay NHS Foundation Trust	RTX	Yes	Large acute trust	North	Lancashire North	3	3	8
142	The University Hospitals of North Midlands	RJE	No	Large acute trust	Midlands and East	NHS England Midlands and East/Stoke-on-trent	2	2	1
143	Walsall Healthcare NHS Trust	RBK	No	Medium acute Trust	Midlands and East	Walsall	3	3	3
144	Warrington and Halton Hospitals NHS Foundation Trust	RWW	Yes	Medium acute Trust	North	Warrington	2	3	6

Id	Name of organisation	NHS Trust code	FT status	Category of trust	NHS England region	Main commissioner	N of hospitals	N of locations	N of inspections
145	West Hertfordshire Hospitals NHS Trust	RWG	No	Large acute trust	Midlands and East	Herts Valleys	3	3	4
146	West Middlesex University Hospital NHS Trust	RFW	No	Small acute trust	London	Hounslow	1	1	2
147	West Suffolk NHS Foundation Trust	RGR	Yes	Small acute trust	Midlands and East	West Suffolk	2	2	3
148	Western Sussex Hospitals NHS Foundation Trust	RYR	Yes	Large acute trust	South	Coastal West Sussex	4	5	5
149	Weston Area Health NHS Trust	RA3	No	Small acute trust	South	North Somerset	1	1	6
150	Wirral University Teaching Hospital NHS Foundation Trust	RBL	Yes	Large acute trust	North	Wirral	2	2	5
151	Worcestershire Acute Hospitals NHS Trust	RWP	No	Large acute trust	Midlands and East	South Worcestershire	4	5	4
152	Wrightington, Wigan and Leigh NHS Foundation Trust	RRF	Yes	Large acute trust	North	Wigan Borough	4	6	5
153	Wye Valley NHS Trust	RLQ	No	Small acute trust	Midlands and East	Herefordshire	4	16	4
154	Yeovil District Hospital NHS Foundation Trust	RA4	Yes	Small acute trust	South	Somerset	2	2	2
155	York Teaching Hospital NHS Foundation Trust	RCB	Yes	Medium acute Trust	North	Vale of York	3	12	5

FT: Foundation Trust; NHS: National Health Service

Table 6.2 Scheme of CQC's inspections for each acute NHS trust for period between September 2012 and June 2016

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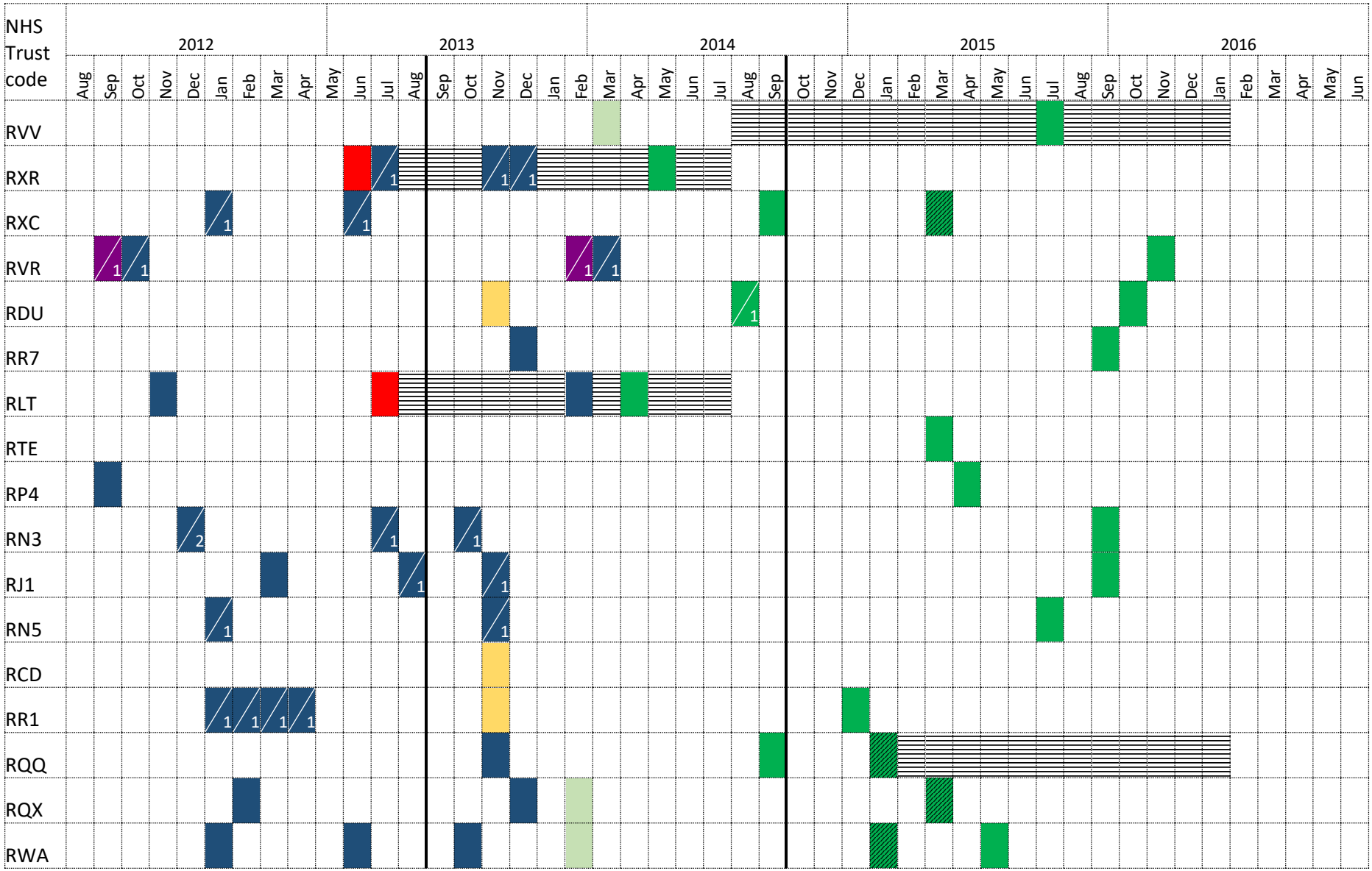
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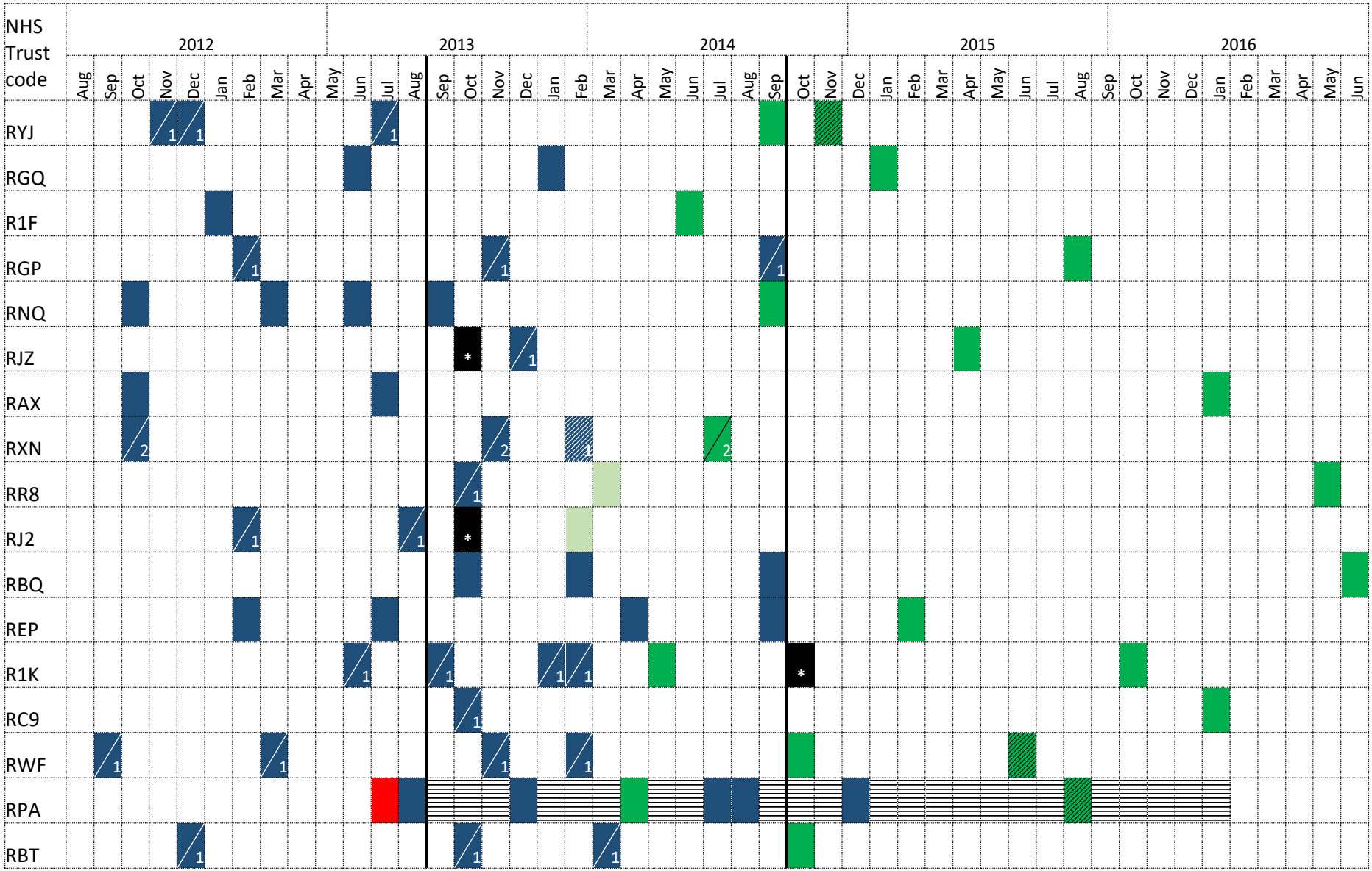
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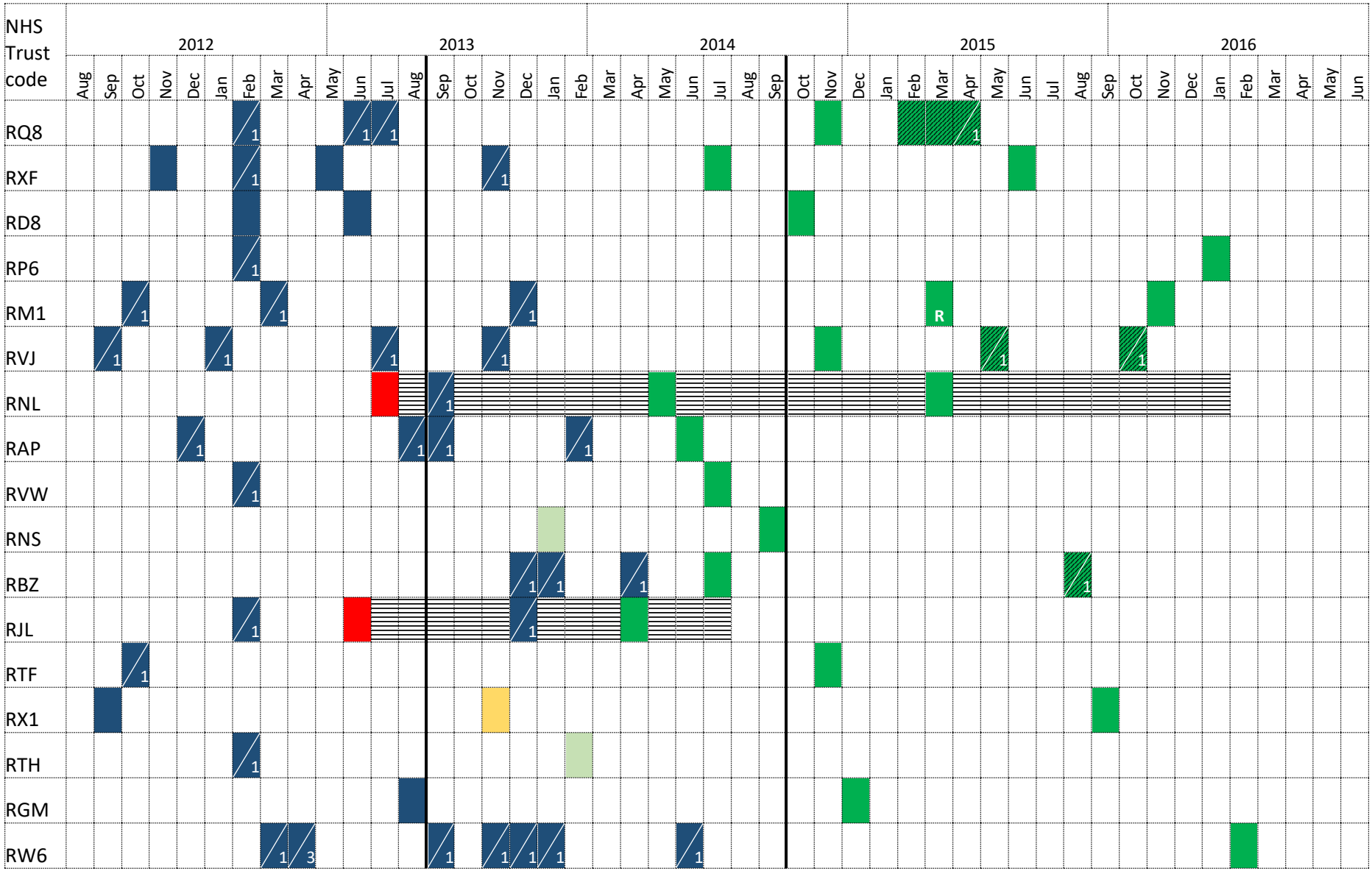
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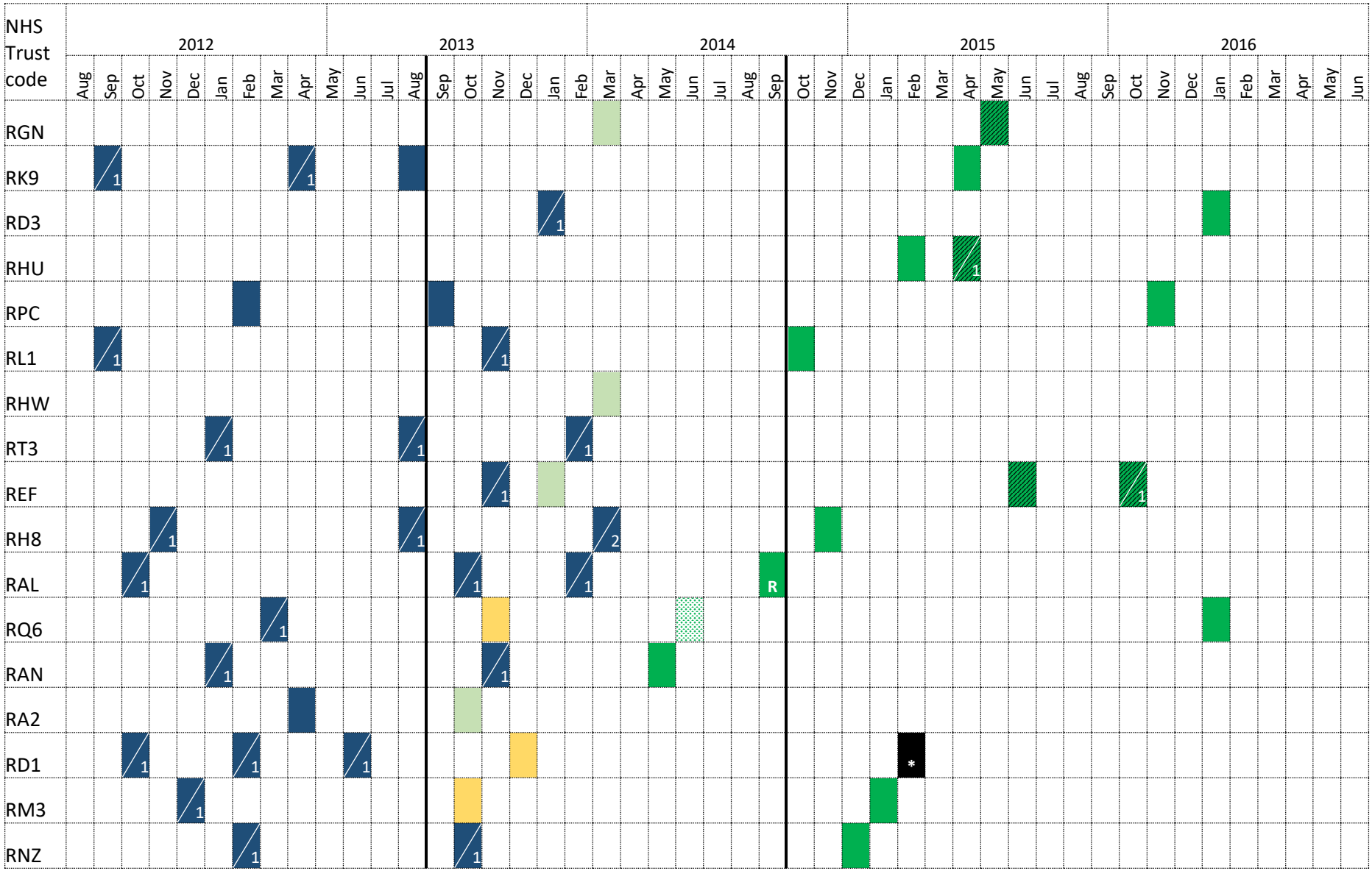
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RK9
RD3
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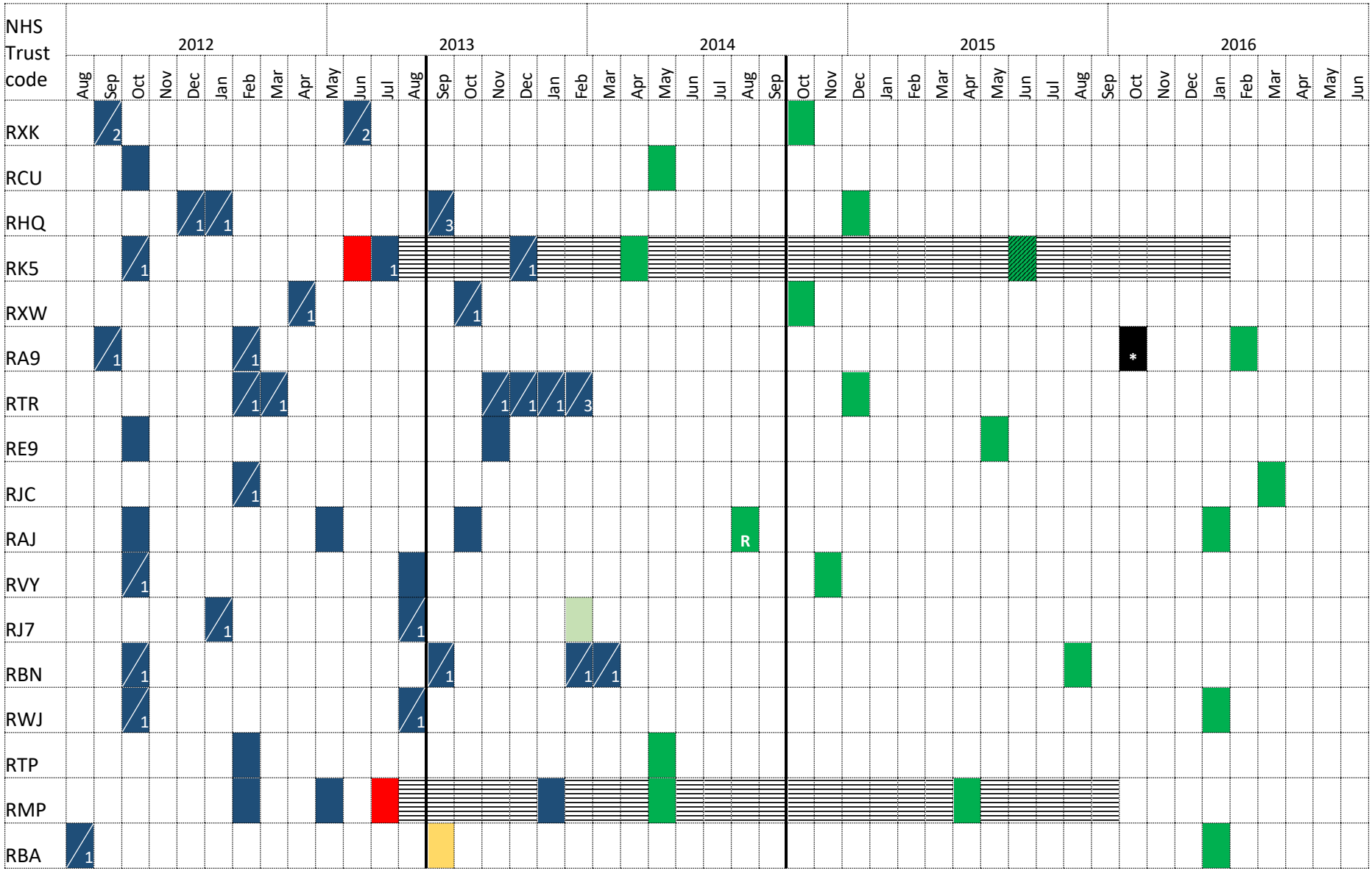
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RXK
RCU
RHQ
RK5
RXW
RA9
RTR
RE9
RJC
RAJ
RVY
RJ7
RBN
RWJ
RTP
RMP
RBA
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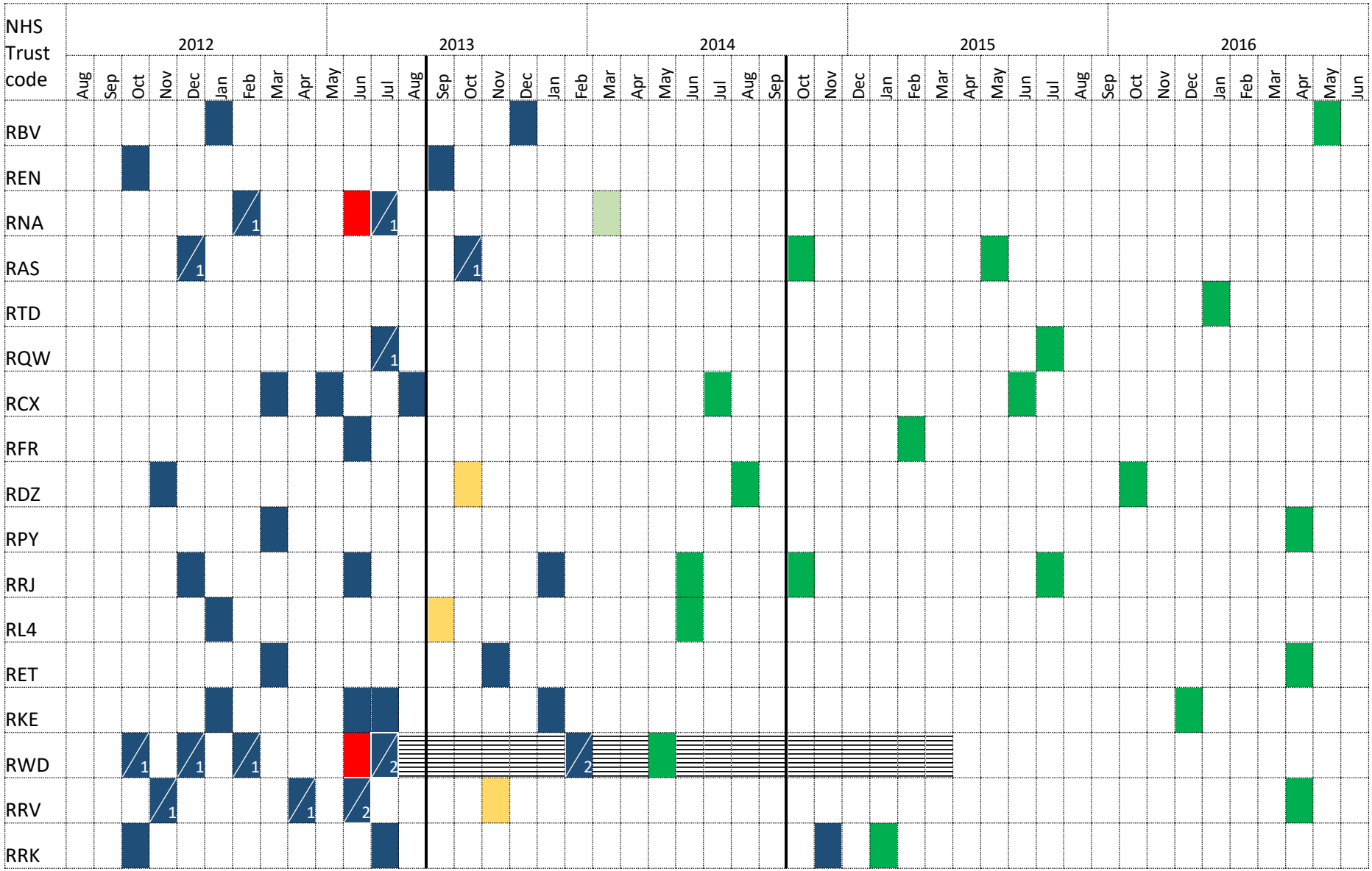
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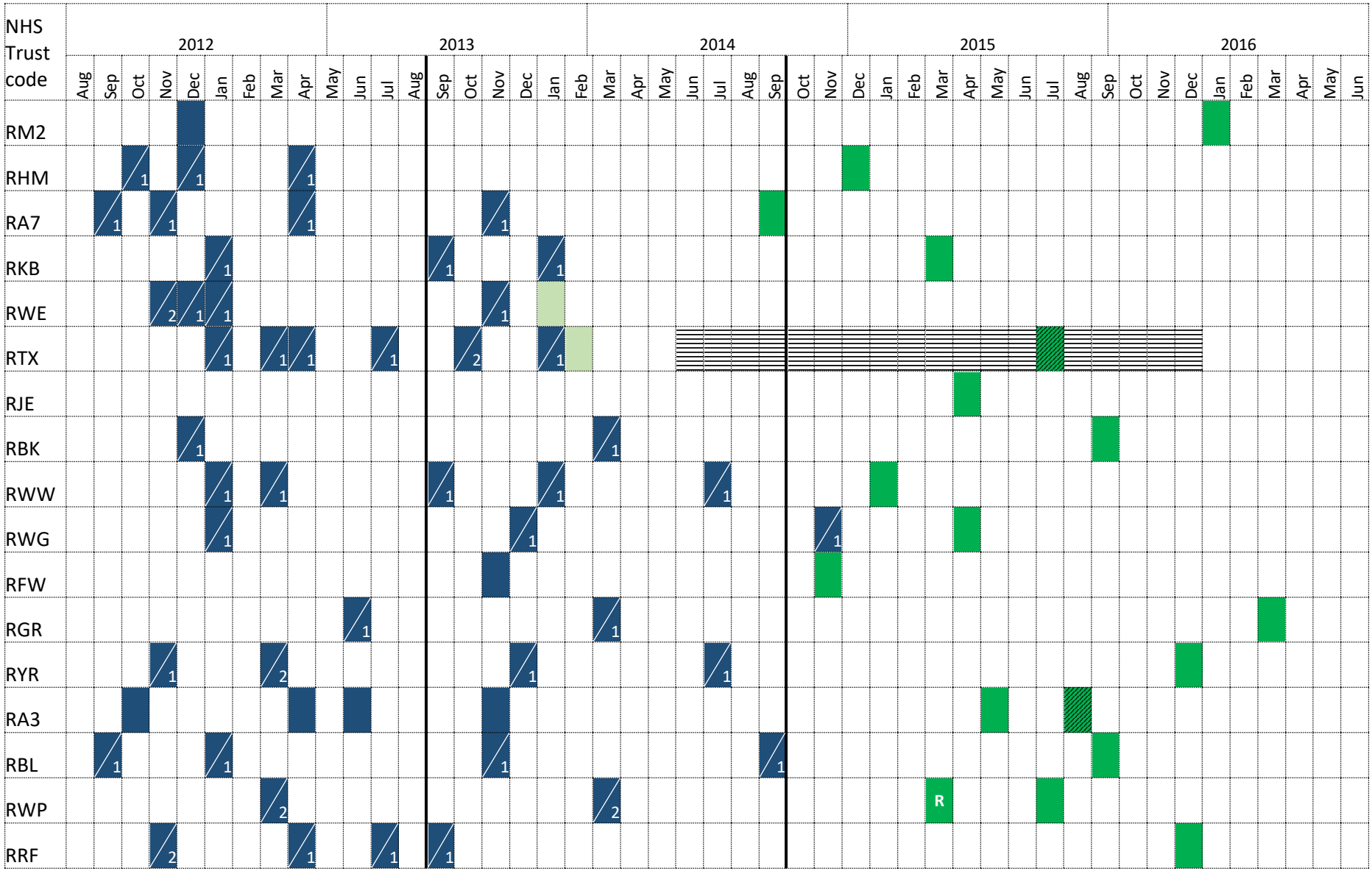
RPY
RRJ
RL4
RET
RKE
RWD
RRV
RRK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RHM
RA7
RKB
RWE
RTX
RJE
RBK
RWW
RWG
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RYR
RA3
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RWP
RRF
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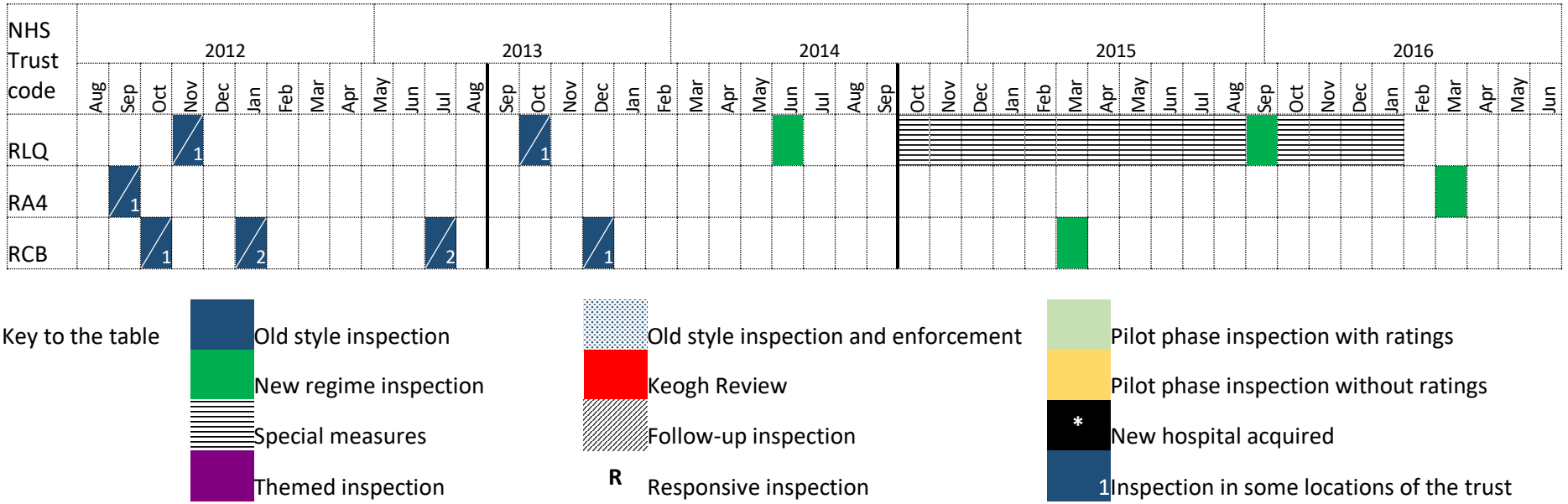
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RLQ
RA4
RCB
Key to the table
Old style inspection
New regime inspection
Special measures
Themed inspection
Old style inspection and enforcement
Keogh Review
Follow-up inspection
R Responsive inspection
Pilot phase inspection with ratings
Pilot phase inspection without ratings
* New hospital acquired
1 Inspection in some locations of the trust

Table 6.3 Unadjusted model coefficients for rates of falls with harm, pressure ulcers, Summary Hospital Mortality Index, A&E waiting times, RTT waiting times, .patients' perception of being treated with dignity and respect, and staff leaving the NHS trust

	Unadjusted model rates of falls with harm	Unadjusted model rates of pressure ulcers	Unadjusted model Summary Hospital Mortality Index	Unadjusted model rates of over 4 h A&E wait	Unadjusted model rates of over 18 weeks RTT wait	Unadjusted model treatment with dignity and respect	Unadjusted model rates of staff leaving.
	Obs=6,209 Trusts=148	Obs=7,243 Trusts=149	Obs=2,561 Trusts=136	Obs=33,637 Trusts=142	Obs=16,157 Trusts=151	Obs=1,632 Trusts=150	Obs=7,059 Trusts=151
Intercept	0.01 (0.005, 0.01)	0.04 (0.039, 0.046)	1.002 (0.99, 1.018)	0.05 (0.04, 0.05)	0.11 (0.1, 0.12)	88.5 (88.1, 88.9)	0.02 (0.019, 0.02)
Trend pre-inspections	0.98 (0.97, 0.98)	0.99 (0.98, 0.99)	-0.00007 (-0.0005, 0.0003)	1.003 (1.002, 1.004)	1.04 (1.04, 1.05)	0.003 (0.00006, 0.0066)	1.002 (1.0005, 1.004)
Change in level after announcement	0.98 (0.86, 1.13)	1.002 (0.94, 1.07)	-0.0015 (-0.014, 0.011)	0.92 (0.86, 0.99)	0.81 (0.75, 0.87)	0.58 (-0.28, 1.44)	0.96 (0.91, 1.01)
Change in slope after announcement	0.99 (0.94, 1.04)	0.99 (0.97, 1.02)	0.0019 (-0.01, 0.01)	1.002 (0.99, 1.01)	0.98 (0.95, 1.02)	-0.07 (-0.44, 0.3)	1.02 (0.99, 1.04)
Change in level after inspection	1.04 (0.94, 1.15)	0.99 (0.95, 1.04)	-0.004 (-0.008, 0.0007)	0.99 (0.92, 1.06)	1.05 (0.99, 1.11)	-0.1 (-0.97, 0.76)	1.02 (0.98, 1.07)
Change in slope after inspection	1.02 (0.98, 1.08)	1.02 (0.99, 1.04)	-0.001 (-0.01, 0.01)	0.99 (0.99, 1.007)	0.98 (0.95, 1.02)	0.14 (-0.23, 0.51)	0.98 (0.96, 0.99)
Time squared	-	-	-	-	1.0007 (1.0006, 1.008)	-	-
Sine	-	-	-	1.26 (1.23, 1.28)	1.05 (1.05, 1.06)	-	0.93 (0.93, 0.94)
Cosine	-	1.03 (1.017, 1.04)	-	0.97 (0.95, 0.99)	1.03 (1.02, 1.04)	-	1.02 (1.008, 1.03)
Sine*2	-	-	-	-	0.99 (0.98, 0.99)	-	0.93 (0.92, 0.94)
Cosine*2	-	-	-	-	0.97 (0.96, 0.97)	-	0.86 (0.86, 0.87)
Medical rotations	-	-	-	-	-	-	2.9 (2.83, 2.99)

6.1 Subgroup analysis by performance rating

Table 6.4 Descriptive information of all acute Trust in England by performance rating

	Excellent n=37	Good n=73	Fair n=37	Weak n=6	p-value
Foundation Trust	28 (76%)	52 (71%)	16 (43%)	1 (17%)	<0.001
Type of trust					
Large acute trust	8 (22%)	15 (21%)	12 (32%)	5 (83%)	0.02
Medium acute Trust	8 (22%)	27 (37%)	9 (24%)	1 (17%)	
Small acute trust	3 (8%)	15 (21%)	7 (19%)	0 (0%)	
Acute teaching trust	10 (27%)	10 (14%)	5 (14%)	0 (0%)	
Acute specialist trust	8 (22%)	6 (8%)	4 (11%)	0 (0%)	
NHS England region					
North	14 (38%)	27 (37%)	9 (24%)	0 (0%)	0.06
Midlands and East	8 (22%)	19 (26%)	17 (46%)	1 (17%)	
South	6 (16%)	19 (26%)	6 (16%)	3 (50%)	
London	9 (24%)	8 (11%)	5 (14%)	2 (33%)	
Number of beds, median (IQR)	731 (481, 1100)	683 (480, 896)	666 (504, 1063)	887 (700, 1084)	0.4
Population in 1,000, median (IQR)	500 (400, 805)	407.5 (330, 527.5)	467 (357.5, 700)	625 (450, 900)	0.04
Number of Trust Hospitals, median (IQR)	2 (1, 4)	3 (2, 5)	2 (1, 4)	3 (2, 4)	0.4
Number of locations, median (IQR)	3 (2, 6)	5 (2, 8)	3 (2, 6)	4 (2, 5)	0.2
Special measures	0 (0%)	10 (14%)	7 (19%)	2 (33%)	0.03
Type of inspection					
New regime	15 (56%)	29 (55%)	18 (67%)	4 (67%)	0.7
No inspected	10 (27%)	20 (27%)	10 (27%)	0 (0%)	0.5
Overall rating					
Outstanding	3 (11%)	1 (2%)	0 (0%)	0 (0%)	0.1
Good	10 (36%)	15 (25%)	9 (27%)	0 (0%)	
Requires improvement	15 (54%)	39 (65%)	19 (58%)	5 (83%)	
Inadequate	0 (0%)	5 (8%)	5 (15%)	1 (17%)	
Merged Trusts	5 (14%)	6 (8%)	1 (3%)	1 (17%)	0.3
Index Multiple Deprivation, median (IQR)	26.1 (16.7, 29.8)	19.9 (16.4, 27.6)	20.8 (17.3, 26.3)	20.4 (12.4, 23.8)	0.5
Index Multiple Deprivation- Health, median (IQR)	0.2 (-0.3, 0.6)	0.04 (-0.4, 0.5)	-0.03 (-0.3, 0.4)	-0.1 (-0.8, 0.1)	0.6

	Excellent n=37	Good n=73	Fair n=37	Weak n=6	p-value
Monitor Sustainability rating					
Significant risk	0 (0%)	4 (8%)	4 (27%)	0 (0%)	0.005
Material risk	4 (14%)	3 (6%)	2 (13%)	0 (0%)	
Emerging or minor concerns	14 (48%)	35 (69%)	2 (13%)	1 (100%)	
No evident concerns	8 (28%)	9 (18%)	7 (47%)	0 (0%)	
Lowest risk	3 (10%)	0 (0%)	0 (0%)	0 (0%)	
Monitor Governance rating					
Subject to enforcement action	2 (7%)	10 (21%)	7 (47%)	0 (0%)	0.2
Under review	4 (13%)	4 (8%)	1 (7%)	0 (0%)	
No evident concerns	23 (79%)	34 (71%)	7 (47%)	1 (100%)	
TDA escalating score					
Enforcement action	0 (0%)	2 (10%)	3 (15%)	1 (20%)	0.9
Significant delivery issues	3 (38%)	8 (38%)	7 (35%)	3 (60%)	
Some delivery issues	2 (25%)	7 (33%)	6 (30%)	1 (20%)	
Limited/no issues	3 (38%)	3 (14%)	4 (20%)	0 (0%)	
Sound FT application	0 (0%)	1 (5%)	0 (0%)	0 (0%)	
Number of inspections, median (IQR)	3 (2, 4)	4 (3, 5)	4 (3, 5)	6 (4, 7)	0.07
Months since previous inspection, median (IQR)	11.5 (8, 21.5)	11 (8, 18)	10 (6, 16)	10 (8, 12)	0.4
Reporting culture 2016					
Poor	2 (5%)	11 (15%)	9 (24%)	2 (33%)	0.2
Significant Concerns	13 (35%)	22 (30%)	16 (43%)	3 (50%)	
Good	19 (51%)	34 (47%)	11 (30%)	1 (17%)	
Outstanding	3 (8%)	6 (8%)	1 (3%)	0 (0%)	
Performance rating - Financial 2009					
Excellent	25 (68%)	37 (51%)	9 (24%)	1 (17%)	<0.001
Good	10 (27%)	28 (38%)	19 (51%)	1 (17%)	
Fair	1 (3%)	7 (10%)	8 (22%)	3 (50%)	
Weak	1 (3%)	1 (1%)	1 (3%)	1 (17%)	

6.1.1 Adverse events

6.1.1.1 Falls with harm

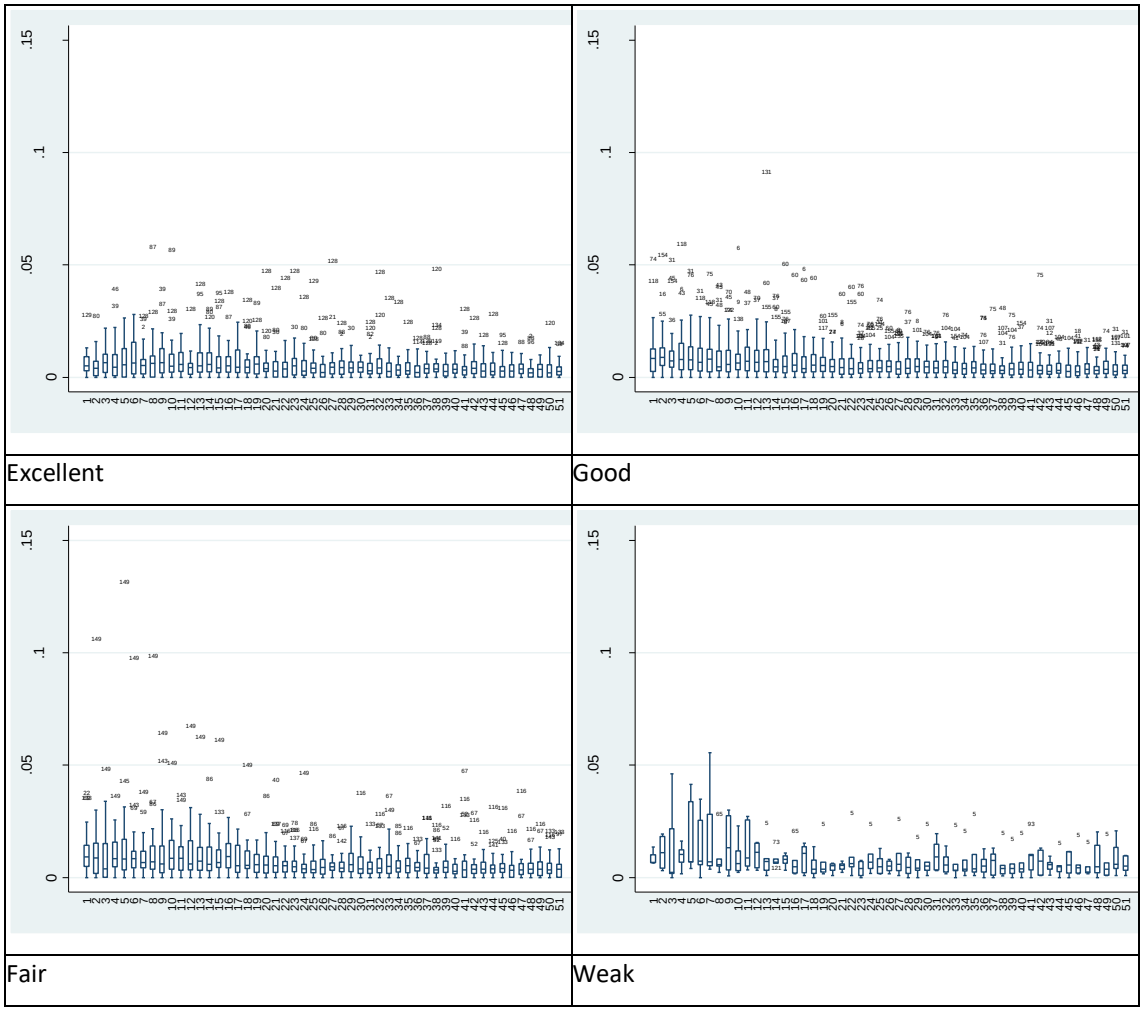


Figure 6.1 Rates of falls with harm for all NHS Trusts over time by performance rating

Table 6.5 Unadjusted model coefficients for rates of falls with harm by performance ratings

	Unadjusted rate of falls with harm (95% CI)			
	Excellent Obs=1,340 Trusts=35	Good Obs=2,985 Trusts=70	Fair Obs=1,509 Trusts=35	Weak Obs=286 Trusts=6
Intercept	0.005 (0.004, 0.006)	1.01 (0.71, 1.45)	1.21 (0.86, 1.71)	0.87 (0.43, 1.77)
Pre-inspection slope	0.97 (0.96, 0.99)	1 (0.98, 1.03)	1.01 (0.99, 1.03)	0.99 (0.95, 1.03)
Announcement change	0.95 (0.78, 1.16)	1.74 (1.21, 2.5)	0.78 (0.56, 1.1)	0.81 (0.42, 1.58)
Announcement slope	1.01 (0.94, 1.09)	0.84 (0.74, 0.96)	1.01 (0.89, 1.15)	1.06 (0.83, 1.34)
Post-inspection change	0.98 (0.85, 1.12)	1.28 (0.99, 1.64)	1.06 (0.82, 1.36)	1.1 (0.68, 1.77)
Post-inspection slope	1 (0.93, 1.07)	1.18 (1.04, 1.34)	0.98 (0.87, 1.11)	0.96 (0.76, 1.22)

6.1.1.2 Pressure ulcers

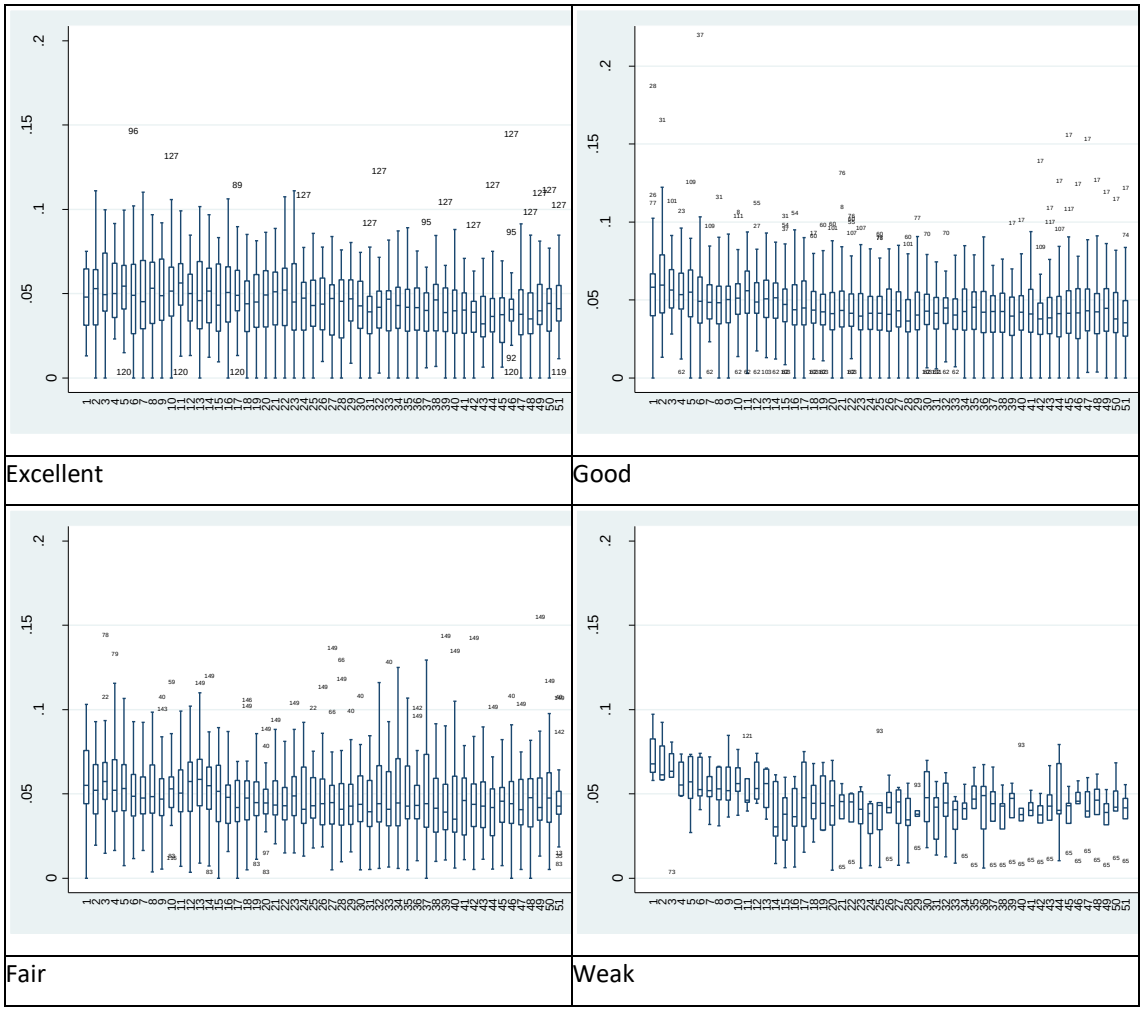


Figure 6.2 Rates of pressure ulcers for all NHS Trusts over time by performance rating

Table 6.6 Unadjusted model coefficients for rates of pressure ulcers by performance ratings

	Unadjusted rate pf pressure ulcers (95% CI)			
	Excellent Obs=1,694 Trusts=36	Good Obs=3,442 Trusts=71	Fair Obs=1,753 Trusts=35	Weak Obs=300 Trusts=6
Intercept	1.17 (0.95, 1.44)	0.04 (0.036, 0.045)	1.1 (0.9, 1.34)	0.8 (0.53, 1.22)
Pre-inspection slope	1.02 (1.001, 1.03)	0.99 (0.98, 0.99)	1.01 (0.99, 1.02)	0.98 (0.95, 1.003)
Announcement change	1.01 (0.86, 1.18)	1.003 (0.92, 1.1)	1.02 (0.87, 1.19)	0.88 (0.64, 1.21)
Announcement slope	0.99 (0.93, 1.05)	1 (0.97, 1.04)	0.98 (0.92, 1.04)	1.02 (0.9, 1.15)
Post-inspection change	0.96 (0.86, 1.7)	0.98 (0.92, 1.04)	1.08 (0.97, 1.21)	1.09 (0.88, 1.36)
Post-inspection slope	0.99 (0.94, 1.05)	1.01 (0.98, 1.05)	1.02 (0.96, 1.08)	1.002 (0.89, 1.13)
Cosine	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)

6.1.2 Summary Hospital Mortality Index

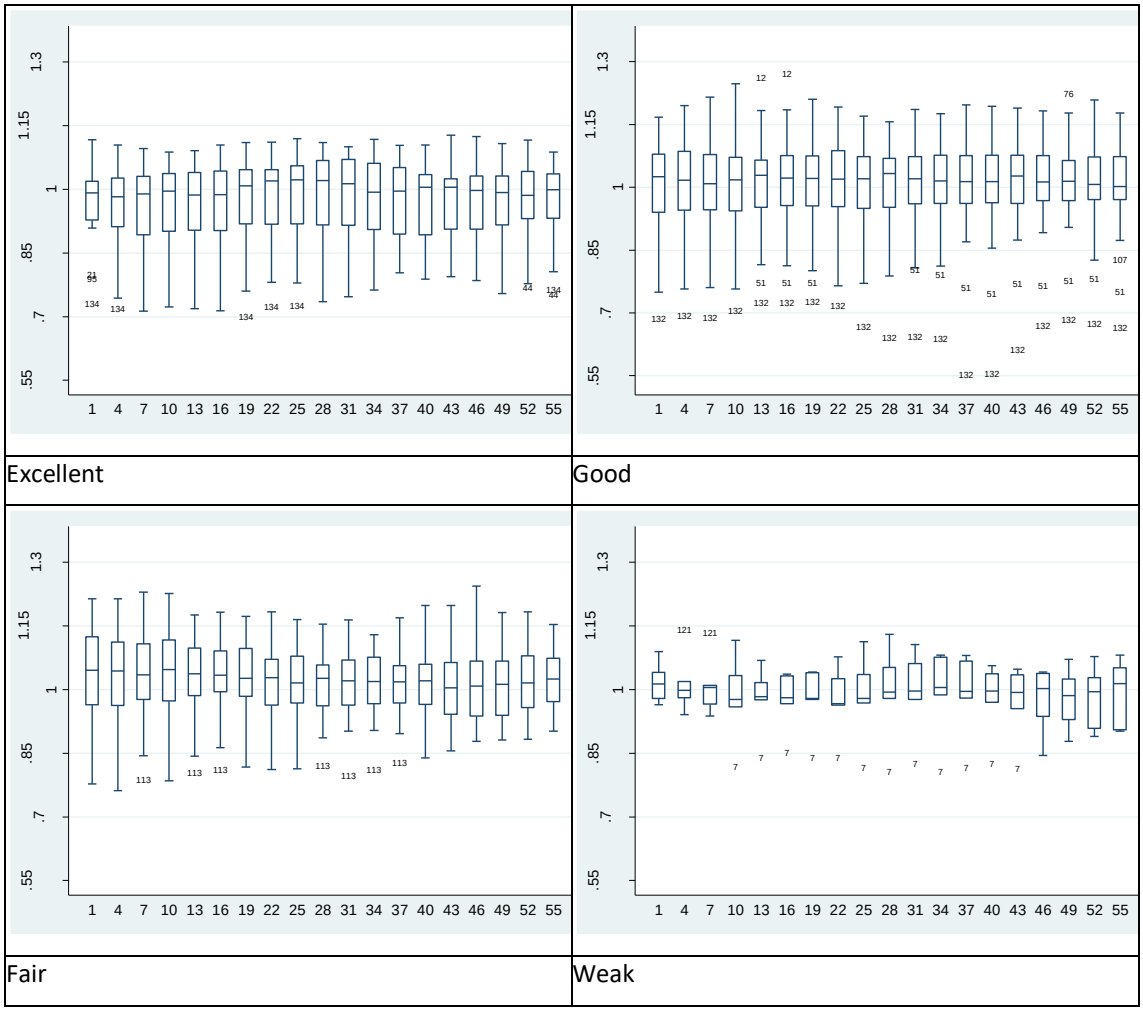


Figure 6.3 Summary Hospital Mortality Index for all acute NHS Trusts for all NHS Trusts over time by performance rating

Table 6.7 Unadjusted model coefficients for summary hospital mortality index by performance ratings

	Unadjusted summary hospital mortality index (95% CI)			
	Excellent Obs=538 Trusts=29	Good Obs=1,273 Trusts=67	Fair Obs=625 Trusts=33	Weak Obs=111 Trusts=6
Intercept	-0.03 (-0.08, 0.0077)	1.01 (0.99, 1.03)	0.0026 (-0.037, 0.04)	-0.03 (-0.11, 0.049)
Pre-inspection slope	0.00015 (-0.0009, 0.001)	0.0002 (-0.0004, 0.0008)	-0.0011 (-0.002, -0.0001)	-0.0002 (-0.002, 0.002)
Announcement change	-0.008 (-0.04, 0.025)	0.002 (-0.016, 0.02)	-0.006 (-0.03, 0.02)	-0.005 (-0.07, 0.06)
Announcement slope	0.011 (-0.02, 0.04)	-0.002 (-0.02, 0.02)	0.0038 (-0.026, 0.03)	0.015 (-0.05, 0.08)
Post-inspection change	-0.0012 (-0.01, 0.01)	-0.002 (-0.008, 0.004)	-0.0036 (-0.015, 0.008)	-0.014 (-0.04, 0.009)
Post-inspection slope	-0.014 (-0.05, 0.02)	0.003 (-0.015, 0.02)	-0.0009 (-0.03, 0.03)	-0.015 (-0.08, 0.05)

6.1.3 Waiting times

6.1.3.1 A&E waiting time

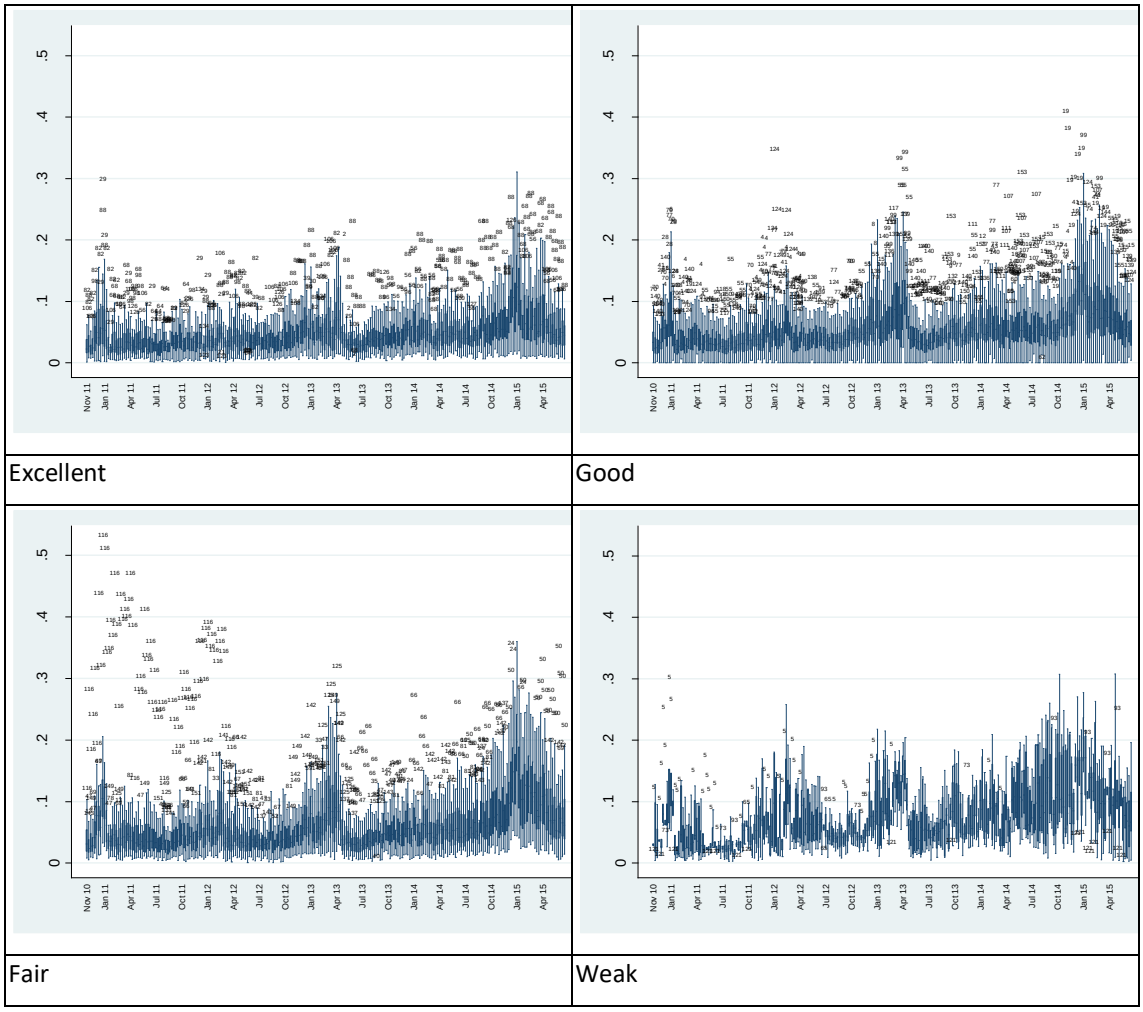


Figure 6.4 Rates of attendances waiting over 4h in A&E for all NHS Trusts over time by performance rating

Table 6.8 Unadjusted model coefficients for rates of attendances waiting over 4 h in A&E by performance ratings

	Unadjusted rate of attendances waiting over 4 h in A&E (95% CI)			
	Excellent Obs=6,976 Trusts=30	Good Obs=16,652 Trusts=70	Fair Obs=8,224 Trusts=34	Weak Obs=1,375 Trusts=6
Intercept	0.88 (0.69, 1.13)	0.05 (0.04, 0.05)	0.94 (0.75, 1.2)	1.65 (1.02, 2.69)
Pre-inspection slope	0.99 (0.99, 1.001)	1.004 (1.003, 1.005)	0.998 (0.996, 0.999)	1.002 (0.99, 1.01)
Announcement change	1.9 (0.75, 1.09)	0.95 (0.86, 1.05)	0.94 (0.79, 1.12)	1.12 (0.78, 1.59)
Announcement slope	1.01 (0.99, 1.03)	0.99 (0.99, 1.01)	1.02 (0.99, 1.03)	0.99 (0.96, 1.03)
Post-inspection change	0.88 (0.73, 1.05)	1.01 (0.91, 1.11)	1.04 (0.88, 1.23)	1.01 (0.71, 1.42)
Post-inspection slope	0.99 (0.97, 1.01)	1.01 (0.99, 1.02)	0.99 (0.97, 1.01)	1.003 (0.97, 1.04)
Sine	1.26 (1.23, 1.28)	1.26 (1.23, 1.28)	1.26 (1.23, 1.28)	1.26 (1.23, 1.28)
Cosine	0.97 (0.95, 0.99)	0.97 (0.95, 0.99)	0.97 (0.95, 0.99)	0.97 (0.95, 0.99)

6.1.3.2 RTT waiting time

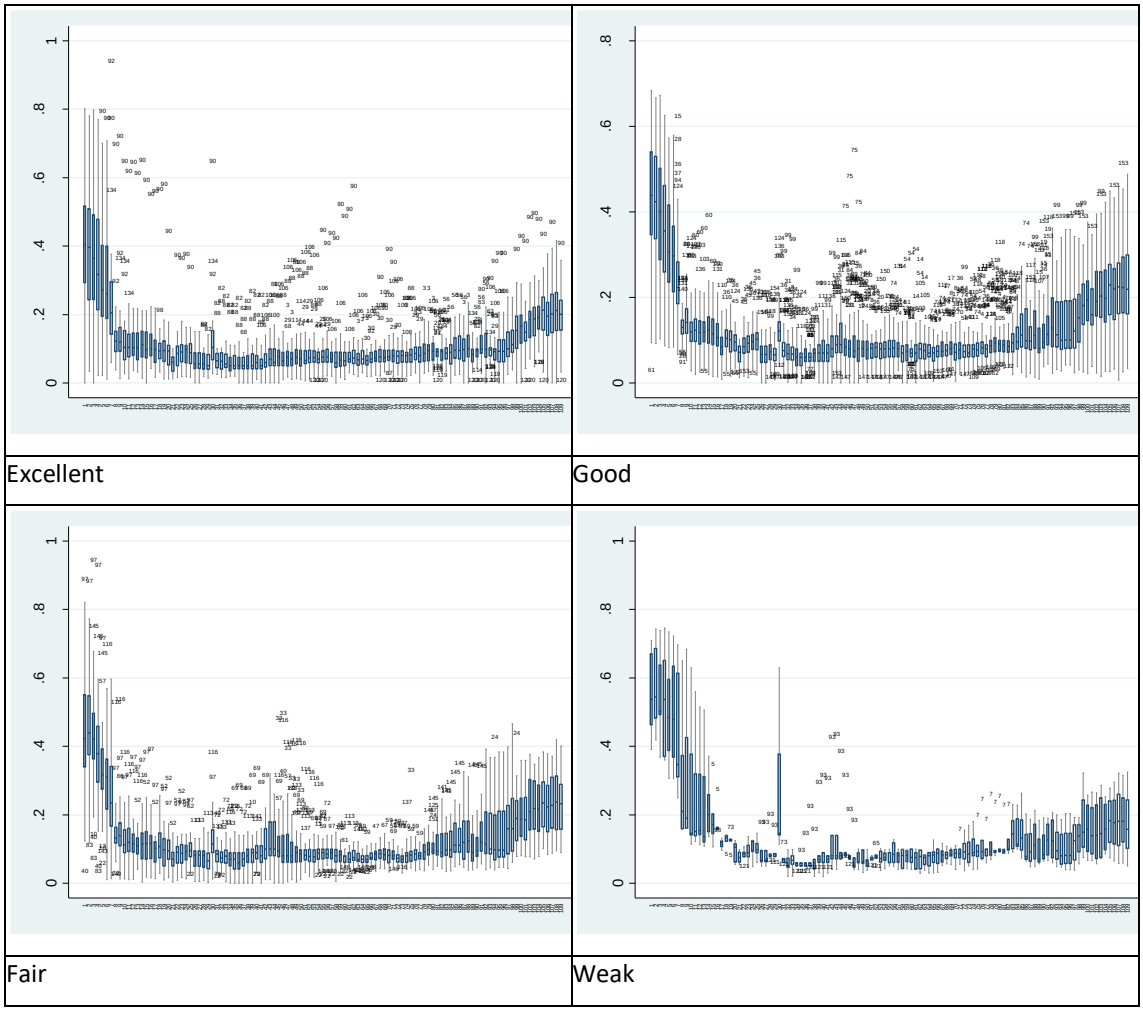


Figure 6.5 Rates of referrals to treatment waiting over 18 weeks for all acute NHS Trusts over time by performance rating

Table 6.9 Unadjusted model coefficients for rates of referrals waiting over 18 weeks by performance ratings

	Unadjusted rate of referrals to treatment waiting over 18 weeks (95% CI)			
	Excellent	Good	Fair	Weak
	Obs=3,769 Trusts=36	Obs=7,866 Trusts=73	Obs=3,939 Trusts=37	Obs=541 Trusts=6
Intercept	1.12 (0.89, 1.43)	0.11 (0.09, 0.12)	1.14 (0.9, 1.44)	1.08 (0.66, 1.77)
Pre-inspection slope	1.003 (0.99, 1.01)	1.04 (1.04, 1.05)	1.003 (0.99, 1.01)	0.99 (0.99, 1.01)
Announcement change	1.04 (0.85, 1.27)	0.8 (0.71, 0.89)	0.99 (0.81, 1.2)	1.14 (0.75, 1.71)
Announcement slope	0.96 (0.88, 1.04)	0.99 (0.94, 1.04)	1.003 (0.92, 1.09)	1.02 (0.85, 1.22)
Post-inspection change	0.96 (0.83, 1.1)	1.05 (0.97, 1.14)	1.01 (0.88, 1.17)	1.02 (0.75, 1.38)
Post-inspection slope	1.04 (0.95, 1.13)	0.98 (0.93, 1.03)	0.99 (0.91, 1.08)	0.97 (0.81, 1.16)
Squared time	1.001 (1.0006, 1.001)	1.001 (1.0006, 1.001)	1.001 (1.0006, 1.001)	1.001 (1.0006, 1.001)
Sine	1.06 (1.05, 1.06)	1.06 (1.05, 1.06)	1.06 (1.05, 1.06)	1.06 (1.05, 1.06)
Cosine	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)
Sine*2	0.99 (0.98, 0.99)	0.99 (0.98, 0.99)	0.99 (0.98, 0.99)	0.99 (0.98, 0.99)
Cosine*2	0.97 (0.96, 0.97)	0.97 (0.96, 0.97)	0.97 (0.96, 0.97)	0.97 (0.96, 0.97)

6.1.4 Treatment with dignity and respect

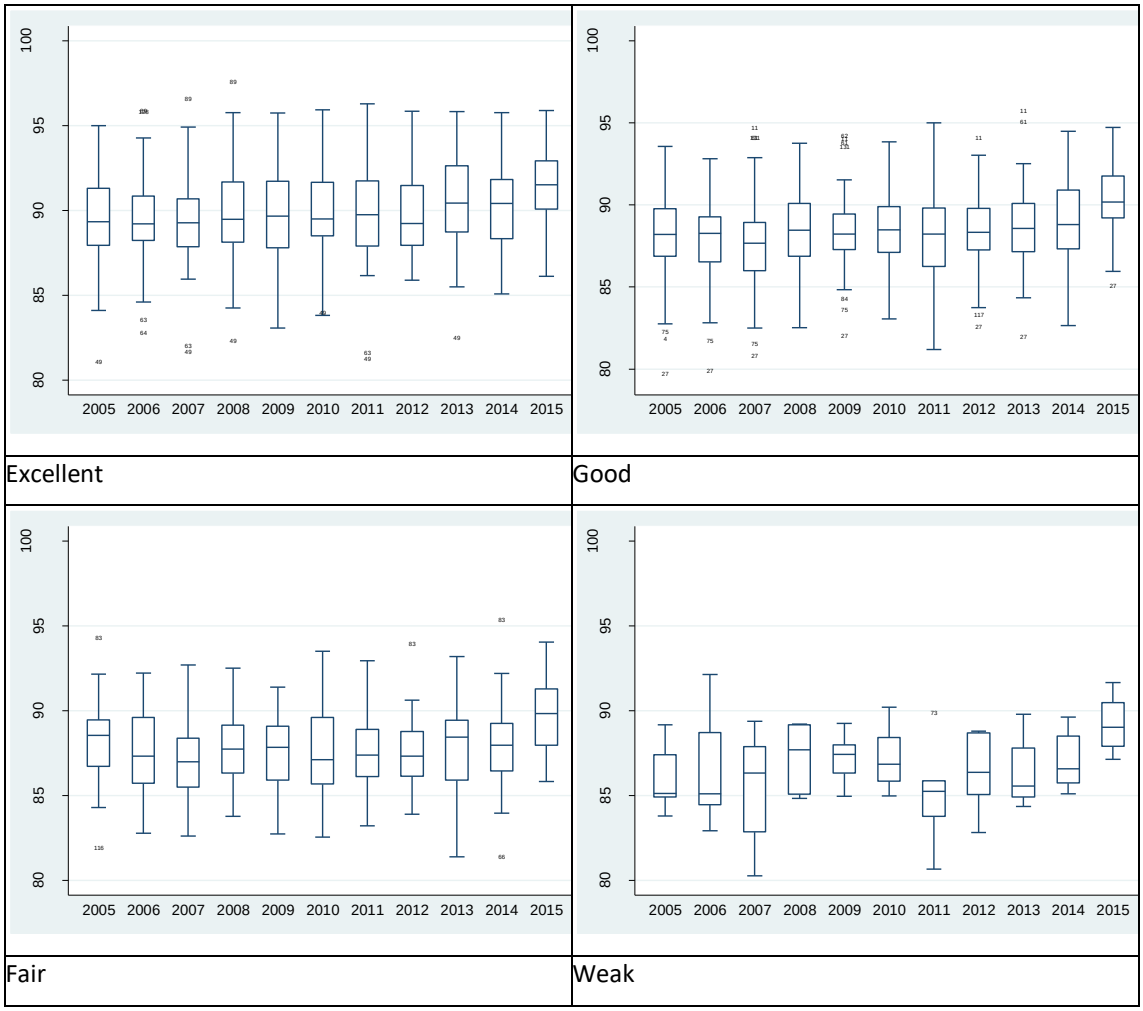


Figure 6.6 Patients' perception of being treated with dignity and respect over time by performance rating

Table 6.10 Unadjusted model coefficients for patients' perception of being treated with dignity and respect by performance ratings

	Unadjusted patients' perception of being treated with dignity and respect (95% CI)			
	Excellent	Good	Fair	Weak
	Obs=385 Trusts=35	Obs=782 Trusts=72	Obs=385 Trusts=35	Obs=66 Trusts=6
Intercept	1.5 (0.6, 2.4)	88.5 (87.9, 88.9)	-0.9 (-1.8, -0.02)	-2 (-3.9, -0.15)
Pre-inspection slope	0.0004 (-0.008, 0.009)	0.005 (0.0001, 0.01)	-0.006 (-0.01, 0.002)	-0.003 (-0.02, 0.015)
Announcement change	-1.4 (-3.7, 0.9)	1.6 (0.4, 2.9)	-2.3 (-4.4, -0.2)	-3.2 (-8.3, 1.9)
Announcement slope	0.76 (-0.19, 1.7)	-0.55 (-1.07, -0.016)	0.8 (-0.1, 1.7)	1.9 (-1.5, 5.5)
Post-inspection change	-2.1 (-4.2, -0.07)	0.8 (-0.38, 2.05)	-0.6 (-2.9, 1.6)	-5.5 (-15.2, 4.1)
Post-inspection slope	-0.75 (-1.7, 0.2)	0.6 (0.08, 1.14)	-0.7 (-1.6, 0.2)	-1.9 (-5.4, 1.7)

6.1.5 Staff leaving acute NHS Trusts

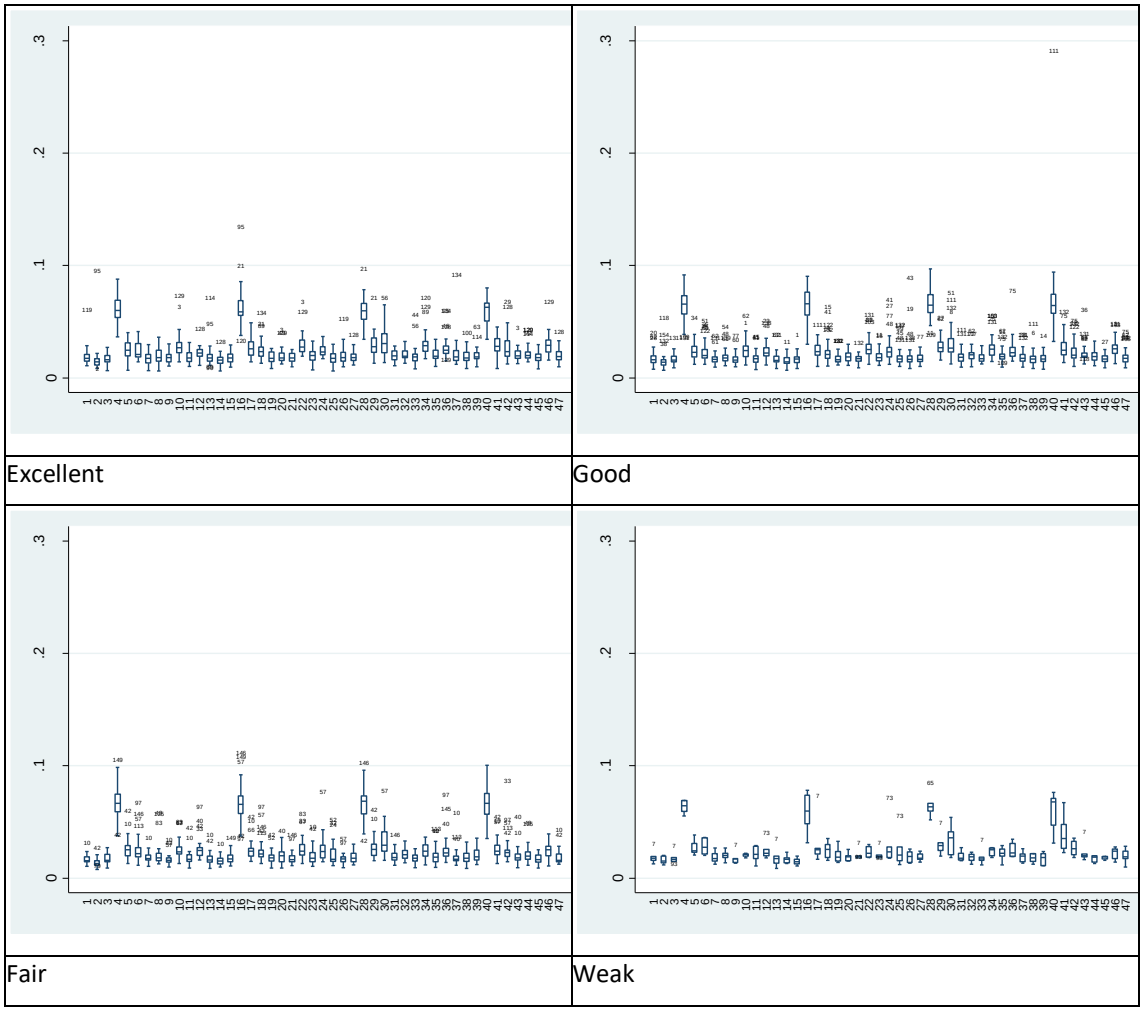


Figure 6.7 Rates of staff leaving for all NHS Trusts over time by performance rating

Table 6.11 Unadjusted model coefficients for rates of staff leaving NHS Trusts by performance ratings

	Unadjusted rate of staff leaving NHS Trusts (95% CI)			
	Excellent Obs=1,662 Trusts=36	Good Obs=3,384 Trusts=72	Fair Obs=1,684 Trusts=36	Weak Obs=282 Trusts=6
Intercept	1.08 (0.99, 1.17)	0.019 (0.018, 0.02)	1.04 (0.96, 1.12)	0.99 (0.84, 1.19)
Pre-inspection slope	1.003 (0.99, 1.01)	1.002 (0.99, 1.005)	0.99 (0.99, 1.004)	0.99 (0.98, 1.005)
Announcement change	0.84 (0.74, 0.96)	0.99 (0.92, 1.07)	1.01 (0.88, 1.15)	0.98 (0.74, 1.29)
Announcement slope	1.05 (1, 1.1)	1.005 (0.98, 1.03)	1.002 (0.96, 1.05)	1.04 (0.94, 1.14)
Post-inspection change	0.92 (0.84, 1.003)	1.06 (1.003, 1.11)	1.003 (0.92, 1.1)	0.97 (0.8, 1.17)
Post-inspection slope	0.95 (0.91, 0.99)	0.99 (0.97, 1.02)	0.99 (0.95, 1.04)	0.97 (0.88, 1.06)
Medical rotation	2.67 (2.59, 2.75)	2.67 (2.59, 2.75)	2.67 (2.59, 2.75)	2.67 (2.59, 2.75)
Sine	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)
Cosine	0.94 (0.93, 0.94)	0.94 (0.93, 0.94)	0.94 (0.93, 0.94)	0.94 (0.93, 0.94)
Sine*2	0.86 (0.86, 0.87)	0.86 (0.86, 0.87)	0.86 (0.86, 0.87)	0.86 (0.86, 0.87)
Cosine*2	0.92 (0.91, 0.93)	0.92 (0.91, 0.93)	0.92 (0.91, 0.93)	0.92 (0.91, 0.93)

Appendix Chapter 7

7.1 Adverse events

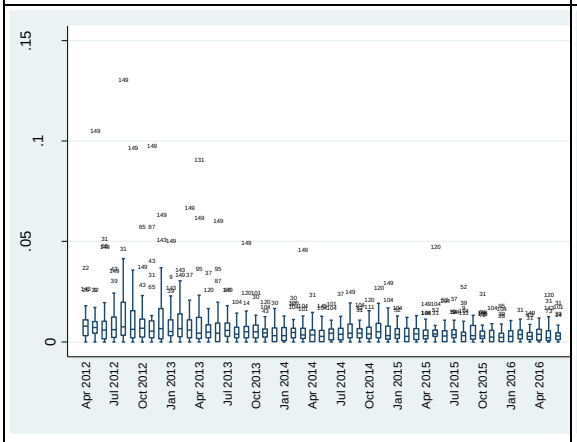
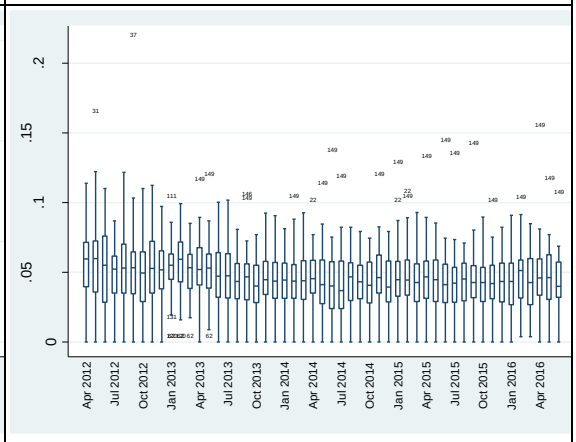
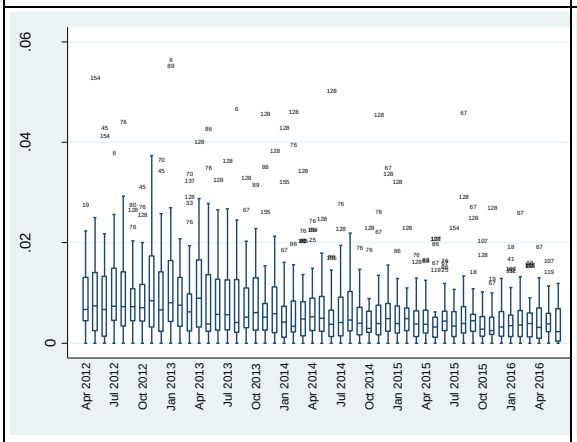
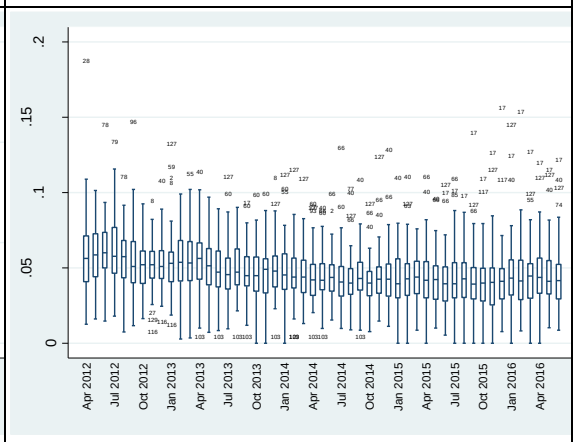
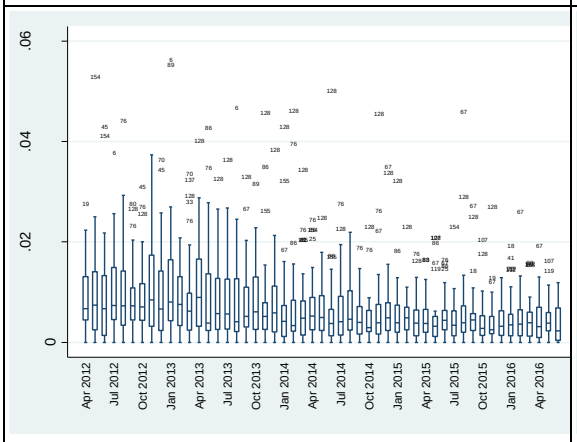
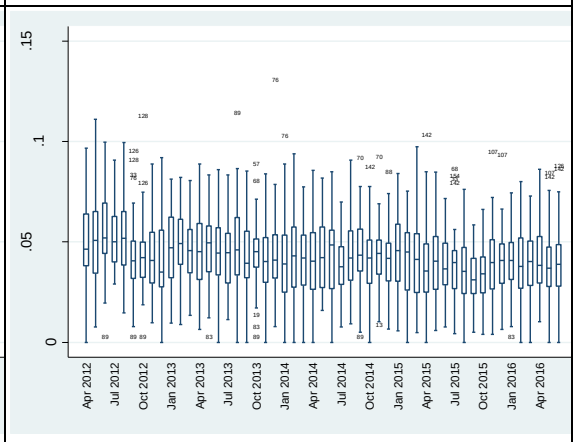
Falls with harm	Pressure ulcers
	
Old regime	
	
New regime	
	
No inspection	

Figure 7.1 Rates of adverse events for all NHS Trusts over time by type of inspection

Table 7.1 Unadjusted and adjusted model coefficients for adverse events by type of inspection

	Unadjusted rate of falls (95% CI) Obs=6,255 Trusts=149	Adjusted rate of falls (95% CI) Obs=6,255 Trusts=149	Unadjusted rate of pressure ulcers (95% CI) Obs=7,291 Trusts=150	Adjusted rate of pressure ulcers (95% CI) Obs=7,291 Trusts=150
Intercept				
Old Regime	0.004 (0.003, 0.006)	0.004 (0.003, 0.005)	0.04 (0.03, 0.05)	0.05 (0.04, 0.05)
New regime	1.15 (0.84, 1.57)	1.25 (0.94, 1.67)	1.02 (0.84, 1.24)	0.97 (0.8, 1.16)
No inspection	1.43 (0.99, 2.05)	1.48 (1.06, 2.07)	0.88 (0.7, 1.11)	0.87 (0.7, 1.08)
Pre-inspection slope				
Old regime	0.96 (0.94, 0.97)	0.96 (0.94, 0.97)	0.98 (0.98, 0.99)	0.99 (0.98, 0.99)
New regime	1.02 (1.005, 1.04)	1.02 (1.01, 1.04)	1.003 (0.99, 1.01)	1.003 (0.99, 1.01)
No inspection	1.02 (1.001, 1.05)	1.02 (1, 1.04)	0.99 (0.98, 1.01)	0.99 (0.99, 1.01)
Announcement change				
Old regime	1.27 (0.98, 1.64)	1.27 (0.98, 1.64)	0.92 (0.83, 1.03)	0.92 (0.83, 1.02)
New regime	0.69 (0.5, 0.97)	0.69 (0.5, 0.97)	1.09 (0.95, 1.26)	1.1 (0.95, 1.26)
No inspection	0.71 (0.49, 1.03)	0.71 (0.49, 1.03)	1.2 (1.04, 1.43)	1.22 (1.04, 1.43)
Announcement slope				
Old regime	0.96 (0.88, 1.05)	0.96 (0.88, 1.05)	0.99 (0.95, 1.03)	0.99 (0.95, 1.03)
New regime	1.05 (0.94, 1.18)	1.05 (0.94, 1.18)	0.99 (0.94, 1.05)	0.99 (0.94, 1.05)
No inspection	1.06 (0.93, 1.21)	1.06 (0.93, 1.21)	0.99 (0.94, 1.05)	0.99 (0.94, 1.05)
Post-inspection change				
Old regime	1.09 (0.91, 1.31)	1.09 (0.91, 1.31)	1.05 (0.97, 1.14)	1.05 (0.96, 1.14)
New regime	0.92 (0.72, 1.16)	0.91 (0.72, 1.16)	0.96 (0.87, 1.08)	0.97 (0.87, 1.07)
No inspection	0.82 (0.63, 1.07)	0.82 (0.63, 1.07)	0.96 (0.86, 1.09)	0.97 (0.85, 1.09)
Post-inspection slope				
Old regime	1.08 (0.98, 1.18)	1.08 (0.98, 1.18)	1.02 (0.98, 1.06)	1.02 (0.98, 1.06)
New regime	0.93 (0.83, 1.04)	0.93 (0.83, 1.04)	1.002 (0.95, 1.05)	1.002 (0.95, 1.05)
No inspection	0.92 (0.81, 1.05)	0.92 (0.81, 1.05)	1.005 (0.95, 1.06)	1.005 (0.95, 1.06)
Large acute NHS Trust	-	Reference	-	-
Medium acute NHS Trust	-	0.99 (0.82, 1.19)	-	-
Small acute NHS Trust	-	1.26 (1.02, 1.56)	-	-
Teaching acute NHS Trust	-	0.73 (0.59, 0.91)	-	-
Specialist acute NHS Trust	-	1.99 (1.47, 2.69)	-	0.53 (0.45, 0.63)
Cosine	-	-	1.02 (1.01, 1.04)	1.02 (1.01, 1.04)

7.2 Summary Hospital Mortality Index

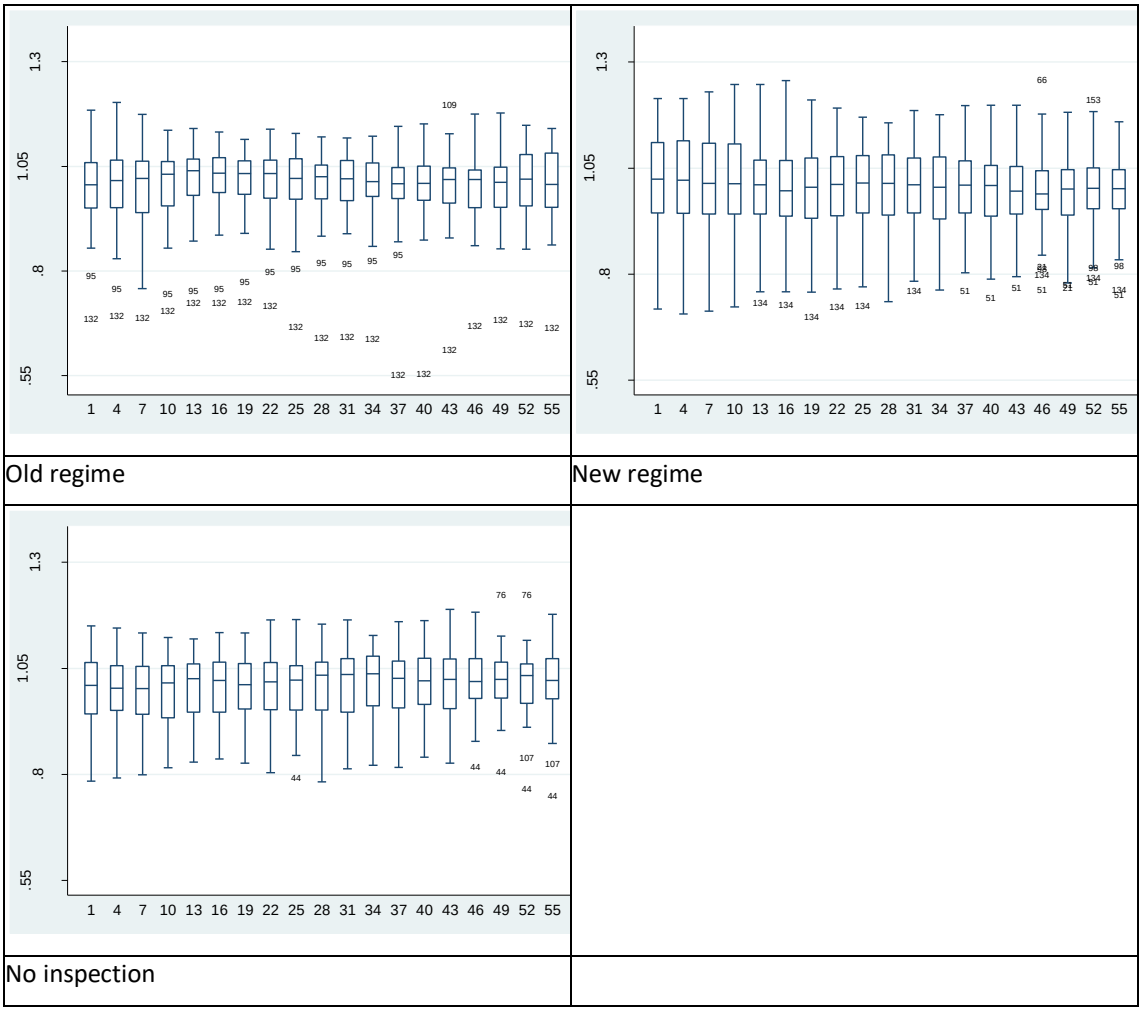


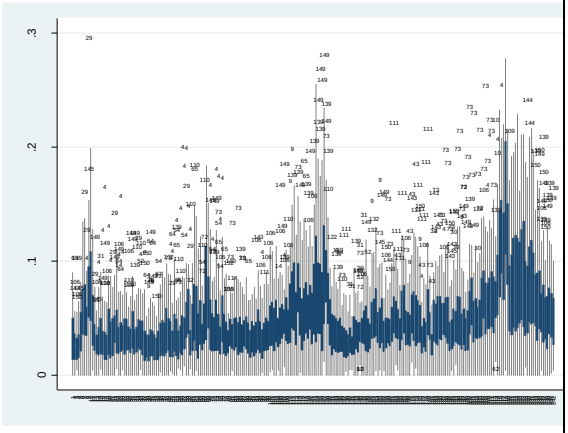
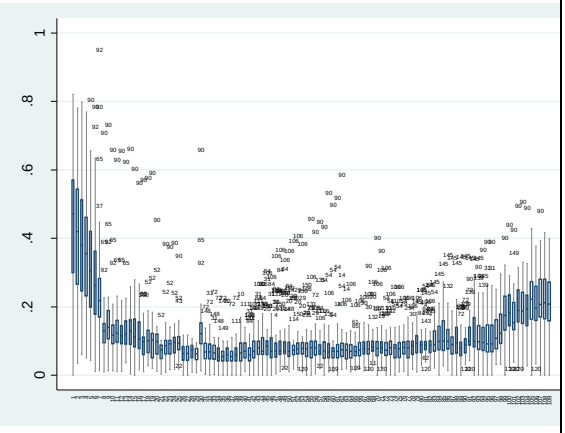
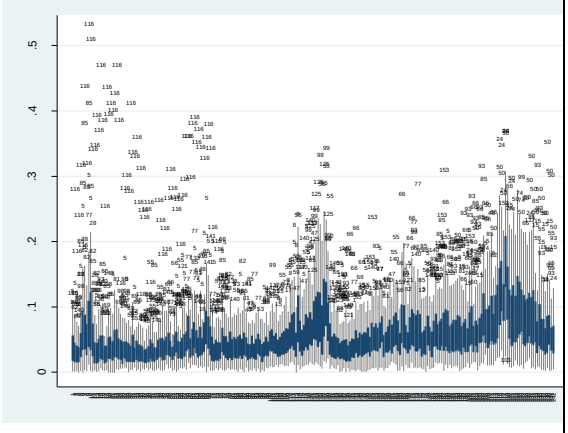
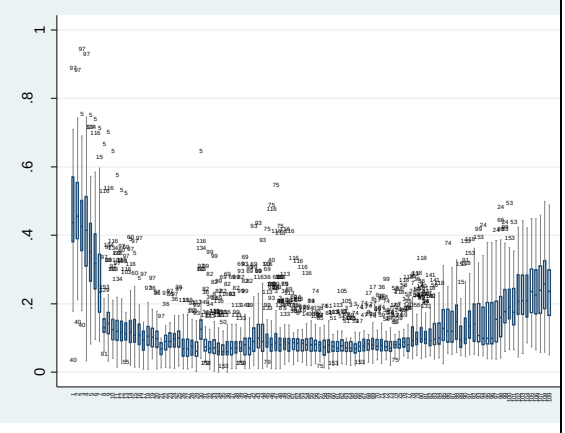
Figure 7.2 Summary Hospital Mortality Index for all NHS Trusts over time by type of inspection

Table 7.2 Unadjusted and adjusted model coefficients for summary hospital mortality index by type of inspection

	Unadjusted summary hospital mortality index (95% CI) Obs=2,514 Trusts=137	Adjusted summary hospital mortality index (95% CI) Obs=2,514 Trusts=137
Intercept		
Old Regime	1.01 (0.99, 1.04)	1.05 (1.02, 1.08)
New regime	-0.02 (-0.06, 0.01)	-0.01 (-0.04, 0.02)
No inspection	-0.01 (-0.05, 0.03)	-0.02 (-0.05, 0.01)
Pre-inspection slope		
Old regime	0.0005 (-0.0002, 0.001)	0.0005 (-0.0002, 0.001)
New regime	-0.001 (-0.002, -0.0002)	-0.001 (-0.002, -0.0002)
No inspection	-0.0002 (-0.001, 0.0009)	-0.0002 (-0.001, 0.0009)
Announcement change		
Old regime	-0.01 (-0.03, 0.002)	-0.01 (-0.03, 0.002)
New regime	0.02 (-0.002, 0.05)	0.02 (-0.0004, 0.05)
No inspection	0.02 (-0.003, 0.04)	0.02 (-0.003, 0.04)

	Unadjusted summary hospital mortality index (95% CI)	Adjusted summary hospital mortality index (95% CI)
Announcement slope		
Old regime	0.007 (-0.009, 0.02)	0.008 (-0.009, 0.02)
New regime	-0.009 (-0.03, 0.01)	-0.01 (-0.03, 0.01)
No inspection	-0.004 (-0.02, 0.02)	-0.004 (-0.02, 0.02)
Post-inspection change		
Old regime	-0.008 (-0.01, 0.0005)	-0.008 (-0.01, 0.0006)
New regime	0.004 (-0.006, 0.01)	0.004 (-0.006, 0.01)
No inspection	0.02 (0.006, 0.03)	0.02 (0.006, 0.03)
Post-inspection slope		
Old regime	-0.008 (-0.03, 0.009)	-0.008 (-0.02, 0.009)
New regime	0.01 (-0.01, 0.03)	0.01 (-0.009, 0.04)
No inspection	0.004 (-0.02, 0.03)	0.004 (-0.02, 0.03)
North	-	
Midlands and East	-	-0.007 (-0.03, 0.02)
South	-	-0.04 (-0.07, -0.02)
London	-	-0.17 (-0.21, -0.14)

7.3 Waiting times

Over 4 h A&E wait	Over 18 weeks RRT wait
	
Old regime	
	
New regime	

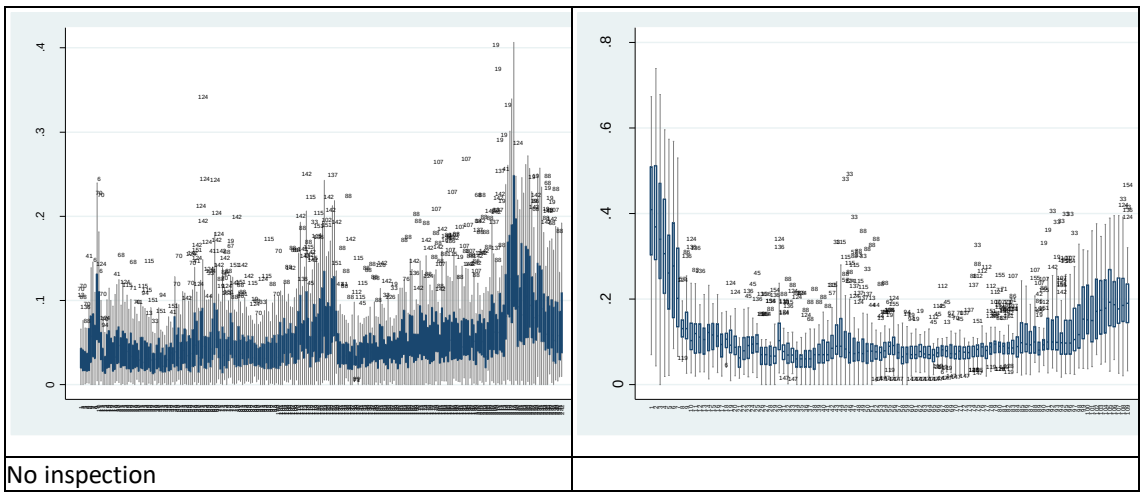


Figure 7.3 Rates of attendances waiting over 4 h in A&E and referrals waiting over 18 weeks for all NHS Trusts over time by type of inspection

Table 7.3 Unadjusted and adjusted model coefficients for waiting times by type of inspection

	Unadjusted rate of over 4h A&E wait (95% CI) Obs=33,778 Trusts=143	Adjusted rate of over 4h A&E wait (95% CI) Obs=33,778 Trusts=143	Unadjusted rate of over 18w RTT wait (95% CI) Obs=16,157 Trusts=152	Adjusted rate of over 18w RTT wait (95% CI) Obs=16,233 Trusts=153
Intercept				
Old Regime	0.04 (0.037, 0.05)	0.06 (0.05, 0.07)	0.11 (0.1, 0.13)	0.1 (0.09, 0.12)
New regime	1.12 (0.89, 1.39)	1.03 (0.83, 1.3)	1.11 (0.93, 1.31)	1.07 (0.91, 1.26)
No inspection	1.04 (0.81, 1.34)	1.07 (0.83, 1.38)	0.7 (0.57, 0.85)	0.7 (0.57, 0.85)
Pre-inspection slope				
Old regime	1.003 (1.002, 1.004)	1.003 (1.002, 1.005)	1.04 (1.04, 1.05)	1.05 (1.04, 1.05)
New regime	1 (0.99, 1.002)	0.99 (0.99, 1.002)	1.002 (0.99, 1.01)	1.001 (0.99, 1.005)
No inspection	1 (0.99, 1.002)	1 (0.99, 1.002)	0.995 (0.99, 0.998)	0.99 (0.99, 0.99)
Announcement change				
Old regime	0.93 (0.82, 1.05)	0.93 (0.82, 1.05)	0.87 (0.82, 0.93)	0.8 (0.75, 0.85)
New regime	1.01 (0.86, 1.19)	1.01 (0.86, 1.19)	0.96 (0.84, 1.09)	0.97 (0.85, 1.11)
No inspection	1.1 (0.92, 1.3)	1.1 (0.92, 1.31)	1.33 (1.24, 1.43)	1.33 (1.25, 1.43)
Announcement slope				
Old regime	0.99 (0.98, 1.01)	0.99 (0.99, 1.01)	0.93 (0.89, 0.96)	0.92 (0.89, 0.96)
New regime	1.01 (0.99, 1.03)	1.01 (0.99, 1.03)	1.06 (1.002, 1.13)	1.07 (1.005, 1.13)
No inspection	0.98 (0.97, 1.001)	0.98 (0.97, 1)	1.05 (1.006, 1.1)	1.06 (1.01, 1.11)
Post-inspection change				
Old regime	0.89 (0.78, 1.01)	0.89 (0.79, 1.01)	1.11 (1.008, 1.22)	1.12 (1.02, 1.23)
New regime	1.25 (1.07, 1.47)	1.25 (1.07, 1.47)	0.98 (0.86, 1.12)	0.97 (0.85, 1.11)
No inspection	1.1 (0.92, 1.31)	1.1 (0.92, 1.32)	0.8 (0.71, 0.9)	0.79 (0.7, 0.89)

	Unadjusted rate of over 4h A&E wait (95% CI)	Adjusted rate of over 4h A&E wait (95% CI)	Unadjusted rate of over 18w RTT wait (95% CI)	Adjusted rate of over 18w RTT wait (95% CI)
Post-inspection slope				
Old regime	1.01 (0.99, 1.02)	1.01 (0.99, 1.02)	1.04 (1.004, 1.08)	1.04 (1.01, 1.09)
New regime	0.98 (0.97, 1.002)	0.98 (0.97, 1.001)	0.94 (0.88, 0.997)	0.94 (0.88, 0.99)
No inspection	1.02 (1.001, 1.03)	1.02 (1.001, 1.04)	0.95 (0.91, 1.001)	0.95 (0.91, 0.99)
NHS reform	-	-	-	0.84 (0.82, 0.87)
Beds	-	-	-	1.0003 (1.0001, 1.0004)
Reporting culture	-		-	-
Poor	-	Reference	-	-
Significant concerns	-	0.8 (0.65, 0.97)	-	-
Good	-	0.69 (0.57, 0.84)	-	-
Outstanding	-	0.54 (0.38, 0.77)	-	-
Time squared	-	-	1.0007 (1.0006, 1.0008)	1.0007 (1.0006, 1.0008)
Sine	1.26 (1.24, 1.29)	1.26 (1.24, 1.29)	1.06 (1.05, 1.07)	1.07 (1.06, 1.08)
Cosine	0.97 (0.96, 0.99)	0.97 (0.96, 0.99)	1.03 (1.02, 1.04)	1.03 (1.02, 1.04)
Sine*2	-	-	0.96 (0.96, 0.97)	0.96 (0.96, 0.97)

7.4 Treatment with dignity and respect

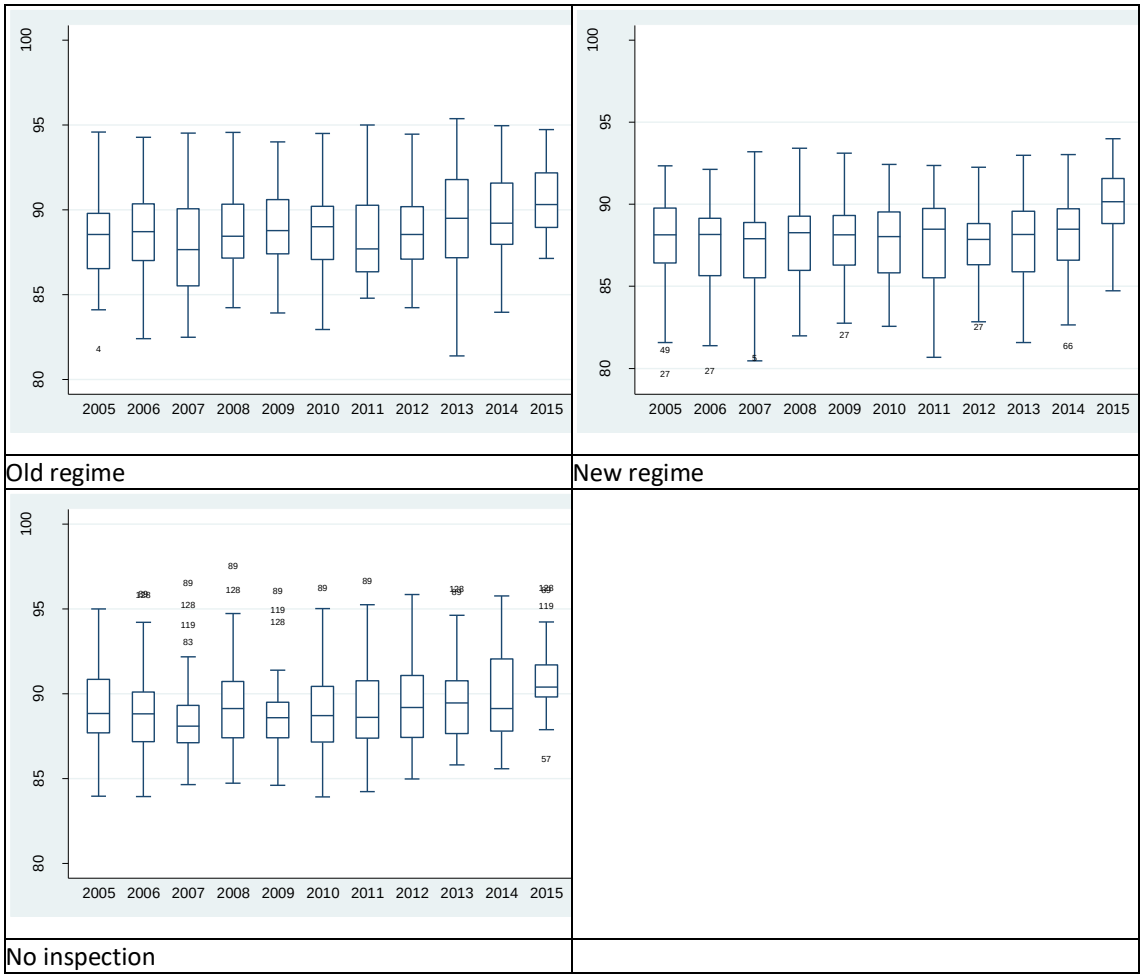
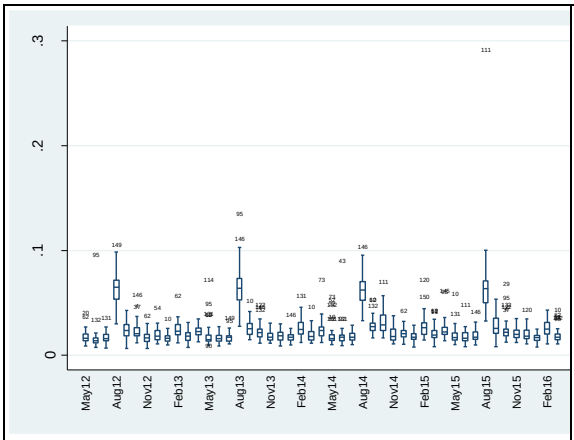


Figure 7.4 Patients' perception of care for all NHS Trusts over time by type of inspection

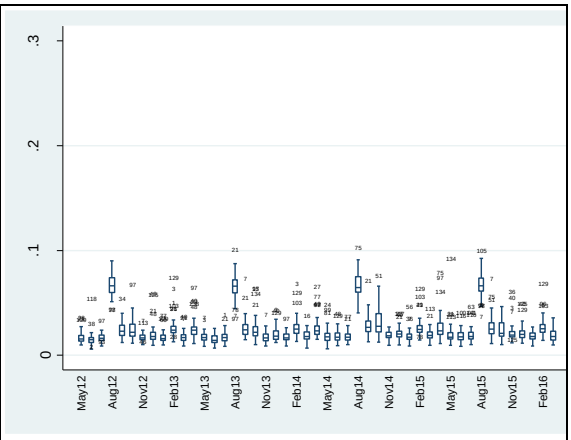
Table 7.4 Unadjusted and adjusted model coefficients for patients' perception of being treated with dignity and respect by type of inspection

	Unadjusted patients' perception of being treated with dignity and respect (95% CI)	Adjusted patients' perception of being treated with dignity and respect (95% CI)
	Obs=1,643 Trusts=151	Obs=1,643 Trusts=151
Intercept		
Old Regime	89.04 (88.37, 89.71)	87.6 (86.95, 88.22)
New regime	-1.36 (-2.24, -0.48)	-0.69 (-1.38, 0.006)
No inspection	0.24 (-0.77, 1.26)	0.22 (-0.58, 1.02)
Pre-inspection slope		
Old regime	0.007 (0.0007, 0.01)	0.007 (0.001, 0.013)
New regime	-0.005 (-0.01, 0.002)	-0.006 (-0.013, 0.0016)
No inspection	-0.004 (-0.01, 0.005)	-0.004 (-0.01, 0.005)
Announcement change		
Old regime	-0.72 (-2.06, 0.63)	-0.52 (-1.82, 0.78)
New regime	2.09 (-0.03, 4.22)	1.92 (-0.17, 4.01)
No inspection	0.47 (-0.52, 1.45)	0.34 (-0.62, 1.31)
Announcement slope		
Old regime	0.66 (-0.004, 1.32)	0.58 (-0.07, 1.23)
New regime	-1.03 (-1.97, -0.1)	-0.95 (-1.87, -0.02)
No inspection	0.02 (-0.05, 0.08)	0.02 (-0.05, 0.08)
Post-inspection change		
Old regime	-2.08 (-3.76, -0.39)	-1.99 (-3.66, -0.32)
New regime	2.11 (-0.07, 4.29)	1.97 (-0.19, 4.13)
No inspection	-0.57 (-2.04, 0.9)	-0.41 (-1.86, 1.04)
Post-inspection slope		
Old regime	-0.58 (-1.25, 0.08)	-0.5 (-1.15, 0.15)
New regime	1.09 (0.16, 2.03)	1.01 (0.09, 1.94)
No inspection	0 (0, 0)	0 (0, 0)
Specialist Trust	-	4.71 (3.82, 5.6)
Foundation Trust	-	1.21 (0.68, 1.75)

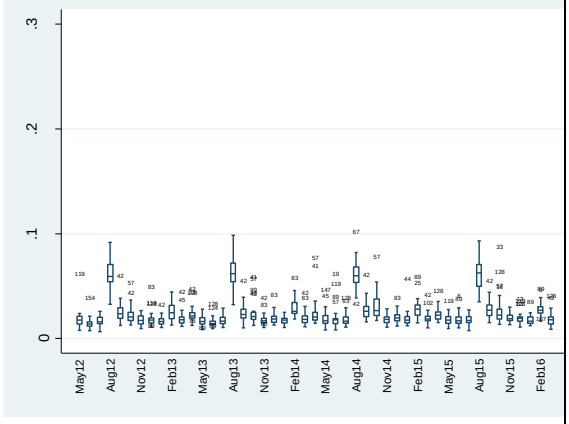
7.5 Staff leaving acute NHS Trusts



Old regime



New regime



No inspection

Figure 7.5 Rates of staff leaving a Trust for all NHS Trusts over time by type of inspection

Table 7.5 Unadjusted and adjusted model coefficients for staff leaving NHS Trusts by type of inspection

	Unadjusted rate of staff leaving NHS Trusts (95% CI) Obs=7,106 Trusts=152	Adjusted rate of staff leaving NHS Trusts (95% CI) Obs=7,106 Trusts=152
Intercept		
Old Regime	0.019 (0.018, 0.02)	0.017 (0.016, 0.018)
New regime	1.05 (0.97, 1.12)	1.03 (0.97, 1.1)
No inspection	1.002 (0.91, 1.1)	1.01 (0.94, 1.1)
Pre-inspection slope		
Old regime	1.001 (0.99, 1.004)	1.001 (0.99, 1.004)
New regime	1.002 (0.99, 1.006)	1.002 (0.99, 1.006)
No inspection	1.001 (0.99, 1.006)	1 (0.99, 1.006)
Announcement change		
Old regime	0.99 (0.91, 1.1)	0.99 (0.91, 1.1)
New regime	0.94 (0.83, 1.06)	0.94 (0.83, 1.06)
No inspection	1.02 (0.89, 1.18)	1.02 (0.89, 1.18)

	Unadjusted rate of staff leaving NHS Trusts (95% CI)	Adjusted rate of staff leaving NHS Trusts (95% CI)
Announcement slope		
Old regime	0.99 (0.97, 1.03)	0.99 (0.97, 1.03)
New regime	1.03 (0.99, 1.08)	1.03 (0.99, 1.08)
No inspection	0.98 (0.93, 1.03)	0.98 (0.93, 1.03)
Post-inspection change		
Old regime	1.12 (1.05, 1.19)	1.12 (1.05, 1.2)
New regime	0.89 (0.82, 0.98)	0.9 (0.82, 0.98)
No inspection	1.06 (0.96, 1.16)	1.06 (0.96, 1.16)
Post-inspection slope		
Old regime	0.99 (0.97, 1.03)	1 (0.97, 1.03)
New regime	0.97 (0.93, 1.01)	0.97 (0.93, 1.01)
No inspection	1.02 (0.97, 1.07)	1.02 (0.97, 1.07)
Medical rotation	2.65 (2.57, 2.73)	2.65 (2.57, 2.73)
Cosine	0.93 (0.93, 0.94)	0.93 (0.93, 0.94)
Sine	1.04 (1.03, 1.05)	1.04 (1.03, 1.05)
Cosine*2	0.92 (0.91, 0.93)	0.92 (0.91, 0.93)
Sine*2	0.86 (0.86, 0.87)	0.86 (0.86, 0.87)
Large acute NHS Trust	-	reference
Medium acute NHS Trust	-	1.06 (1.01, 1.1)
Small acute NHS Trust	-	1.03 (0.98, 1.08)
Teaching acute NHS Trust	-	1.09 (1.03, 1.14)
Specialist acute NHS Trust	-	1.13 (1.07, 1.2)
North region	-	reference
Midlands and East region	-	1.08 (1.04, 1.12)
South region	-	1.06 (1.02, 1.11)
London region	-	1.36 (1.3, 1.43)

Appendix Chapter 8

8.1 Adverse events

8.1.1 Falls with harm

Table 8.1 Characteristics of Trusts classified as improving and not improving for rates of fall with harm

	Not improving n=39	Improving n=109	p-value
Foundation Trust	26 (66.7%)	68 (62.4%)	0.63
Type of trust			
Large acute trust	10 (25.6%)	30 (27.5%)	0.005
Medium acute Trust	14 (35.9%)	31 (28.4%)	
Small acute trust	3 (7.7%)	23 (21.1%)	
Acute teaching trust	4 (10.3%)	21 (19.3%)	
Acute specialist trust	8 (20.5%)	4 (3.7%)	
NHS England region			
North	12 (30.8%)	36 (33.0%)	0.82
Midlands and East	12 (30.8%)	31 (28.4%)	
South	8 (20.5%)	28 (25.7%)	
London	7 (17.9%)	14 (12.8%)	
Beds, median (IQR)	650 (485, 855)	736 (524, 1063)	0.13
Population in thousands, median (IQR)	447.5 (350, 600)	460 (331, 600)	0.91
Special measures	3 (7.7%)	16 (14.7%)	0.26
Type of inspection			
New regime	14 (58%)	50 (58%)	0.99
No inspected	15 (38.5%)	23 (21.1%)	0.033
Overall rating			
Outstanding	3 (8.1%)	5 (4.6%)	0.35
Good	12 (32.4%)	26 (24.1%)	
Requires improvement	21 (56.8%)	66 (61.1%)	
Inadequate	1 (2.7%)	11 (10.2%)	
Merged Trusts	3 (7.7%)	9 (8.3%)	0.91
Monitor Sustainability rating			
Significant risk	2 (8%)	6 (9%)	0.34
Material risk	2 (8%)	8 (12%)	
Emerging or minor concerns	12 (46%)	40 (61%)	
No evident concerns	9 (35%)	10 (15%)	
Lowest risk	1 (4%)	2 (3%)	
Monitor Governance rating			
Subject to enforcement action	5 (19%)	14 (21%)	0.91
Under review	4 (15%)	8 (12%)	
No evident concerns	17 (65%)	44 (67%)	
TDA escalating score			
Enforcement action	1 (8%)	5 (12%)	0.46
Significant delivery issues	4 (31%)	18 (42%)	
Some delivery issues	6 (46%)	9 (21%)	
Limited/no issues	2 (15%)	9 (21%)	
Sound FT application	0 (0%)	2 (5%)	

	Not improving n=39	Improving n=109	p-value
Number of inspections, median (IQR)	3 (3, 4)	4 (3, 5)	0.16
Months since previous inspection, median (IQR)	11 (7, 18)	10 (7, 13)	0.16
Reporting culture 2016			
Poor	3 (7.7%)	22 (20.2%)	0.16
Significant Concerns	17 (43.6%)	36 (33.0%)	
Good	15 (38.5%)	46 (42.2%)	
Outstanding	4 (10.3%)	5 (4.6%)	
Rate of falls with harm, median (IQR)	0.0046 (0.0025, 0.0098)	0.0088 (0.0047, 0.013)	0.017

8.1.2 Pressure ulcers

Table 8.2 Characteristics of Trusts classified as improving and not improving for rates of pressure ulcers

	Not improving n=43	Improving n=105	p-value
Foundation Trust	30 (69.8%)	64 (61.0%)	0.31
Type of trust			
Large acute trust	8 (18.6%)	32 (30.5%)	0.49
Medium acute Trust	17 (39.5%)	28 (26.7%)	
Small acute trust	8 (18.6%)	18 (17.1%)	
Acute teaching trust	7 (16.3%)	18 (17.1%)	
Acute specialist trust	3 (7.0%)	9 (8.6%)	
NHS England region			
North	12 (27.9%)	36 (34.3%)	0.73
Midlands and East	12 (27.9%)	31 (29.5%)	
South	11 (25.6%)	25 (23.8%)	
London	8 (18.6%)	13 (12.4%)	
Beds, median (IQR)	674.5 (508, 953)	741.5 (500, 1047)	0.54
Population in thousands, median (IQR)	402.5 (350, 640)	462.5 (340, 600)	0.86
Special measures	6 (14.0%)	13 (12.4%)	0.80
Type of inspection			
New regime	19 (63%)	46 (57%)	0.58
No inspected	13 (30.2%)	25 (23.8%)	0.42
Overall rating			
Outstanding	4 (9.5%)	4 (3.9%)	0.34
Good	13 (31.0%)	25 (24.3%)	
Requires improvement	23 (54.8%)	64 (62.1%)	
Inadequate	2 (4.8%)	10 (9.7%)	
Merged Trusts	4 (9.3%)	8 (7.6%)	0.73
Monitor Sustainability rating			
Significant risk	3 (10%)	5 (8%)	0.98
Material risk	3 (10%)	7 (11%)	
Emerging or minor concerns	17 (59%)	35 (56%)	
No evident concerns	5 (17%)	14 (22%)	
Lowest risk	1 (3%)	2 (3%)	
Monitor Governance rating			
Subject to enforcement action	6 (21%)	13 (21%)	0.32
Under review	6 (21%)	6 (10%)	
No evident concerns	17 (59%)	44 (70%)	

	Not improving n=43	Improving n=105	p-value
TDA escalating score			
Enforcement action	2 (14%)	4 (10%)	0.11
Significant delivery issues	3 (21%)	19 (45%)	
Some delivery issues	7 (50%)	8 (19%)	
Limited/no issues	1 (7%)	10 (24%)	
Sound FT application	1 (7%)	1 (2%)	
Number of inspections, median (IQR)	3 (3, 4)	4 (3, 5)	0.32
Months since previous inspection, median (IQR)	9 (6, 15)	10 (8, 15)	0.24
Reporting culture 2016			
Poor	7 (16.3%)	18 (17.1%)	0.66
Significant Concerns	16 (37.2%)	37 (35.2%)	
Good	19 (44.2%)	42 (40.0%)	
Outstanding	1 (2.3%)	8 (7.6%)	
Rate of pressure ulcers, median (IQR)	0.04 (0.026, 0.059)	0.060 (0.046, 0.073)	<0.001

Table 8.3 Unadjusted model coefficients for adverse events accounting by previous performance

	Unadjusted rates of falls with harm (95% CI) Obs=6,235 Trusts=148	Unadjusted rates of pressure ulcers (95% CI) Obs=7,267 Trusts=148
Intercept		
Not improving old regime	0.01 (0, 0.01)	0.06 (0.04, 0.08)
Improving old regime	0.5 (0.3, 0.86)	0.65 (0.48, 0.9)
Not improving new regime	1.44 (0.79, 2.64)	1.13 (0.8, 1.59)
Improving new regime	0.54 (0.32, 0.89)	0.61 (0.45, 0.82)
Not improving no inspection	1.01 (0.54, 1.86)	0.8 (0.55, 1.17)
Improving no inspection	0.71 (0.41, 1.25)	0.57 (0.41, 0.79)
Pre-inspection slope		
Not improving old regime	1.03 (1, 1.06)	1.02 (1.01, 1.04)
Improving old regime	0.92 (0.89, 0.94)	0.95 (0.94, 0.97)
Not improving new regime	1 (0.97, 1.03)	0.99 (0.98, 1.01)
Improving new regime	0.94 (0.91, 0.97)	0.96 (0.94, 0.97)
Not improving no inspection	0.93 (0.9, 0.96)	0.98 (0.97, 1)
Improving no inspection	0.98 (0.95, 1.02)	0.95 (0.94, 0.97)
Announcement change		
Not improving old regime	1.04 (0.7, 1.54)	0.92 (0.78, 1.09)
Improving old regime	1.27 (0.88, 1.83)	1.01 (0.85, 1.2)
Not improving new regime	0.76 (0.42, 1.38)	1.07 (0.84, 1.36)
Improving new regime	0.87 (0.55, 1.38)	1.11 (0.9, 1.36)
Not improving no inspection	1.09 (0.6, 1.98)	1.36 (1.03, 1.78)
Improving no inspection	0.75 (0.44, 1.27)	1.21 (0.96, 1.53)
Announcement slope		
Not improving old regime	0.9 (0.82, 0.99)	0.96 (0.92, 1)
Improving old regime	1.09 (1.06, 1.13)	1.05 (1.03, 1.07)
Not improving new regime	1.11 (0.93, 1.33)	0.99 (0.92, 1.07)

	Unadjusted rates of falls with harm (95% CI) Obs=6,235 Trusts=148	Unadjusted rates of pressure ulcers (95% CI) Obs=7,267 Trusts=148
Improving new regime	1.13 (1, 1.28)	1.05 (0.99, 1.12)
Not improving no inspection	1.07 (0.89, 1.29)	0.99 (0.91, 1.08)
Improving no inspection	1.18 (1.01, 1.37)	1.03 (0.96, 1.11)
Post-inspection change		
Not improving old regime	1.32 (0.95, 1.83)	0.91 (0.79, 1.05)
Improving old regime	0.78 (0.56, 1.11)	1.19 (1.02, 1.39)
Not improving new regime	0.52 (0.33, 0.82)	1.09 (0.9, 1.31)
Improving new regime	0.84 (0.58, 1.21)	1.1 (0.93, 1.3)
Not improving no inspection	0.57 (0.36, 0.91)	1.13 (0.92, 1.39)
Improving no inspection	0.74 (0.49, 1.11)	1.11 (0.92, 1.33)
Post-inspection slope		
Not improving old regime	1.07 (0.98, 1.17)	1.02 (0.98, 1.06)
Improving old regime	1 (0.99, 1.01)	0.99 (0.98, 1.02)
Not improving new regime	0.9 (0.76, 1.08)	1 (0.93, 1.08)
Improving new regime	0.94 (0.83, 1.06)	0.99 (0.94, 1.05)
Not improving no inspection	0.97 (0.89, 1.06)	1.01 (0.96, 1.05)
Improving no inspection	0.95 (0.89, 1.03)	1.01 (0.97, 1.04)

8.2 Summary Hospital Mortality Index

Table 8.4 Characteristics of Trusts classified as improving and not improving for summary hospital mortality index

	Not improving n=76	Improving n=60	p-value
Foundation Trust	51 (67%)	32 (53%)	0.10
Type of trust			
Large acute trust	22 (29%)	18 (30%)	1.00
Medium acute Trust	25 (33%)	20 (33%)	
Small acute trust	15 (20%)	11 (18%)	
Acute teaching trust	14 (18%)	11 (18%)	
NHS England region			
North	30 (39%)	13 (22%)	0.17
Midlands and East	19 (25%)	21 (35%)	
South	18 (24%)	17 (28%)	
London	9 (12%)	9 (15%)	
Beds, median (IQR)	718.5 (515.5, 1044)	754.5 (569, 1035.5)	0.73
Population in thousands, median (IQR)	443 (330.5, 585)	482 (345, 600)	0.43
Special measures	5 (7%)	14 (23%)	0.005
Type of inspection			
New regime	28 (52%)	34 (71%)	0.050
No inspected	22 (29%)	12 (20%)	0.23

	Not improving n=76	Improving n=60	p-value
Overall rating			
Outstanding	2 (3%)	3 (5%)	0.70
Good	22 (29%)	13 (22%)	
Requires improvement	46 (61%)	38 (63%)	
Inadequate	6 (8%)	6 (10%)	
Merged Trusts	6 (8%)	6 (10%)	0.67
Monitor Sustainability rating			
Significant risk	3 (6%)	5 (16%)	0.59
Material risk	7 (14%)	3 (9%)	
Emerging or minor concerns	30 (61%)	19 (59%)	
No evident concerns	8 (16%)	5 (16%)	
Lowest risk	1 (2%)	0 (0%)	
Monitor Governance rating			
Subject to enforcement action	8 (16%)	11 (34%)	0.17
Under review	7 (14%)	4 (13%)	
No evident concerns	34 (69%)	17 (53%)	
TDA escalating score			
Enforcement action	1 (4%)	5 (18%)	0.24
Significant delivery issues	13 (48%)	9 (32%)	
Some delivery issues	8 (30%)	7 (25%)	
Limited/no issues	5 (19%)	5 (18%)	
Sound FT application	0 (0%)	2 (7%)	
Number of inspections, median (IQR)	4 (3, 5)	4 (3, 5)	0.35
Months since previous inspection, median (IQR)	11 (8, 18)	10 (7, 15)	0.34
Reporting culture 2016			
Poor	11 (14%)	14 (23%)	0.54
Significant Concerns	29 (38%)	22 (37%)	
Good	33 (43%)	21 (35%)	
Outstanding	3 (4%)	3 (5%)	
Summary Hospital Mortality Index, median (IQR)	0.99 (0.92, 1.03)	1.08 (0.97, 1.12)	<0.001

Table 8.5 Unadjusted model coefficients for summary hospital mortality index accounting by previous performance

	Unadjusted summary hospital mortality index (95% CI) Obs=2,574 Trusts=136
Intercept	
Not improving old regime	1.03 (0.99, 1.07)
Improving old regime	-0.05 (-0.11, 0.006)
Not improving new regime	-0.02 (-0.07, 0.03)
Improving new regime	-0.05 (-0.1, -0.008)
Not improving no inspection	0.006 (-0.04, 0.06)
Improving no inspection	-0.08 (-0.15, -0.02)

	Unadjusted summary hospital mortality index (95% CI) Obs=2,574 Trusts=136
Pre-inspection slope	
Not improving old regime	0.002 (0.001, 0.002)
Improving old regime	-0.004 (-0.005, -0.003)
Not improving new regime	-0.0005 (-0.001, 0.0002)
Improving new regime	-0.004 (-0.005, -0.003)
Not improving no inspection	-0.0002 (-0.001, 0.0006)
Improving no inspection	-0.004 (-0.005, -0.003)
Announcement change	
Not improving old regime	-0.007 (-0.02, 0.01)
Improving old regime	-0.01 (-0.04, 0.02)
Not improving new regime	0.009 (-0.01, 0.03)
Improving new regime	0.02 (-0.008, 0.04)
Not improving no inspection	0.005 (-0.02, 0.03)
Improving no inspection	0.03 (0.004, 0.06)
Announcement slope	
Not improving old regime	-0.003 (-0.03, 0.004)
Improving old regime	0.01 (-0.001, 0.03)
Not improving new regime	0.0004 (-0.01, 0.01)
Improving new regime	0.005 (-0.006, 0.01)
Not improving no inspection	0.001 (-0.0007, 0.004)
Improving no inspection	0.004 (0.002, 0.007)
Post-inspection change	
Not improving old regime	0.003 (-0.01, 0.02)
Improving old regime	-0.03 (-0.05, -0.005)
Not improving new regime	-0.009 (-0.03, 0.01)
Improving new regime	-0.0003 (-0.02, 0.02)
Not improving no inspection	-0.01 (-0.03, 0.001)
Improving no inspection	0.02 (0.00003, 0.04)
Post-inspection slope	
Not improving old regime	0.0007 (-0.007, 0.008)
Improving old regime	-0.005 (-0.02, 0.009)
Not improving new regime	-0.0002 (-0.01, 0.01)
Improving new regime	0.001 (-0.009, 0.01)
Not improving no inspection	0 (-0.001, 0.1)
Improving no inspection	0 (-0.001, 0.1)

Table 8.6 Unadjusted model coefficients for crude mortality rates accounting by previous performance

	Unadjusted crude mortality rates (95% CI) Obs=2,574 Trusts=136
Intercept	
Not improving old regime	0.034 (0.031, 0.037)
Improving old regime	-0.00035 (-0.005, 0.004)
Not improving new regime	0.00015 (-0.004, 0.004)
Improving new regime	-0.0017 (-0.005, 0.002)
Not improving no inspection	0.0004 (-0.004, 0.004)
Improving no inspection	-0.002 (-0.007, 0.003)
Pre-inspection slope	
Not improving old regime	0.00006 (0.00002, 0.00009)
Improving old regime	-0.00009 (-0.00016, -0.00003)
Not improving new regime	0.00001 (-0.00004, 0.00006)
Improving new regime	-0.00007 (-0.0001, -0.00002)
Not improving no inspection	0.00005 (-0.000006, 0.0001)
Improving no inspection	-0.00005 (-0.0001, 0.00001)
Announcement change	
Not improving old regime	0.0002 (-0.0007, 0.001)
Improving old regime	0.0002 (-0.0015, 0.002)
Not improving new regime	-0.0005 (-0.002, 0.0007)
Improving new regime	-0.00003 (-0.001, 0.001)
Not improving no inspection	0.0008 (-0.0003, 0.002)
Improving no inspection	0.001 (-0.0003, 0.002)
Announcement slope	
Not improving old regime	-0.0002 (-0.0005, 0.0002)
Improving old regime	0.00057 (-0.0001, 0.001)
Not improving new regime	-0.00004 (-0.0006, 0.0005)
Improving new regime	0.00003 (-0.0005, 0.0005)
Not improving no inspection	-0.00004 (-0.0002, 0.00007)
Improving no inspection	0.00005 (-0.00009, 0.0002)
Post-inspection change	
Not improving old regime	-0.0017 (-0.002, -0.001)
Improving old regime	-0.002 (-0.003, -0.0009)
Not improving new regime	0.0004 (-0.0006, 0.001)
Improving new regime	0.0005 (-0.0005, 0.001)
Not improving no inspection	-0.0007 (-0.001, 0.0001)
Improving no inspection	0.0006 (-0.0004, 0.0016)

	Unadjusted crude mortality rates (95% CI) Obs=2,574 Trusts=136
Post-inspection slope	
Not improving old regime	0.0002 (-0.0002, 0.0006)
Improving old regime	-0.0004 (-0.001, 0.0003)
Not improving new regime	0.00007 (-0.0005, 0.0006)
Improving new regime	0.0001 (-0.0004, 0.0007)
Not improving no inspection	0 (-0.001, 0.1)
Improving no inspection	0 (-0.001, 0.1)

8.3 Waiting times

8.3.1 A&E waiting times

Table 8.7 Characteristics of Trusts classified as improving and not improving for rates of attendance over 4h A&E wait

	Not improving n=110	Improving n=32	p-value
Foundation Trust	70 (63.6%)	19 (59.4%)	0.66
Type of trust			
Large acute trust	34 (30.9%)	6 (18.8%)	0.006
Medium acute Trust	34 (30.9%)	11 (34.4%)	
Small acute trust	21 (19.1%)	5 (15.6%)	
Acute teaching trust	20 (18.2%)	5 (15.6%)	
Acute specialist trust	1 (0.9%)	5 (15.6%)	
NHS England region			
North	37 (33.6%)	9 (28.1%)	0.36
Midlands and East	31 (28.2%)	10 (31.3%)	
South	25 (22.7%)	11 (34.4%)	
London	17 (15.5%)	2 (6.3%)	
Beds, median (IQR)	750 (544, 1024)	640 (458, 1047)	0.13
Population in thousands, median (IQR)	450 (350, 600)	463.5 (320, 612)	0.94
Special measures	17 (15.5%)	2 (6.3%)	0.18
Type of inspection			
New regime	51 (61%)	13 (57%)	0.67
No inspected	27 (24.5%)	9 (28.1%)	0.68
Overall rating			
Outstanding	4 (4%)	1 (4%)	0.041
Good	19 (20%)	13 (46%)	
Requires improvement	62 (65%)	13 (46%)	
Inadequate	10 (11%)	1 (4%)	
Merged Trusts	12 (10.9%)	0 (0.0%)	0.051
Monitor Sustainability rating			
Significant risk	6 (9%)	2 (11%)	0.048
Material risk	7 (10%)	3 (16%)	
Emerging or minor concerns	42 (62%)	7 (37%)	
No evident concerns	13 (19%)	5 (26%)	
Lowest risk	0 (0%)	2 (11%)	
Monitor Governance rating			
Subject to enforcement action	15 (23%)	4 (21%)	0.81
Under review	8 (13%)	1 (5%)	
No evident concerns	42 (65%)	14 (74%)	
TDA escalating score			
Enforcement action	5 (13%)	1 (8%)	0.43
Significant delivery issues	18 (45%)	3 (23%)	
Some delivery issues	9 (23%)	6 (46%)	
Limited/no issues	7 (18%)	3 (23%)	
Sound FT application	1 (3%)	0 (0%)	
Number of inspections, median (IQR)	4 (3, 5)	4 (2, 5.5)	0.57
Weeks since previous inspection, median (IQR)	43 (30, 63)	48 (32, 60)	0.71
Reporting culture 2016			
Poor	21 (19.1%)	5 (15.6%)	0.94
Significant Concerns	40 (36.4%)	11 (34.4%)	
Good	44 (40.0%)	14 (43.8%)	
Outstanding	5 (4.5%)	2 (6.3%)	
Rate of attendances over 4h wait, median (IQR)	0.028 (0.018, 0.047)	0.029 (0.015, 0.055)	0.73

8.3.2 RTT waiting times

Table 8.8 Characteristics of Trusts classified as improving and not improving for rates of referrals waiting over 18 weeks

	Not improving n=95	Improving n=59	p-value
Foundation Trust	63 (66%)	35 (59%)	0.38
Type of trust			
Large acute trust	26 (27%)	14 (24%)	0.64
Medium acute Trust	24 (25%)	21 (36%)	
Small acute trust	17 (18%)	9 (15%)	
Acute teaching trust	15 (16%)	10 (17%)	
Acute specialist trust	13 (14%)	5 (8%)	
NHS England region			
North	35 (37%)	15 (25%)	0.27
Midlands and East	29 (31%)	16 (27%)	
South	18 (19%)	18 (31%)	
London	13 (14%)	10 (17%)	
Beds, median (IQR)	682 (463, 977)	706 (491, 1072)	0.49
Population in thousands, median (IQR)	450 (330, 600)	490 (350, 647.5)	0.42
Special measures	12 (13%)	7 (12%)	0.89
Type of inspection			
New regime	40 (56%)	26 (60%)	0.67
No inspected	24 (25%)	16 (27%)	0.80
Overall rating			
Outstanding	6 (6%)	4 (7%)	0.99
Good	26 (27%)	16 (28%)	
Requires improvement	56 (59%)	33 (57%)	
Inadequate	7 (7%)	5 (9%)	
Merged Trusts	7 (7%)	5 (8%)	0.80
Monitor Sustainability rating			
Significant risk	5 (8%)	3 (9%)	0.84
Material risk	5 (8%)	5 (15%)	
Emerging or minor concerns	36 (56%)	16 (48%)	
No evident concerns	16 (25%)	8 (24%)	
Lowest risk	2 (3%)	1 (3%)	
Monitor Governance rating			
Subject to enforcement action	13 (21%)	6 (19%)	0.91
Under review	7 (12%)	3 (10%)	
No evident concerns	43 (68%)	22 (71%)	
TDA escalating score			
Enforcement action	2 (7%)	4 (15%)	0.33
Significant delivery issues	14 (50%)	7 (27%)	
Some delivery issues	6 (21%)	9 (35%)	
Limited/no issues	6 (21%)	5 (19%)	
Sound FT application	0 (0%)	1 (4%)	
Number of inspections, median (IQR)	4 (3, 5)	4 (3, 5)	0.60
Months since previous inspection, median (IQR)	10 (6, 15)	10 (8, 15)	0.46
Reporting culture 2016			
Poor	15 (16%)	11 (19%)	0.66
Significant Concerns	30 (32%)	23 (39%)	
Good	43 (45%)	22 (37%)	
Outstanding	7 (7%)	3 (5%)	
Rate of referrals waiting over 18 w, median (IQR)	0.42 (0.33, 0.51)	0.49 (0.35, 0.58)	0.037

Table 8.9 Unadjusted model coefficients for waiting times accounting by previous performance

	Unadjusted rates of attendances over 4 h A&E wait (95% CI) Obs=33,740 Trusts=142	Unadjusted rates of referrals waiting over 18 w (95% CI) Obs=12,689 Trusts=154
Intercept		
Not improving old regime	0.05 (0.046, 0.06)	0.09 (0.08, 0.1)
Improving old regime	0.41 (0.29, 0.57)	0.6 (0.47, 0.76)
Not improving new regime	1.02 (0.83, 1.25)	0.99 (0.81, 1.2)
Improving new regime	0.52 (0.38, 0.7)	0.77 (0.62, 0.95)
Not improving no inspection	1.04 (0.82, 1.33)	0.95 (0.77, 1.19)
Improving no inspection	0.45 (0.31, 0.63)	0.58 (0.45, 0.74)
Pre-inspection slope		
Not improving old regime	1.005 (1.003, 1.006)	1.01 (1.008, 1.014)
Improving old regime	0.99 (0.99, 0.99)	0.98 (0.98, 0.99)
Not improving new regime	1 (0.99, 1.001)	0.99 (0.99, 1.002)
Improving new regime	0.99 (0.99, 0.99)	0.98 (0.98, 0.98)
Not improving no inspection	1 (0.99, 1.002)	0.99 (0.99, 1.002)
Improving no inspection	0.99 (0.99, 0.99)	0.98 (0.97, 0.98)
Announcement change		
Not improving old regime	0.9 (0.78, 1.04)	0.96 (0.82, 1.12)
Improving old regime	1.15 (0.85, 1.55)	1.19 (0.92, 1.54)
Not improving new regime	1.05 (0.87, 1.26)	1.06 (0.87, 1.31)
Improving new regime	1.04 (0.8, 1.37)	1.28 (1.02, 1.61)
Not improving no inspection	1.14 (0.94, 1.39)	0.99 (0.84, 1.19)
Improving no inspection	1.1 (0.8, 1.5)	1.22 (1.01, 1.46)
Announcement slope		
Not improving old regime	0.99 (0.98, 1.01)	1.01 (0.94, 1.07)
Improving old regime	1.01 (0.98, 1.04)	0.99 (0.9, 1.1)
Not improving new regime	1.01 (0.99, 1.02)	1.002 (0.92, 1.09)
Improving new regime	1.04 (1.01, 1.07)	1.05 (0.96, 1.15)
Not improving no inspection	0.98 (0.97, 0.99)	1.003 (0.93, 1.08)
Improving no inspection	1.01 (0.98, 1.03)	1.03 (0.95, 1.11)
Post-inspection change		
Not improving old regime	0.85 (0.74, 0.98)	0.9 (0.81, 1.01)
Improving old regime	1.24 (0.92, 1.67)	1.001 (0.83, 1.21)
Not improving new regime	1.31 (1.09, 1.57)	1.12 (0.96, 1.3)
Improving new regime	1.32 (1.01, 1.72)	1.07 (0.9, 1.26)
Not improving no inspection	1.2 (0.97, 1.47)	0.95 (0.79, 1.13)
Improving no inspection	1.02 (0.76, 1.38)	0.85 (0.69, 1.05)
Post-inspection slope		
Not improving old regime	1.01 (0.99, 1.02)	1.01 (0.95, 1.08)
Improving old regime	0.99 (0.97, 1.03)	1.03 (0.93, 1.15)
Not improving new regime	0.99 (0.97, 1.01)	0.99 (0.92, 1.09)
Improving new regime	0.96 (0.94, 0.99)	0.98 (0.89, 1.07)

	Unadjusted rates of attendances over 4 h A&E wait (95% CI) Obs=33,740 Trusts=142	Unadjusted rates of referrals waiting over 18 w (95% CI) Obs=12,689 Trusts=154
Not improving no inspection	1.02 (1, 1.04)	0.99 (0.93, 1.08)
Improving no inspection	1.01 (0.98, 1.03)	1.003 (0.93, 1.09)
Sine	1.26 (1.24, 1.29)	1.05 (1.04, 1.05)
Cosine	0.97 (0.96, 0.99)	0.98 (0.97, 0.99)
Sine*2	-	0.96 (0.95, 0.97)

8.4 Treatment with dignity and respect

Table 8.10 Characteristics of Trusts classified as improving and not improving for patients' perception of being treated with dignity and respect

	Not improving n=57	Improving n=93	p-value
Foundation Trust	29 (51%)	66 (71%)	0.013
Type of Trust			
Large acute Trust	19 (33%)	22 (24%)	0.053
Medium acute Trust	13 (23%)	32 (34%)	
Small acute Trust	15 (26%)	11 (12%)	
Acute teaching Trust	7 (12%)	18 (19%)	
Acute specialist Trust	3 (5%)	10 (11%)	
NHS England region			
North	23 (40%)	25 (27%)	0.10
Midlands and East	18 (32%)	26 (28%)	
South	12 (21%)	24 (26%)	
London	4 (7%)	18 (19%)	
Beds, median (IQR)	706 (481, 1016)	700 (511, 1020)	0.85
Population in thousands, median (IQR)	445.5 (330, 575)	480 (350, 600)	0.42
Special measures	12 (21%)	7 (8%)	0.016
Type of inspection			
New regime	29 (66%)	36 (53%)	0.17
No inspected	13 (23%)	25 (27%)	0.58
Overall rating			
Outstanding	2 (4%)	7 (8%)	0.16
Good	10 (18%)	29 (31%)	
Requires improvement	40 (70%)	50 (54%)	
Inadequate	5 (9%)	7 (8%)	
Merged Trusts	5 (9%)	8 (9%)	0.97
Monitor Sustainability rating			
Significant risk	6 (21%)	2 (3%)	0.046
Material risk	2 (7%)	8 (13%)	
Emerging or minor concerns	14 (48%)	38 (59%)	
No evident concerns	7 (24%)	13 (20%)	
Lowest risk	0 (0%)	3 (5%)	
Monitor Governance rating			
Subject to enforcement action	11 (38%)	8 (13%)	0.016
Under review	2 (7%)	10 (16%)	
No evident concerns	16 (55%)	46 (72%)	
TDA escalating score			
Enforcement action	5 (18%)	1 (3%)	0.33
Significant delivery issues	12 (43%)	10 (34%)	
Some delivery issues	6 (21%)	10 (34%)	
Limited/no issues	4 (14%)	7 (24%)	
Sound FT application	1 (4%)	1 (3%)	

	Not improving n=57	Improving n=93	p-value
Number of inspections, median (IQR)	4 (3, 5)	4 (3, 5)	0.27
Months since previous inspection, median (IQR)	11 (8, 16)	10 (8, 18)	0.90
Reporting culture 2016			
Poor	9 (16%)	16 (17%)	0.76
Significant Concerns	22 (39%)	32 (34%)	
Good	24 (42%)	38 (41%)	
Outstanding	2 (4%)	7 (8%)	
Patients' perception of being treated with dignity and respect, mean (SD)	89.20 (1.98)	87.88 (3.04)	0.005

Table 8.11 Unadjusted model coefficients for patients' perception of being treated with dignity and respect accounting by previous performance

	Unadjusted patients' perception of being treated with dignity and respect (95% CI) Obs=1,642 Trusts=150
Intercept	
Not improving old regime	88.38 (87.24, 89.52)
Improving old regime	1.22 (-0.16, 2.59)
Not improving new regime	-1.41 (-2.81, -0.006)
Improving new regime	0.03 (-1.33, 1.38)
Not improving no inspection	-1.13 (-2.79, 0.54)
Improving no inspection	2.15 (0.71, 3.59)
Pre-inspection slope	
Not improving old regime	-0.01 (-0.02, -0.004)
Improving old regime	0.03 (0.02, 0.04)
Not improving new regime	-0.005 (-0.01, 0.004)
Improving new regime	0.03 (0.03, 0.04)
Not improving no inspection	-0.001 (-0.01, 0.01)
Improving no inspection	0.03 (0.02, 0.04)
Post-inspection change	
Not improving old regime	0.49 (-0.77, 1.75)
Improving old regime	-0.93 (-2.47, 0.61)
Not improving new regime	0.13 (-1.37, 1.63)
Improving new regime	-1.16 (-2.61, 0.29)
Not improving no inspection	-1.59 (-3.53, 0.34)
Improving no inspection	-0.47 (-2.11, 1.18)
Post-inspection slope	
Not improving old regime	0.08 (0.003, 0.16)
Improving old regime	-0.02 (-0.12, 0.07)
Not improving new regime	0.07 (-0.03, 0.16)
Improving new regime	-0.04 (-0.11, 0.04)
Not improving no inspection	0.11 (-0.004, 0.23)
Improving no inspection	-0.16 (-0.27, -0.05)

8.5 Staff leaving acute NHS Trusts

Table 8.12 Characteristics of Trusts classified as improving and not improving for rates of staff leaving NHS Trusts

	Not improving n=99	Improving n=52	p-value
Foundation Trust	58 (59%)	38 (73%)	0.079
Type of trust			
Large acute trust	26 (26%)	14 (27%)	0.20
Medium acute trust	23 (23%)	21 (40%)	
Small acute trust	19 (19%)	6 (12%)	
Acute teaching trust	18 (18%)	7 (13%)	
Acute specialist trust	13 (13%)	4 (8%)	
NHS England region			
North	38 (38%)	12 (23%)	0.029
Midlands and East	29 (29%)	15 (29%)	
South	16 (16%)	19 (37%)	
London	16 (16%)	6 (12%)	
Beds, median (IQR)	683 (417, 980)	719.5 (537, 1035.5)	0.38
Population in thousands, median (IQR)	453.3 (320, 600)	455 (380, 612)	0.36
Special measures	10 (10%)	9 (17%)	0.20
Type of inspection			
New regime	40 (54%)	25 (66%)	0.23
No inspected	25 (25%)	14 (27%)	0.82
Overall rating			
Outstanding	6 (6%)	3 (6%)	0.80
Good	24 (25%)	16 (31%)	
Requires improvement	59 (61%)	28 (54%)	
Inadequate	7 (7%)	5 (10%)	
Merged Trusts	6 (6%)	6 (12%)	0.24
Monitor Sustainability rating			
Significant risk	4 (7%)	4 (11%)	0.34
Material risk	5 (9%)	5 (13%)	
Emerging or minor concerns	30 (53%)	22 (58%)	
No evident concerns	17 (30%)	5 (13%)	
Lowest risk	1 (2%)	2 (5%)	
Monitor Governance rating			
Subject to enforcement action	10 (19%)	9 (24%)	0.38
Under review	7 (13%)	3 (8%)	
No evident concerns	37 (69%)	26 (68%)	
TDA escalating score			
Enforcement action	5 (13%)	1 (8%)	0.46
Significant delivery issues	16 (40%)	5 (38%)	
Some delivery issues	9 (23%)	6 (46%)	
Limited/no issues	9 (23%)	1 (8%)	
Sound FT application	1 (3%)	0 (0%)	
Number of inspections, median (IQR)	4 (3, 5)	4 (3, 5)	0.78
Months since previous inspection, median (IQR)	10 (7, 18)	12 (8, 16)	0.75
Reporting culture 2016			
Poor	15 (15%)	10 (19%)	0.344
Significant Concerns	35 (35%)	17 (33%)	
Good	40 (41%)	24 (46%)	
Outstanding	9 (9%)	1 (2%)	
Rate of staff leaving NHS Trusts, median (IQR)	0.02 (0.01, 0.02)	0.02 (0.02, 0.02)	0.068

Table 8.13 Unadjusted model coefficients for rates of staff leaving NHS Trusts accounting by previous performance

	Unadjusted rate of staff leaving NHS Trusts (95% CI) Obs=7,089 Trusts=151
Intercept	
Not improving old regime	0.021 (0.019, 0.022)
Improving old regime	0.81 (0.71, 0.92)
Not improving new regime	1.01 (0.92, 1.1)
Improving new regime	0.89 (0.8, 0.99)
Not improving no inspection	0.97 (0.87, 1.08)
Improving no inspection	0.86 (0.76, 0.98)
Pre-inspection slope	
Not improving old regime	1.005 (1.001, 1.009)
Improving old regime	0.99 (0.98, 0.99)
Not improving new regime	0.99 (0.99, 1.004)
Improving new regime	0.99 (0.99, 0.99)
Not improving no inspection	1.002 (0.99, 1.01)
Improving no inspection	0.99 (0.98, 0.99)
Announcement change	
Not improving old regime	0.93 (0.84, 1.03)
Improving old regime	1.25 (1.03, 1.51)
Not improving new regime	1.05 (0.92, 1.2)
Improving new regime	0.98 (0.84, 1.14)
Not improving no inspection	1.03 (0.88, 1.2)
Improving no inspection	1.26 (1.05, 1.52)
Announcement slope	
Not improving old regime	1.01 (0.98, 1.04)
Improving old regime	0.96 (0.9, 1.03)
Not improving new regime	0.99 (0.95, 1.04)
Improving new regime	1.05 (0.99, 1.11)
Not improving no inspection	0.97 (0.92, 1.02)
Improving no inspection	0.96 (0.9, 1.02)
Post-inspection change	
Not improving old regime	1.08 (1.004, 1.15)
Improving old regime	1.06 (0.93, 1.21)
Not improving new regime	0.94 (0.86, 1.03)
Improving new regime	0.93 (0.83, 1.03)
Not improving no inspection	1.06 (0.95, 1.18)
Improving no inspection	1.12 (0.98, 1.27)
Post-inspection slope	
Not improving old regime	0.98 (0.95, 1.02)
Improving old regime	1.05 (0.99, 1.12)

	Unadjusted rate of staff leaving NHS Trusts (95% CI) Obs=7,089 Trusts=151
Not improving new regime	1.01 (0.96, 1.06)
Improving new regime	0.96 (0.91, 1.01)
Not improving no inspection	1.03 (0.98, 1.08)
Improving no inspection	1.05 (0.99, 1.12)
Medical rotation	2.73 (2.63, 2.83)
Sine	1.03 (1.02, 1.04)
Cosine	0.93 (0.93, 0.94)
Sine*2	0.86 (0.85, 0.87)
Cosine*2	0.92 (0.91, 0.93)

Appendix Chapter 9

UNIVERSITY of York
The Department of Health Sciences

Information Sheet

Economic evaluation of Care Quality Commission inspections of NHS Acute Trusts in England.

What is the purpose of this study?
The Care Quality Commission (CQC) is an independent institution that inspects how healthcare providers are performing compared to a set of standards. These inspections are intended to improve quality of care provided and ultimately, the health of the population. Our certainty about the effect of these inspection on health outcomes is very limited, since there is no formal and rigorous assessment. Moreover, it remains unknown whether this intervention is a good value for money.
The main objective of this research project is to determine the effect and costs associated to CQC external inspections of NHS acute trusts in England, measuring the effect on several organisational and clinical outcomes. The purpose of this research is to provide with robust evidence to inform future policy-making, in order to ensure efficient use of scarce resources.

Who is doing the study?
This study is being performed by Ana Cristina Castro, Department of Health Sciences, University of York, as part of her PhD thesis. The supervisors are Prof Karen Bloor, University of York, and Prof Carl Thompson, University of Leeds.

Why have I been asked to participate?
We have selected four Acute NHS Trusts to include one Trust from the four regions in England and reflect the reality of different sizes/categories of Trusts.

What will be involved if I take part in this study?
You will receive a costs audit tool in advance, so you can review it and be aware of the data that will be requested. A meeting will be arranged at a time/date of your convenience, where you will complete the audit tool with the assistance of the main researcher. This process will be recorded to obtain more details and to be analysed later. Filling out the cost audit tool will take about 2 hours of your time and will be performed at your work place. Your participation does not pose any risk for you.

What are the advantages/benefits and disadvantages/risks of taking part?
The information collected will be useful to inform future policy-making that could benefit you in the long term.

Will the information I give be kept confidential?
Identity of the Trust will be protected by using an identification code. Data will be kept in a password protected computer at the University of York and only the research team will have access to it. Your name will not be disclosed under any circumstances. If the database is requested during the publication phase, we will keep the identity of the Trust anonymous. The data handling procedures are in accordance with the Data Protection Act 1998.

What will happen to the results of the study?
Results will be disseminated in conference presentations and through academic peer-reviewed publications. You will receive a report with the results for your Trust and a comparison with the results of the other three Trusts involved in this study. If you want to present this results to staff within your institution, this will be possible upon request.

Who has reviewed this study?
This study has been approved by the research ethics committee at the University of York.

Who do I contact in the event of a complaint?
Prof Karen Bloor
Email address: Karen.bloor@york.ac.uk
Phone number: 01904 321369

If you agree to take part, would like more information or have any questions or concerns about the study please contact Ana Cristina Castro, PhD Student, in the Research Centre in Social Sciences, 6 innovation close, Heslington, YO10 5ZF. Email: acc540@york.ac.uk.

Thank you for taking the time to read this information sheet.

Date: September 27th 2016 Version: 2.0

Figure 9.1 Information sheet for finance or quality governance directors

Table 9.1 Detailed costing of work carried out by the medium size acute trusts before, during and after the CQC inspection

Type of cost	Activities to be costed	number of times	number of hours	number of people	Average payment band	Agenda for Change 2014/15	Unit costs for health and social care 2015
Trust approach (before inspection)	Workshops with board members	1	1.5	15+1	15 directors+8D	£1,415.09	£1,417.07
	Review of clinical standards and self-assessment by clinical teams to identify areas of improvement	2	7.5	120	8A	£40,032.00	£41,760.00
	Engagement and communication briefings with all staff.	4	1	100	5	£5,000.00	£5,228.31
	Drawing up briefing material for staff	1	15	2	8D+8B	£951.20	£1,001.48
	Attending pre-inspection briefings given by each division	12	1	10	8B	£3,130.20	£3,336.37
	External consultancy fees					£6,000.00	£6,000.00
	Update of all policies organisational wide	8	37.5	1	7	£5,453.00	£5,897.23
	Environment (e.g. deep cleaning, painting)					£14,500.00	£14,500.00
	Quality of care (i.e. directorates were asked to review serious incidents reports and check recommendations were implemented. Knowing the profile of reported incidents)	1	37.5	1	7	£681.63	£740.87
	Quality of care (i.e. Organisational risk registers: consistency)	2	37.5	2	8C+8B	£4,296.50	£4,544.42
Mandatory (before inspection)	Reply to inspection report due to factual inaccuracy	1	4	9	Executive directors	£3,669.23	£3,669.23
	Collecting data in response to CQC's first data request to provider	12	4	1	8B	£1,252.08	£1,315.59
	Drawing up a report in response to CQC's first data request to provider	3	37.5	2	8D+8B	£7,134.00	£7,511.08

Type of cost	Activities to be costed	number of times	number of hours	number of people	Average payment band	Agenda for Change 2014/15	Unit costs for health and social care 2015
Mandatory (before inspection)	Collecting and drawing up a report in response to CQC's second data request to provider	1	37.5	2	8D+8B	£2,378.00	£2,503.69
	Review and reply to pre-inspection data pack for factual inaccuracies	1	37.5	1	8B	£978.19	£1,027.81
During inspection	Organising meetings between inspection teams and management, staff and/or board	1	2.5	3	Clinical director+ matron + divisional manager	£234.01	£247.80
	Introduction to the organisation (day 0)	2	7.5	3	Chief executive+ medical director+ director of nursing	£4,288.46	£4,288.46
	Focus groups and interviews	1	29	79	8C	£3,471.17	£3,471.17
	Command room	4	13	3	8D+8B+7	£3,802.11	£5,022.10
	Extra data requests on-site	4	4	1	8B	£4,242.68	£4,456.40
	ID badges for inspectors					£417.36	£438.53
After inspection	Quality summit	1	4	10	Executive directors+ chair	£75.00	£75.00
	Action plan to improve deficient aspects of care after inspection	2	37.5	2	8D+8B	£4,756.00	£5,007.38
	Engaging meetings	3	1.5	5	2 directors+ deputy director of operations + Trust secretary + assistant director of governance	£1,198.90	£1,219.93
	Implementation of changes after verbal feedback given by CQC					£40,200.00	£40,200.00
CQC fee	CQC's annual subscription fee					£198,000.00	£198,000.00
Total						£357,556.80	£362,879.93

Table 9.2 Detailed costing of work carried out by the small size acute trusts before, during and after the CQC inspection

Type of cost	Activities to be costed	number of times	number of hours		number of people		average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
Trust approach (before inspection)	Workshops with trust board members	4	2	3	8	10	7	-	£3,935.10	£5,149.44	£3,940.85	£5,158.07
	Workshops with non-executive directors	2	2	3	8	10	7	-	£1,324.20	£2,793.99	£1,327.07	£2,798.30
	Workshops with senior management (divisional managers)	3	2	3	8	15	8A	8D	£1,067.52	£5,038.88	£1,134.65	£5,476.78
	Self-assessment by clinical teams to identify areas of improvement	16	1	1.5	4	5	8A	8D	£1,423.36	£4,479.00	£1,512.86	£4,868.25
	Meetings of director of nursing (or equivalent) with working groups	50	2	-	4	10	3*band 6 + band 8C	9*band 8A + band 8C	£7,760.33	£23,145.33	£8,187.44	£24,110.21
	Review of clinical standards: meetings of the lead of working group with the team	50	1	2	5	10	band 2 + 3*band 4 + band 8B	band 2 + 2*band 5 + 2*band 6+ 2*band7 + 2*band 8A + band 8B	£3,321.31	£17,196.73	£3,450.33	£18,051.69
	Engagement briefings with all staff.	29	0.5	1	10	20	1	7	£1,889.65	£11,547.82	£1,913.87	£12,220.57
	Teaching afternoon with medical staff	1	1	-	20	50	10 junior Drs + 10 consultants	25 junior Drs + 25 consultants	£679.63	£1,504.84	£1,519.49	£3,604.49
	Drawing up booklets for general staff	1	4	8	1	-	8A	-	£88.96	£177.92	£92.73	£185.45
	Attending pre-inspection briefings given by each division	2	1	1.5	40	50	5	10*band 6 + 15*band 7 + 15*band 8A + 10*band 8B	£1,009.90	£3,079.70	£1,051.16	£3,239.31
	External consultancy fees (i.e. Capstick and KPMG)								£29,504.00	£29,504.00	£29,504.00	£29,504.00

Type of cost	Activities to be costed	number of times	number of hours		number of people		average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
Trust approach (before inspection)	Update of all policies organisational wide								£0.00	£0.00	£0.00	£0.00
	Environment (e.g. deep cleaning, painting)								£0.00	£0.00	£0.00	£0.00
	Quality of care (e.g. review of serious incidents reports)								£0.00	£0.00	£0.00	£0.00
Mandatory (before inspection)	Reply to inspection report due to factual inaccuracy	1	33	37.5	7		COO+ band 6 + 5 divisional managers (8A)	COO+ band 6 + 5 divisional managers (8D)	£5,913.63	£9,548.47	£6,178.43	£10,195.37
	Collecting and drawing up a report in response to CQC's first data request to provider	1	7.5	15	7		8	Executive team	£3,294.93	£6,589.85	£3,300.32	£6,600.64
	Approval session for first data request	2 to 3	1		4		COO + band 6+ secretary + director comm (8B)		£225.38	£338.07	£231.52	£354.83
	Collecting and drawing up a report in response to CQC's second data request to provider	1	10	12.5	12		COO+ 5 divisional managers (8A)+ trust secretary+ clin qual (6)+ assoc dir (8A)+ HR+Info team (2*6)	COO+ 5 divisional managers (8D)+ trust secretary+ clin qual (6)+ assoc dir (8A)+ HR+ Info team (2*6)	£3,134.79	£4,861.30	£3,252.28	£5,123.49
	Approval session for second data request	4 to 5	1		4		Director operations + secretary + director comm (8B) + clin qual (6)		£450.75	£563.44	£463.04	£578.80
	Review and reply to pre-inspection data pack for factual inaccuracies	1	3	3.5	7		CEO+5 exec directors+ trust secretary		£1,317.97	£1,537.63	£1,320.13	£1,540.15

Type of cost	Activities to be costed	number of times	number of hours		number of people		average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
During inspection	Organising meetings between inspection teams and management, staff and/or board	2	4	7.5	1		4		£84.66	£158.74	£83.69	£156.92
	Introduction to the organisation (day 0)	1	2	2.5	6		CEO + executives		£841.96	£1,052.45	£841.96	£1,052.45
	Preparation of presentation for day 0	1	4	7.5	1		CEO		£517.95	£971.15	£517.95	£971.15
	Focus groups and interviews	9	1	1.5	5	12	5	7	£2,358.74	£3,144.99	£2,358.74	£3,144.99
	Command room	3	7	7.5	2		8A	8C	£1,860.47	£4,891.58	£1,946.45	£5,204.05
	Extra data requests on-site	3	7	7.5	1		6		£1,124.20	£1,204.50	£1,168.64	£1,252.12
	Daily briefings with chief of inspection	2	0.3	0.5	15	20	Executive team + 9*band 6	Board members + 5*band6	£324.17	£347.33	£345.84	£370.55
	ID badges for inspectors								£335.95	£527.32	£340.64	£530.49
	Hiring of venues for listening events, meetings with staff and/or quality summit		36				120 per 4 hours		£108.05	£108.05	£108.05	£108.05
After inspection	Quality summit	1	3	4	14		CEO+ all board members+ Dorset council+ CCG+ hospice		£1,080.00	£1,080.00	£1,080.00	£1,080.00
	Action plan to improve deficient aspects of care after inspection (initial set-up)	4	1.5	2	30	40	COO+ director of nursing+ 10*band 6 + 10*band 7 + 8*band 8A	COO+ director of nursing+ 5*band 6 + 10*band 7 + 10*band 8A + 8*band 8B + 5*band 8C	£3,633.72	£7,521.04	£3,832.71	£7,891.63

Type of cost	Activities to be costed	number of times	number of hours		number of people		average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
After inspection	Action plan to improve deficient aspects of care after inspection (long term follow-up)	3	1.5	2	6	10	Director of nursing+ 2*band 6+ band 7+ band 8A	Director of nursing+ 2*band 6+ band 7+ band 8A+ 2*band 8B+ band 8C	£726.06	£1,659.72	£750.79	£1,722.63
	Responding to data requests after the inspection	22	30	37.5	1		6		£10,188.20	£12,735.25	£10,869.35	£13,586.69
	Implementation of quality improvement initiatives in response to action plan agreed during quality summit.	6	1	1.5	5	10	COO or CEO + band 4+ 3*band 7	COO or CEO + band 4 + 3*band 7+ 2*band 8A+ 3*band 8B	£1,957.31	£6,144.45	£2,033.28	£7,487.85
	Implementation of changes after verbal feedback given by CQC								£0.00	£0.00	£0.00	£0.00
CQC fee	CQC's annual subscription fee								£78,208.00	£78,208.00	£78,208.00	£78,208.00
Total									£169,690.85	£246,810.98	£172,866.26	£256,377.96

Table 9.3 Detailed costing of work carried out by the large teaching acute trusts before, during and after the CQC inspection

Type of cost	Activities to be costed	Number of times	Number of hours		Number of people		Average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
Trust approach (before inspection)	Workshops with trust board members	4	1	1.25	15	18	Executives+4*NED + 5*8D (clinical division managers)	Executives+5*NED+ 7*8D (clinical division managers)	£3,786.84	£5,532.89	£3,851.72	£5,380.59
	Review of clinical standards and self-assessment by clinical teams to identify areas of improvement	64	1	1.25	10	13	7*band 5 + 3*band 8D	9*band 5 + 4*band 8D	£12,821.84	£21,033.10	£13,146.58	£21,592.08
	Meetings of director of nursing (or equivalent) with working groups	10	1	1.25	9	12	2*band 8C + 7*band 8D	3*band 8C + 9*band 8D	£3,238.62	£5,372.56	£3,507.37	£5,815.65
	Meetings of each working group to coordinate implementation of remedial changes pre-inspection	15	1	1.25	3	5	1*band 2 + 2*band 7	2*band 2 +3*band 7	£675.35	£1,344.41	£715.78	£1,422.41
	Engagement and communication briefings with all staff.	6	4	4	20	30	2*band 1 to 7 +1*band 8A to 8C +3*band 9	3*band 1 to 7 + 2*band 8A -8B + 1* band 8C + 4*band 9	£9,104.38	£13,325.01	£9,529.37	£13,943.35
	Reviewing and approving documentation to be sent before the inspection.	64	2	3	6	8	3*band 7 + 3*band 8D	4*band 7 + 4*band 8D	£21,377.07	£42,754.13	£23,216.25	£46,432.49
	Attending pre-inspection briefings given by each division	10	1	1.25	20	30	2*band 1 - 2 +3*band 3 to 6 +2*band 7 -8A	3*band 1 - 2 + 4* band 3 - 4 + 5*band 5 +4*band 6 -7 + 3*band 8A	£2,570.80	£4,908.06	£2,679.73	£5,121.57
	External consultancy fees (i.e. project management support)	1	247		1		£101.54		£25,080.00	£25,080.00	£25,080.00	£25,080.00
	Environment (e.g. deep cleaning, painting)								£125,000.00	£125,000.00	£125,000.00	£125,000.00

Type of cost	Activities to be costed	Number of times	Number of hours		Number of people		Average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
Mandatory (before inspection)	Reply to inspection report due to factual inaccuracy	10	1	1.25	5	8	2*band 7 + 3*band 8D	3*band 7 + 5*band 8D	£1,486.64	£3,020.73	£1,614.87	£3,281.43
	Collecting and drawing up a report in response to CQC's first data request to provider	8	1	1.25	15	17	10*band 8A + 5*band 8D	12*band 8A + 5*band 8D	£3,272.20	£4,535.05	£3,513.83	£4,865.05
	Collecting and drawing up a report in response to CQC's second data request to provider	3	1	1.25	15	17	10*band 7 + 5*band 8D	12*band 7 + 5*band 8D	£1,110.21	£1,525.34	£1,205.24	£1,655.73
	Review and reply to pre-inspection data pack for factual inaccuracies	8	1	1.25	11	11	6*band 7 + 5*band 8D	6*band 7 + 5*band 8D	£2,373.53	£2,966.92	£2,577.48	£3,221.85
During inspection	Organising meetings between inspection teams and management, staff and/or board	36	1	1	2	2	band 8A + 8D	band 8A + 8D	£2,144.34	£2,144.34	£2,216.55	£2,216.55
	Drawing up welcome packs for inspectors	2	6	10	2	2	band 4 + 8D	band 4 + 8D	£574.89	£958.16	£586.20	£977.01
	Focus groups and interviews	19	1	1.25	209	388	band 3	band 8B	£3,832.84	£8,178.45	£7,257.90	£17,170.07
	ID badges for inspectors								£100.00	£100.00	£100.00	£100.00
	Hiring of venues for listening events, meetings with staff and/or quality summit								£0.00	£0.00	£0.00	£0.00

Type of cost	Activities to be costed	Number of times	Number of hours		Number of people		Average payment band		Agenda for Change 2015/16		Unit costs for health and social care 2016	
			low	high	low	high	low	high	lowest	highest	lowest	highest
After inspection	Action plan to improve deficient aspects of care after inspection	8	1	1.25	4	5	3* band 8A + 1*band 9	1* band 8A + 4*band 9	£1,116.40	£1,615.36	£960.65	£2,203.03
	Implementation of quality improvement initiatives in response to action plan agreed during quality summit.	4	1	1.25	2	2	8A+8D	8A+8D	£238.26	£297.83	£256.83	£321.04
	Implementation of changes after verbal feedback given by CQC								£0.00	£0.00	£0.00	£0.00
	Organising quality summit	1	7	14	2	2	band 4 + 8D	band 4 + 8D	£335.36	£670.71	£341.95	£683.90
	Quality summit	1	3	4	11	11	Executives +5*NED	Executives +5*NED	£2,376.41	£3,168.55	£2,376.41	£3,168.55
CQC fee	CQC's annual subscription fee								£128,484.00	£128,484.00	£128,484.00	£128,484.00
Total									£351,099.98	£402,015.59	£358,218.71	£418,136.35

Appendix Chapter 10

Table 10.1 Summary of evidence of interventions effective to improve the seven measures selected and factors associated with success of interventions

	Interventions with evidence of improving measure	Quality of evidence	Time to effect	Factors associated with success
Falls with harm	Multifactorial assessment and intervention (NICE, 2013)	Clinical trials in sub-acute settings (Haines et al., 2004, Healey et al., 2004, Stenvall et al., 2007)	After 45 days in hospital (Haines et al., 2004)	Staffing levels (Griffiths et al., 2014, Griffiths et al., 2016, Aiken et al., 2016) Reduction of safety incidents (Aiken et al., 2002, Griffiths et al., 2014, Robb et al., 2010, Shekelle et al., 2013)
Pressure ulcers	Multicomponent intervention: risk factors and skin assessment, evaluation of nutritional and hydration needs, high-specification mattresses, and repositioning (NICE, 2014)	Large number of low quality studies with inconsistent results (Gillespie et al., 2014, McInnes et al., 2015, NICE, 2014)	Not clear. RCTs assessed individual components. Quality improvement studies suggest between three months (Courtney et al., 2006) and one-year after implementation (McInerney, 2008, Morehead and Blain, 2014, Cano et al., 2015, Sullivan and Schoelles, 2013).	Staffing levels (Griffiths et al., 2014, Griffiths et al., 2016, Aiken et al., 2016, Cano et al., 2015) Reduction of safety incidents (Aiken et al., 2002, Griffiths et al., 2014, Robb et al., 2010, Shekelle et al., 2013)

	Interventions with evidence of improving measure	Quality of evidence	Time to effect	Factors associated with success
Risk-adjusted mortality	Specific interventions: -nurse-led early discharge planning programmes, -rapid response teams to reduce cardiopulmonary arrest, -use of antibiotic guidelines for pneumonia, -implementation of sepsis bundles, -interdisciplinary teamwork interventions, -increasing the proportion of support staff (Zegers et al., 2016) Multifactorial hospital-wide approaches: -Identification of high-mortality diagnoses. -Selection of interventions based on deficient aspects of care. -Involvement of frontline staff and consultants. -Training staff to improve care. -Establishing accessible monitoring systems. (Wright et al., 2006, Robb et al., 2010)	Consistent positive effect in meta-analyses of RCTs (Zegers et al., 2016) Single trust quality improvement projects	One year (Robb et al., 2010) to three years post-intervention (Wright et al., 2016)	Staffing levels (Griffiths et al., 2014, Griffiths et al., 2016, Aiken et al., 2016) Reduction of safety incidents (Aiken et al., 2002, Griffiths et al., 2014, Robb et al., 2010, Shekelle et al., 2013) Early warning systems (Zegers et al., 2016, Robb et al., 2010. Shekelle et al., 2013) Communication between and within teams (Zegers et al., 2016) Distributed and designated leadership (NHS England, 2015) Prevention of hospital-acquired infections (Zegers et al., 2016, Wright et al., 2006, Robb et al., 2010, Shekelle et al., 2013)

	Interventions with evidence of improving measure	Quality of evidence	Time to effect	Factors associated with success
A&E waiting times	Fast-track approaches (e.g. see and treat) (CRD, 2015) Team triage approaches Strategies used to meet the 4-hour target: -Increasing hours of staff (i.e. senior doctors, non-clinical staff, junior doctors and nurses), -Having a person in charge of monitoring the 4-hour target, -Improving access to emergency beds, and -Triage by senior staff (Munro et al., 2006)	Moderately strong evidence (Oredsson et al., 2011) Limited evidence (Oredsson et al., 2011) Cross-sectional survey (Munro et al., 2006)	One month of implementation of 'see and treat' (Rogers et al., 2004) or a combination of strategies (Munro et al., 2006)	Staff skills mix (NHS England, 2015) Prevention of hospital use (NHS England, 2015, Oredsson et al., 2011, CRD, 2015) Management of flow and demand, coordination with social and primary care (NHS England, 2015)
RTT waiting times	-Improving the use of existing capacity (e.g. performing more day surgeries, addressing bottlenecks in care pathways, pooling waiting lists) -Strategies for restructuring intake/referral processes (e.g. direct booking systems and generic waiting lists)	Low quality evidence (Kreindler et al., 2010) Low quality evidence (Ballini et al., 2015) due to high heterogeneity of interventions used, outcomes measured, and study designs	Observed effects from six to 10 months (Lukman et al., 2004, McKessock et al., 2001)	Consideration of the functioning of the whole care system, engaging doctors, analysing available data, investment in long-term increases in capacity, and involving the entire organisation in reducing waiting times (Appleby et al., 2005) Management of flow and demand (Appleby et al., 2005, NHS Improvement, 2017) Coordination with social and primary care (NHS Improvement, 2017)

	Interventions with evidence of improving measure	Quality of evidence	Time to effect	Factors associated with success
Rate of leavers	-Strategies to achieve better teamwork (DiMeglio et al., 2005), -Improvement of leadership practices (Gagnon et al., 2006, Cowden et al., 2011), -Mentorship or preceptorship programmes (Chen and Lou, 2014), -Multicomponent orientation programmes (Salt et al., 2008).	Large number of low quality studies, focused on nurses, with inconsistent results (Lartey et al., 2014, Drennan et al., 2015, Halter et al., 2017)	Effect between three (DiMeglio et al., 2005, Chen and Lou, 2014) and six months (Salt et al., 2008)	Staff skills mix (Aiken et al., 2008) Communication between and within teams (Shader et al., 2001, Estryn-Behar et al., 2010, DiMeglio et al., 2005) Supervision and support (Hellman, 1997, Coomber and Barriball, 2007, Cowden et al., 2011, Gagnon et al., 2006, Chen and Lou, 2014) Working environment (Shader et al., 2006) Workload (Coomber and Barriball, 2007, Yin and Yang, 2002, Aiken et al., 2002) Distributed and designated leadership (NHS England, 2015)
Patient's perception of care	-Building new facilities, -Training of physicians on communication skills, -Standardisation of pain management protocols -Dog therapy (Davidson et al., 2017) Systemic changes of the working environment (NHS Confederation, 2011, The Point of Care Foundation, NICE, 2012). - Learning what the patients' needs are, -Adapting care to each patient, -Recognising other care needs (e.g. emotional support), -Ensuring continuity of care, -Engaging patients in decision-making	Evidence is scarce, low quality, and heterogeneous regarding interventions, conditions and outcomes measured. Qualitative synthesis	No information about time to effect. Given the scale of the suggested changes, improvements would be evident after three months	Staff skill mix (Aiken et al., 2016) Working environment (NHS Confederation, 2011, The Point of Care Foundation, NICE, 2012)

Abbreviations

NHS: National Health Service

CQC: Care Quality Commission

CHI: Commission for Healthcare Improvement

CHAI: Commission for Healthcare Audit and Inspection

A&E: Accident and Emergency department

IOM: Institute of Medicine

WHO: World Health Organisation

OECD: Organisation for Economic Cooperation and Development

JCAHO: Joint Commission on Accreditation of Healthcare Organisations

SHMI: Summary Hospital Mortality Index

HSMR: Hospital Standardised Mortality Ratio

CQUIN: Commissioning for Quality and Innovation

PROMs: Patient Reported Outcome Measures

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

COHSASA: Council for Health Service Accreditation of Southern Africa

GRADE system: Grading of Recommendations Assessment, Development and Evaluation

JCI: Joint Commission International

AMI: Acute Myocardial Infarction

HF: Heart Failure

MRSA: Methicillin Resistant Staphylococcus Aureus

ITS: Interrupted Time-Series

RCT: Randomised Controlled Trial

CBA: Controlled Before and After

NRLS: National Reporting and Learning System

A&E: Accident and Emergency

RTT: Referral to treatment

IMD: Index of Multiple Deprivation

ST: Safety Thermometer

COO: Chief Operating Officer

CEO: Chief Executive Officer

HSCIC: Health and Social Care Information Centre

PLACE: Patient-Led Assessments of the Care Environment

SUS: Secondary Uses Service

HES: Hospital Episode Statistics

References

1962. Report Of Medical Services Review Committee: Summary Of Conclusions And Recommendations. *The British Medical Journal,* 2**,** 1178-1186.

1975. Report Of Council On The Merrison Report To A Special Meeting Of The Representative Body. *The British Medical Journal,* 2**,** 700-703.

ADIL, M. 2008. Risk-based regulatory system and its effective use in health and social care. *The Journal of the Royal Society for the Promotion of Health,* 128**,** 196-201.

AIKEN, L. H., CLARKE, S. P., SLOANE, D. M., LAKE, E. T. & CHENEY, T. 2008. Effects of hospital care environment on patient mortality and nurse outcomes. *J Nurs Adm,* 38**,** 223-9.

AIKEN, L. H., CLARKE, S. P., SLOANE, D. M., SOCHALSKI, J. & SILBER, J. H. 2002. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *JAMA,* 288**,** 1987-1993.

AIKEN, L. H., SLOANE, D., GRIFFITHS, P., RAFFERTY, A. M., BRUYNEEL, L., MCHUGH, M., MAIER, C. B., MORENO-CASBAS, T., BALL, J. E., AUSSERHOFER, D. & SERMEUS, W. 2016. Nursing skill mix in European hospitals: cross-sectional study of the association with mortality, patient ratings, and quality of care. *BMJ Quality & Safety*.

AKERLOF, G. A. & KRANTON, R. 2010. Identity economics. *The Economists' Voice,* 7.

AL TEHEWY, M., SALEM, B., HABIL, I. & EL OKDA, S. 2009. Evaluation of accreditation program in non-governmental organizations' health units in Egypt: short-term outcomes. *Int J Qual Health Care,* 21**,** 183-9.

ALKHENIZAN, A. & SHAW, C. 2011. Impact of Accreditation on the Quality of Healthcare Services: a Systematic Review of the Literature. *Annals of Saudi Medicine,* 31**,** 407-416.

ARROW, K. 1962. Economic welfare and the allocation of resources for invention. *The rate and direction of inventive activity: Economic and social factors.* Princeton University Press.

AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE. 2017. *National Health Performance Framework: Domain 3 - Health system performance. Safety* [Online]. Available: http://meteor.aihw.gov.au/content/index.phtml/itemId/392584 [Accessed].

BAILEY, C. S., GURR, K. R., BAILEY, S. I., TAYLOR, D., ROSAS-ARELLANO, M. P., TALLON, C., BUREAU, Y. & URQUHART, J. C. 2016. Does the wait for lumbar degenerative spinal stenosis surgery have a detrimental effect on patient outcomes? A prospective observational study. *CMAJ Open,* 4**,** E185-E193.

BARKER, K. N., FLYNN, E. A., PEPPER, G. A., BATES, D. W. & MIKEAL, R. L. 2002. Medication errors observed in 36 health care facilities. *Archives of Internal Medicine,* 162**,** 1897-1903.

BARNETT, A. G., VAN DER POLS, J. C. & DOBSON, A. J. 2005. Regression to the mean: what it is and how to deal with it. *International Journal of Epidemiology,* 34**,** 215-220.

BARTROFF, J. & SONG, J. 2014. Sequential Tests of Multiple Hypotheses Controlling Type I and II Familywise Error Rates. *Journal of statistical planning and inference,* 153**,** 100-114.

BARUA, B., ESMAIL, N. & JACKSON, T. 2014. The effect of wait times on mortality in Canada. Fraser Institute.

BEAUSSIER, A.-L., DEMERITT, D., GRIFFITHS, A. & ROTHSTEIN, H. 2015. Why Risk-based Regulation of Healthcare Quality in the NHS Cannot Succeed. *HowSAFE working paper 5.*

BEGG, D. K. H., VERNASCA, G., FISCHER, S. & DORNBUSCH, R. 2014. *Economics,* London, McGraw-Hill Education.

BENSON, L., BOYD, A. & WALSHE, K. 2004. *Learning from CHI: the impact of healthcare regulation*, Commission for Health Improvement London.

BERO, L. A., GRILLI, R., GRIMSHAW, J. M., HARVEY, E., OXMAN, A. D. & THOMSON, M. A. 1998. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. *BMJ,* 317**,** 465-468.

BERWICK , D. M. 1989. Continuous Improvement as an Ideal in Health Care. *New England Journal of Medicine,* 320**,** 53-56.
BERWICK, D. M. 2003. Disseminating innovations in health care. *JAMA,* 289**,** 1969-1975.
BERWICK, D. M., JAMES, B. & COYE, M. J. 2003. Connections between Quality Measurement and Improvement. *Medical Care,* 41**,** I30-I38.
BESLEY, T. J., BEVAN, G. & BURCHARDI, K. 2009. Naming & Shaming: The impacts of different regimes on hospital waiting times in England and Wales. Centre for Economic Policy Research.
BEST, A., GREENHALGH, T., LEWIS, S., SAUL, J. E., CARROLL, S. & BITZ, J. 2012. Large-System Transformation in Health Care: A Realist Review. *The Milbank Quarterly,* 90**,** 421-456.
BEVAN, G. 2009. The search for a proportionate care law by formula funding in the English NHS. *Financial Accountability & Management,* 25**,** 391-410.
BEVAN, G. 2010. Performance Measurement of "Knights" and "Knaves": Differences in Approaches and Impacts in British Countries after Devolution. *Journal of Comparative Policy Analysis: Research and Practice,* 12**,** 33-56.
BEVAN, G. 2011. Regulation and system management. *In:* MAYS, N., DIXON, A. & JONES, L. (eds.) *Understanding New Labour's market reforms of the English NHS.* King's Fund.
BEVAN, G. 2014. The impacts of asymmetric devolution on health care in the four countries of the UK. London: The Health Foundation and Nuffield Trust.
BEVAN, G. 2015. Incentives and models of governance. *Health Economics, Policy and Law,* 10**,** 345-350.
BEVAN, G. & CORNWELL, J. 2006. Structure and logic of regulation and governance of quality of health care: was OFSTED a model for the Commission for Health Improvement? *Health Economics, Policy and Law,* 1**,** 343-370.
BEVAN, G. & FASOLO, B. 2013. Models of governance of public services: empirical and behavioural analysis of 'econs' and 'humans'. *In:* ANGUS & OLIVER (eds.) *Behavioural public policy.* Cambridge, UK: Cambridge University Press.
BEVAN, G. & HOOD, C. 2006a. Have targets improved performance in the English NHS? *BMJ,* 332**,** 419-422.
BEVAN, G. & HOOD, C. 2006b. What's measured is what matters: targets and gaming in the English public health care system. *Public administration,* 84**,** 517-538.
BEVAN, G. & SKELLERN, M. 2011. Does competition between hospitals improve clinical quality? A review of evidence from two eras of competition in the English NHS. *BMJ,* 343.
BLOMQVIST, A. 1991. The doctor as double agent: information asymmetry, health insurance, and medical care. *J Health Econ,* 10**,** 411-32.
BLOOM, N., PROPPER, C., SEILER, S. & VAN REENEN, J. 2010. The Impact of Competition on Management Quality: Evidence from Public Hospitals. *CEP Discussion Paper,* 983.
BLUMER, H. 1986. *Symbolic Interactionism: Perspective and Method*, University of California Press.
BOGH, S. B., FALSTIE-JENSEN, A. M., BARTELS, P., HOLLNAGEL, E. & JOHNSEN, S. P. 2015. Accreditation and improvement in process quality of care: a nationwide study. *Int J Qual Health Care,* 27**,** 336-43.
BOGH, S. B., FALSTIE-JENSEN, A. M., HOLLNAGEL, E., HOLST, R., BRAITHWAITE, J. & JOHNSEN, S. P. 2016. Improvement in quality of hospital care during accreditation: A nationwide stepped-wedge study. *International Journal for Quality in Health Care,* 28**,** 715-720.
BOGH, S. B., FALSTIE-JENSEN, A. M., HOLLNAGEL, E., HOLST, R., BRAITHWAITE, J., RABEN, D. C. & JOHNSEN, S. P. 2017. Predictors of the effectiveness of accreditation on hospital performance: A nationwide steppedwedge study. *International Journal for Quality in Health Care,* 29**,** 477-483.
BOWLING, A., ROWE, G., LAMBERT, N., WADDINGTON, M., MAHTANI, K. R., KENTEN, C., HOWE, A. & FRANCIS, S. A. 2012. The measurement of patients' expectations for health care: a review and psychometric testing of a measure of patients' expectations. *Health Technol Assess,* 16**,** i-xii, 1-509.

BOX, G. & JENKINS, G. 1976. *Time series analysis: Forecasting and control,* San Francisco, Holden-Day.
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. European Health Policy Group, 2014 London. The King's Fund.
BOYD, A., ADDICOTT, R., ROBERTSON, R., ROSS, S. & WALSHE, K. 2017. Are inspectors' assessments reliable? Ratings of NHS acute hospital trust services in England. *Journal of Health Services Research & Policy,* 22**,** 28-36.
BOYD, J., GRAHAM, C. & POWELL, C. 2007. The key findings report for the 2005 inpatients survey. *In:* THE ACUTE CO-ORDINATION CENTRE FOR THE NHS ACUTE PATIENT SURVEY PROGRAMME (ed.). Oxford: Picker Institute Europe.
BRADFORD HILL, A. 1965. The Environment and Disease: Association or Causation? *Proceedings of the Royal Society of Medicine,* 58**,** 295-300.
BRAITHWAITE, J., CHURRUCA, K., ELLIS, L., LONG, J., CLAY-WILLIAMS, R., DAMEN, N., HERKES, J., POMARE, C. & LUDLOW, K. 2017a. Complexity Science in Healthcare – aspirations, approaches, applications and accomplishments: A white paper. Sydney, Australia: Australian Institute of Health Innovation, Macquarie University.
BRAITHWAITE, J., COGLIANESE, C. & LEVI-FAUR, D. 2007. Can regulation and governance make a difference? *Regulation & Governance,* 1**,** 1-7.
BRAITHWAITE, J., HIBBERT, P., BLAKELY, B., PLUMB, J., HANNAFORD, N., LONG, J. C. & MARKS, D. 2017b. Health system frameworks and performance indicators in eight countries: A comparative international analysis. *SAGE Open Med,* 5**,** 2050312116686516.
BRAYBROOKE, J., AHN, H., GALLANT, A., FORD, M., BRONSTEIN, Y., FINKELSTEIN, J. & YEE, A. 2007. The impact of surgical wait time on patient-based outcomes in posterior lumbar spinal surgery. *European Spine Journal,* 16**,** 1832-1839.
BRERETON, L. & VASOODAVEN, V. 2010. The impact of the NHS market: An overview of the literature. London: Civitas.
BROOK, R. H., MCGLYNN, E. A. & SHEKELLE, P. G. 2000. Defining and measuring quality of care: a perspective from US researchers. *Int J Qual Health Care,* 12**,** 281-95.
BROOM, A. & WILLIS, E. 2007. Competing paradigms and health research. *In:* SAKS, M. & ALLSOP, J. (eds.) *Researching health: qualitative, quantitative and mixed methods.* London: SAGE Publications Inc.
BRUBAKK, K., VIST, G. E., BUKHOLM, G., BARACH, P. & TJOMSLAND, O. 2015. A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. *BMC Health Serv Res,* 15**,** 280.
BUCHAN, I. E., KONTOPANTELIS, E., SPERRIN, M., CHANDOLA, T. & DORAN, T. 2017. North-South disparities in English mortality1965–2015: longitudinal population study. *Journal of Epidemiology and Community Health,* 71**,** 928-936.
BUCHANAN, D. A., FITZGERALD, L. & KETLEY, D. 2006. *The sustainability and spread of organizational change: Modernizing healthcare*, Routledge.
BUETOW, S. A. & ROLAND, M. 1999. Clinical governance: bridging the gap between managerial and clinical approaches to quality of care. *Quality in Health Care,* 8**,** 184-190.
BUKONDA, N., TAVROW, P., ABDALLAH, H., HOFFNER, K. & TEMBO, J. 2002. Implementing a national hospital accreditation program: the Zambian experience. *Int J Qual Health Care,* 14 Suppl 1**,** 7-16.
BUTLER, M., COLLINS, R., DRENNAN, J., HALLIGAN, P., O'MATHÚNA, D. P., SCHULTZ, T. J., SHERIDAN, A. & VILIS, E. 2011. Hospital nurse staffing models and patient and staff-related outcomes. *Cochrane Database of Systematic Reviews*.
CAMPBELL, M. J., JACQUES, R. M., FOTHERINGHAM, J., MAHESWARAN, R. & NICHOLL, J. 2012. Developing a summary hospital mortality index: retrospective analysis in English hospitals over five years. *BMJ,* 344.
CAMPBELL, S. M., ROLAND, M. O. & BUETOW, S. A. 2000. Defining quality of care. *Social Science & Medicine,* 51**,** 1611-1625.

CANADIAN INSTITUTE FOR HEALTH INFORMATION 2012. A Performance Measurement Framework for the Canadian Health System. Canada.
CANO, A., ANGLADE, D., STAMP, H., JOAQUIN, F., LOPEZ, J. A., LUPE, L., SCHMIDT, S. P. & YOUNG, D. L. 2015. Improving Outcomes by Implementing a Pressure Ulcer Prevention Program (PUPP): Going beyond the Basics. *Healthcare (Basel),* 3**,** 574-85.
CANTIELLO, J., KITSANTAS, P., MONCADA, S. & ABDUL, S. 2016. The evolution of quality improvement in healthcare: Patient-centered care and health information technology applications. *Journal of Hospital Administration,* 5**,** 62.
CARE QUALITY COMMISSION 2010a. Essential standards of quality and safety: guidance about compliance. London.
CARE QUALITY COMMISSION 2010b. Focused on better care: annual report and account 2009/10. London.
CARE QUALITY COMMISSION 2013a. Annual report and accounts 2012/13. London.
CARE QUALITY COMMISSION 2013b. A new start: Consultation on changes to the way CQC regulates, inspects and monitors care. *Care Quality Commission, Newcastle-upon-Tyne*.
CARE QUALITY COMMISSION 2014a. Annual report and accounts 2013/14. London.
CARE QUALITY COMMISSION. 2014b. *How we regulate services* [Online]. Available: http://webarchive.nationalarchives.gov.uk/20141203132318/http://www.cqc.org.uk/content/how-we-regulate-services [Accessed].
CARE QUALITY COMMISSION 2014c. NHS acute hospitals: Indicators and methodology. Guidance to support the July 2014 Intelligent Monitoring update.
CARE QUALITY COMMISSION 2015a. Enforcement policy. Newcastle: Care Quality Commission.
CARE QUALITY COMMISSION 2015b. Guidance for providers on meeting the regulations.
CARE QUALITY COMMISSION 2015c. How CQC regulates NHS and independent acute hospitals. Provider handbook. Newcastle upon Tyne: Care Quality Commission.
CARE QUALITY COMMISSION 2015d. Northamptonshire Healthcare NHS Foundation Trust - Quality report.
CARE QUALITY COMMISSION 2016a. 2015 Inpatient Survey: Quality and Methodology Report. *NHS Patient Survey Programme.* London: CQC.
CARE QUALITY COMMISSION 2016b. Annual report and accounts 2015/16. London.
CARE QUALITY COMMISSION 2016c. CQC launches consultation on its next phase of regulation. Newcastle Upon Tyne: CQC.
CARE QUALITY COMMISSION 2016d. CQC publishes findings from inspection of Bootham Park Hospital, York. Newcastle Upon Tyne: CQC.
CARE QUALITY COMMISSION 2017a. Annual report and accounts 2016/17. London.
CARE QUALITY COMMISSION. 2017b. *Coordinated care* [Online]. Available: http://www.cqc.org.uk/what-we-do/coordinated-care/coordinated-care [Accessed 21 December 2017].
CARE QUALITY COMMISSION 2017c. How CQC monitors, inspects and regulates NHS trusts Newcastle Upon Tyne: Care Quality Commission.
CARTER, E. J., POUCH, S. M. & LARSON, E. L. 2014. The Relationship Between Emergency Department Crowding and Patient Outcomes: A Systematic Review. *Journal of Nursing Scholarship,* 46**,** 106-115.
CARTER, N. 1991. Learning to measure performance: the use of indicators in organizations. *Public Administration,* 69**,** 85-101.
CASEY, M. M., MOSCOVICE, I. S. & DAVIDSON, G. 2006. Pharmacist staffing, technology use, and implementation of medication safety practices in rural hospitals. *J Rural Health,* 22**,** 321-30.
CHANDRA, A., GLICKMAN, S. W., OU, F. S., PEACOCK, W. F., MCCORD, J. K., CAIRNS, C. B., PETERSON, E. D., OHMAN, E. M., GIBLER, W. B. & ROE, M. T. 2009. An analysis of the Association of Society of Chest Pain Centers Accreditation to American College of Cardiology/American Heart Association non-ST-segment elevation myocardial infarction guideline adherence. *Ann Emerg Med,* 54**,** 17-25.

CHEN, C.-M. & LOU, M.-F. 2014. The effectiveness and application of mentorship programmes for recently registered nurses: a systematic review. *Journal of Nursing Management,* 22**,** 433-442.
CHEN, J., RATHORE, S. S., RADFORD, M. J. & KRUMHOLZ, H. M. 2003. JCAHO Accreditation And Quality Of Care For Acute Myocardial Infarction. *Health Affairs,* 22**,** 243-254.
CHERLIN, E. J., CURRY, L. A., THOMPSON, J. W., GREYSEN, S. R., SPATZ, E., KRUMHOLZ, H. M. & BRADLEY, E. H. 2013. Features of High Quality Discharge Planning for Patients Following Acute Myocardial Infarction. *Journal of General Internal Medicine,* 28**,** 436-443.
CHI 2004. What CHI has found in: acute services. London: Commission for Health Improvement.
CLARKE, J., GEWIRTZ, S. & MCLAUGHLIN, E. 2000. *New managerialism, new welfare?*, SAGE Publications Ltd.
CLINICAL INDICATORS TEAM 2017. Deaths associated with hospitalisation, England, January 2016 – December 2016: Background quality report. *Summary Hospital-level Mortality Indicator (SHMI)* NHS Digital.
CLWYD, A. & HART, T. 2013. A Review of the NHS Hospitals Complaints System Putting Patients Back in the Picture.
COCHRANE, A. L. 1972. *Effectiveness and efficiency: random reflections on health services,* London, Nuffield Provincial Hospitals Trust.
COCHRANE EFFECTIVE PRACTICE AND ORGANISATION OF CARE (EPOC) 2017. Synthesising results when it does not make sense to do a meta-analysis. *EPOC Resources for review authors*.
CONNER-SPADY, B., SANMARTIN, C., SANMUGASUNDERAM, S., DE COSTER, C., LORENZETTI, D., MCLAREN, L., MCGURRAN, J. & NOSEWORTHY, T. 2007. A systematic literature review of the evidence on benchmarks for cataract surgery waiting time. *Canadian Journal of Ophthalmology / Journal Canadien d'Ophtalmologie,* 42**,** 543-551.
COOK, T. D. & CAMPBELL, D. T. 1986. The Causal Assumptions of Quasi-Experimental Practice: The Origins of Quasi-Experimental Practice. *Synthese,* 68**,** 141-180.
COOK, T. D., SHADISH, W. R. & WONG, V. C. 2008. Three conditions under which experiments and observational studies produce comparable causal estimates: New findings from within-study comparisons. *Journal of Policy Analysis and Management,* 27**,** 724-750.
COOMBER, B. & BARRIBALL, L. K. 2007. Impact of job satisfaction components on intent to leave and turnover for hospital-based nurses: A review of the research literature. *International Journal of Nursing Studies,* 44**,** 297-314.
COOPER, Z., GIBBONS, S., JONES, S. & MCGUIRE, A. 2011. Does Hospital Competition Save Lives? Evidence From The English NHS Patient Choice Reforms. *The Economic Journal,* 121**,** F228-F260.
COWDEN, T., CUMMINGS, G. & PROFETTO-MCGRATH, J. 2011. Leadership practices and staff nurses' intent to stay: a systematic review. *Journal of Nursing Management,* 19**,** 461-477.
CRD 2015. Triage and minimising crowding in emergency departments. *Effectiveness Matters.* Centre for Reviews and Dissemination and the Yorkshire and Humber AHSN Improvement Academy.
CURRIE, V., HARVEY, G., WEST, E., MCKENNA, H. & KEENEY, S. 2005. Relationship between quality of care, staffing levels, skill mix and nurse autonomy: literature review. *Journal of Advanced Nursing,* 51**,** 73-82.
CURRY, L. A., SPATZ, E., CHERLIN, E., THOMPSON, J. W., BERG, D., TING, H. H., DECKER, C., KRUMHOLZ, H. M. & BRADLEY, E. H. 2011. What distinguishes top-performing hospitals in acute myocardial infarction mortality rates? A qualitative study. *Annals of Internal Medicine,* 154**,** 384-90.
CURTIS, L. & BURNS, A. 2015. *Unit costs of health and social care 2015, Personal Social Services Research Unit,* Canterbury, University of Kent.
CURTIS, L. & BURNS, A. 2016. *Unit costs of health and social care 2016, Personal Social Services Research Unit,* Canterbury, University of Kent.

DARZI, A. 2008. *High quality care for all: NHS next stage review final report*, The Stationery Office.
DAY, B. 2013. The Consequences of Waiting. *In:* GLOBERMAN, S. (ed.) *Reducing Wait Times for Health Care: What Canada Can Learn from Theory and International Experience.* Fraser Institute.
DAY, P. & KLEIN, R. 2004. The NHS improvers. *London: King's Fund*.
DESMEULES, F., DIONNE, C. E., BELZILE, É. L., BOURBONNAIS, R. & FRÉMONT, P. 2012. The impacts of pre-surgery wait for total knee replacement on pain, function and health-related quality of life six months after surgery. *Journal of Evaluation in Clinical Practice,* 18**,** 111-120.
DEVKARAN, S. & O'FARRELL, P. N. 2014. The impact of hospital accreditation on clinical documentation compliance: a life cycle explanation using interrupted time series analysis. *BMJ Open,* 4**,** e005240.
DEVKARAN, S. & O'FARRELL, P. N. 2015. The impact of hospital accreditation on quality measures: an interrupted time series analysis. *BMC Health Serv Res,* 15**,** 137.
DICKEY, D. A. & FULLER, W. A. 1979. Distribution of the Estimators for Autoregressive Time Series with a Unit Root. *Journal of the American Statistical Association,* 74**,** 427-431.
DICKIE, G. 1997. *Introduction to aesthetics: An analytic approach*, Oxford University Press.
DIEZ ROUX, A. 2002. A glossary for multilevel analysis. *Journal of Epidemiology and Community Health,* 56**,** 588-594.
DIMEGLIO, K., PADULA, C., PIATEK, C., KORBER, S., BARRETT, A., DUCHARME, M., LUCAS, S., PIERMONT, N., JOYAL, E., DENICOLA, V. & CORRY, K. 2005. Group cohesion and nurse satisfaction: examination of a team-building approach. *J Nurs Adm,* 35**,** 110-20.
DIMICK, J. B. & RYAN, A. M. 2014. Methods for evaluating changes in health care policy: The difference-in-differences approach. *JAMA,* 312**,** 2401-2402.
DIXON, J., HOLLAND, P. & MAYS, N. 1998. Primary care: core values Developing primary care: gatekeeping, commissioning, and managed care. *BMJ,* 317**,** 125-128.
DOH 2009. The Handbook to the NHS Constitution. London: Department of Health.
DOH 2010. Department of Health annual report and accounts 2009 to 2010. London: Department of Health.
DOH 2011. Department of Health annual report and accounts 2010 to 2011. London: Department of Health.
DOH 2012. Department of Health annual report and accounts 2011 to 2012. London: Department of Health.
DOH 2013. Department of Health annual report and accounts 2012 to 2013. London: Department of Health.
DOH 2014. Department of Health annual report and accounts 2013 to 2014. London: Department of Health.
DOH 2015a. Department of Health annual report and accounts 2014 to 2015. London: Department of Health.
DOH 2015b. The Handbook to the NHS Constitution. London: Department of Health.
DOH 2015c. Referral to treatment consultant-led waiting times: Rules Suite. London: Department of Health.
DOH 2016a. Department of Health annual report and accounts 2015 to 2016. London: Department of Health.
DOH 2016b. The NHS Outcomes Framework 2016/2017. *In:* DEPARTMENT OF HEALTH (ed.).
DOH 2017. Department of Health annual report and accounts 2016 to 2017. London: Department of Health.
DONABEDIAN, A. 1966. Evaluating the Quality of Medical Care. *The Milbank Memorial Fund Quarterly,* 44**,** 166-206.
DONABEDIAN, A. 1978. The quality of medical care. *Science,* 200**,** 856-864.
DONABEDIAN, A. 1980. *The Definition of Quality and Approaches to Its Assessment*, Health Administration Press.

DONABEDIAN, A. 2002. *An introduction to quality assurance in health care*, Oxford University Press.
DONALDSON, C. & GERARD, K. 1993. Market Failure in Health Care. *Economics of Health Care Financing: The Visible Hand.* London: Macmillan Education UK.
DOWLING, B. 1997. Effect of Fundholding on Waiting Times: Database Study. *BMJ: British Medical Journal,* 315**,** 290-292.
DR FOSTER 2015. Is 'special measures' working? London: Dr Foster.
DRUKKER, D. M. 2003. Testing for serial correlation in linear panel-data models. *Stata Journal,* 3**,** 168-177.
DUCKETT, S. J. 1983. Changing hospitals: the role of hospital accreditation. *Soc Sci Med,* 17**,** 1573-9.
DUSHEIKO, M., GRAVELLE, H. & JACOBS, R. 2004. The effect of practice budgets on patient waiting times: allowing for selection bias. *Health Economics,* 13**,** 941-958.
DUSHEIKO, M., GRAVELLE, H., JACOBS, R. & SMITH, P. 2006. The effect of financial incentives on gatekeeping doctors: Evidence from a natural experiment. *Journal of Health Economics,* 25**,** 449-478.
DUSHEIKO, M., GRAVELLE, H., YU, N. & CAMPBELL, S. 2007. The impact of budgets for gatekeeping physicians on patient satisfaction: Evidence from fundholding. *Journal of Health Economics,* 26**,** 742-762.
EISENHARDT, K. M. 1989. Agency Theory: An Assessment and Review. *The Academy of Management Review,* 14**,** 57-74.
ELECTRONIC STAFF RECORD PROGRAMME 2017. Data Warehouse.
ENTHOVEN, A. 1985. Reflections on the management of the national health service: An international perspective on the NHS. Nuffield Trust.
ESTRYN-BEHAR, M., VAN DER HEIJDEN, B. I. J. M., FRY, C. & HASSELHORN, H.-M. 2010. Longitudinal Analysis of Personal and Work-Related Factors Associated With Turnover Among Nurses. *Nursing Research,* 59**,** 166-177.
EVANS, D. B., EDEJER, T. T. T., LAUER, J., FRENK, J. & MURRAY, C. J. 2001. Measuring quality: from the system to the provider. *International Journal for Quality in Health Care,* 13**,** 439-446.
EVETTS, J. 2003. The Sociological Analysis of Professionalism: Occupational Change in the Modern World. *International Sociology,* 18**,** 395-415.
FALSTIE-JENSEN, A. M., LARSSON, H., HOLLNAGEL, E., NORGAARD, M., SVENDSEN, M. L. & JOHNSEN, S. P. 2015a. Compliance with hospital accreditation and patient mortality: a Danish nationwide population-based study. *Int J Qual Health Care,* 27**,** 165-74.
FALSTIE-JENSEN, A. M., NORGAARD, M., HOLLNAGEL, E., LARSSON, H. & JOHNSEN, S. P. 2015b. Is compliance with hospital accreditation associated with length of stay and acute readmission? A Danish nationwide population-based study. *Int J Qual Health Care,* 27**,** 451-8.
FLODGREN, G., GONÇALVES-BRADLEY, D. C. & POMEY, M. P. 2016. External inspection of compliance with standards for improved healthcare outcomes. *Cochrane Database of Systematic Reviews*.
FLODGREN, G., POMEY, M. P., TABER, S. A. & ECCLES, M. P. 2011. Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes. *Cochrane Database Syst Rev***,** CD008992.
FOURNIER, V. 1999. The Appeal to 'Professionalism' as a Disciplinary Mechanism. *The Sociological Review,* 47**,** 280-307.
FOY, R., OVRETVEIT, J., SHEKELLE, P. G., PRONOVOST, P. J., TAYLOR, S. L., DY, S., HEMPEL, S., MCDONALD, K. M., RUBENSTEIN, L. V. & WACHTER, R. M. 2011. The role of theory in research to develop and evaluate the implementation of patient safety practices. *BMJ Quality & Safety,* 20**,** 453-459.
FRANCIS, R. 2010. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 – March 2009 London: House of Commons.

FRANCIS, R. 2013. *Report of the Mid Staffordshire NHS Foundation Trust public inquiry: executive summary*, The Stationery Office.
FRANK, R. H. 1989. Beyond Self-Interest. *Challenge,* 32**,** 4-13.
FREIDSON, E. 2001. *Professionalism, the third logic: On the practice of knowledge*, University of Chicago press.
FREY, B. S. 1997. *Not just for the money: An Economic Theory of Personal Motivation,* Cheltenham-Brookfield, Edward Elgar Publishing Ltd.
GAGNON, S., RITCHIE, J., LYNCH, A., DROUIN, S., CASS, V., RINFRET, N., ROULEAU, C. & VALOIS, M. 2006. Job satisfaction and retention of nursing staff: The impact of nurse management leadership. *Canadian Health Services Research Foundation*.
GARCIA, S. M., TOR, A. & SCHIFF, T. M. 2013. The Psychology of Competition:A Social Comparison Perspective. *Perspectives on Psychological Science,* 8**,** 634-650.
GARVIN, D. A. 1984. What Does "Product Quality" Really Mean? *Sloan Management Review,* 26**,** 25.
GAUCI BORDA, R. & NORMAN, I. J. 1997. Factors influencing turnover and absence of nurses: a research review. *International Journal of Nursing Studies,* 34**,** 385-394.
GAYNOR, M. S., PROPPER, C. & MORENO-SERRA, R. 2011. Death by market power: reform, competition and patient outcomes in the National Health Service. *CMPO Working Paper* 10**,** 58.
GIRLING, A. J., HOFER, T. P., WU, J., CHILTON, P. J., NICHOLL, J. P., MOHAMMED, M. A. & LILFORD, R. J. 2012. Case-mix adjusted hospital mortality is a poor proxy for preventable mortality: a modelling study. *BMJ Quality & Safety,* 21**,** 1052-1056.
GODDARD, M. 2003. Regulation of health care markets. *Journal of Health Services Research & Policy,* 8**,** 193-195.
GOLDSTEIN, H. 2005. Multilevel Models. *Encyclopedia of Biostatistics.* John Wiley & Sons, Ltd.
GOODACRE, S., CAMPBELL, M. & CARTER, A. 2015. What do hospital mortality rates tell us about quality of care? *Emergency Medicine Journal,* 32**,** 244-247.
GRAHAM, I. D., LOGAN, J., HARRISON, M. B., STRAUS, S. E., TETROE, J., CASWELL, W. & ROBINSON, N. 2006. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof,* 26**,** 13-24.
GREENFIELD, D. & BRAITHWAITE, J. 2008. Health sector accreditation research: a systematic review. *Int J Qual Health Care,* 20**,** 172-83.
GREENFIELD, D., PAWSEY, M., HINCHCLIFF, R., MOLDOVAN, M. & BRAITHWAITE, J. 2012. The standard of healthcare accreditation standards: a review of empirical research underpinning their development and impact. *BMC Health Serv Res,* 12**,** 329.
GREENHALGH, T., ROBERT, G., MACFARLANE, F., BATE, P. & KYRIAKIDOU, O. 2004. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *Milbank Quarterly,* 82**,** 581-629.
GRIFFITHS, P., BALL, J., DRENNAN, J., DALL'ORA, C., JONES, J., MARUOTTI, A., POPE, C., RECIO SAUCEDO, A. & SIMON, M. 2016. Nurse staffing and patient outcomes: Strengths and limitations of the evidence to inform policy and practice. A review and discussion paper based on evidence reviewed for the National Institute for Health and Care Excellence Safe Staffing guideline development. *International Journal of Nursing Studies*.
GRIFFITHS, P., BALL, J., DRENNAN, J., JAMES, L., JONES, J., RECIO, A. & SIMON, M. 2014. The association between patient safety outcomes and nurse/healthcare assistant skill mix and staffing levels and factors that may influence staffing requirements.
GRIFFITHS, R. 1983. NHS management inquiry.
GROL, R. P. T. M., BOSCH, M. C., HULSCHER, M. E. J. L., ECCLES, M. P. & WENSING, M. 2007. Planning and Studying Improvement in Patient Care: The Use of Theoretical Perspectives. *The Milbank Quarterly,* 85**,** 93-138.
GURKA, M. J. 2006. Selecting the best linear mixed model under REML. *The American Statistician,* 60**,** 19-26.

GUTTMANN, A., SCHULL, M. J., VERMEULEN, M. J. & STUKEL, T. A. 2011. Association between waiting times and short term mortality and hospital admission after departure from emergency department: population based cohort study from Ontario, Canada. *BMJ,* 342.
GUYATT, G., CAIRNS, J., CHURCHILL, D. & ET AL. 1992. Evidence-based medicine: A new approach to teaching the practice of medicine. *JAMA,* 268**,** 2420-2425.
HAM, C. 2009a. *Health policy in Britain*, Palgrave Macmillan.
HAM, C. 2009b. Lessons from the past decade for future health reforms. *BMJ,* 339.
HAM, C. 2014a. Reforming the NHS from within. *Beyond Hierarchy, Inspection and Markets, Kings Fund, London*.
HAM, C. 2014b. Reforming the NHS from within: Beyond hierarchy, inspection and markets. London: The King's Fund.
HAMILTON, B. H. & BRAMLEY-HARKER, R. E. 1999. The Impact of the NHS Reforms on Queues and Surgical Outcomes in England: Evidence From Hip Fracture Patients. *The Economic Journal,* 109**,** 437-462.
HARRISON, S. & POLLITT, C. 1994. *Controlling Health Professionals: The future of work and the organization in the NHS,* Buckingham, Open University Press.
HARVEY, L. & GREEN, D. 1993. Defining Quality. *Assessment & Evaluation in Higher Education,* 18**,** 9-34.
HASLAM, D. 2007. What is the Healthcare Commission trying to achieve? *Journal of the Royal Society of Medicine,* 100**,** 15-18.
HAWKES, N. 2010. Patient coding and the ratings game. *BMJ: British Medical Journal,* 340**,** 950-952.
HEALTH SELECT COMMITTEE 2011. Annual accountability hearing with the Care Quality Commission: Ninth report of session 2010–12. London.
HEALTH SELECT COMMITTEE 2013. Minutes of Evidence: Session 2013-14. London: House of Commons.
HEALTHCARE COMMISSION 2008a. Making a difference? An evaluation of the performance of the Healthcare Commission 2004-2008. London: CHAI.
HEALTHCARE COMMISSION 2008b. Not just a matter of time: A review of urgent and emergency care services in England. London: Commission for Healthcare Audit and Inspection.
HEALTHCARE COMMISSION 2009. The Healthcare Commission 2004-2009: Regulating healthcare - experience and lessons. London: CHAI.
HELLMAN, C. M. 1997. Job Satisfaction and Intent to Leave. *The Journal of Social Psychology,* 137**,** 677-689.
HENSHER, M. & EDWARDS, N. 1999. Hospital provision, activity, and productivity in England since the 1980s. *BMJ,* 319**,** 911-914.
HERNAN, M. A. 2011. With great data comes great responsibility: publishing comparative effectiveness research in epidemiology. *Epidemiology,* 22**,** 290-1.
HIBBARD, J. H., STOCKARD, J. & TUSLER, M. 2003. Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts? *Health Affairs,* 22**,** 84-94.
HIBBARD, J. H., STOCKARD, J. & TUSLER, M. 2005. Hospital Performance Reports: Impact On Quality, Market Share, And Reputation. *Health Affairs,* 24**,** 1150-1160.
HOCHBERG, Y. & TAMHANE, A. C. 2008. Introduction. *Multiple Comparison Procedures.* John Wiley & Sons, Inc.
HODGE, W., HORSLEY, T., ALBIANI, D., BARYLA, J., BELLIVEAU, M., BUHRMANN, R., O'CONNOR, M., BLAIR, J. & LOWCOCK, E. 2007. The consequences of waiting for cataract surgery: a systematic review. *CMAJ : Canadian Medical Association Journal,* 176**,** 1285-1290.
HOGAN, H., ZIPFEL, R., NEUBURGER, J., HUTCHINGS, A., DARZI, A. & BLACK, N. 2015. Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis. *BMJ : British Medical Journal,* 351.

HOOD, C. & SCOTT, C. D. 2000. *Regulating government in a 'managerial age': towards a cross-national perspective*, Centre for Analysis of Risk and Regulation, London School of Economics and Political Science.
HOUSE OF PARLIAMENT 2014. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. *In:* PARLIAMENT (ed.) *2936.* London.
HOVLID, E., FRICH, J. C., WALSHE, K., NILSEN, R. M., FLAATTEN, H. K., BRAUT, G. S., HELGELAND, J., TEIG, I. L. & HARTHUG, S. 2017. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. *BMJ Open,* 7.
HQIP. 2018. *The National Clinical Audit Programme* [Online]. Healthcare Quality Improvement Partnership. Available: https://www.hqip.org.uk/national-programmes/a-z-of-nca/ [Accessed 10 March 2018].
HSCIC 2013a. The quality of nationally submitted health and social care data: England, annual report, 2013, experimental statistics.
HSCIC 2013b. The Use of Palliative Care Coding in the Summary Hospital-level Mortality Indicator (SHMI).
INSTITUTE FOR HEALTHCARE IMPROVEMENT 2008. Achieving the vision of excellence in quality: Recommendations for the English NHS system of quality improvement. Cambridge, MA: Institute for Healthcare Improvement.
INSTITUTE OF MEDICINE (US) 1990a. 1, Health, health care, and quality of care. *In:* LOHR, K. N. (ed.) *Medicare: A Strategy for Quality Assurance, Volume I.* Washington, DC: National Academies Press (US).
INSTITUTE OF MEDICINE (US) 1990b. 5, Defining Quality of Care. *In:* LOHR, K. N. (ed.) *Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods.* Washington, DC: National Academies Press (US).
INSTITUTE OF MEDICINE (US) 2001a. 2, Defining the Contents of the Data Set: The National Health Care Quality Framework. *In:* HURTADO, M. P., SWIFT, E. K. & CORRIGAN, J. M. (eds.) *Envisioning the National Health Care Quality Report.* Washington, DC.
INSTITUTE OF MEDICINE (US) 2001b. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: The National Academies Press.
JACOBS, R., MANNION, R., DAVIES, H. T., HARRISON, S., KONTEH, F. & WALSHE, K. 2013. The relationship between organizational culture and performance in acute hospitals. *Soc Sci Med,* 76**,** 115-25.
JOINT COMMISSION INTERNATIONAL 2008. Quality oversight in England - findings, observations, and recommendations for a new model. Oak Brook, IL.
JOINT WORKING PARTY 1967. First report of the Joint Working Party on the Organisation of Medical Work in Hospitals. London: Ministry of Health.
JONES, P. & SCHIMANSKI, K. 2010. The four hour target to reduce emergency department 'waiting time': A systematic review of clinical outcomes. *Emergency Medicine Australasia,* 22**,** 391-398.
JOSHI, M. S. & HINES, S. C. 2006. Getting the board on board: Engaging hospital boards in quality and patient safety. *Jt Comm J Qual Patient Saf,* 32**,** 179-87.
JOWETT, P. & ROTHWELL, M. 1988. *Performance indicators in the public sector,* Houndmills, Basingstoke, Hampshire, Macmillan Press.
JUUL, A. B., GLUUD, C., WETTERSLEV, J., CALLESEN, T., JENSEN, G. & KOFOED-ENEVOLDSEN, A. 2005. The effects of a randomised multi-centre trial and international accreditation on availability and quality of clinical guidelines. *Int J Health Care Qual Assur Inc Leadersh Health Serv,* 18**,** 321-8.
KANNAMPALLIL, T. G., SCHAUER, G. F., COHEN, T. & PATEL, V. L. 2011. Considering complexity in healthcare systems. *Journal of Biomedical Informatics,* 44**,** 943-947.
KAPLAN, H. C., BRADY, P. W., DRITZ, M. C., HOOPER, D. K., LINAM, W. M., FROEHLE, C. M. & MARGOLIS, P. 2010. The Influence of Context on Quality Improvement Success in Health Care: A Systematic Review of the Literature. *Milbank Quarterly,* 88**,** 500-559.

KENNEDY, I. 2001. The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: learning from Bristol. London: Department of Health.
KENNEDY, I. 2013. Review of the response of Heart of England NHS Foundation Trust to concerns about Mr Ian Paterson's surgical practice; lessons to be learned; and recommendations.
KEOGH, B. 2013. *Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report*, NHS.
KLEIN, R. 2013. *The New Politics of the NHS: From Creation to Reinvention*, CRC Press.
KLUGER, A. N. & DENISI, A. 1998. Feedback Interventions. *Current Directions in Psychological Science,* 7**,** 67-72.
KOBEWKA, D. M., VAN WALRAVEN, C., TURNBULL, J., WORTHINGTON, J., CALDER, L. & FORSTER, A. 2017. Quality gaps identified through mortality review. *BMJ Quality & Safety,* 26**,** 141-149.
KONTOPANTELIS, E., DORAN, T., SPRINGATE, D. A., BUCHAN, I. & REEVES, D. 2015a. Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. *BMJ: British Medical Journal,* 350.
KONTOPANTELIS, E., DORAN, T., SPRINGATE, D. A., BUCHAN, I. & REEVES, D. 2015b. Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. *BMJ : British Medical Journal,* 350.
KRAMER, M., SCHMALENBERG, C., MAGUIRE, P., BREWER, B. B., BURKE, R., CHMIELEWSKI, L., COX, K., KISHNER, J., KRUGMAN, M., MEEKS-SJOSTROM, D. & WALDO, M. 2008. Structures and practices enabling staff nurses to control their practice. *Western Journal of Nursing Research,* 30**,** 539-59.
KRISTENSEN, S. R., MEACOCK, R. & SUTTON, M. 2015. Methodology for Modelling Changes in Health Services Delivery and Policy. Manchester Centre for Health Economics, University of Manchester.
LAFFONT, J.-J. & TIROLE, J. 1993. *A theory of incentives in procurement and regulation*, MIT press.
LAFOND, S., CHARLESWORTH, A. & ROBERTS, A. 2017. A year of plenty? An analysis of NHS finances and consultant productivity. London: The Health Foundation.
LANDON, B. E., NORMAND, S. L., LESSLER, A., O'MALLEY, A. J., SCHMALTZ, S., LOEB, J. M. & MCNEIL, B. J. 2006. Quality of care for the treatment of acute medical conditions in US hospitals. *Arch Intern Med,* 166**,** 2511-7.
LARSON, M. S. 1977. *The Rise of Professionalism: A Sociological Analysis,* Berkeley, University of California Press.
LE GRAND, J. 2003. *Motivation, Agency, and Public Policy: Of Knights and Knaves, Pawns and Queens,* Oxford, Oxford University Press.
LE GRAND, J. 2007. *The Other Invisible Hand: Delivering Public Services through Choice and Competition*, Princeton University Press.
LE GRAND, J. & HUNTER, D. 2006. Choice and competition in the British National Health Service. *Eurohealth,* 12**,** 5-7.
LE GRAND, J., MAYS, N. & MULLIGAN, J. A. 1998. *Learning from the NHS Internal Market: A Review of the Evidence,* London, King's Fund.
LEE, D. S. & LEMIEUX, T. 2009. Regression Discontinuity Designs in Economics. *National Bureau of Economic Research Working Paper Series,* No. 14723.
LESSER, C. S., LUCEY, C. R., EGENER, B., BRADDOCK, C. H., LINAS, S. L. & LEVINSON, W. 2010. A behavioral and systems view of professionalism. *JAMA,* 304**,** 2732-2737.
LEYLAND, A. H. & GOLDSTEIN, H. 2001. Multilevel Modelling of Health Statistics. Chichester, UK: Wiley.
LIMB, M. 2016. GPs call for an end to CQC inspections. *BMJ: British Medical Journal,* 352.
LIPSKY, M. 2010. *Street-level bureaucracy: Dilemmas of the individual in public service*, Russell Sage Foundation.
LOCKE, E. A. & LATHAM, G. P. 2002a. Building a practically useful theory of goal setting and task motivation. A 35-year odyssey. *Am Psychol,* 57**,** 705-17.

LOCKE, E. A. & LATHAM, G. P. 2002b. Building a practically useful theory of goal setting and task motivation: A 35-year odyssey. *American psychologist,* 57**,** 705.
LOCKE, E. A. & LATHAM, G. P. 2006. New directions in goal-setting theory. *Current directions in psychological science,* 15**,** 265-268.
LOCKER, T. E. & MASON, S. M. 2005. Analysis of the distribution of time that patients spend in emergency departments. *BMJ,* 330**,** 1188-1189.
LOCKER, T. E. & MASON, S. M. 2006. Are these emergency department performance data real? *Emergency Medicine Journal,* 23**,** 558-559.
LOHR, K. N. & SCHROEDER, S. A. 1990. A strategy for quality assurance in Medicare. *New England Journal of Medicine,* 322**,** 707-712.
LONGO, D. R., HEWETT, J. E., GE, B. & SCHUBERT, S. 2007. Hospital patient safety: characteristics of best-performing hospitals. *J Healthc Manag,* 52**,** 188-204; discussion 204-5.
LOPEZ BERNAL, J., CUMMINS, S. & GASPARRINI, A. 2017. Interrupted time series regression for the evaluation of public health interventions: a tutorial. *International Journal of Epidemiology,* 46**,** 348-355.
LUTFIYYA, M. N., SIKKA, A., MEHTA, S. & LIPSKY, M. S. 2009. Comparison of US accredited and non-accredited rural critical access hospitals. *Int J Qual Health Care,* 21**,** 112-8.
MACHELL, S., GOUGH, P., NAYLOR, D., NATH, V., STEWARD, K. & WILLIAMS, S. 2010. Putting quality first in the boardroom: Improving the business of caring. London: The King's Fund and Burdett Trust for Nursing.
MADSEN, J. 2014. NHS Safety Thermometer: Patient Harms and Harm Free Care. England: Health and Social Care Information Centre.
MAHON, A., WILKIN, D. & WHITEHOUSE, C. 1994. Choice of hospital for elective surgery referral: GPs' and patients' views. *In:* ROBINSON, R. & LE GRAND, J. (eds.) *Evaluating the National Health Service Reforms.* London: King's Fund.
MANNION, R., DAVIES, H., FREEMAN, T., MILLAR, R., JACOBS, R. & KASTERIDIS, P. 2015. Overseeing oversight: governance of quality and safety by hospital boards in the English NHS. *Journal of Health Services Research & Policy,* 20**,** 9-16.
MANNION, R., DAVIES, H. T. O. & MARSHALL, M. N. 2005. Cultural characteristics of “high” and “low” performing hospitals. *Journal of Health Organization and Management,* 19**,** 431-439.
MARINER, W. K. 2009. Toward an Architecture of Health Law. *American Journal of Law & Medicine,* 35**,** 67-88.
MASON, S., WEBER, E. J., COSTER, J., FREEMAN, J. & LOCKER, T. 2012. Time Patients Spend in the Emergency Department: England's 4-Hour Rule—A Case of Hitting the Target but Missing the Point? *Annals of Emergency Medicine,* 59**,** 341-349.
MATRIX KNOWLEDGE GROUP 2010. Literature review on the impact of hospital accreditation. Haute Autorité de Santé.
MAYNARD, A. 1991. Developing the Health Care Market. *The Economic Journal,* 101**,** 1277-1286.
MAYNARD, A. 2014. Contracting for quality in the NHS: Putting the Francis report in perspective. Office of Health Economics.
MAYNARD, A. & BLOOR, K. 2003. Trust and performance management in the medical marketplace. *J R Soc Med,* 96**,** 532-9.
MAYS, N. & DIXON, A. 2011. Assessing and explaining the impact of New Labour’s market reforms. *In:* MAYS, N., DIXON, A. & JONES, L. (eds.) *Understanding New Labour's market reforms of the English NHS.* King's Fund.
MCDOWALL, D., MCLEARY, R., MEIDINGER, E. E. & HAY, R. A. J. 1980. *Interrupted time series analysis,* Beverly Hills, SAGE Publications, Inc.
MCGLYNN, E. A., SHEKELLE, P. & HUSSEY, P. 2008. Developing, disseminating and assessing standards of the National Health Service: An assessment of current status and opportunities for improvement Santa Monica, CA: RAND Corporation.
MCGUIRE, T. G. 2000. Chapter 9 - Physician Agency. *In:* CULYER, A. J. & NEWHOUSE, J. P. (eds.) *Handbook of Health Economics.* Elsevier.

MCLAUGHLIN, C. P. & KALUZNY, A. D. 2004. *Continuous Quality Improvement in Health Care: Theory, Implementation, and Applications*, Jones and Bartlett.
MILLAR, R., MANNION, R., FREEMAN, T. I. M. & DAVIES, H. T. O. 2013. Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. *Milbank Quarterly,* 91**,** 738-770.
MILLER, D. G. 2014. *English Lexicogenesis*, OUP Oxford.
MINISTRY OF HOUSING. 2015. *English indices of deprivation 2015* [Online]. Available: https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015 [Accessed 25 February 2018].
MONTIN, L., LEINO-KILPI, H., SUOMINEN, T. & LEPISTÖ, J. 2008. A systematic review of empirical studies between 1966 and 2005 of patient outcomes of total hip arthroplasty and related factors. *Journal of Clinical Nursing,* 17**,** 40-45.
MOORE, G., AUDREY, S., BARKER, M., BOND, L., BONELL, C., HARDEMAN, W., MOORE, L., O'CATHAIN, A., TINATI, T., WIGHT, D. & BAIRD, J. 2014. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance.
MORROW, G., BURFORD, B., ROTHWELL, C., CARTER, M., MCLACHLAN, J. & ILLING, J. 2014. Professionalism in healthcare professionals. London: Health and care professions council.
MUMFORD, V., FORDE, K., GREENFIELD, D., HINCHCLIFF, R. & BRAITHWAITE, J. 2013. Health services accreditation: what is the evidence that the benefits justify the costs? *Int J Qual Health Care,* 25**,** 606-20.
MUMFORD, V., GREENFIELD, D., HOGDEN, A., FORDE, K., WESTBROOK, J. & BRAITHWAITE, J. 2015. Counting the costs of accreditation in acute care: an activity-based costing approach. *BMJ Open,* 5.
NATIONAL ADVISORY GROUP ON THE SAFETY OF PATIENTS IN ENGLAND 2013. A promise to learn– a commitment to act. London: Department of Health.
NATIONAL AUDIT OFFICE 2003. Achieving improvements through Clinical Governance. A progress report on implementation by NHS Trusts. London: The Stationary Office.
NATIONAL AUDIT OFFICE 2004. Improving Emergency Care in England. London.
NATIONAL AUDIT OFFICE 2014. NHS waiting times for elective care in England. London: The Stationery Office: Report by the Comptroller and Auditor General.
NATIONAL HEALTH PERFORMANCE COMMITTEE 2009. The National Health Performance Framework. Australia.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE 2014. Safe staffing for nursing in adult inpatient wards in acute hospitals. NICE.
NG, G. K., LEUNG, G. K., JOHNSTON, J. M. & COWLING, B. J. 2013. Factors affecting implementation of accreditation programmes and the impact of the accreditation process on quality improvement in hospitals: a SWOT analysis. *Hong Kong Med J,* 19**,** 434-46.
NHS COMMISSIONING BOARD AUTHORITY 2012. Authorisation of Clinical Commissioning Groups. London.
NHS CONFEDERATION 2011. Feeling better? Improving patient experience in hospital. London.
NHS CONFEDERATION 2013. Challenging bureaucracy. London: NHS Confederation.
NHS DIGITAL 2017. Workforce Validation Engine (WoVEn) Report: External User Guidance V6. Health and Social Care Information Centre.
NHS EMPLOYERS 2014. *Pay and Conditions Circular (M&D) 2/2014*.
NHS EMPLOYERS 2015. *Pay and Conditions Circular (M&D) 1/2015*.
NHS ENGLAND 2014. Five-Year Forward View.
NHS ENGLAND 2015a. A&E Attendances and Emergency Admissions Monthly Return Definitions. London.
NHS ENGLAND 2015b. NHS England allocates £560 billion of NHS funding to deliver NHS Five Year Forward View.
NHS ENGLAND 2015c. Recording and reporting referral to treatment (RTT) waiting times for consultant-led elective care. London: NHS England.
NHS ENGLAND 2015d. Safer, faster, better: good practice in delivering urgent and emergency care. *Transforming urgent and emergency care services in England.* London: NHS England.

NHS EXECUTIVE 1997. Review of breast cancer services in Exeter and quality assurance for breast screening. Department of Health.
NHS EXECUTIVE 1998. *A first class service: quality in the new NHS*, Department of Health.
NHS IMPROVEMENT 2016a. Request under the Freedom of Information Act 2000 (the "FOI Act"). London.
NHS IMPROVEMENT 2016b. Single Oversight Framework. London.
NHS IMPROVEMENT 2017. Good practice guide: Focus on improving patient flow. *National priorities for acute hospitals 2017.* London.
NHS PROVIDERS 2017. Regulation Survey Report 2017: Impact of regulation in a shifting environment. NHS Providers.
NHS STAFF COUNCIL 2014. Annex 3: Pay bands and pay points on the second pay spine in England from 1 April 2014. *NHS terms and conditions of service handbook.*
NHS STAFF COUNCIL 2015. Annex 3: Pay bands and pay points on the second pay spine in England from 1 April 2015. *NHS terms and conditions of service handbook.*
NICE 2012. Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. London: National Clinical Guideline Centre.
NUFFIELD TRUST 2015. Rating providers for quality: a policy worth pursuing? . London.
O'CATHAIN, A., MURPHY, E. & NICHOLL, J. 2007. Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. *BMC Health Services Research,* 7**,** 85.
O'NEILL, O. 2002. *A Question of Trust*, Cambridge.
OH, H. S., CHUNG, H. W., KIM, J. S. & CHO, S. I. 2006. National survey of the status of infection surveillance and control programs in acute care hospitals with more than 300 beds in the Republic of Korea. *Am J Infect Control,* 34**,** 223-33.
OPM EVALUATION TEAM. 2009. Evaluation of the healthcare commission's healthcare associated infections inspection programme. *OPM report* [Online].
OREDSSON, S., JONSSON, H., ROGNES, J., LIND, L., GORANSSON, K. E., EHRENBERG, A., ASPLUND, K., CASTREN, M. & FARROHKNIA, N. 2011. A systematic review of triage-related interventions to improve patient flow in emergency departments. *Scand J Trauma Resusc Emerg Med,* 19**,** 43.
OSTROM, C. W. 1990. *Time Series Analysis: Regression Techniques*, SAGE Publications, Inc.
OUDHOFF, J., TIMMERMANS, D., KNOL, D., BIJNEN, A. & VAN DER WAL, G. 2007. Waiting for elective general surgery: impact on health related quality of life and psychosocial consequences. *BMC Public Health,* 7**,** 164.
ØVRETVEIT, J. 2011. Understanding the conditions for improvement: research to discover which context influences affect improvement success. *BMJ Quality & Safety,* 20**,** i18-i23.
PANCHAMIA, N. & THOMAS, P. 2014. Public Service Agreements and the Prime Minister's Delivery Unit. Institute for Government.
PARASURAMAN, A., ZEITHAML, V. A. & BERRY, L. L. 1985. A Conceptual Model of Service Quality and Its Implications for Future Research. *Journal of Marketing,* 49**,** 41-50.
PARK, R., BROOK, R. H., KOSECOFF, J. & ET AL. 1990. Explaining variations in hospital death rates: Randomness, severity of illness, quality of care. *JAMA,* 264**,** 484-490.
PASQUALE, M. D., PEITZMAN, A. B., BEDNARSKI, J. & WASSER, T. E. 2001. Outcome analysis of Pennsylvania trauma centers: factors predictive of nonsurvival in seriously injured patients. *J Trauma,* 50**,** 465-72; discussion 473-4.
PENFOLD, R. B. & ZHANG, F. 2013. Use of interrupted time series analysis in evaluating health care quality improvements. *Acad Pediatr,* 13**,** S38-44.
PFADENHAUER, L. M., GERHARDUS, A., MOZYGEMBA, K., LYSDAHL, K. B., BOOTH, A., HOFMANN, B., WAHLSTER, P., POLUS, S., BURNS, J., BRERETON, L. & REHFUESS, E. 2017. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. *Implementation Science,* 12**,** 21.

PFEFFER, N. & COOTE, A. 1991. *Is Quality Good for You?: A Critical Review of Quality Assurance in Welfare Services*, Institute for Public Policy Research.
PIONTEK, F. A., COSCIA, R., MARSELLE, C. S., KORN, R. L. & ZARLING, E. J. 2003. Impact of American College of Surgeons verification on trauma outcomes. *J Trauma,* 54**,** 1041-6; discussion 1046-7.
PIRSIG, R. M. 1992. *Lila: An Inquiry Into Morals*, Bantam Books.
PITCHES, D. W., MOHAMMED, M. A. & LILFORD, R. J. 2007. What is the empirical evidence that hospitals with higher-risk adjusted mortality rates provide poorer quality care? A systematic review of the literature. *BMC Health Services Research,* 7**,** 91.
PLSEK, P. E. & GREENHALGH, T. 2001. The challenge of complexity in health care. *BMJ,* 323**,** 625-628.
POLLITT, C. 1995. Justification by works or by faith? Evaluating the new public management. *Evaluation,* 1**,** 133-154.
POPPER, K. 2005. *The logic of scientific discovery,* London, Routledge Classics.
POULSEN, J. B., MOLLER, K., JENSEN, C. V., WEISDORF, S., KEHLET, H. & PERNER, A. 2011. Effect of transcutaneous electrical muscle stimulation on muscle volume in patients with septic shock. *Crit Care Med,* 39**,** 456-61.
POWER, M., BREWSTER, L., PARRY, G., BROTHERTON, A., MINION, J., OZIERANSKI, P., MCNICOL, S., HARRISON, A. & DIXON-WOODS, M. 2016. Multimethod study of a large-scale programme to improve patient safety using a harm-free care approach. *BMJ Open,* 6.
POWER, M., FOGARTY, M., MADSEN, J., FENTON, K., STEWART, K., BROTHERTON, A., CHEEMA, K., HARRISON, A. & PROVOST, L. 2014. Learning from the design and development of the NHS Safety Thermometer. *International Journal for Quality in Health Care,* 26**,** 287-297.
POWER, M., STEWART, K. & BROTHERTON, A. 2012. What is the NHS Safety Thermometer? *Clinical Risk,* 18**,** 163-169.
PRODUCTIVITY COMMISSION 2016. *11 Public hospitals,* Australia.
PROPPER, C., BURGESS, S. & GOSSAGE, D. 2008. Competition and Quality: Evidence from the NHS Internal Market 1991–9. *The Economic Journal,* 118**,** 138-170.
PROPPER, C., BURGESS, S. & GREEN, K. 2004. Does competition between hospitals improve the quality of care? *Journal of Public Economics,* 88**,** 1247-1272.
PROPPER, C., CROXSON, B. & SHEARER, A. 2002. Waiting times for hospital admissions: the impact of GP fundholding. *Journal of Health Economics,* 21**,** 227-252.
PROPPER, C., WILSON, D. & SÖDERLUND, N. 1998. The effects of regulation and competition in the NHS internal market: the case of general practice fundholder prices. *Journal of Health Economics,* 17**,** 645-673.
QUALITY ASSURANCE PROJECT 2005. The Zambia accreditation program evaluation: Operations research results.
QUALITYWATCH. 2017. *Indicators* [Online]. The Health Foundation and Nuffield Trust. Available: http://www.qualitywatch.org.uk/indicators-results/ [Accessed 22 August 2017].
QUIMBO, S. A., PEABODY, J. W., SHIMKHADA, R., WOO, K. & SOLON, O. 2008. Should we have confidence if a physician is accredited? A study of the relative impacts of accreditation and insurance payments on quality of care in the Philippines. *Soc Sci Med,* 67**,** 505-10.
RABE-HESKETH, S. & SKRONDAL, A. 2012. *Multilevel and longitudinal modeling using Stata*, STATA press.
RALEIGH, V. 2012. Measuring accountability for outcomes: is transparency enough? . [Accessed 28th August 2017].
RALEIGH, V., SIZMUR, S., TIAN, Y. & THOMPSON, J. 2015a. Impact of case-mix on comparisons of patient-reported experience in NHS acute hospital trusts in England. *Journal of Health Services Research & Policy,* 20**,** 92-99.
RALEIGH, V., THOMPSON, J., JABBAL, J., GRAHAM, C., SIZMUR, S. & COULTER, A. 2015b. Patients' experience of using hospital services: An analysis of trends in inpatient surveys in NHS acute trusts in England, 2005–13. London: The King's Fund.
REDFERN, J. & BOWLING, A. 2000. Efficiency of care at the primary–secondary interface: variations with GP fundholding. *Health & Place,* 6**,** 15-23.

RITCHIE, J. 2000. The report of the inquiry into quality and practice within the National Health Service arising from the actions of Rodney Ledward. London: Department of Health.
ROBB, E., JARMAN, B., SUNTHARALINGAM, G., HIGGENS, C., TENNANT, R. & ELCOCK, K. 2010. Using care bundles to reduce in-hospital mortality: quantitative survey. *BMJ,* 340.
ROBERTSON, R., WALSHE, K., BOYD, A., RICHARDSON, E. & ROBERTS, J. Does regulation improve care quality? A framework for understanding the impact of regulation, applied to the Care Quality Commission's regulatory model. Health Services Research UK, 2017 Nottingham.
ROGERS, P. J. 2005. Logic Model. *In:* MATHISON, S. (ed.) *Encyclopedia of Evaluation.* Thousand Oaks, California: SAGE Publications, Inc.
ROSS, M. A., AMSTERDAM, E., PEACOCK, W. F., GRAFF, L., FESMIRE, F., GARVEY, J. L., KELLY, S., HOLMES, K., KARUNARATNE, H. B., TOTH, M., DADKHAH, S. & MCCORD, J. 2008. Chest pain center accreditation is associated with better performance of centers for Medicare and Medicaid services core measures for acute myocardial infarction. *Am J Cardiol,* 102**,** 120-4.
ROYAL COLLEGE OF SURGEONS. 2018. *Surgical Outcomes* [Online]. Available: https://www.rcseng.ac.uk/patient-care/surgical-staff-and-regulation/surgical-outcomes/ [Accessed 10 March 2018].
RUSSELL, M., GIORGIA, M. & ANDREW, S. 2008. Implementing payment by results in the English NHS: Changing incentives and the role of information. *Journal of Health Organization and Management,* 22**,** 79-88.
RYAN, A. M., BURGESS, J. F. & DIMICK, J. B. 2015. Why We Should Not Be Indifferent to Specification Choices for Difference-in-Differences. *Health Services Research,* 50**,** 1211-1235.
SAKS, M. 1995. *Professions and the Public Interest: Medical Power, Altruism and Alternative Medicine*, Routledge.
SAKS, M. 2015. The Changing Medical Profession in England. *In:* CARVALHO, T. & SANTIAGO, R. (eds.) *Professionalism, Managerialism and Reform in Higher Education and the Health Services: The European Welfare State and the Rise of the Knowledge Society.* London: Palgrave Macmillan UK.
SALMON, J. W., HEAVENS, J., LOMBARD, C. & TAVROW, P. 2003. The impact of accreditation on the quality of hospital care: KwaZulu-Natal province, Republic of South Africa. *LLC* [Online], 2.
SARI, A. B.-A., SHELDON, T. A., CRACKNELL, A. & TURNBULL, A. 2006. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ*.
SCHAEFER, C. & WIIG, S. 2017. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. *Safety in Health,* 3**,** 3.
SCHUSTER, M. A., ONORATO, S. E. & MELTZER, D. O. 2017. Measuring the cost of quality measurement: A missing link in quality strategy. *JAMA,* 318**,** 1219-1220.
SEELY, A. & WEBB, D. 2010. June 2010 Budget: a summary. Library House of Commons: HM treasury.
SEKIMOTO, M., IMANAKA, Y., KOBAYASHI, H., OKUBO, T., KIZU, J., KOBUSE, H., MIHARA, H., TSUJI, N. & YAMAGUCHI, A. 2008. Impact of hospital accreditation on infection control programs in teaching hospitals in Japan. *Am J Infect Control,* 36**,** 212-9.
SHADER, K., BROOME, M. E., BROOME, C. D., WEST, M. E. & NASH, M. 2001. Factors Influencing Satisfaction and Anticipated Turnover for Nurses in an Academic Medical Center. *Journal of Nursing Administration,* 31**,** 210-216.
SHADISH, W. R., COOK, T. D. & CAMPBELL, D. T. 2002. *Experimental and Quasi-experimental Designs for Generalized Causal Inference,* Boston, Houghton Mifflin.
SHEA, B. J., GRIMSHAW, J. M., WELLS, G. A., BOERS, M., ANDERSSON, N., HAMEL, C., PORTER, A. C., TUGWELL, P., MOHER, D. & BOUTER, L. M. 2007. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Medical Research Methodology,* 7**,** 10.

SHEINGOLD, B. H. & HAHN, J. A. 2014. The history of healthcare quality: The first 100 years 1860–1960. *International Journal of Africa Nursing Sciences,* 1**,** 18-22.
SHEKELLE, P. G., PRONOVOST, P. J., WACHTER, R. M. & ET AL. 2013. The top patient safety strategies that can be encouraged for adoption now. *Annals of Internal Medicine,* 158**,** 365-368.
SICILIANI, L., CHALKLEY, M. & GRAVELLE, H. 2017. Competition policy in five European countries: What can be learned for health policy in England. London: University of York.
SIMON, H. A. 1955. A Behavioral Model of Rational Choice. *The Quarterly Journal of Economics,* 69**,** 99-118.
SIMONS, R., KASIC, S., KIRKPATRICK, A., VERTESI, L., PHANG, T. & APPLETON, L. 2002. Relative importance of designation and accreditation of trauma centers during evolution of a regional trauma system. *J Trauma,* 52**,** 827-33; discussion 833-4.
SIMONSON, I. & NYE, P. 1992. The effect of accountability on susceptibility to decision errors. *Organizational Behavior and Human Decision Processes,* 51**,** 416-446.
SIZMUR, S. 2011. Multilevel analysis of inpatient experience. Oxford: Picker Institute Europe.
SLOVIC, P. & VÄSTFJÄLL, D. 2010. Affect, Moral Intuition, and Risk. *Psychological Inquiry,* 21**,** 387-398.
SMITH, I. L., NIXON, J., BROWN, S., WILSON, L. & COLEMAN, S. 2016. Pressure ulcer and wounds reporting in NHS hospitals in England part 1: Audit of monitoring systems. *Journal of Tissue Viability,* 25**,** 3-15.
SMITH, J. 2005. The Shipman Inquiry: final report. London: Department of Health.
SOBOLEV, B., MERCER, D., BROWN, P., FITZGERALD, M., JALINK, D. & SHAW, R. 2003. Risk of emergency admission while awaiting elective cholecystectomy. *Cmaj,* 169**,** 662-5.
SÖDERLUND, N., CSABA, I., GRAY, A., MILNE, R. & RAFTERY, J. 1997. Impact of the NHS reforms on English hospital productivity: an analysis of the first three years. *BMJ,* 315**,** 1126-1129.
STAFFORD, M. C. & WARR, M. 1993. A Reconceptualization of General and Specific Deterrence. *Journal of Research in Crime and Delinquency,* 30**,** 123-135.
STATISTICS CANADA. 2017. *Data tables, maps and fact sheets* [Online]. Available: http://www.statcan.gc.ca/pub/82-221-x/2013001/tbl-eng.htm#sa [Accessed].
STEFFEN, G. E. 1988. Quality medical care: A definition. *JAMA,* 260**,** 56-61.
STELFOX, H. T. & STRAUS, S. E. 2013. Measuring quality of care: considering measurement frameworks and needs assessment to guide quality indicator development. *Journal of Clinical Epidemiology,* 66**,** 1320-1327.
STEVENS, L. 2016. New joint data chief at CQC and NHS Improvement. *Digital Health*, 20 December 2016.
STEVENS, S. 2004. Reform Strategies For The English NHS. *Health Affairs,* 23**,** 37-44.
STEWART-BROWN, S., SURENDER, R., BRADLOW, J., COULTER, A. & DOLL, H. 1995. The Effects Of Fundholding In General Practice On Prescribing Habits Three Years After Introduction Of The Scheme. *BMJ: British Medical Journal,* 311**,** 1543-1547.
STRADLING, D., YU, W., LANGDORF, M. L., TSAI, F., KOSTANIAN, V., HASSO, A. N., WELBOURNE, S. J., SCHOOLEY, Y., FISHER, M. J. & CRAMER, S. C. 2007. Stroke care delivery before vs after JCAHO stroke center certification. *Neurology,* 68**,** 469-70.
STUART, E. A. & NAEGER, S. 2017. Introduction to Causal Inference Approaches. *In:* SOBOLEV, B. & GATSONIS, C. (eds.) *Methods in Health Services Research.* Boston, MA: Springer US.
SUÑOL, R., VALLEJO, P., THOMPSON, A., LOMBARTS, M. J., SHAW, C. D. & KLAZINGA, N. 2009. Impact of quality strategies on hospital outputs. *Qual Saf Health Care,* 18 Suppl 1**,** i62-8.
SUNSTEIN, C. R. 2005. Moral Heuristics. *Behavioral and Brain Sciences,* 28**,** 531-542.
SURENDER, R., BRADLOW, J., COULTER, A., DOLL, H. & BROWN, S. S. 1995. Prospective study of trends in referral patterns in fundholding and non-fundholding practices in the Oxford region, 1990-4. *BMJ,* 311**,** 1205-1208.
SURENDER, R., FITZPATRICK, R. & BROWN, S. 1998. The patient's view of general practice fundholding: results of a cross-sectional survey. *Health & Social Care in the Community,* 6**,** 370-377.

SUTHERLAND, K. & LEATHERMAN, S. 2006. *Regulation and quality improvement: a review of the evidence*, Health Foundation.
SUTINEN, J. G. & KUPERAN, K. 1999. A socio-economic theory of regulatory compliance. *International Journal of Social Economics,* 26**,** 174-193.
TAN, K. B., CHANG, S. A., SOH, V. C., THAMBOO, T. P., NILSSON, B. & CHAN, N. H. 2004. Quality indices in a cervicovaginal cytology service: before and after laboratory accreditation. *Arch Pathol Lab Med,* 128**,** 303-7.
TAYLOR, N., CLAY-WILLIAMS, R., HOGDEN, E., BRAITHWAITE, J. & GROENE, O. 2015. High performing hospitals: a qualitative systematic review of associated factors and practical strategies for improvement. *BMC Health Services Research,* 15**,** 244.
TAYLOR, P. 2013. Standardized mortality ratios. *International Journal of Epidemiology,* 42**,** 1882-1890.
THE CAVENDISH REVIEW 2013. An Independent Review into Healthcare Assistants and Support Workers in the NHS and social care settings. London.
THE COCHRANE COLLABORATION 2011. 9.4.11 Use of vote counting for meta-analysis. *In:* HIGGINS, J. & GREEN, S. (eds.) *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011].*
THE COMMONWEALTH FUND 2017. International Profiles of Health Care Systems. *In:* MOSSIALOS, E., DJORDJEVIC, A., OSBORN, R. & SARNAK, D. (eds.).
THE ECONOMIST. 2014. Health reform in a cold climate. *The Economist*.
THE HEALTH FOUNDATION 2010. Evidence scan: Complex adaptive systems. London.
THE HEALTH FOUNDATION 2011. Evidence scan: Competition in healthcare. London.
THE KING'S FUND. 2017. *What are the priorities for health and social care?* [Online]. London. Available: https://www.kingsfund.org.uk/publications/what-are-priorities-health-and-social-care [Accessed 29/08/2017].
THE POINT OF CARE FOUNDATION. *PFCC: Patient and Family-Centred Care toolkit* [Online]. Available: https://www.pointofcarefoundation.org.uk/resource/patient-family-centred-care-toolkit/ [Accessed 30 October 2017].
THOMPSON, E. P. 1978. *The Poverty of theory and other essays,* New York, The Merlin Press.
THORLBY, R., SMITH, J., DAYAN, M. & WILLIAMS, S. 2014. The Francis Report: one year on. Research report. London: Nuffield Trust.
THORNLOW, D. K. & MERWIN, E. 2009. Managing to improve quality: the relationship between accreditation standards, safety practices, and patient outcomes. *Health Care Manage Rev,* 34**,** 262-72.
TIMMINS, N. 2010. How New Labour succeeded with NHS policy. *Financial Times*.
TIMMINS, N. 2012. *Never again? or The story of the Health and Social Care Act 2012,* London, The Institute for Government and The King' Fund.
TODD, J. K. 2006. *On Track to Quality*, Lighthouse Point Press.
TOFFOLUTTI, V., MCKEE, M. & STUCKLER, D. 2017. Evidence Points To 'Gaming' At Hospitals Subject To National Health Service Cleanliness Inspections. *Health Affairs,* 36**,** 355-361.
TOWERS, T. J. & CLARK, J. 2014. Pressure and performance: buffering capacity and the cyclical impact of accreditation inspections on risk-adjusted mortality. *J Healthc Manag,* 59**,** 323-35.
UK STATISTICS AUTHORITY 2009. Code of Practice for Official Statistics. London.
UK STATISTICS AUTHORITY 2016. National Statistician's Guidance: Management Information and Official Statistics. London.
VEDUNG, E. & VAN DER DOELEN, F. C. J. 2017. The sermon: information programs in the public policy process - choice, effects, and evaluation. *In:* BEMELMANS-VIDEC, M.-L., RIST, R. C. & VEDUNG, E. (eds.) *Carrots, sticks and sermons : policy instruments and their evaluation.* London: Routledge, Taylor and Francis Group.
VERGARA, I., BILBAO, A., GONZALEZ, N., ESCOBAR, A. & QUINTANA, J. M. 2011. Factors and Consequences of Waiting Times for Total Hip Arthroplasty. *Clinical Orthopaedics and Related Research,* 469**,** 1413-1420.

WAGNER, A. K., SOUMERAI, S. B., ZHANG, F. & ROSS-DEGNAN, D. 2002. Segmented regression analysis of interrupted time series studies in medication use research. *Journal of Clinical Pharmacy and Therapeutics,* 27**,** 299-309.

WALKER, J., PAN, E., JOHNSTON, D., ADLER-MILSTEIN, J., BATES, D. W. & MIDDLETON, B. 2005. The value of health care information exchange and interoperability. *Health affairs,* 24**,** W5-10.

WALSHE, K. 2003. *Regulating healthcare: a prescription for improvement?,* Maidenhead, Open University Press.

WALSHE, K. 2007. Understanding what works--and why--in quality improvement: the need for theory-driven evaluation. *Int J Qual Health Care,* 19**,** 57-9.

WALSHE, K. 2009. Pseudoinnovation: the development and spread of healthcare quality improvement methodologies. *International Journal for Quality in Health Care,* 21**,** 153-159.

WALSHE, K., BOYD, A., ADDICOTT, R., ROBERTSON, R. & ROSS, S. 2014. Evaluating the Care Quality Commission's acute hospital regulatory model: final report. Manchester Business School and The King's Fund.

WAN, T. T. & CONNELL, A. M. 2003. *Monitoring the quality of health care: Issues and scientific approaches*, Springer Science & Business Media.

WEBSTER, C. 2002. *The National Health Service: A Political History*, Oxford University Press.

WEEKS, W., SCHMIDEK, J., WALLACE, A. & DIMICK, J. 2007. Do JCAHO accredited hospitals perform better on quality measures? Analysis of process-of-care measures.

WEST, M., BAKER, R., DAWSON, J., DIXON-WOODS, M., LILFORD, R., MARTIN, G., MCKEE, L., MURTAGH, M. & WILKIE, P. 2013. Quality and safety in the NHS: Evaluating progress, problems and promise.

WHYNES, D. K., HERON, T. & AVERY, A. J. 1997. Prescribing Cost Savings by GP Fundholders: Long-Term or Short-Term? *Health Economics,* 6**,** 209-211.

WHYNES, D. K. & REED, G. 1994. Fundholders' referral patterns and perceptions of service quality in hospital provision of elective general surgery. *British Journal of General Practice,* 44**,** 557-560.

WIERZBICKA, A. 1996. *Semantics: Primes and Universals*, Oxford University Press UK.

WILLIAMS, S. C., SCHMALTZ, S. P., MORTON, D. J., KOSS, R. G. & LOEB, J. M. 2005. Quality of Care in U.S. Hospitals as Reflected by Standardized Measures, 2002–2004. *New England Journal of Medicine,* 353**,** 255-264.

WILSON, R. P. H., BUCHAN, I. & WALLEY, T. 1995. Alterations In Prescribing By General Practitioner Fundholders: An Observational Study. *BMJ: British Medical Journal,* 311**,** 1347-1350.

WORLD HEALTH ORGANIZATION 2003. Quality and accreditation in health care services: a global review. Geneva.

WRIGHT, J., DUGDALE, B., HAMMOND, I., JARMAN, B., NEARY, M., NEWTON, D., PATTERSON, C., RUSSON, L., STANLEY, P., STEPHENS, R. & WARREN, E. 2006. Learning from death: a hospital mortality reduction programme. *J R Soc Med,* 99**,** 303-8.

XAVIER, A. 2003. Hospital Competition, GP Fundholders and Waiting Times in the UK Internal Market: The Case of Elective Surgery. *International Journal of Health Care Finance and Economics,* 3**,** 25-51.

YIN, J.-C. T. & YANG, K.-P. A. 2002. Nursing turnover in Taiwan: a meta-analysis of related factors. *International Journal of Nursing Studies,* 39**,** 573-581.

ZARBO, R. J. & D'ANGELO, R. 2006. Transforming to a Quality CultureThe Henry Ford Production System. *Pathology Patterns Reviews,* 126**,** S21-S29.

ZEGERS, M., HESSELINK, G., GEENSE, W., VINCENT, C. & WOLLERSHEIM, H. 2016. Evidence-based interventions to reduce adverse events in hospitals: a systematic review of systematic reviews. *BMJ Open,* 6.