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**NHS arm's length bodies and health regulation in England: who regulates the
regulators?**

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Hypothesis

“In the health sector there are micro and macro deficiencies present in regulatory systems”.

Abstract

This research uses mixed methods to critically analyse health regulation systems in England, in a macro and micro sense. The qualitative side of the research involves interviews with key staff members from four NHS Trusts and two Clinical Commissioning Groups. These semi-structured interviews offer unique specific insights from the key actors, from varying perspectives in the process. The quantitative element of the research focuses on trends and correlations of the data sets used by particular arm's length bodies operating in the policy area. Specific arm's length bodies operating in the health policy arena, which are assessed in the research, include the Care Quality Commission, Monitor and Dr Foster Intelligence.

The findings and conclusions centre on the deficiencies that are present in the current regulatory regime, what is occurring in this area, and why this is occurring. Following the Grounded Theory Approach, the research develops inductive theory, from the data, culminating in a “Feedback Loop Theory of Regulation”.

Key words: NHS, regulation, mixed methods, arm's length bodies, feedback loop theory, grounded theory, Care Quality Commission, Monitor, and Dr Foster Intelligence.

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Acronyms and terms used

AFT = Aspirant Foundation Trust

ALB = Arm's Length Body

ANOVA = Analysis of Variance

CCG = Clinical Commissioning Group

CCS = Clinical Classification Software

Cdiff = Clostridium Difficile

CHI = Commission for Health Improvement

CPA = Care Programme Approach

CQC = Care Quality Commission

CQUIN = Commissioning for Quality and Innovation

DofH = Department of Health

DSS = Department of Social Security

ERP = Ethics Research Panel

FT = Foundation Trust

GP = General Practitioner

HC = Healthcare Commission

HES = Hospital Episode Statistics

HSCIC = Health & Social Care Information centre

MRSA = Methicillin-Resistant Staphylococcus Aureus

NDPD = Non-Departmental Public Body

NICE = National Institute for Clinical Excellence

NPM = New Public Management

NPSA = National Patient Safety Authority

NRLS = National Reporting and Learning System

NHS = National Health Service

NHSIC = National Health Service Information Centre

NHSLA = National Health Service Litigation Authority

OFSTED = Office for Standards in Education

PCT = Primary Care Trust

PFI = Private Finance Initiative

PPP = Private Public Partnership

SHA = Strategic Health Authority

SHMI = Summary Hospital level Mortality Indicator

HSMR = Hospital Standardised Mortality Ratio

RCT = Rational choice theory

RO = Research Objective

QIPP = Quality Innovation Productivity and Prevention Programme

QRP = Quality and Risk Profile

QUANGO = Quasi Autonomous Non-Governmental Organisation

Chapter 1: Introduction

1.1 Power and Policy

The UK is a representative democracy where government makes public policy through its prime minister, ministers, cabinet and members of parliament. But the making of policy is constrained by the bureaucratic departments made up of civil servants who implement policy. These are in turn influenced and advised by pressure groups, on varying levels depending on which government department. The relationship between the civil service and pressure groups is based on, “shared expertise, reinforced by regular interaction” which tends to “lead to similar perspectives among civil servants and pressure group representatives” (Harrop 1995 p.91). Both ministers and civil servants can also be influenced by the media, whose role in setting the agenda in the Mid Staffordshire debacle, for example, was very significant. The government maintains much structural power but in practice this power; “is often not fully utilised because of cultural inhibitions” (Harrop 1995 p.91). There is significant evidence that bureaucrats make many policies, “the civil service is about twenty times as big as it was a hundred years ago and there are only about three times as many ministers” (Birch 1983 p.157). Academia is another realm which exerts influence over public policy. The degree and nature of this influence varies depending on the policy area, the exposure of the research and the perceived quality of the research.

The role of regulatory bodies in making public policy through continued evaluation cannot be ignored. The body of thought that coincides most with the analysis present in this paper is elite or neo pluralism. “Top down” theories underestimate the power of civil servants, regulators and pressure groups. Similarly “bottom up” theories understate the power of ministers and cabinet. In reality, a multitude of “key actors” influence the making of public policy in the UK, through formulation at the top, through discretion in implementation at the bottom, and through evaluation after implementation.

Government ministers are certainly influential in the making of public policy, seeing “their role as initiating or at least selecting policy, piloting measures through parliament and party” (Harrop 1995 p.75). When compared with other liberal democracies it is evident that British ministers tend to focus on their departmental work. They are described as having a “generalist ethos” and compared to France, Japan and America “few ministers in Britain have a background in the subject matter of their department” (Harrop 1995 p.76). A criticism of the British system is that the short term and non-specialist nature of ministers in Britain often means that long term problems are neglected. This can mean that ministers have a weak grasp of what their department is or is not capable of implementing.

Cabinet is a “key actor” in the making of public policy; “cabinet committees are the bodies which anchor the policy making process, giving agendas, timetables and an overall structure to the flow of policy” (Harrop 1995 p.77). The “top down” school of thought, championed by Weber (1864-1920), supports these claims, arguing that bureaucratic hierarchy of authority, which is systematic and rules based, results in the making of policy at the top, through ministers and powerful politicians. To critique the system of making public policy from this Weberian, top down approach, “breakdown in the delivery of policy, or worse, failure to implement according to top-downers is due to human fallibility and emotion and what is needed to put this right is stricter enforcement and tighter appraisal of the administrative machine” (Hudson and Lowe 2006 p.206).

“Bottom up” theorists and pluralists alike argue that the state is a passive actor, and not regarded as “key” in the policy making process. Lipsky (1971, 1979) was a significant theorist who challenged the top down school of thought arguing; “that policy was not in reality the product of policy makers but was the outcome of the activity of “street-level bureaucrats”, those people at the front line in service delivery” (in Hudson and Lowe 2006 p.208). This bears resemblance to a pluralist notion of power, in that it is “widely dispersed among a variety of groups and actors” (Cox et al. 1986 p.106). This pluralist notion of power may hold true to a certain degree in that there are many actors that influence public policy, but it is hard to accept that the state is a passive actor in the making of public policy in the UK. The state,

through its prime minister, ministers, junior ministers and many other actors, does exert significant power through the statutes and laws it enforces. Furthermore, it is hard not to reject a pure pluralist notion of power because to regard power as widely distributed between all electors and voters, as pluralism would suggest, is perhaps wishful thinking.

Pluralists and/or “bottom up” theorists would claim that electors and voters are key actors in the making of public policy. This is because in a liberal democracy like the UK elections mean citizens can vote for which political party they want to govern the country. In this way they arguably influence policy by their vote, but their separation from the policy making process limits their influence significantly. The problem is that “voters are forced to discriminate between the parties in terms of their general ideologies, value biases and images” (Hill 2000 p.68). This means that they have to judge what policies will arise through a particular political ideology, and vote on that basis. There is no guarantee that the party they vote for will do what they think it will, voters just have hope that they will. This results in low levels of control and power in the actual making of public policy, justifying the rejection of pluralist critiques and notions of power. A more realistic view comes from an elite pluralist model which “understands and accounts for the power of the state and how state actors relate to a range of stakeholders” (Hudson and Lowe 2006 p.123). This increased emphasis on policy networks is more appropriate and realistic.

There are many scholars who purport elite or neo pluralist notions of power. Rhodes and Marsh (2006), for example, claims that policy networks are the main factor in the making and implementation of public policy. Power in this instance is plural in that it is widely distributed, but in a realistic sense i.e. it is widely distributed between “key actors”. Rhodes and Marsh (2006) provides a considered definition of policy networks (although even this definition is a contested concept):

“Policy networks are sets of formal institutional and informal linkages between governmental and other actors structured around shared if endlessly negotiated beliefs and interests in public policymaking and implementation. These actors are interdependent and policy

emerges from the interactions between them.” (in Moran et al. 2006 p.430).

1.2 Issues/Problems with Health Regulation: The Background

Much like power in public policy more generally, power in terms of health policy can be viewed through an elite or neo pluralist lens. Power is retained by government health ministers, the prime minister, as well as the bureaucrats who implement this policy. There is also significant influence exerted by regulators and pressure groups that evaluate the implementation of health policy and implement policies of their own, from an arm's length.

The Institute for Government define the term arm's-length body (ALB) below:

“Arm's-length body is a general term, used to cover at least 11 types of organisation which operate at varying, and often contested, degrees of independence from government. They range from big organisations employing thousands of public servants and administering billions of pounds of public money, to small advisory committees with no independent budget. They regulate some of the most sensitive areas of public and private activity. At the same time they seem to suffer an on-going crisis of legitimacy as all political parties feel the need to rein in the quango state. The government has embarked on an ambitious reform agenda for these public bodies, and is subjecting many of their activities and spending to much closer scrutiny and controls than before. The flux in ALB governance leads to challenges around making do with less, but also an opportunity to look again at how ALBs interact with central government and with their sponsoring departments.” (2013 p.1)

This definition is clearly one which is ambiguous. The degree of independence for instance to warrant being considered “arm's length” is debatable. The aims of arm's length bodies often mimic the aims of their sponsoring department, meaning that in reality the separation may be tokenistic rather than genuine. These debates lead to contestable legitimacy of ALBs and the areas they operate in. Throughout this thesis these debates are examined in relation to specific ALBs operating mainly in the health sector.

Many authors on the topic of regulation (such as Hood et al 1998, Trubeck et al 2008, Walshe and Phipps 2013 and Walshe and Shortell 2004) have noted numerous deficiencies associated with regulatory deployment, by government created ALBs. There is much evidence to suggest that this is an area of public policy which is very hard to manage effectively, with severe consequences when deficiencies persist. It is an area which can be very expensive in terms of financial cost, as well the time and effort dedicated to its implementation (which should not be underestimated). This is relevant to the regulators own efforts, as well as the burden of this on organisations that they regulate. The evaluation of the effectiveness of arm's length bodies is of paramount importance for academics and policy makers alike, because if regulation is not having a positive effect on the NHS (or any other area of policy for that matter), then there is no justification for using it.

Health regulation is an area of English public policy which involves a plethora of different bodies operating independently of one another with the aim of monitoring standards, ensuring minimum standards are met, and providing assurance for the public and government. These standards differ somewhat in their exact focus. The Care Quality Commission (CQC) being primarily based on quality and safety measurements. Monitor focuses on finances and governance although quality is also becoming part of their remit. These two organisations are ALBs, but also of significance in this arena are Dr Foster Intelligence, who are a private public partnership that publish annual hospital guides based on quantitative measurements. Whilst they are not a “regulator” in the traditional sense, i.e. they have no powers for formal intervention, they are commissioned to publish the guides by the government and perform a regulatory function of sorts. From this point onward they are referred to as a key regulatory actor, due to the influence they exert, despite being private public partnership.

1.3 Key Regulatory Actors and Arm's Length Bodies: The CQC, Monitor and Dr Foster

Walshe and Phipps (2013) is a good starting point for looking at a specific ALB: the CQC. This research provides contemporary evidence which outlines many of the issues that the CQC faces, developing a “logic model” of the status quo regarding regulatory arrangements.

The model “tries to map out how they are intended to work, and what assumptions are made or consequences flow from those arrangements” (p.6). The main conclusion is that the CQC represents a “safety net regulator” which is primarily aiming to deal with “poor performance” but suffers from “limited capacity or capability to drive or support wider performance improvement” (p.6). This report focuses on the four main functions of the CQC: registration, compliance, enforcement and information provision. It discusses the logic underlying each function and what consequences there are in their delivery.

With regard to registration, Walshe and Phipps argue that under the current configuration the CQC’s registration process is constructed around the premise of providing “an administrative record of registered providers” (2013 p.10). The research suggests that this administrative record does not require providers to meet essential standards, or provide assurance around these standards.

Compliance is broken down into three components due to its complex nature;

- standard setting
- information gathering and risk assessment
- inspection and reporting

In terms of standard setting, one of the main findings is that “different regulatory purposes require quite different kinds of standards” (2013 p.13). The consensus in the research is that as the compliance with key CQC standards is so high (73% of all organisations) the CQC standards represent minimal standards which focus mainly on preventing the very poorest in quality. Not complying with the CQC five key standards represents being in the worst 27% of providers, as judged by them. The CQC does not rank organisations in terms of excellent, good, average, poor etc. (in the style of the previous health regulator the Healthcare Commission). The minimum standards represent more of a “safety net” focusing only on whether these organisations are performing poorly, and not how well they are doing beyond that.

In terms of information gathering and risk assessment the main CQC tool identified is the Quality and Risk Profile (QRP). These QRPs are made up of a variety of data sources; “some information is drawn from routine data, and this is supplemented by information from other sources such as CQC’s own inspections, feedback from other regulators, complaints, “whistle-blower” reports, etc.” (p.14). These QRPs are then used to determine whether regulatory interventions are needed. The research identifies numerous reasons which limit the effectiveness of the QRPs, for instance; “the quality, completeness and timeliness of information has been questionable” (p.15). It is also identified that the QRPs do not have “sufficient predictive value” (p.15) i.e. the QRPs have little relevance as to the relative risk of organisations actually performing well (or poorly) in the future. Further limiting the effectiveness of the QRPs is the finding that “it is not clear that compliance inspectors have the capacity and resources to use information from the QRP in their inspections” (p.15).

With reference to inspection and reporting, the CQC inspects “most services” at least once every 12 months. These unannounced visits can last a variety of time, depending on the “size and complexity” of the organisation (p.15). One of the main issues identified in the research is that “inspectors carry a mixed portfolio of organisations and are not expected to have any particular content expertise in the sectors they inspect” (p.15). Furthermore, the nature of these inspections comes under criticism, for instance, it is stated that; “the process of inspection is largely oriented towards direct observation and assessment of care processes, and it is not clear to us how well that works in larger organisations, where only a very small proportion of care delivery can ever be observed or assessed” (p.16). The research is also critical of the decision the CQC make to focus on 5 of the 16 key standards as this makes “longitudinal and inter-organisational comparisons of performance” extremely problematic (p.16). They are also doubtful as to the compliance judgements made by inspectors being consistent, as they are based on subjective interpretations.

Enforcement is carried out by the CQC in cases of non-compliance; the nature of enforcement is based on a judgement framework, which determines the appropriate CQC action. Walshe and Phipps conclude that the CQC enforcement actions “are generally

relatively trivial in terms of their actual impact on providers” and describe the mode of enforcement the CQC use as “symbolic action” (p.19). They argue that the number of enforcement actions the CQC can make in reality, is few, due to the intensive labour required and their limited resources.

Information provision is undertaken by the CQC, exemplified through the information they provide on their website, as well as reports, and other publications, such as themed inspections. Notably the research identifies the QRPs as not being published in any consistent format. It is claimed that information provision is limited by the factors already mentioned (standard setting and the high volume and varying quality of information from inspections). The “dichotomous judgements of compliance or non-compliance cover only a partial set of the essential standards and in any case are not particularly discriminating since most providers are fully compliant” (p.20). This research concludes that “the overall impact of the regulator is likely to be low” (p.22) and clearly illustrates that the CQC suffers from several regulatory deficiencies at all levels of its operational activity.

Deficiencies are identified not just with the CQC specifically, but also with the interaction between the CQC and Monitor. One of the significant findings in a recent Health Committee report on regulation in health care is that:

“We remain concerned that the parallel roles of Monitor and the CQC create significant scope for confusion which could result in either regulatory lacunae or regulatory duplication – or both. In our recent report on the CQC we recommended that the Government needs to clarify the roles of the two organisations; we further recommend that this review should be undertaken as a matter of urgency in the light of the recommendations of the Francis Inquiry into events at the Mid Staffordshire NHS Foundation Trust.” (House of Commons Health Committee 2013 p.4/5)

It is argued that many of the associated problems in health regulation generally, stem from the role of regulators being unclear and overlapping. Therefore, this requires the attention of

the government. This report also identifies issues surrounding the transparency of regulators as well as the prioritising of the functions which they enact. It claims for instance that a limiting aspect of the current system is:

“Failures of accountability and transparency in the role of system managers and regulators. The Report found that regulators’ focus was directed at financial and organisational issues, rather than the protection of patients and ensuring that patient safety and quality standards were being observed. This was attributed to poor communication, misaligned methods of assessment, and an over-reliance on assurances given by other organisations.” (House of Commons Health Committee 2013 p.5).

The NHS Confederation offer similar conclusions around the issues that health regulation faces. It is claimed for instance that “there has been insufficient cooperation between the various agencies that request information, particularly at local level” (NHS Confederation 2013 p.2). They also identify aspects of the contemporary regulatory systems which increase the chances of duplication of efforts and inefficiencies for providers. They state that: “providers still lack the right to formally challenge agencies which ask for the same or similar information that has been requested by others” (NHS Confederation 2013 p.2).

Of further concern, the NHS Confederation argues that the NHS reforms merely add to the bureaucracy that is entrenched in the system. They suggest that “we are worried that the current NHS reforms, by making the system more complicated, will increase still further the administrative burden... a more complex system architecture, and more commissioners, will inevitably increase the number of interfaces and transactions, and thus the administrative burden” (NHS Confederation 2013 p.2).

There is clearly much that depends on the relationship between the CQC and Monitor being healthy and transparent. Developing this relationship is ‘key’ to the efficient regulation of NHS providers, and there exists a “memorandum of understanding” that tries to enhance this relationship as outlined below:

“The CQC and Monitor recognise that there is a distinct and unique relationship between the two regulators. Accordingly the framework set out in this Memorandum takes account of that relationship and details ways in which they will work together and alongside one another in delivering their respective statutory functions. The framework is intended to communicate clearly and unambiguously that CQC and Monitor will work together where relevant to do so and will adopt the Better Regulation principles and behaviours.” (CQC and Monitor 2011 p.1).

The issue is, the two regulators have been trying to achieve this “memorandum of understanding”, but there is significant evidence that suggest that deficiencies persist in reality (NHS Confederation 2013, Health Committee 2013, Francis 2013, and Walshe and Phipps 2013). It is suggested that issues with the purpose and remit of the CQC and Monitor, as well as their working relationships in practice, are significant and limit the effectiveness of both as regulators.

There is also evidence to suggest the methodologies deployed by key regulators (the CQC, Monitor and Dr Foster) is also limiting the value of what they do. A starting point to get an overview of these particular issues comes in the form of a qualitative interview undertaken with Anna Walker, who was Chief Executive of the Healthcare Commission from 2004 to 2009. This Nuffield Trust publication involves interviews with key NHS leaders and whilst it is slightly journalistic, it offers reflections of what it is like to work in the NHS at a senior level and the challenges faced by NHS leaders. It therefore warrants inclusion in this thesis. Walker states that “I think this question of what the methodology is to get at what it is that you’re looking at, and what information you use, are a big set of issues. Methodology requires both the looking and seeing, and the statistics.” (in Timmins 2013 p.83).

Anna Walker also claims regarding methodologies that:

“It’s not easy if a trust itself isn’t facing up to the problems. You can go and walk around a ward, but you may not see the problems that are going on. Because they may be about quality of clinical results, or the unseen distribution of infections. You’ve actually got to use a

number of different methodologies to get there. We need to get better at it over time, so it tells you more.” (in Timmins 2013 p.83).

This focuses in on the nature of so called “ad hoc random inspections”. It is logical, as she suggests, that if a combination of various methodologies is not used then this can be limiting to the value of information capture. There is clearly only so much value that can be derived from just going in to a provider of healthcare for one day when one set of staff are operating and making a value judgement based on this.

There is also significant controversy around the deployment of mortality statistics. Anna Walker summarises her position around mortality statistics beneath:

“There is the argument that the mortality rate figures weren’t good enough. That is true. But I have sympathy with the view that they tell you something, because all information tells you something.” (in Timmins 2013 p.82).

Mortality statistics are the main tool that Dr Foster Intelligence use in their hospital guides which are published annually. They are based on standardised Z scores which rank hospitals in terms of actual number of deaths compared with the expected levels. There are various research papers that have been published which indicated that mortality data is flawed methodologically as indicated (Mohammed et al. 2009, Francis 2013, and Nuffield Trust 2013). This is further discussed in more detail in the subsequent literature review.

The former Healthcare Commission Chief Executive also identifies the remit of health regulators as being greater than what they can achieve realistically given the resources that they have at their disposal. She claims that:

“You’ve asked if we expect too much of regulation and inspection. Unequivocally there is that danger. I think the regulator can do something about that by making it clear what they think their role is and what it isn’t.” (Timmins 2013 p.85).

The Department of Health also acknowledges that there needs to be a better alignment of appropriate methodologies used by regulators that are in cooperation with one another. The passage beneath summarises these issues moving forward.

“The Care Quality Commission, the NHS Commissioning Board, Monitor and the NHS Trust Development Authority will be required to agree together the data and methodology for assessing hospitals. This will ensure a single set of expectations on hospitals of what is required of them which are aligned with the way in which commissioners, led by clinicians and guided by the views of local patients, ensure high quality care in the hospitals for which they are responsible. Providers will demonstrate, through annual Quality Accounts, how well they are meeting that single set of expectations.” (Department of Health 2013 p.19).

1.4 Data Sharing

The primary aim of government data sharing is to increase efficiency. This is purported to be achieved by data sharing between government agencies and departments resulting in a better service for citizens without increasing the cost of the service. Bellamy and Taylor argue that for government to increase efficiency savings in the realm of ICT and e-government it is required that there are, “new capabilities for capturing, for sharing, for integrating and for exploiting information by means of new information systems capable of supporting new information flows” (2003 p.86). These improved systems could be capable of reducing the cost of public services, and therefore the cost to the taxpayer, whilst at the same time improving the services in terms of quality. There is substantial evidence supporting this policy for example, it is argued that; “better use of information can improve public services. It can make access more convenient, ensure people get all the services to which they are entitled, or allow services to be personalised” (Cabinet Office 2008 p.5). This statement indicates that the benefits aside from reducing the cost of services can be extensive in the ways they improve quality.

General ideas are often best illustrated by specific detailed examples. Take the example of an

old person being treated for cancer. They are at the hospital seeing a specialist. It is the fourth time in two weeks someone has seen them. Each time, the staff has to go through and take down the basic data about the person and their medical situation. The patient is deaf, in their nineties, frail, and is taking a large quantity of medication for their illness. This part of the consultation takes at least half an hour, with the consultant and a nurse there throughout. The nurse is writing it all down in pencil on a pad. The potential for error is large, as is the chance of replicating procedures. A central shared database, even just within the National Health Service, would improve this process immensely. Costs could be reduced, errors could be reduced, and the stress on the patient might also be reduced.

A purported effect of increasing data sharing is that; “Citizens should gain more efficient and convenient access to public services”, (Council for Science and Technology 2005 p.2) therefore redefining what it means to be a citizen. Running large scale computer development projects notoriously present a major challenge for the public sector. The two significant problems are: firstly; the key thing in these projects is to achieve consensus around the design of the system. Secondly; this design must be adhered to consistently (in its implementation) after its conception. There are multiple stakeholders in big information sharing projects and this can lead to confusion over the design and consistency in implementation.

The following example is an apt illustration of the problems associated with data sharing projects in the public sector. In 2002 the Labour government launched a large scale data sharing scheme. The budget was £11.4bn and Tony Blair claimed that “the possibilities are enormous if we can get this right” (Guardian 2011). The aim: replacing paper medical records with a centralised national electronic database. In 2011 the scheme was scrapped, £6.4bn had already been spent, and “the scheme quickly degraded into a mass of regional and incompatible systems, provided by two companies BT and Computer Sciences Corporation” (Guardian 2011). Getting one central owner of these large projects to control data sensibly is seemingly difficult. This is made even harder because political control can also change while the projects are in motion. It seems very unsatisfactory that a project can spend £6.4bn and

not deliver the proposed outcomes, and this example shows how these types of projects can fail. This does not however mean that they are not worth pursuing, merely that lessons need to be learned from these examples.

Rationalising information handling in a way that advocates increased data sharing has far reaching potential consequences. The ultimate example of this rationalised data sharing was also proposed by the previous Labour government; in the form of citizen ID cards. The proposal aimed to increase efficiency and reduce waste in a number of ways. These include eliminating waste as the same data will no longer be requested from a citizen from a number of departments, therefore reducing unnecessary bureaucracy. Another proposed efficiency saving comes in the form of self service facilities, where the cards can be used to pay bills and a number of other functions that also serve to reduce unnecessary bureaucracy. Even as long ago as 1999, Wired Whitehall outlined these proposals, anticipating “that every individual will eventually be offered a smart card, to be called a “citizen card”, permitting a wide range of transactions to be credited and debited from a “single citizen account” (Bellamy and Taylor 2003 p.84). On the other hand, there are considerable threats to citizenship posed by citizen cards and the associated implications. They can be considered an invasion of personal liberties and against the Human Rights Act (1998) and Data Protection Act (1998). Biometric data was proposed to be put on the cards, and many consider this an unnecessary infringement of citizenship that steps beyond what is justifiable for efficiency savings.

To consider how these acts actually affect public policy and data sharing it is necessary to examine another data sharing example, which, in this case actually worked because the scheme went ahead and was completed. The Department of Social Security (DSS) collects personal data on citizens regarding social security and other similar matters. The BBC issues to certain citizen’s concessionary television licenses, for example they are free for citizens aged over 75 years old. These licenses are subject to certain checks to ensure there are no fraudulent applications, for example by sending the BBC documentary proof that the citizen is who they say they are. This process involves time and effort from the citizens concerned and it requires administrative time and effort from the BBC to check that the personal information

is correct. To reduce this time and effort for both parties, it was proposed that the BBC could perform crosschecks based on the personal information held at the DSS database. This resulted in The Television Licenses (Disclosure of Information) Act 2000 which allowed some data sharing between the DSS and BBC to take place, although this information was limited in its scope and content. As Chissick and Harrington aptly summarise; “the overall proposition might be one of data sharing. However, the final permission to share personal data was narrowly circumscribed” (2004 p.274). The important point is that data sharing occurs in a way that is not allowed to damage citizenship. In this instance the legislation may have curtailed the data sharing to an extent, which could arguably reduce its effectiveness in increasing efficiency, but perhaps this is the price that preserving citizenship requires. It has been illustrated that data sharing can be used to improve government services. Government services can be made more efficient, higher quality, and cheaper. Lessons from previous attempts at data sharing need to be learnt though for the goals of these projects to be realised: such as having one overall controller of the data and following implementation of the project plan consistently.

1.5 Neo-pluralism and rational choice theory

Many of the key issues, problems with regulation, as well as the functions of the various ALBs can be perceived as stemming from the distribution of power in the sector. Taking the most realistic notion of power, that of neo or elite pluralism: which purports that power is widely distributed among key actors, it becomes apparent why there are many of the aforementioned issues and interactions between the various ALBs. As the numbers of ALBs increases in a sector, because of the neo-pluralist distribution of power it becomes expensive to finance. It also means that there is much greater scope for repetition of role/functions by these bodies. This is not only an issue in terms of it being an inefficient allocation of government resources, but the impact of providers of conforming to several arm’s length bodies compared to just one is logically much greater.

Applying rational choice theory to a neo-plural regulatory network such as exists in the health sector, where power is widely distributed between key actors these independent ALBs operate as rational self-maximisers. The rational choice theory element of this stems from economics, the premise being that all people act in a way which they perceive as maximising their own utility from an exchange. Based on the neo-plural nature of regulation, we know that power is distributed among several key actors. These key actors can be considered the individuals from the rational choice theory example in this sense. They seek to make decisions based on maximising their own utility from an exchange. So for example: they want to maximise the budget they get, their impact on the NHS (and therefore their power as an arm's length body) as well as being self-maximising in a self-preservation sense, i.e. the staff at these organisations want to keep their jobs.

This application of rational choice theory on a neo-plural regulatory framework can explain much of the identified issues around cooperation and data sharing. If the CQC and Monitor share a remit around quality (as they do) then it is logical for the CQC to keep their information private from Monitor and vice versa, because from their rational self-interested perspective this information is where the value of the organisation come from.

The issue is, how to best encourage these ALBs operating in a sector with power being shared between many key actors to act in a way which doesn't merely seek to retain the status quo and make themselves appear powerful, and move to a situation where the collective power of the ALBs is enhanced through cooperation and data sharing. Neo pluralist theory explains why the sector looks like it does, there are many organisations operating at arm's length because of the complicated distribution of power. Rational choice theory explains much of the motivation behind organisational behaviour which limits the effectiveness of arm's length bodies when power is distributed in this way.

1.6 Primary Research Objectives

Based on the contemporary backdrop of health policy and regulatory networks in the NHS the

research objectives emerged. There is much evidence to suggest that there are deficiencies associated with NHS regulation at numerous levels. This research seeks to ascertain “what is going on here” in line with the grounded theory approach (Glaser and Strauss 1967). There are issues identified with the key actors in the field: CQC, Monitor and Dr Foster intelligence all have been criticised in terms of their purposes and their implementation of their respective roles. The research objectives are framed based on what can be derived as relevant routes of inquiry from the contemporary literature on these key actors. This research involves inductive, bottom up logic which seeks to evaluate general propositions that are derived from specific examples. The research objectives are as follows:

1. Critically assess the regulation of NHS providers in England (macro level).
2. To compare methodologies used by the regulatory bodies for rating and regulating NHS Trusts in England and assessing the impact of this on service provision.
3. Evaluate the effectiveness and reliability of the regulatory regime and their activities (micro level).
4. To discuss and explore the political, economic and policy orientated ideologies that underpin regulation regimes involved in the NHS.

Research objective one is an overall aim of this research. Research objectives two and three are objectives within this overall aim. Research objective four is then a desire to relate the findings back to the political, ideological and theoretical.

Research objective one was arrived at based on the significant evidence that the regulation of NHS providers at the macro level suffers from issues in terms of its conception as a policy, its implementation by key regulators and its subsequent effects on the NHS. The idea of focusing on the macro regulation i.e. regulation as a whole, is so that the whole picture can be examined in a critical sense. Focusing on providers in England is necessary to target the research objective and give the research a well-defined aim within the macro boundaries. In this sense the data will be from providers and targeted, but the implications of the data will lead to more general theorising around the macro regulatory regime in England.

Research objective two is derived from the various research and publications which suggest that some of the methodologies that are deployed by key health regulators are flawed. By flawed, it is meant that they do not necessarily accurately portray or quantify what they are supposed to. The comparison and analysis of the methodologies therefore serves as a tool to further enhance the macro analysis of the regulatory networks.

Research objective three is designed to examine and assess the specific elements of key regulatory actors i.e. a micro analysis. The basis for this objective is similar to research objective one; but in this case the main focus is on the detail, the specific nuances that result in effective or ineffective implementation of regulatory duties. Whilst the macro analysis serves to lead to theorising, the micro analysis serves to provide specific criticisms and recommendations which are often more simple in their nature. This simplicity does not negate their importance or relevance. Problems which have simple solutions are often the most fruitful to pursue, meaning recommendations can actually be implemented without massive reorganisation or upheaval.

Research objective four serves to unify the research in terms of identifying and critiquing the ideologies (economic, political and policy) that underpin regulatory arrangements. This is on the basis that policy making is determined by these ideologies and exploring them allows a fuller understanding of the motivations and pressured operating in regulatory systems. Understanding these motivations allows for wider theory and conclusions to be derived from the data produced which explains why the current trends identified in research objectives one to three are prevailing.

As has been noted this research deploys the grounded theory method. As such, not all social scientists using this method would use a literature review beforehand, as the theory is supposed to be grounded in the data, and not based on preconceived ideas about phenomena. For example, Strauss and Corbin suggest that

“There is no need to review all of the literature in the field beforehand, as is frequently done by analysts using other research approaches. It is impossible to know prior to the investigation what the salient problems will be or what theoretical concepts will emerge. Also the researcher does not want to be so steeped in the literature that he or she is constrained and even stifled by it.” (1998 p.49).

There are however many researchers who deploy a grounded theory method which includes a literature review, despite these warnings. Lempert (1998) for example describes using a literature review in a “pragmatic” sense: “in order to participate in the current theoretical conversation, I need to understand it... a literature review provides me with the current parameters of the conversation that I hope to enter” (in Strauss and Corbin 1998 p.254). It is also noted by Barbour (2001) that wider pressures are often present in social science research that influence the decision to undertake a literature review: “In practice, however, you are unlikely to obtain research funding without having carried out a thorough literature review or having formulated some idea of the content of the data you are likely to collect” (p.1116). In a sense this is true in this case, it would not have realistically been possible to conceive of such a project which would gain a research grant (as was the case) without having at least some notion of the concepts involved.

There is however a strong justification for a literature review in this research, funding aside. This rests on the premise that regulation in England is extremely complex, with a vast array of actors participating in these interrelated networks. To ask simply “what is going on here?” is not enough. Questions or at least topics in the interview guide need to be determined. Key participants need to be identified. Data for quantitative analysis needs to be decided upon. For all of these things background knowledge is necessary. Similarly to Lempert (1998) the literature review serves a pragmatic purpose, and allows understanding of the current theoretical conversations surrounding health regulation and the peculiarities present. This does not mean that the data produced will not provide theory that is grounded; it simply means that the research is guided in a way which seeks to appropriately address the contemporary issues in the field. So whilst a legitimate criticism (to some extent at least) of

this research which traditional grounded theorists may levy, is that there is a literature review present, an equally legitimate positive implication of this literature review is that the research is consequently better placed to have a greater impact, relevance and practical use than would otherwise be the case. This research uses a modified version of grounded theory, whereby the research is informed by what has been gleaned on the topic previously, but the theory which emerges from the research is grounded in the data.

Original research questions and objectives can be “derived from the literature... literature can provide questions, initial concepts, and ideas for theoretical sampling... used as an analytical tool, it can foster conceptualisation” (Strauss and Corbin 1998 p.53). Lempert also states that; “utilizing comparisons from literature alerts me to gaps in theorizing, as well as the ways that my data tells a different, or more nuanced, story... It does not, however, define my research” (in Strauss and Corbin 1998 p.254). This also applies to this research. There is a lot of research regarding health policy and regulation and this thesis seeks to achieve something new, adding to the debate originally. The fact that literature is being considered previous to data collection enhances the potential for this occurring because specific key issues are recognised, shaping the focus of the research in a way that targets elements which are clearly of interest to policy makers, implementers and evaluators alike.

Chapter 2: Literature Review

2.1 Search method and strategy

The search method for this literature is based on a methodology of using inclusion criteria to arrive at the appropriate literature. The search strategy had the objective of generating literature, of an empirical nature related to regulation in the health policy area as well as appropriate commentary by authors in the field.

The inclusion criteria are as follows:

- Empirical research about health regulation in the UK and internationally.
- Empirical research about a field related to health regulation in the UK and internationally.
- Literature about the development of regulation in the UK and internationally.
- Commentary from academics in the field in the UK and internationally on contemporary trends.
- Theoretical examinations of: the definitions of regulation, what drives regulation, what constitutes successful regulation, arm's length bodies as a concept, the feedback process and data sharing.
- The problems and issues associated with regulation in health and other related fields generally.
- Specific methodological critiques, for example mortality methodologies.
- The research and the views of former and current public sector workers in the field.

In terms of exclusion criteria, literature was omitted if:

- It added nothing to the review conceptually or theoretically.
- It was of such a low standard that it did not warrant inclusion.
- It was not related enough to the topics of interest.

Literature was not excluded from this review lightly. Anything which was found which adds value in terms of understanding what is going on, even in an abstract sense has been

included in the review.

2.2 Database usage

The primary database which was searched was Google Scholar. The Keele EBSCO databases were also used. Using these databases combined with regular google searches and library searches, many sources of literature were discovered including: textbooks, journal articles, eBooks, official websites of government and NGO websites as well as journalistic pieces of sufficient value and quality to warrant inclusion.

The typical search terms are displayed beneath (please note this is not an exhaustive list and other terms may also have been used):

Regulation, health regulation, health care regulation, health policy and regulation, economic regulation, social regulation, definitions of regulation, regulation definitions, regulating healthcare, Care Quality Commission, Monitor, NHS, Dr Foster Intelligence, Hospital Standardised Mortality Ratio, HSMR, HSMI, mortality data, mortality statistics, hospital quality, quantifying quality in health care, NHS regulation, international healthcare regulation, international regulation, regulatory deficiencies, problems with regulation, problems with health regulation, improving regulation in health care, NHS regulation, regulatory policy and does regulation work?

The literature searching resulted in the identification of key texts which relate to the themes that emerged. These texts and the themes which emerged from them are identified and presented in the subsequent sections of this literature review.

2.3 History of Health Regulation in England

This section outlines the key developments in health regulation in England over the last 30 years. The purpose of this is to describe how and why the current situation is prevailing,

providing appropriate context for an understanding of it. There are also specific critiques of the relevant regulators included for each time period, where relevant. This adds to the understanding of the motivations of the government in reforming regulators and changing the policy directions at each point in time.

The background for healthcare regulation stems from early managerialist approaches to providing public services. These policies were initially introduced by the Conservative government of 1979-1997. This involved greater surveillance over medical practice coupled with a greater concern to evaluate outcomes through techniques like medical audit and performance indicators. These early types of neo-Taylorist managerialist techniques have developed significantly since the early eighties and also incorporate a high degree of professionalism. The 1989 Department of Health White Paper and subsequent NHS and Community Care Act encouraged members of the medical profession into NHS management (Clarke et al. 2000 p.104) exemplifying managerialism and professionalism as deeply intertwined. They are both rooted together in health policy, which is no surprise due to the high degree of professionalism, (the competence or skill expected of a professional) (Oxford Dictionary 2013) medical professionals require due to the specialist nature of their work. Furthermore NHS managers were given performance related bonuses to encourage high quality healthcare provision; they were placed on short term contracts and were increasingly subject to performance related pay and rigorous accounting procedures (Clarke et al. 2000 p.106). These early techniques are the root of regulatory activity because they caused widespread evaluation of public services, in a way unlike anything previously attempted in the UK.

When New Labour came to power in 1997 these managerialist techniques were not rejected in relation to healthcare. The focus was on what they termed; "what works", and there was much subsequent regulation policy enforced by this government during their time in power. New Labour focused on a movement towards using New Public Management (NPM) and finance techniques to generate new capital assets through new Private Public Partnerships (PPPs) and the Private Finance Initiative (PFI). New Labour also argued they would cut red

tape to make savings in the NHS, whilst defining what is expected of NHS Trusts in terms of quality and outcome. This was to be in tandem with the close and detailed monitoring and inspection of professional activity on various levels, as a means for increasing efficiency. In essence the Conservatives wanted to increase efficiency and reduce cost in the NHS. Labour essentially wanted the same thing, but as Clarke et al. summarise; “far from rolling back the state we can discern an extension of its involvement and ultimately its power, despite the rhetoric of partnership and co-operation” (2000 p.116). During their time in power New Labour introduced many new agencies such as the National Institute for Clinical Excellence (NICE), Monitor, the Care Quality Commission (CQC) and the NHS modernisation agency (Wright 2009 p.334), which exemplifies the degree and scope of the increased regulation during this period.

In 1997 The Government White Paper: “The New NHS, Modern, Dependable” (Department of Health) was published. This outlined the initial aims Labour had regarding performance ratings. This paper can be seen as one of the initial impetus that sparked widespread system evaluation even further. It states regarding monitoring and evaluation:

“The NHS does not have systematic information about what patients feel about the care it offers. The Government will therefore introduce a new national survey of patient and user experience. It will be carried out annually, at Health Authority level, and the results will be published both locally and nationally. This means that 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.” (Department of Health 1997 section 8.10).

In 1999 “The NHS Performance Assessment Framework” was introduced, this was aiming to be a single system for measuring and assessing NHS performance based on six main areas: health improvement, fair access, effective delivery of appropriate healthcare, efficiency, patient/carer experience and health outcomes of NHS care (Department of Health 1999). The Performance Assessment Framework was “supported by a set of national headline

Performance Indicators” (Department of Health 1999). NHS Trusts were assessed based on this framework which also introduced the clinical effectiveness aspect into this assessment and evaluation.

2.3.1 The Commission for Health Improvement (2000-2004)

In the 1999 Health Act many changes were introduced. The main two being that GP fundholding was abolished and that the Commission for Health Improvement (CHI) was introduced. Tony Blair described it as “Ofsted for the NHS” (Nuffield Trust 2013 p.15), almost certainly due to the perceived success of Ofsted in the regulation of schools. Bevan and Cornwell (2006) conducted important research involving comparisons between CHI and Ofsted as regulators. Despite the Prime Ministers claims, they determined that due to “structural differences” and “the regional proximity between CHI and the NHS” that “CHI could never have been an Ofsted for the NHS” (2006 p.343). Central control played a significant part of the government’s policy with CHI working to achieve centrally set targets for the various categories specified. As Dixon et al. state “from 2000 onwards Labour relied heavily on centrally driven performance” (2012 p.5).

In 2001 it was determined that CHI would use star ratings to rank and compare NHS Trusts, based on the information they obtained across the specific categories. The passage below describes the star rating system:

- “Trusts with the highest levels of performance are awarded a performance rating of three stars.
- Trusts that are performing well overall, but have not quite reached the same consistently high standards, are awarded a performance rating of two stars.
- Trusts where there is some cause for concern regarding particular areas of performance are awarded a performance rating of one star.
- Trusts that have shown the poorest levels of performance against the indicators or little progress in implementing clinical governance are awarded a performance rating of zero stars.” (CHI 2001 ii)

Whilst CHI was unlike Ofsted structurally, they did attempt to create their own version of league tables in this way. After the star ratings were introduced, the idea was that through publicly “naming and shaming” NHS hospitals which were considered to be performing poorly, this would drive up standards. In 2000/2001 CHI identified twelve hospitals that were given zero scores on the star rating system. This was in national newspapers and television broadcasts and even termed the “Dirty Dozen” by the Secretary of State for Health, subsequently half of the Chief Executives from these hospitals were fired (or forced to resign) (Bevan and Hamlin 2009 section 2.2). Bevan and Hamlin go as far as to suggest that the CHI star rating system was “designed to inflict reputational damage on hospitals performing poorly” (2009 section 2.2).

In 2001/2002 performance assessment was extended to all NHS Trusts and CHI’s Clinical Governance Review was included in the framework. This further developed the role of regulation with regard to clinicians. In 2002/2003 CHI published ratings for all Trusts for the first time. This also extended the remit of the regulator, working on the same premise of inflicting harm on the reputations of poor Trusts just as had been the case with hospitals.

The impact of star ratings is extremely contentious. Bevan and Hood (2006) for example conducted an analysis of data on performance in England before and after the star rating for three key targets. They also compared this data with that of other UK countries which did not adopt the star rating system. The main finding of this research was that the star rating system in England had improved reported performance (2006 p.422). This however comes with some significant disclaimers:

“The effect on services excluded from star ratings is unclear. In some cases data have been manipulated to achieve targets. Systems need to be put in place to minimise gaming to meet targets and ensure targets are not causing unwanted effects elsewhere.” (2006 p.422).

Bevan and Hamlin developed a table of six criticisms levied at the star ratings system in England from the substantial literature on this topic. They are as follows: “in measuring what

matters, selection of targets, nature of measures, aggregation for ranking, gaming and damaging morale” (2009 section 2.3). They argue that the first four of these criticisms are statistically based, but the final two are to do with perverse unintended consequences of the star rating system. After the substantial criticisms by numerous authors, in 2004 CHI was abolished, but in a sense it was replaced by the HC which undertook a very similar function.

2.3.2 The Healthcare Commission (2004-2009)

The 2003 Health and Social Care Act introduced a new role and priorities for the HC (which was initially called the Commission for Healthcare Audit and Inspection). The new regulator “heralded a desired shift in the balance of power in the NHS away from “top down command and control” to the concept of “earned autonomy” where high performing Trusts could enjoy more freedom to innovate” (Nuffield Trust 2013 p.17). Foundation Trusts were introduced and Monitor was introduced as the regulator of these Foundation Trusts. The premise was that to become a Foundation Trust, providers had to prove that they were low risk and financially robust, meaning that regulators could target higher risk providers.

In 2005 an Annual Health Check replaced the star ratings system. This involved a single rating for Trusts which was derived from a four point system. The Healthcare Commission describes this as “broadly aligned with the approach used for local government” (2005 p.11). Self-declaration now played a greater role in the Healthcare Commission’s area and the idea was that The Healthcare Commission would be an “information-led, risk based system of regulation” (Kennedy 2008 p.1). One of the proposed benefits of such an approach was that the Healthcare Commission could be a “lean organisation – a third the size of other comparable bodies while regulating a much larger sector” (Kennedy 2008 p.1). Under this system, boards were now legally responsible for organisational performance.

The impact of the HC based on the Annual Health Check suggests that Trusts generally improved over this period. For example it is stated that “since 2005/06, we have seen a decrease each year in the proportion of trusts scoring weak for overall quality, as well as a

decrease in the proportion of trusts scoring weak for financial management” (CQC 2009ⁱⁱⁱ p.12). Similar criticism was however made on this perceived progress, the Nuffield Trust for example, acknowledge that much of this progress may well have been derived from improved ability to “satisfy the regulator” rather than actually improving standards (2013 p.21). So, despite there being some evidence that the HC had improved performance in terms of quality and financial management, the contentious nature of these claims led to it being abolished in 2008 and the CQC replaced the functions which it performed.

2.3.3 The Care Quality Commission (2009-present)

The 2008 Health and Social Care Act established the CQC as the primary regulator for health and social care dissolving the Commission for Healthcare Audit and Inspection, the Commission for Social Care Inspection and the Mental Health Act Commission. The main general objectives established in this Act were:

- “(a) The improvement of health and social care services,
- (b) The provision of health and social care services in a way that focuses on the needs and experiences of people who use those services, and
- (c) The efficient and effective use of resources in the provision of health and social care services”. (2008 p.2)

This Act brought together the previously separate domains of health and social care, with a key element being the required the registration of all services providing this type of care. This registration proved to be a substantial and time consuming task, and by 2011 it became apparent that “the timescale and resources implications of the legal requirement to introduce universal registration of primary and social care providers were not adequately analysed and that the registration process was not tested and proven before wider implementation” (Nuffield Trust 2013 p.27).

The CQC developed sixteen key essential standards that now apply to all registered

providers. They check whether providers are compliant with these key standards based on self-reported data and their own inspections. A lot of these judgements are derived from Quality and Risk Profiles (QRPs) which come primarily from existing data about providers. The Nuffield Trust highlights the pitfalls of such an approach, suggesting “the QRP has limited reliability because of patchy data collections and social care data is virtually non-existent” (2013 p.28).

In February 2013, the CQC commissioned an independent report into its regulatory model, this report outlines the main impact of the CQC as well as the challenges it has faced (and still faces). The first main conclusion of the report is that:

“The current regulatory model, which was designed largely to achieve “safety net” regulation in health and social care, is probably not sustainable and requires change and development. There seems to be an absence of good evidence to support the current regulatory model, and to back up important changes to that model which has been made over time.” (Walshe and Phipps 2013 p.67).

This is backed up by the evidence that; the decisions to go back to a model of twelve monthly inspections and to use only a selection of the essential standards (rather than all of them) were made, but no supporting evidence was provided to justify these decisions.

The second conclusion Walshe and Phipps make around the impact of the CQC is that the changes to the CQCs regulatory model need to be better: “grounded in an empirical analysis of current practice and wider regulatory knowledge” and “their intended mechanisms should be spelt out explicitly so that they can be tested and challenged” (2013 p.67). They argue that evaluations and decision making needs to be more empirically based, with an enhanced internal capacity for research and evaluation.

The third conclusion levied rests on the complex and fluid relationship between the various regulatory agencies and organisation which they regulate. They claim that the success of

initiatives will vary over time and that consequently for regulation to be effective “the regulatory process itself (needs) to be auto-evaluative” (Walshe and Phipps 2013 p.68). Essentially, the need to evaluate their own initiatives before rolling out changes is of significant importance.

The history of health regulation has been outlined, giving an overview of the process and a context from which to consider it. Now the landmark texts and empirical literature which emerges in this review is discussed.

2.4 Definitions of regulation

This section outlines relevant definitions of regulation, which is important because regulation can mean many different things, depending on your perspective.

Baldwin et al. (2012) argue that regulation has been defined in a number of different ways. They refer to “Selznick’s notion of regulation as a sustained and focused control exercised by a public agency over activities that are valued by a community” (p.2-3) as a definition which encompasses generally what regulation is. Selznick’s (1985) classical definition of regulation suggests that there are four key characteristics which are central to the nature and purpose of regulation. They are as follows:

1. “Formal remit or acknowledged authority,
2. centralization of oversight,
3. third party accountability,
4. action in the public interest.” (in Walshe and Shortell 2004 p.20)

But Baldwin and Cave (1999) recommend that regulation is considered based on several other definitions, for instance “as a specific set of commands – where regulation involves the promulgation of a binding set of rules to be applied by a body devoted to this purpose” (p.3). With regard to this definition, they list the Health and Safety Executive and the legislation

which they implement as an example.

Another definition which is given is “as deliberate state influence – where regulation has a more broad sense and cover all state actions that are designed to influence business or social behaviour” (p.3). They argue that regulation defined in this sense has many examples such as command based regimes, those based on economic incentives (or disincentives), contractual powers, deployment of resources, franchises and the supply of information.

A further wide ranging definition, is classified by Baldwin and Cave (1999) as “all forms of social or economic influence – where all mechanisms affecting behaviour – whether these be state based or from other sources (e.g. markets) – are deemed regulatory” (p.3). They argue that regulation as defined in this sense can be carried out by numerous bodies other than the state, such as “corporations, self-regulators, professional or trade bodies, and voluntary organizations” (p.3).

Walshe and Shortell (2004 p.21) describes the disputed nature of definitions of regulation:

“Regulation is also, in academic terms, a contested domain. It has been studied and written about by economists, lawyers, organizational behaviour specialists, sociologists, political scientists and so on, and each group brings disciplinary baggage and preconceptions of its own field to the subject.”

Clearly the context of regulation varies depending on which field of study you perceive it from. Despite this, Walshe and Shortell argues that there are two distinct types of regulation:

“economic regulation and social regulation” (2004 p.21). Economic regulation is primarily concerned with matters of demand, supply and price of a good or service, and the control or influence of these things. Social regulation is of a broader nature Walshe and Shortell claims “it aims to control or influence the behaviour of regulated organizations in ways which may be only indirectly related to issues of supply, demand and price” (p.22).

So definitions of regulation vary from sector to sector, and even within sectors the concept is contentious. Another important debate in public policy concerning regulation is what constitutes a legitimate area for regulation to operate in. On this issue Baldwin and Cave (1999) suggest that five factors should be considered:

1. "Is the action or regime supported by legislative authorities?
2. Is there an appropriate scheme of accountability?
3. Are procedures fair, accessible, and open?
4. Is the regulator acting with sufficient expertise?
5. Is the action or regime efficient? (p.27)

The Better Regulation Taskforce (1999) similarly considered accountability and consistency as goals for regulation, as well as transparency, targeting (goals), and proportionality (in Allsop and Saks 2002 p.32). The objectives for regulatory behaviour (Baldwin et al. 2012 and The Better Regulation Taskforce 1999) operate as a lens in which regulation is viewed in this research. Assessing if these objectives are followed, let alone achieved gives insight to the research. Consequentially, the purpose of regulation forms a part of the emphasis of the interviews in this research. Baldwin and Cave 1999 and Walshe and Shortell 2004 can be considered key texts in this literature review because they give significant insight into the meaning and purpose of regulation.

2.4.1 Theories of regulation

A relevant discussion on what drives the trends and cycles of regulatory behaviour comes from Baldwin and Cave (1999). The focus is on what drives regulation and examines what tensions emerge between the driving forces. The first theory they outline which aims to explain regulation is public interest theory, which argues that regulatory behaviour is "to achieve certain publicly desired results in circumstances where, for instance, the market would fail to yield these" (p.19). This theory purports that regulation simply encourages a market to provide public goods, but the obvious flaw with it is that defining what outcome

represents a public good is far from straightforward.

The second theory outlined is interest group theory, which sees regulation as a product of relationships between groups and the state. The criticism levied at this theory by Baldwin and Cave claims that to understand regulation in such a way understates the role of private economic power in influencing regulation (1999 p.33).

The third theory of regulation outlined clearly has roots in rational choice theory, as the main assumption underpinning the theory is that, "parties in regulation are rational maximisers of their own welfare" (1999 p.33). From this perspective the regulatory bodies are merely seeking to pursue their own agenda, whether that may be budget maximisation or self-preservation. The problem with this theory (similarly to rational choice theory) is that individuals tend not to be rational maximisers of their own welfare in practice, often opting for an irrational course of action.

A fourth theory exists which argues that it is the force of ideas that drives regulation and steers developments (1999 p.33). Following the premise that innovation can spread and when national initiatives take place the ideas steers regulatory behaviour down the appropriate route. The problem with this claim is that this is extremely hard to measure and separate from the role of economic interest.

The final theory Baldwin and Cave reference is institutional theory, which argues that it is the influence of organisational rule and social setting that drives regulation. From this perspective "actors are not seen purely as individuals but as shaped in action, knowledge and preference by organisational rule and social environment" (p.33). Institutional theory clearly holds some relevance in a complex organisation such as the NHS which is like a living organism, ever changing in structure and hierarchy. The problem with this perspective is that it is hard to balance this theory in with the others. Whilst individuals are part of an institution and social setting, they do remain individuals, and may act as such.

These five theories are all relevant in health regulation. The complexity and number of stakeholders in the regulatory process means that all theories outlined by Baldwin and Cave (1999) are true to at least some extent at varying stages and sometimes in direct contradiction to one another (like public verses private interests).

Walshe (2003) similarly offers theories from which to consider regulation. One of the main driving forces which is identified as the cause for regulation is economic causes. Especially market failure i.e. where the market fails to produce the desired level of healthcare based on supply and demand alone: the allocation of goods and services based on the market is not efficient. In the health sector, Walshe identifies monopolistic suppliers and monopolistic purchasers as two of the main reasons behind this market failure (2003 p.22-23). In the health sector it is common for there to be one supplier and one purchaser in a particular location, and this can lead to complacency and exploitation. Walshe also argues that another factor increasing this market failure is “huge information asymmetries” (p.23). Given the nature of healthcare as a service it is perhaps unsurprising that these asymmetries exist, healthcare is highly professionalised and the knowledge required to understand any area of it is very specialist. This means that it is very difficult for healthcare consumers to make well informed decisions about the services they use.

Also present in healthcare are externalities and the notion of it being a “public rather than a private good” (p.23). The externalities of healthcare are positive, in that they have a positive effect for people other than those who directly consume it. In the same sense healthcare can be considered a public good: it benefits those who consume it as well as others in society. A good example of this is vaccinations. Vaccinations benefit the person who is vaccinated because it means they are less likely to develop a particular disease. They also benefit the rest of society, even if they are not vaccinated, because they are less likely to develop the disease because those vaccinated will be less likely to spread the disease.

In traditional economics “markets are founded on a rather straightforward model of transactions between buyers and sellers or producers and consumers” (Walshe 2003 p.23).

Health systems fit more into a model with “multiple interacting and independent stakeholders” (p.23) this complicated the market and the interaction between these stakeholders significantly. Walshe suggests the following examples of stakeholders in the healthcare market:

“Funders who meet the costs of healthcare, like governments and employers: purchasers like health insurers health plans: healthcare providers in many shapes and sizes, including organizations and professionals in groups and as individuals: and, of course, consumers of health services and the wider public” (2003 p.23).

When markets fail the economic regulatory response is to promote competition and whilst regulation in healthcare can aim to promote competition, there are also many different types of regulation in healthcare aimed at social rather than economic regulation. Social theories of regulation will now be considered.

As previously mentioned healthcare can be seen as different from other commodities because it is a public good, i.e. the availability of healthcare benefits all individuals in a society, not merely those who consume the healthcare. Walshe describes the potential social values which link in with healthcare provision as “equity and fairness, diversity, social solidarity, accountability, freedom of information, paternalism and privacy” (p.27).

Walshe (2003) also posits political causes of regulation as an explanation for its growth. It is argued that over recent decades “political accountability has changed” (p.28). ALBs make accountability of government services less straightforward and more convoluted. Walshe states that “in both the private and public sector, we have moved from a simple, democratic model of accountability (whether it is electors or stakeholders who are voting) to a stakeholder model of accountability, in which regulation is used to make public and private sector organisations accountable to a wide range of stakeholders” (p.28). The idea of distancing politicians from controversy by ALB as a “convenient mechanism” also ties in with the political causes of regulation. Regulation can divert the blame when things go the wrong, away from

the government department that would otherwise be seen as fully accountable.

Walshe (2003) identify organisational causes as a further explanation of the development of regulation. This is especially true in relation to healthcare: “healthcare organisations can be seen as having relatively weak internal hierarchies and structures... regulation may be a mechanism for giving those who lead or manage such weak organisations greater internal power within those organisations” (p.31). Also in relation to the NHS, Walshe identifies regulation as being necessary for performance management of large organisations because of the associated managerial challenges. It is claimed for instance that: “regulation may provide an alternative or supplementary mechanism for performance management, in which the very large organisation is treated as a network, chain or smaller set of organisations” (p.31). Regulation in the health sector treats the NHS in this way, it is broken into many smaller organisations such as Trusts, CCGs, and even individual providers. Performance management is clearly part of the remit of health regulators and so organisational causes of regulation are significant. Walshe 2003 can be considered a key text in this literature review because of the increased theoretical understanding of regulation it brings.

2.4.2 Characteristics of effective regulation

Theories of what causes regulation have been outlined, but equally important are theories of what effective regulation should look like. Based on empirical research on US healthcare regulation Walshe and Shortell (2004) propose a framework of ten factors that are of significant importance in effective healthcare regulation. This framework is outlined beneath.

1. Regulation should be focused on performance improvement. “Too often, regulatory performance is measured in terms of the regulatory process (number of standards set, surveys completed or sanctions issued) rather than in terms of its impact” (p.230).
2. Regulation should be responsive, this in particular incorporates “the principle of contingency ... it is very difficult for highly prescriptive approaches to regulation to be sufficiently responsive” (p.231). Essentially a one size all approach does not work.

3. Regulation should be proportionate. “In the sense that major problems receive a substantial regulatory response but minor issues attract less attention” (p.231) so as to best use the resources available to regulators.
4. Regulatory methods should be rigorous and robust. “Especially those used in regulatory direction and detection” (p.231) – validity and reliability need to be accurate, assumptions need to be tested.
5. Regulation needs to balance flexibility and consistency.
6. Regulators need to be cost conscious “aware of and sensitive to the full, real costs of regulatory arrangements” (p.234) too often these costs are “underestimated or ignored and that important costs (especially those incurred by regulated organizations) are hidden and unmeasured” p.234)
7. Regulatory arrangements should be open and transparent. Three areas where openness is particularly important are the development of regulatory standards, the publication of findings from regulatory detection mechanisms such as surveys and inspections, and the implementation of regulatory enforcement” (p.234-5).
8. A wide range of enforcement strategies is needed. “Regulators often have significant enforcement powers in theory but can make little or no use of them in practice” (p.235).
9. Accountability and independence. “A balance is needed, giving the regulator considerable freedom of action but still holding it ultimately to account for its actions” (p.235).
10. The regulator needs to commit to evaluation and review. “New regulatory policies and approaches should be piloted and tested before being introduced, the impact and effectiveness of regulatory activities should be evaluated, and the results of evaluation research should be used to modify and improve systems of regulation” (p.236).

If transparency is a characteristic of regulation by arm's length bodies, as suggested by Walshe and Shortell (2004), then it is useful to properly define this concept. Transparency is defined by the Institute for Government as:

“A principle that allows those affected... to know not only the basic facts and figures but also the mechanisms and processes. It is the duty of civil servants, managers and trustees to act visibly, predictably and understandably.” (2012 p.2).

This definition encapsulates what transparency means to an extent, but in reality determining degrees of transparency can be more troublesome. So whilst it is probable that transparency is desirable, it is not necessarily clear how it can be properly ascertained whether transparency truly exists.

All ten factors are very useful in informing the direction in which the evaluative questions the interviews in this thesis follow. One of the main focal points of the interviews is to ascertain whether regulation is working effectively. Without knowing what “effectively” is, this is impossible to determine. The Walshe and Shortell research is valuable, because not only is it empirical, but it gives this detailed and comprehensive theoretical framework from which to consider regulation. Due to these reasons, it can be considered one of the landmark texts in this literature review.

2.5 Theories of ALBs

Theories of regulation have been outlined and considered, but it is also prudent to discuss the theory that underpins the basic premise of deploying so called “arm’s length bodies” more generally. Their utilisation by governments has been significant, historically as well as currently, but why is this case? Why create a separate entity to carry out a function which an area of government wishes to be followed? Why does the relevant department not just implement the policy directly?

Gash et al. (2010) argues that there are three main reasons or theories concerning why to place public sector bodies at arm’s length from politics:

“1. To depoliticise decision-making and build public trust, by increasing the actual and perceived independence of decisions, where political influence is seen as undesirable or destabilising. Examples include grant-making bodies (e.g. Arts Council), regulatory bodies (e.g. Ofcom), and tribunals (e.g. Police Arbitration Tribunal).

2. To increase managerial freedoms, including:

- Freedom from civil service managerial norms, including pay norms (e.g. Driver and Vehicle Licensing Agency).
- Freedom to focus on a specialist function, rather than being a low-priority area within a government department (e.g. Health and Safety Executive).

3. To allow government to access external skills and expertise, often at lower cost than consultancy or research (e.g. Science Advisory Council).” (2010 p.18)

These three theories all hold some relevance to why ALBs operate in the health sector, in a regulatory sense. The first is especially relevant, not only does the creation of ALBs (such as the CQC and Monitor for example) depoliticise decision making, but it depoliticises the effects of decision making. This may be of much more use for a government, so when something goes wrong, the ALB is culpable, rather than the Department of Health. In reality this may not be true, but if the media have decided that the CQC is to blame for not noticing a provider that is performing poorly in terms of quality, this means the Department of Health be perceived more favourably than if the media decided it was the Department of Health’s fault directly.

ALBs have been around for a very long time, back in 1918 the Haldane Review “assessed the government’s use of ALBs and concluded that, while such bodies were necessary, the number of them needed to be actively controlled” (in Gash et al. 2010 p.18). Similarly in 1945 a review by Lord Anderson came to the conclusion that “the issue of “quango” (Quasi-Autonomous Non-Governmental Organisation) proliferation came to be seen as an increasing problem” (in Gash et al. 2010 p.18). In the 1980s there was also considerable emphasis on arm’s length bodies due to Thatcher’s promise to have a “bonfire of the quangos” (Telegraph 2012). In 1980 when Sir Leo Pliatzky conducted a review into ALBs, it was identified that there were “489 executive bodies, 1,561 advisory bodies and 67 tribunal bodies” and also

coined the term “non-departmental public bodies” (NDPB) to distinguish them from broader quangos (in Gash et al. 2010 p.18). Interestingly though despite the stance being so staunchly against ALBs, in reality;

“During the years of Conservative rule, the number of executive NDPBs was kept under close review and went from an estimated 492 in 1979 to just 320 NDPBs in 1995. However, while the number of bodies was reduced, their total expenditure actually increased significantly, partly because several NDPBs were simply merged” (Gash et al. 2010 p.19).

A similar picture exists for the Labour government 1997-2010, i.e. one of the political stance being very against ALBs, but the reality being an increasing amount spent on them. Flinders (2008) claim, for instance: “On the one hand, there were periodic attacks on the number of ALBs but on the other hand new organisations proliferated and total expenditure on government at arm’s length increased in real terms” (in Gash et al. 2010 p.20).

Since the coalition government came to power in 2010 the same trends have prevailed. In a paper published by the House of Commons Public Administration Committee titled: “smaller government- shrinking the quango state” (2011) the principles of “cost savings and increased accountability” are listed as the main reasons for reducing the number of “quangos” (p.3). But in the healthcare policy sector, this has not really been the case, the CQC remain the primary regulator of healthcare. Monitor remains another force in regulating hospitals, verifying Foundation Trust status and sending in taskforces when things go wrong. Dr Foster Intelligence (whilst they are not an ALB or regulator per se) are still contracted in a private public partnership which involves them publishing annual hospital guides. NICE remain at the forefront of best clinical practice guidelines. NHS England now regulates the new CCGs. An ironic situation exists where despite purported efficiency and accountability drives, very few “quangos” have been removed (none in the healthcare regulatory arena) and if anything less accountability exists. This claim is justified by the fact that the CQC has stopped rating Trusts on a universally comparable star rating system, meaning that when a Trust fails on a basic measure of care provision it can be very unclear which regulatory body is responsible. The

overlap between the key regulators is significant, and the CQC now lacks the overall responsibility which provided the accountability previously.

2.5.1 The Purpose of Arm's Length Bodies in the NHS

The Health and Social Care Act (2012) has many implications for health policy, too many to go into all in detail. One of the main areas worth considering, due to its relevance to the research objectives however, is competition policy, as this has a large impact on health regulators. Reforms proposed by the government have indicated that the role of Monitor will focus more on competition. However recommendations by the NHS Future Forum (as well as hostility from GPs and pressure groups) have led to the government changing the Health and Social Care Act in many areas, including Monitor's role. It has now been stated that Monitor's role will focus on accountability rather than creating competition. There has been much criticism of the Act with the Chief Executive of the NHS stating that the Bill could create "the biggest quango in the sky" (GP 2011 p.1), referring to the Consortia that have been developed to commission healthcare.

In a sense this strategy follows in line with the rhetoric of NPM, including the paradoxical centralisation of strategy and decentralisation of delivery. Monitor's role in the process, does not however, follow the NPM guise, as accountability opposed to competition is the opposite of the NPM ideology: of making the public sector more like the private sector (for purported increased efficiency). Cope and Goodship (1999) summarises the simultaneous centralisation and decentralisation associated with policy making of this kind:

"Steering agencies, such as the central government, increasingly, both directly and indirectly, regulate rowing agencies, such as executive agencies, local authorities, and quangos, by setting policy goals, for rowing agencies to achieve, fixing budgets within which rowing agencies must operate, awarding contracts (or quasi-contracts) to competing rowing agencies, making key appointments to ensure the "right" people head up the rowing agencies to do the "right" thing, and establishing regulatory agencies, such as the Audit Commission, to

monitor the performance of rowing agencies.” (in Horton 1999 p.56).

The regulation of public services and NPM are interlinked and regulation of this nature has increased significantly and quickly within government (Hood et al. 1998). There are many types of regulation in varying spheres of society, and whilst health care regulation is different from the other types, it must not be studied in isolation. There are common denominators linking all regulatory behaviour, including both the private and public sector. From an economic perspective regulation can be seen to seek to correct a market or public service so that it adopts the pareto-optimum level of production.

Gash et al. (2010) conducted a major investigation into arm's length bodies in the UK. They conclude that the two main major challenges facing arm's length bodies were:

1. **“Lack of clarity over ALB roles and responsibilities**, which can lead to significant duplication of activity between ALBs and sponsor departments, occasional neglect of important issues, and problems of policy coordination. Of these, the issue of duplication appears to be a particular concern, with examples of entire functions being duplicated across NDPBs (Non-Departmental Public Bodies) and their sponsor departments.”

2. **“Difficulties in achieving the right balance between freedom and control of ALBs.**

We found examples of both ‘micro-management’ of ALBs and institutional neglect. While micro-management creates administrative burdens in terms of reporting, neglect can result in ALBs being less in touch with government's policy objectives and leaves sponsor departments less able to manage risk and performance. Where apparent, both imbalances contributed to low-trust institutional relationships, and sometimes led to downward spirals of institutional conflict.” (Gash et al. 2010 p.11).

It is clear that the role and responsibilities of ALBs need to be clearly understood by all concerned parties for there to be much likelihood of them being successful. If these are not defined properly then there will likely be confusion around what is expected in terms of

regulatory output. The issue of duplication as a consequence of this is also mentioned in much of the literature around regulation, and duplication of the function of ALBs can mean a much greater burden for those organisations that are regulated by them.

The level of control/independence of ALBs is another area which is a potential issue in NHS regulation. In theory many of the regulators (the CQC, Monitor and NICE for example) are purported to operate independently from the Department of Health. In reality though, their goals are set by the department, so this independence is hard to fully assess.

The Institute for Government (2012) issued a guide on what ALBs' purposes are theoretically as well as how they tend to work successfully. This guide includes five main principles which information arm's length bodies need to follow to work effectively, they are as follows:

"Information should be:

- Readily **accessible** and **useable**: Information needs to be accessible and in a format that is easy to understand and work with. Information must be well signposted and easy to find.
- **Relevant** to the needs of **different audiences**: ALBs should know their audiences and reflect this in the information they provide. The Electoral Commission breaks down information according to customer type, e.g. electoral administrators, candidates and campaigners, police officers, journalists, voters.
- **Timely**: The general principle should be to make information available as soon as possible after production – so data for instance could be made available quarterly – rather than simply through annual reports which can be up to 18 months out of date.
- Put in **context** and **explained**: Information without context is at best unhelpful and at worst can be misleading. This means including trends, benchmarks, and giving the reasons behind information.
- **Proportionate**: This guide is principally directed at public bodies performing significant public functions with their own staff and budgets. All public bodies are bound by the Information Commissioner's publication scheme, but small advisory bodies, will need to

consider which parts of the guide are most relevant to their audiences. Key information for advisory committees, which should appear on Department websites, is the basis on which members are appointed; any restrictions on their activity as a result of their appointment and how the department deals with their advice.” (Institute for Government 2012 p.3).

These five criteria focus in on information provided by arm’s length bodies. This has particular relevance in relation to: the CQC, Monitor and Dr Foster Intelligence, who all publish significant amounts of information about NHS providers.

These five criteria all fit the functions of these three ALBs. It is logical to assume that there is no point having data if it is not accessible and useable. This data should clearly be relevant to the different audiences: the public, the organisations regulated that the information is about, the Department of Health, the government, the private sector and academics, for example. Timeliness is essential for these bodies, because the worth of their functions relies on the data having a meaning in the present. Context is also paramount, as is proportionality.

2.5.3 What Makes Each Arm’s Length Body Successful?

Rutter et al. (2012) came up with a framework with four key themes related to the successfulness of ALBs. The key themes of the framework are outlined beneath.

- **“Accountabilities:** Overall roles and responsibilities of department, ALB and minister are clear, understood by all parties and kept up to date in line with underpinning legislation. Both sides have the same expectations about the role of the ALB and the chair/chief executive, the degree of independence and the relationship with the department.
- **Strategic approach:** The department adopts a differentiated approach according to the role, status and salience of the ALB. There is a clear and agreed view on risk which informs the sponsorship approach. There is good strategic alignment between ALBs, departments and Ministers. The ALB understands how to contribute to policy making in

the department where it has discretion and is routinely involved in policy development where it has expertise and/or is expected to implement the policy.

- **Financial and performance management:** Both sides have access to the timely and reliable data they need. Data requests are proportionate; framework is clear regarding data requirements. A process for data quality assurance is in place and agreed by the department and ALB. This process is clearly communicated and adhered to. There should be agreed clarity about disclosure once assurance has taken place. Budgeting is stable, transparent and realistic; recognition that budgeting is also about income and income streams. Performance is managed effectively by the ALB and it is held to account by the department. Communication and engagement relationships between the ALB and the department should be open, honest and constructive; expectations are made clear. Communications are coherent and consistent. There is a common understanding on both sides on public positioning with no surprises policy observed; potentially sensitive issues are raised in advance to allow a conversation to take place.
- **Relationship management:** Department and ALB show mutual respect and understanding; the terms and language used in communications are appropriate to individual/specific ALBs. There is a clear and agreed map of relationships with regular meetings scheduled; the role of 'the Centre' is clear and well understood. Quality of relationships is good with sufficient time invested in building them. The department has confidence in the board to manage both the ALB's business and can operate effectively in a public sector environment. Clear processes are in place to resolve any disputes in a timely and effective manner." (2012 p.45).

This understanding corresponds with the criticisms levied at health regulators, as well as the Institute for Government guide on ALBs. Accountability is a reoccurring concept, especially in reference to fully and properly defined roles and purposes. Strategy is another reoccurring concept, perhaps understood differently this could be called avoiding unnecessary bureaucracy. It is easy to see the linkage between accountabilities and strategy as well, if purpose is unclear or overlapping then inevitably strategy will also suffer, leading to unnecessary bureaucracy and/or inefficiency. Financial and performance management again

comes back to the basic ideas: of information being timely, proportionate and transparent. The relationships between the ALB and the department is clearly another issue, which in the health sector can perhaps be extended to the relationship between the various ALBs who operate independently but supposedly in partnership with one another.

Charles Lindblom famously stated that “every interest has its watchdog” (1959 p.85) and the meso-theory of pluralism has relevance with regard to the relationship of the media and regulation of health care. From a classical pluralist perspective power is widely distributed between all actors, the state is a passive actor and policy making is an open and competitive process (such as Lindblom’s incrementalism). Perhaps a more realistic meso-theory comes from the slightly adapted version of pluralism: neo-pluralism. From this perspective power is significantly distributed between key actors, the state is an interested actor, with some state agencies getting captured by pressure groups and policy making is an interdependent and negotiated process (such as Rhodes and Marsh’s policy networks model 1992).

This is relevant because the state agencies in the NHS regulatory area (CQC, Monitor, NICE, Dr Foster) can get captured by pressure groups leading to influence on future policy formulation. It is also often the case that the pressure groups will become known to the regulators through some sort of media exposure. As previously mentioned this tends to be in some negative sense, it could be a BBC Panorama episode which investigates a particular hospital, such as the BBC Panorama episode investigating and showing abuse by care staff at Winterbourne View (BBC 2012). This could also be a newspaper article (local or national) which criticises the NHS for using a particular drug over a more expensive alternative; such as an article in The Guardian, which criticises the use of cheaper drugs to stop older people going blind (2010). Alternatively this could be through new media such as Facebook or Twitter. A contemporary example comes from JulieBailey@curetheNHS who has over 3000 followers on Twitter and was instrumental in the identification of poor care standards at Mid Staffordshire NHS Foundation Trust (Bailey 2013). The point to be made is that the media can be seen to give credence to pressure groups and it is through this becoming clear that state agencies are forced to act (or be seen to be acting) in the public interest.

2.6 Economics and Regulation

Economics is based on a very simple premise; that in the world there only exist finite amounts of resources, yet demand for these resources is seemingly infinite. This is known as the problem of relative scarcity. It is hence no surprise that economics is a feature in the explanations of regulation, where the problem of relative scarcity always exists in one way or another.

The objectives of regulation tie in with the objectives of health provision in general i.e. due to the problem of relative scarcity, efficiency and equity are pursued. An important historical factor which further increases the relative scarcity problem in health provision is population growth. "Since the early eighteenth century birth rates have exceeded death rates in every decade and both seemed to have declined consistently throughout the period" (Culyer 1980 p.204). The result is that more people are being born and these people are living longer. A larger population means that allocation of resources is more important because if the resources are not increasing in line with the population who consume them then relative scarcity is more prominent. Economics is intertwined with health regulation and this is no surprise given the nature of relative scarcity, efficiency and equity, all of which are exacerbated by population growth.

2.7 The Nature of "quasi-autonomous"

Regulators generally have a policy with regard to some type of competition, either in a developmental or restrictive capacity. There is another third possibility suggested by Paton: that; "regulation may be developed for a separate purpose, without privatization or marketization, in an attempt to obtain the alleged benefits of independent regulation for state systems in pursuit of specific standards" (2006 p.87). Essentially the state has to decide how to share power with regulators that it creates under this scenario (which is prevailing) and it uses a mixture of independent and internal regulators in the healthcare sector. The CQC, Monitor, NICE and The Healthcare Commission are all bodies that have been created by the

state to regulate a specific area of the NHS and they are all purportedly independent of government.

The fact remains however that the state funds this regulation and has a say in these bodies priorities and targets. So in reality, these bodies are not completely independent of the state, or they are quasi-autonomous. But the government also works in a private public partnership with Dr Foster Intelligence, who publishes annual hospital guides based on quantitative data analysis. Dr Foster Intelligence are a private company who have their own targets, who process health data for the government, and so can perhaps be considered more independent than the other “regulators”. Paton (2006) identifies this phenomenon as developing under the New Labour new regulatory state which purports “control without command”, but in practice control is retained (p.87). The idea that the healthcare regulators are external to government champions the premise that the government is transparent, whereas this idea may be symbolic rather than a reality. Paton (2006) also notes that politics is shaping the NHS especially since the “agenda is very different from that eulogised by the marketers.” (p.125)

2.8 Problems Associated with Regulation

Hood et al.’s (1998) paper on regulation contains findings which are relevant in identifying problems associated with its deployment by the UK government. This article identifies significant changes to internal regulation, which Hood et al claim has “increased in formality, complexity, intensity and specialisation over the past two decades” (p.62). The theory is that if regulation is more formal, complex, and intense and specialist in its nature, this should encourage better quality public services. If these services are scrutinised in every way possible then the problems can be identified and remedied, resulting in an improved and more efficient service.

The concept of efficiency is something to consider. Begg et al. (2003) defines efficiency from an economic perspective; for economic welfare to be maximised, it must not be possible to

increase output by reorganising the factors of production or to increase welfare by redistributing commodities used for consumption (p.214). In this situation there is allocative efficiency, also known as the pareto-optimum (i.e. no one person can be made better off without making another worse off). It is important to consider what this means, because efficiency is evidently not just about quality. The factors of production must be appropriately used, to ensure that the welfare derived from those factors is maximised. In the healthcare arena the factors of production are vast and the welfare derived from these factors is also immense and very hard to measure. The purpose of this regulation is to ascertain whether the right factors of production are being used, and whether this is producing a maximised level of welfare output. Efficiency is about quality and cost. Regulators want to work out if public services are performing on both fronts.

Hood et al. (1998) suggest that there is a “marked disjunction between the regimes and control techniques applied by the regulators of government to those they regulate, and the way the regulators are themselves assessed and controlled” (p.62). They also make the reasonable claim that if regulation itself is justifiable due to its benefits on service provision then “there is a strong presumption in favour of applying them (regulations) also to the regulators themselves” (p.66). Put another way, if it is worth investigating the supply of public services through regulation, to check they are working well, then it is logical to investigate regulation too, to check it is working well. This premise is one of the primary reasons why research such as this thesis actually exists.

Hood et al. (1998) identify four problems with regulation. The four problems link in with research objective one, because they relate to high level macro conceptualisations of regulation. They are as follows:

Firstly, that “there is a lack of fora for regulators in government in which good practice can be identified.” Secondly, that “there is a lack of systematic exposure of regulators in government to productive competition and rivalry.” Thirdly, “there is a lack of clear central responsibility.” Finally that there is a “lack of snap inspections or random scrutinies, especially at top and

centre of government" (p.66).

A defender of the regulatory regimes that exist in the UK today would argue that these problems have been solved, in turn, by historical changes in the structure of healthcare regulation. For instance, with regard to the first criticism Hood et al. (1998) make, the purpose of clinical governance reviews and the NICE is to identify good practice and ensure that it is followed. The same cannot however be said for good practice when it comes to methods used to regulate hospitals. The CQC relies on many methods (such as QRPs) which have very little supporting research evidence (if any). Dr Foster leans more towards quantitative information such as HSMRs, HSMIs and waiting times. This illustrates how the deficiencies identified may have been alleviated in some ways yet extenuated in others. The CQC, Monitor and Dr Foster Intelligence all use varying methods in their analyses of health provision, exemplifying this criticism may remain true to some extent.

In relation to the second point Hood et al. make it is also argued that regulators impose competition and rivalry on public service organisations but are not subject to these themselves. Also argued, is that when their functions do overlap the response is to collaborate, not to compete (1998 p.66). Although, an advocate of the current regulatory regime would argue that competition does exist due to the number of different bodies with similar interests in the healthcare arena. The CQC, Monitor, NICE, and Dr Foster Intelligence all represent regulators who compete in some ways and collaborate in others, whether the balance of this competition/collaboration is apt will later be discussed in detail. There certainly is a wide distribution of power in this sector, with a plurality of regulators operating concurrently.

In relation to Hood et al.'s third point concerning clear central responsibility, the CQC certainly does have more central responsibility than the previous commissions. Over time the nature of CHI, the HC and now the CQC has changed, with their remits expanding gradually, as well as exerting more power and influence on the healthcare sector. However, on the other hand there also exists significant overlap of the range of activities of the various bodies, meaning

the criticism still remains valid. This becomes ever more evident when you consider that whilst the CQC remains the main regulator of healthcare in name, it has stopped rating Trusts and hospitals on a star system, yet Dr Foster rate each Trust and hospital annually. Also when lethally unsafe care does come to the forefront, Monitor is the body who intervenes. Based on these factors, clear central responsibility is still a significant issue.

Similarly, it can be argued that with reference to Hood et al.'s final criticism (a lack of random inspections), that this role has been fulfilled to some extent at least. Monitor and the CQC certainly serve this purpose, in that they conduct random inspections of Foundation Trusts and providers (respectively). There is however reason to suspect that the nature of these random inspections is dubious. For example: they only conduct random inspections based on the risk rating that they have already assigned to a provider, meaning in a sense they are not random at all. Also, if the methods that they use to determine the risk ratings are not appropriate, then this technique fails to correct the criticism Hood et al. identifies.

A more contemporary analysis of health care regulation comes from Trubeck et al. (2008). This similarly identifies four deficits in relation to health care regulation, but they are different from those identified by Hood et al. (1998). Perhaps this reflects the changing nature of health care regulation, and its increasing scope and role. They are as follows: Firstly: no system ensures widespread input. Secondly, an information deficit exists due to agencies lacking adequate information about the problems. Thirdly, there exists a capacity deficit, as a result of a narrow range of regulatory tools which may limit the ability to resolve health care problems. Finally, that an implementation deficit exists, relating to the difference between identifying inefficiencies and dealing with them appropriately. (Trubeck et al. 2008 p.2-6).

Trubeck, et al. (2008) argues that there has been progress in reducing these deficits through increased pluralism of the healthcare regulatory systems. This has come in the form of increasing economic incentives, statistical analyses and comparative ratings. An important question that arises from the Trubeck et al. (2008) research is "to what extent do the various methods of metrics and guidelines rely on external versus internal methods" (or a combination

of both)? (p.5) This is of particular relevance to the CQC, which is where the criticism is levied towards, because in the past it is argued it has relied on NHS Trusts own self-reported evaluations (e.g. BBC 2013).

Power (1997) refers to this as enforced self-regulation, where; “audits become rituals of verification; formalised systems of surveillance that present opportunities for gaming and blame redistribution” (p.192). It is important for the ultimate success of regulation that it is not about these rituals of verification, but a comprehensive evaluation of the services being regulated, ensuring that quality remains high on all fronts. The nature and ultimate success of self-regulation as well as external methods of regulation is a topic which will be discussed and evaluated in this research.

Self-regulation is enforced in a variety of ways. For example, NHS Trusts are encouraged to apply to become Foundation Trusts (FTs); FTs are free from central control and are no longer directly accountable to the Secretary of State of Health, but to Monitor (Wright 2009 p.345). Similarly, NHS FTs must report to the CQC concerning the degree to which they consider themselves to be working within the compliance framework that is set out by the CQC.

Problems associated with regulation are complex and even contradictory in their nature. Pressure for increased levels of healthcare regulation in terms of size, scope, formality and intensity has come from the right and left alike. The main reason for this is that if regulation is effective in what it sets out to achieve, then this results in a better service quality, which is cost efficient. But does this regulation set out what it sets out to achieve? If the regulatory arrangements in place in the healthcare sector are not fulfilling the proposed functions, then this will mean the healthcare sector remains inefficient i.e. the best combination of the factors of production must be used to produce the maximum level of welfare.

Going back to Hood et al.'s (1998) point that the response of regulators is to collaborate rather than compete. The current situation involves a number of regulators, who exist as separate entities who pursue similar but different aims. They have developed over time with

increasing levels of autonomy. The CQC and Monitor collaborate through sharing information on particular areas of mutual interests. Regulators also compete in the sense that Dr Foster Intelligence is a private public partnership which is not involved with the CQC despite significant overlap of their regulatory activities. It is extremely important to get this balance right because collaboration can reduce replication of activities, saving time and money, but on the other hand, competition ensures that standards remain high.

2.9 Data Sharing and Regulation

The theme of data sharing is an area of e-government which is becoming prevalent in public policy due to its potential to save costs, improve quality and remove duplication of activities. Taylor and Bellamy: contemporary e-government advocates, refer to the “new capabilities for capturing, for sharing, for integrating and for exploiting information by means of new information systems capable of supporting new information flows” (2003 p.86). This developing area of public policy is identified as potentially extremely beneficial in terms of cost and quality. A way of significantly reducing replication of regulatory activity, by encouraging corroboration whilst retaining competition, could be to create a central database on which all the healthcare regulators share information about Trusts and hospitals. This also has the benefit of saving money because replication of data collection is minimised and time for the same reason. It also has the benefit of creating transparency in the regulatory systems, which is often popular politically, and would significantly increase the likelihood of lethally unsafe care being identified.

As was previously noted, to study healthcare regulation in isolation would be wrong as there is much overlap between the regulation of healthcare and the regulation in the private sector. Harford (2011) a contemporary economist, discusses problems experienced by financial regulators; including lack of data and no way of systematically finding out data from complex financial systems. Andrew Haldane, who is the director for financial stability at the Bank of England, advocate utilising data sharing technologies to create a:

“Heat map of stresses in the financial system, harnessing the technologies used now to check the health of an electricity grid. With the right data and the right software to interpret it, regulators could look at a financial network map, highlighting critical connections, overstressed nodes, and unexpected interactions.” (in Harford 2011 p.195).

Such a policy in the financial system has significant scope for preventing financial meltdowns; the same logic reigns true for the healthcare systems. The potentially real time map of data concerning risks in NHS Trusts, hospitals or GP practices would identify risks emerging more quickly and save lives in the process. Media scandals due to sudden publication of high mortality ratios in Dr Foster hospital guide would be prevented because if one Trust began to have higher mortality ratios, it would become immediately apparent to the CQC and Monitor could intervene appropriately. The potential for e-government techniques to notice serious service failure is vast and the benefits far reaching. It can also be foreseen that data sharing in this realm would lead to shorter feedback loops, which would be of great use to the NHS in terms of noticing dangerous cases and trends.

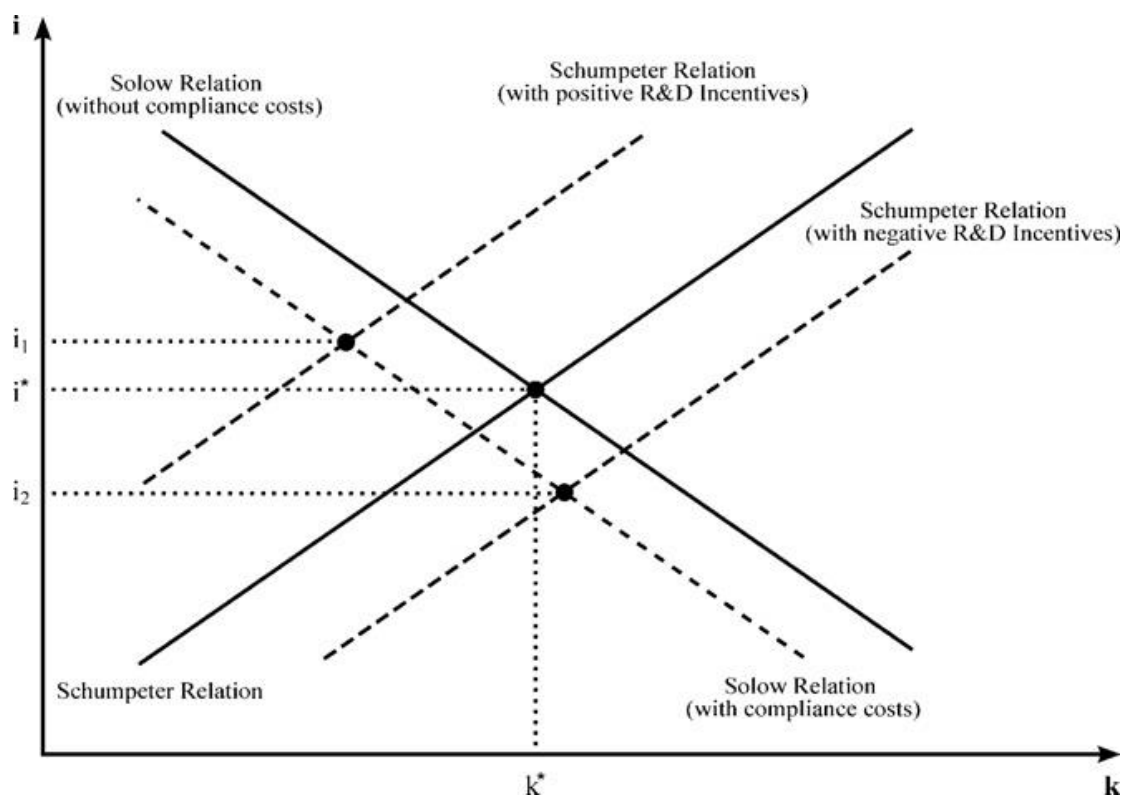
2.10 Empirical International research about regulation in a macro sense

An interesting international empirical research study of the wider influence of regulations on innovation comes from Blind (2012). This research aims to “assess the impacts of regulation on innovation, taking into account the variety of regulations, their ambivalent impacts and their dynamic relationship” (p.392). This research analyses the impact of six different types of regulation on innovation in 21 OECD (Organisation for Economic Cooperation and Development) countries over a time period of six years. To do this several assumptions are made: “First, we assume impact mechanisms of regulation on the aggregate innovation activities and success not only among the considered OECD countries, but secondly among the different types of regulations also within a country.” This research distinguishes “between the impacts of compliance cost on the availability of resources for innovation on the one hand and the incentives set for performing innovation activities on the other hand” (p.392). The final

assumption which is made is that “the influence of regulation on innovation over time is assumed to be constant” (p.392).

Blind assesses the impact of regulation “based on the considerations of Carlin and Soskice (2006), who determine an equilibrium rate of technological progress and consequently innovation endogenously” (p.392). Based on “the Solow growth model” it can be ascertained that there is “a negative relationship between the rate of labour productivity enhancing technological progress or innovation (i) – analogously to an increasing population or labour force – the equilibrium capital intensity (k)” (2012 p.392). In contrast to this Solow relation, another model called the Schumpeter relation “assumes that with increasing capital intensity (k), more resources are available for investments in research and development, which allows innovation and the rate of technical progress (i) to increase” (p.392). The two relations are illustrated in the figure 1 beneath:

Figure 1: the Solow-Schumpeter Relation



It can be seen in the graph above that when regulation is introduced into this equilibrium scheme, two effects can be seen: “first, the compliance of regulations reduces – like a tax –

the available resources for investment in research and development” (p.392). This means that consequently, there is a lower capital intensity (k) and a reduced level of technical progress and innovation (i). The second effect is that “regulation changes the incentives for investments in R&D” (p.392). This can work in both directions with things like patent protection, meaning create “additional incentives to invest in R&D” may become present whereas on the other hand “others such as price restrictions and product market rules, may reduce incentives” (p.392). This study argues that the impact of regulation on innovation depends on two things: the extent of the compliance cost and the incentive effect.

The findings of this research are that essentially regulations can have a positive or negative impact on innovation; it really depends on the type and extent of the regulations. The results of the six regressions carried out reveal that in the 21 countries “five out of the six regulation indicators reach very high levels of significance” (p.397). It was found that product and service legislations and environmental laws and compliance, both have a negative influence on the countries’ innovation performance. It was also found that “non-restrictive price regulations, an efficient enforcement of IPR and a legal and regulatory framework encouraging the competitiveness of enterprises are positive for innovation performance”(p.397).

This research is useful for understanding regulation more generally, as these trends are drawn out over many countries and many different types of regulatory behaviour. The point being, if across the world regulation can encourage and discourage innovation (depending on its form) then regulation in the NHS should also follow this pattern. This means it is useful to consider regulation in the NHS based on these factors, not necessarily in relation to innovation per se, more in relation to performance.

Asking questions like “does compliance to regulations enhance or worsen performance?” are key to understanding the relationship between regulation and performance. The implication of this research (despite innovation and performance not being the same thing) is that in certain areas it will enhance performance and other it will limit it. The specific conditions under which

performance is either enhanced or reduced as a result of regulation are therefore worth examining.

Fidler (2005) is an international study which contains an analysis of the major substantive changes in the new IHR (International Health Regulations). This is of value for this review because it shows how regulation in the NHS fits in with wider international trends. The study finds that there are five major substantive changes from the prior regime they are listed beneath.

1. "A dramatic expansion of the scope of the IHR;
2. The creation of obligations on states parties to develop minimum core surveillance and response capacities;
3. Granting WHO (The World Health Organization) the authority to access and use non-governmental sources of surveillance information;
4. Granting WHO the power to declare the existence of public health emergencies of international concern and to issue recommendations on how States Parties should deal with such emergencies and routine public health risks; and
5. The incorporation of human rights concepts into the implementation of the IHR by States Parties." (2005 p.358)

Fidler argues that whilst WHO had authority and responsibilities under what it terms "the old IHR" the new IHR: "contain authority and responsibilities for WHO never before created for an international health organization in the history of the classical regime" (p.376). It is also suggested that the expanded scope of WHO authority and responsibility can be seen in a number of features of the new IHR such as surveillance, confidentiality of information and response interventions (2005 p.376). This in essence mimics the trends which have prevailed in the UK. Hood et al. (1998) and Trubeck et al. (2008) for instance, both identify that the role of UK regulators has increased in terms of authority, overall control and remit. There are obvious parallels between regulation of health in the UK and in the rest of the world. Fidler also argues that:

“In contrast to the limited international governance footprint of the old IHR, the new IHR construct a synthesized approach to global governance in terms of actors, threats and objectives. The new IHR integrate governmental, intergovernmental and non-governmental actors through the provisions on surveillance. Each category of actors is vital to global surveillance working effectively.” (2005 p.386)

Again there are significant parallels to be drawn between the UK and the rest of the world. Surveillance in the UK health arena has increased (as identified by Hood et al. 1998 and Trubeck et al. 2008), and the role of non-governmental actors, such as Dr Foster has increased. Fidler concludes that “the state-centric approach to surveillance has become a relic of the past” (p.386). This supports a neo-pluralist notion of power in health i.e. that power is widely distributed between key actors in the field.

An international comparison of regulatory regimes in the health sector comes from Nunes et al. (2011). The aim of this paper is:

“To determine the importance of the principle of public accountability in healthcare regulation, stressing the fact that sunshine regulation—as a direct and transparent control over health activities—is vital for an effective regulatory activity, for an appropriate supervision of the different agents, to avoid quality shading problems and for healthy competition in this sector” (p.352).

Nunes et al do not see regulatory theory in the same way as Walshe and Shortell (2004): as an instrument of performance improvement. They argue that the high complexity of the healthcare system has “contributed to the need for effective accountability by the healthcare providers so that two essential objectives in the health sector are achieved” these are: “to promote a healthy competition among the operators and to achieve important social values such as the right to information and to freedom of choice” (p.353).

Nunes et al. claims that different accountability levels operate depending on the level of societal participation in the democratic process. They state that “in the long run, the inevitable competition in the healthcare sector implies that both quality and economic performance indicators are publicly accessible” (p.355). It is argued that both in the UK and Portugal publishing of data on the internet by the CQC and Portuguese Regulatory Authority of Health are examples of public accountability. Nunes et al. suggests that reforms in developed countries share the purpose of maximising efficiency and guaranteeing performance levels in access and quality of healthcare (p.358). The paper also identifies similar problems associates with regulation across liberal democracies in Europe claiming that: “capacity to meet the citizens’ wishes is normally confronted with a problem of information asymmetry due to the specificity of the economic good at issue” (p.358).

Nunes et al claims that the search for efficiency may easily cause malfunctioning of the healthcare services that needs to be regulated and supervised. It is suggested that public accountability is the “main driver of a new culture in the health sector; independently of the degree of the State’s intervention and the introduction of the market rules” (p.360), and that “sunshine regulation” is dependent on this principle. Nunes et al. makes direct comparisons between the UK and Portugal:

“In Portugal the National System of Health Evaluation intends to guarantee appropriate quality standards of the healthcare services through the benchmarking of a set of quality indicators that will subsequently lead to the relative grading of the healthcare providers. The subsequent social pressure, based on the analysis of this data, makes it possible to reduce the information asymmetry as well as to improve the consumer sovereignty indicators, which for different sorts of reasons are deeply reduced in the healthcare sector. As in England the determination of the performance indicators is essential for the proper application of public accountability and for an efficient regulation of these activities.” (p.361)

The conclusion of this research is that “sunshine regulation” is a significant driver of performance improvement, through increased accountability and transparency in most

healthcare systems in industrialised countries. As market forces are deployed and purchasers and providers of healthcare are given more autonomy, “sunshine regulation contributes to the achievement of high levels of transparency, which are fundamental to overcome some of the market failures that are inevitable in the transformation of a vertical and integrated public system” (p362-3).

Nunes et al (2009) is another international research paper which identifies universal trends about regulation in industrialised countries. The aim of the study is to “evaluate if independent healthcare regulation is an important tool with regard to the construction of fair processes for setting limits to healthcare” (p.257). It evaluates whether new regulatory models in the form of independent agencies result in better performance and “with regard to the public disclosure of the reasons and rationales of healthcare rationing” (p.257).

Nunes et al (2009) conclude that across the western world regulation has grown and different approaches have been used to address government inefficiencies and market failure. They suggest an “entrepreneurial culture” can result in high efficiency but there are specific issues, such as: “information asymmetry, externalities, service scarcity, market uncertainty and monopoly creation” (p.263). They claim that the purpose and objectives of regulation need to be reframed and that “the main goal of healthcare regulation in public healthcare systems should be the search for equilibrium between equity and efficiency and regulatory agencies should try to accomplish social as well as economical regulation (p.263). Accountability in regulatory systems is championed as the solution to optimising equity and quality in healthcare systems across developed countries.

Walshe and Shortell (2004) explore the offer a further international perspective, exploring social regulation in the USA healthcare system. This paper presents findings based on exploratory qualitative study of regulators and organisations who are regulated by them and offers “a framework of the emergent characteristics of effective regulation which might be used in future evaluations of healthcare regulation (p.79). The objectives and research methods of this research are similar to the approach being undertaken in this thesis, despite

being focused on the USA instead of England. Both research involves qualitative investigation of regulatory systems and seeks to theorise as to what successful regulation might look like. Due to these factors it can be considered one of the landmark texts in this literature review.

Walshe and Shortell highlight the long history of healthcare regulation in the USA over the past 80 years. They state that “now at least 25 such organizations involved in accrediting various types of healthcare organization” (p.81). Regulation in the USA is very different to what is used in the UK, as practice can vary significantly from state to state.

This research identifies four themes for additional exploration: “experiences of regulatory processes and interactions; how systems of regulation had changed over time; the impact or effects of regulation; and current or future innovations in healthcare regulation” (p.86).

Again similarly to the methods deployed in this thesis, the sample and methods includes identifying people involved with healthcare regulation and qualitative interviews being undertaken. The participants in this research include:

“Those working in nongovernmental and governmental regulatory agencies, in a variety of regulated healthcare organizations, and in other organizations or agencies with an interest in healthcare regulation. They included senior healthcare executives, clinicians, quality management staff, regulatory staff, academics and researchers.” (p.86).

The findings of this research are extremely significant. Many of the issues identified are similar to those which emerge later in this thesis, despite being about the USA rather than England. Walshe and Shortell identify issues with “regulatory fragmentation and duplication” where numerous agencies (such as NGO, state and federal agencies) undertake regulation on very similar areas of work within healthcare organisations (p.87). They describe the effect of this as “a high level of duplication, which many interviewees asserted resulted in an unnecessarily onerous regulatory burden and higher regulatory costs” (p.87).

The rigour of regulatory methods and processes was also identified as an issue in the research. Interviewees in the research questioned the validity of standards; whether or not it was evidence based and could be based on a small number of cases. They state for example:

“Some interviewees suggested that standards were often developed in response to a particular problem, perhaps at just one or two healthcare organizations, and then applied generally across all healthcare organizations regardless of whether the same problem existed elsewhere” (p.89).

This research also finds that some regulatory agencies do not keep their standards up to date. This is especially true for public agencies such as CMS and state survey agencies which are described as “outdated and of limited relevance” (p.89).

The volume of regulatory operating in the US healthcare system is seen as an issue by many interviewees. They suggest that “standards tended to proliferate and that the number of standards or regulations often made the regulatory process almost unworkable (p.89). It is suggested participants supported the view that regulators were fair and accepted many were well informed and their standards appropriate. In some instances however regulators agencies were perceived as “lacking in fundamental knowledge and understanding, staffed by people who did not have any practical experience, and disconnected from the world that they were regulating” (p.89).

The significant costs of US regulation in healthcare are outlined, but perhaps of more interest, compliance is listed as a potentially large cost which may be understudied. It is claimed for instance: “we know very little about the costs of regulatory interaction and regulatory compliance for healthcare organizations, though our interviewees generally felt they were very high” (90-1).

In terms of the impact of regulation on the performance of healthcare organisations there are important findings from the research. It is stated for instance that interviewees agreed health regulation has a “significant impact” on organisations behaviour however “there was much less consensus about how beneficial that impact was, and whether or not it led to improvements in performance and quality” (p.91). This key empirical research concludes several things about healthcare regulation:

- Better co-operation among regulatory agencies could reduce duplication, especially if this was required by the government and build into legislative mandates.
- Regulatory governance could be improved by including stakeholder groups in membership boards.
- Linking improvement in performance of regulated agencies to regulatory agencies income could work as a technique for prioritising performance improvement.
- Regulatory impact analyses could be used more widely to test the value of new regulations prior to implementation.
- The number of total regulation could be limited to prioritise useful regulation and remove outdate regulation. (2004 p.97)

2.11 Empirical research specifically related to mortality data

There is significant literature around HSMRs SHMIs and the data coding techniques of Dr Foster. One of the key landmark empirical studies which emerged in this review is Mohammed et al. (2009) titled “Evidence of methodological bias in hospital standardised mortality ratios: retrospective database study of English hospitals”. This research paper is heavily critical of HSMRs, claiming that they do not represent an accurate measure of mortality data. This is argued to be a consequence of the coding and risk predictions that go into the HSMRs. This research article goes on to conclude that claims “variations in hospital standardised mortality ratios from Dr Foster Unit reflecting differences in quality of care are less than credible” (2009 p.228). Thus it is possible that HSMRs do not truly reflect hospital quality, as Dr Foster would hope. This paper criticises HSMRs as a method on the basis of

coding depth, community provision, the failing hospital hypothesis, the quality of care hypothesis and the constant risk fallacy. These claims will be further assessed in the quantitative analysis, based on the findings from this research as well as retorts from Dr Foster and comments made in the Francis Report.

Issues with mortality data go back even further than Dr Foster, and another key landmark text in the area of mortality data is “the report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995” (2001) by Kennedy.

The issues in the inquiry address the deaths of children who underwent heart surgery at the Bristol Royal Infirmary during the period 1984-1995. Before this inquiry had even properly begun, two surgeons had been removed from the workforce, due to the apparent issues becoming public. In Kennedy’s report, statistical analysis was undertaken, and in this analysis it became apparent that there were several issues which prevented high mortality rates compared to other hospitals being identified. The analysis undertaken at the Infirmary attempted to use hospital episode statistics (HES) to identify high rates of mortality, however missing data was a significant issue with the HES: the inquiry found that around 5 per cent of those deaths were missing from the HES figures. There were further issues found related to the primary diagnosis made by clinicians, which often changed and could be considered idiosyncratic.

The subsequent coding was also found to be an extremely flawed process with obvious coding errors for example of the 785,263 in-patient episodes coded under Obstetrics, (which specialises in pregnancy and childbirth) 16,992 were recorded for male patients. Clearly this is a coding mistake and if such basic information is wrong then the usefulness of such data is clearly limited. The statisticians in the Bristol inquiry therefore decided to compare the mortality rate to eleven centres which were conducting the same types of heart operations on children. The Inquiry took data from the other centres and modelled the risk associated. To do this, different factors were considered: the age of the patients, the type of operation and the year it was performed for example. It was then calculated, for a centre which performs the

same kinds of operation as Bristol, what the expected mortality should be. According to the inquiries analysis, that the HES showed evidence of excess mortality from 1991 to March 1995 in open-heart operations on children under one year old. In this period, the mortality rate in Bristol was around double that of other centres.

This statistical analysis shows that it is possible to draw out trends which illustrate overly high mortality rates, even when there are issues with some of the data. Because there was doubt surrounding the accuracy of the data sets using 95% confidence intervals meant that that this could be taken into account. The findings clearly made an impact because even aside from the problems identified at Bristol, a unit at Oxford (which was being used for comparison) was also identified as an outlier and has subsequently been banned from performing these types of operation.

The Francis Inquiry (2013) is another key landmark text which has emerged in the literature review; this is unsurprising due to the comprehensive nature of the inquiry and the topics within the review. Specifically on the topic of mortality methodologies, for example, it has been confirmed by the Francis Inquiry that HSMRs suffer from a lack of clarity and full understanding. It was stated that: “Robert Francis QC has recommended, given the lack of understanding surrounding mortality statistics and their use, that the Department of Health set up an independent working group to urgently review the gathering and use of mortality data in the NHS” (Francis 2013). The HSMR methodology deployed by Dr Foster and others aiming to quantify mortality statistics will be subject to fuller scrutiny to assess their effectiveness, which is limited currently for the reasons discussed.

Another key landmark text identified in this review is Jacques et al. (2013) which also focuses on the topic of mortality data. This empirical research study uses “Hospital Episode Statistics linked to mortality data from the Office for National Statistics” (p.1) and uses an improved method for calculating mortality called the Summary Hospital-Level Mortality Index (SHMI). In the study “SHMI was calculated for all patients who were discharged or died in general acute hospital trusts in England for the period 01/04/2005 to 30/09/2010” (p.1).

This study is landmark in the sense that it applies significantly to some of the findings which later emerge in this thesis, commenting on whether quality as measured by mortality data has increased or not. The study concluded that “as measured by the SHMI there has been a 24% improvement in mortality in acute general trusts in England over a period of five and a half years.” There are significant caveats which are included in the study for instance it is noted that “part of this improvement is an artificial effect caused by changes in the depth of coding of comorbidities and other effects due to change in case-mix or non-constant risk” (p.1).

Freemantle et al (2013) is another key landmark text identified which focuses on HSMRs and SHMIs. This research centres on the strengths and limitations of both HSMR and SHMI as mortality performance indicators. In terms of their critique of HSMR, significant issues are raised “specifically about the application of death rates as a measure of overall quality of care, the inconsistency of its findings, and the fact that the HSMR had been subject to little empirical evaluation” (p.1). It is also noted that the HSMR methodology only “included only 78% of all in hospital deaths, did not consider all patients’ comorbidities and did not take into account post discharge outcomes and readmissions so that in many circumstances one patient death could be counted multiple times” (p.1). Clearly for these reasons HSMR must be limited in its value as a measure of mortality. The Freemantle research also notes that the HSMR methodology “lended itself to gaming” which clearly limits its value as a methodology (there are also links between this and earlier attempts at gaming with the CHI and HC). The conclusion of this research is that the HSMR being used commercially to judge hospitals performance is wrong, due to the many methodological flaws which have been outlined.

The many criticisms levied about HSMR about a mortality performance indicator led to the development of SHMI (summary hospital mortality indicator). The SHMI method is described in the passage beneath.

“The SHMI method estimates the expected number of deaths by fitting a logistic regression model using data from each non-specialist acute NHS Trust in England, grouped by diagnostic group (using the Clinical Classification Software, CCS categories) and adjusted for

patient age, sex, Charlson comorbidity score and for mode of admission (elective vs emergency). The expected number of deaths is calculated as a sum of the probability of death for all trusts based on the risk stratification algorithm and compared with the observed number of deaths for each trust. Any excess in observed versus expected deaths is taken as a marker to suggest a more in depth investigation of the hospitals quality of care delivery.” (Freemantle et al. 2013 p.1)

Up until 2012 this resulted in two statistical indicators: PO and OD banding: “the PO banding, based on Poisson distribution, inappropriately indicated too many trusts to be performing outside the expected range because the statistical methods did not account for the substantial unexplained variation in the statistical model, a phenomenon known as overdispersion” 2013 p.1)

In 2012 PO banding was removed for these reasons, and OD banding was deployed instead. The methodology of OD banding is described by Freemantle et al.: “OD banding is based upon an approximate random effects model and makes a reasonable attempt to overcome the limitations of the error structure of the SHMI, albeit acting indirectly. OD banding achieves a substantial adjustment for over dispersion, and the resulting measure does not find evidence of variation between trusts at the conventional 3 SD level, thus identifying no trusts that would be conventionally considered outliers based on mortality.” (2013 p.1)

Freemantle et al. research aims to develop a measure which deals with the methodological limitations of the SHMI called QUORUM (quality and outcomes research unit measure): “specifically the potential inadequacies of case-mix adjustment and absence of directly estimated error structure and estimates of model uncertainty” (2013 p.1). This essentially adds additional predictive variables to make the predictive power greater. The conclusion of the research is that:

“Owing to legitimate but unexplained variation, it is unlikely that measures like QUORUM and SHMI will be useful beyond identifying a very small number of trusts as potential outliers for a

period with values more than 3 SDs (standard deviations) above the mean. Like the SHMI, our attempts to advance the methodology remain challenged by substantial over dispersion which, when accounted for in the mixed effects model, result in no trusts being identified as outliers in 2010/2011.” (2013 p.1)

So despite the best attempts to reduce the over dispersion effects “there is no sound methodological basis for the use of values between 2 and 3 SDs of the overall mean as markers of poor performance.” Moving forward the research claims that:

“Future developments should concentrate upon driving healthcare providers to collect more clinically relevant data centrally, for example Scottish Early Warning System (SEWS) (early warning scores), and prescribing and the derivation of much more detailed linked patient datasets. This may then be used to explore quality within focused clinical areas rather than averaging across multifarious service provision.” (2013 p.1)

This key text is very useful because it proves that whatever mortality performance indicator is deployed it is very hard to accurately measure. There are significant methodological limitations identified with HSMR, SHMI and even the authors own method (QUORUM). These findings are of great value to this thesis, especially the quantitative element as they challenge the methods used by ALBs in the evaluation of the NHS based on mortality data.

2.12 Literature Review: Conclusions

This literature review has demonstrated that there is significant evidence that deficiencies are present in both a macro-regulatory and micro-regulatory sense in the contemporary healthcare policy area. There is also much evidence that this may be stemming from the specific methodologies deployed by the various health care regulators. This research seeks to add to the contemporary literature in this area in a unique way that develops theory which is grounded in the data.

In terms of grounded theory method, it is claimed that most researchers use a pragmatic variant, whereby they can achieve added value by identifying new themes from the data alongside those that could have been anticipated from the outset. (Barbour 2001 p.1116) Therefore as previously mentioned the aspect of traditional grounded theory method which suggests not using a literature review is not necessarily always appropriate.

The data in this research is collected based on what is already known about these phenomena. This research is not entered into with preconceived ideas about what may be occurring it is simply guided by the vast range of current and previous literature of the topic of health regulation. So whilst deficiencies with regulation have been identified in the literature review, it is not taken for granted that they necessarily are truths. Rather, it is suggested that they represent important routes of enquiry to guide the topics within the qualitative interviews and secondary data sets used within the qualitative analysis.

Chapter 3: Research methods

Research Objectives

1. Critically assess the regulation of NHS providers in England (macro level).
2. To compare methodologies used by the regulatory bodies for rating and regulating NHS Trusts in England and assessing the impact of this on service provision.
3. Evaluate the effectiveness and reliability of the regulatory regime and their activities (micro level).
4. To discuss and explore the political, economic and policy orientated ideologies that underpin the various regulation regimes involved in the NHS.

It was identified that an appropriate method to fulfil the research objectives would be to use mixed research methods. The qualitative side of this research deploys semi-structured interviews with key staff from providers and commissioners of NHS healthcare. The premise for using this style of interviews and these participants, is that directly interacting with the key people who implement health policy will allow a greater understanding of the issues in the field (some of which have already been outlined). The interviews are semi-structured, so as to allow a deep understanding of the complex issues involved, whilst retaining some structure that is based around key areas to focus on, for ease of analysis. Too much structure would have limited the richness of data obtained from the interviews, and also the varied nature of the interview participants would have meant that the exact same questions would not apply to all. For example, a Finance Director at a large NHS Foundation Trust is likely to know a lot about Monitor (as they are primarily the financial regulator) and perhaps less about the CQC and QRPS (which are more service quality focused). Similarly, a Quality and Safety Manager at a CCG may have significant knowledge around the QRPs and the CQC generally as a regulator, but little about Monitor.

Equally pertinent in shaping the design was the consciousness that completely open ended interviews are extremely hard to present coherently and compare to one another in a meaningful way. For these reasons, semi-structured interviews were the preferred choice.

From these interviews data has been coded using Nvivo software into themes that relate to the research objectives and the background literature for health regulation. These themes are subsequently developed into theory grounded in the data (inductively), which seeks to assess critically “what is going on here?” (Glaser and Strauss 1967).

The quantitative element of the research derives primarily from research objectives one and two. The aim of the quantitative research is to use secondary data, obtained from the databases on the CQC, Monitor and Dr Foster websites (and archives) to critically assess the regulation in a macro sense, as well as viewing the methodologies through a critical lens. In terms of the macro evaluation, the quantitative research seeks to use the data set to examine what the trend are over time and whether health regulation activities are impacting on service provision. The data sets are examined, correlated and the relationships are scrutinised, so as to ascertain:

- “What is going on here?” (Glaser and Strauss 1967),
- Are the methodologies appropriate?
- Do they accurately quantify what they are purported to quantify?

In the quantitative section (chapter 5) there are separate research questions listed, these questions serve the purpose of focusing the analysis and can be seen as extensions of research objectives one and two. It must be clearly acknowledged that whilst these secondary research questions are separate in one sense, they form part of the overall objectives and are brought together with the qualitative side of the research. They fulfil the same objectives and are expressed together in the research conclusions (chapter 7).

3.1 Grounded theory

This research follows the grounded theory approach to data collection and subsequent analysis.

“Grounded theory has its origins in symbolic interactionism, taking the perspective that reality is negotiated between people, always changing, and constantly evolving... the assumption is that through detailed exploration, with theoretical sensitivity, the researcher can construct theory *grounded* in data” (Richards and Morse 2007 p.59).

The aim is for this research to achieve just that. The qualitative semi-structured research interviews are the primary tool for generating this data, from which the theory will be grounded and conceptualised.

Richards and Morse also assert that:

“This is an appropriate method for the researcher wishing to learn *from* the participants how to understand a process or situation... grounded theory studies are usually situated in experiences in which change is expected, and the method has become dominant in research areas where the understanding of change and process is central, such as health and business studies” (2007 p.60).

This is certainly true about this research, since the 2012 Health and Social Care Act, policy in this area has become an incredibly fluid area, where change and process are constant features. This research seeks to learn *from* the participants in the interviews, who are key actors within their organisations and heavily involved in health regulation. Learning from the participants in this way serves to understand the regulatory processes in the health policy arena, from the multiple viewpoints of those involved.

Grounded theory is an inductive approach to developing knowledge about a topic. Induction is defined as: “a type of reasoning that begins with study of a range of individual cases and extrapolates from them to form a conceptual category” (Bryant and Charmaz 2007 p.15). Strauss and Corbin aptly describe the nature in which theory is grounded: “theory that was derived from data, systematically gathered and analysed through the research process” (1998 p.12). They also describe the general advantage and reason why the grounded theory

method is becoming increasingly popular among social scientists: “grounded theories, because they are drawn from data, are likely to offer insight, enhance understanding, and provide a meaningful guide to action” (Strauss and Corbin 1998 p.12). This essentially serves as justification for the grounded method being used in this instance; it can allow for insight to enhance understanding and make meaningful suggestions, with regard to policy action. If these advantages are realised in this research then the utility will be high.

It is also important to distinguish between description and analysis. Description involves merely noting what is going on at a superficial level. Analysis however is more than that: “analysis is the interplay between researchers and data” (Strauss and Corbin 1998 p.13). Analysis is the way in which data can be manipulated, so as to realise trends, similarities, differences and theoretical linkages. For grounded theory methods to work, the findings and conclusions must move from the descriptive to the analytical, enhancing the meaning and content.

In terms of the methodological software tools deployed to achieve congruence within the grounded theory method, Nvivo and SPSS are used in the qualitative and quantitative aspects of the research respectively. Both programmes have served the research process well, giving differing benefits and reasons to be deployed under the grounded theory methodological guise.

There are a number of ways in which Nvivo provides assistance to analysis in line with the grounded theory method, Richards and Morse summarise these benefits below, and there are additional comments elaborating on some of the observations:

- “Provision for storage and managing of data and interpretations in a single unit or project”; this advantage should not be overlooked due to its simplicity. The fact that all the data can be amassed onto one program makes it easier to draw out linkages between things. It also means practically it is easier to focus on one thing, rather than having several programmes open at the same time.

- “Ways of combining and comparing projects”; one of the initial useful aspects of Nvivo was for comparing and drawing out trends in the current literature for the review, for instance.
- “Ways of backing up and safely storing projects”; a key element to any ethically sound research. Access to the project is strictly password only access and Nvivo usefully saves the project periodically without being told to do so.
- “Ways of interfacing with other software”
- “Handling of text data for the project prepared in word processors”; this is the case with the interview transcripts, which were transcribed onto Microsoft Word and then copied into Nvivo and labelled with the appropriate code for each interviewee.
- “Ability to create and edit text within the project. All will allow the typing of memos”; the importance of memo writing in grounded theory method is large. Memos have often been used during transcription when an idea arises through thinking about the data during the transcription. It can be quickly noted down as a memo so that when the transcription is completed it can be revisited, further developed and analysed.
- “Inclusion of text data files in the project”
- “Handling non-text data”
- “Storing information (such as demographics) about people or places etc.”
- “Creation and editing of documents and memos from within the program”
- “Annotating or commenting text”
- “Coding of selected data at categories created by the researcher (called nodes)”; this played a significant part of the research. The data being put into nodes was integral to the development of theory that is grounded in the data. Coding data into nodes allows categorised and relevant data to be easily viewable in one separate section whilst the raw data remains untouched. This separate node is also very useful because Nvivo references where all the data has come from that is within it.
- “Ability to view all of the data you have coded at a category”
- “Ability to see on the screen what coding has been done”
- “Auto-coding of data (mechanical finding and coding of words or segments)”

- “Text search of words in data and sometimes coding of the finds”; this is another useful aspect of Nvivo which aids the analysis. Searching for key words allows for quicker initial searches that often end up being coded into relevant nodes.
- “Counting of codes or occurrences of words; quantitative content analysis”
- “Management and viewing of coding categories”
- “Asking questions (with “search” or “query” tools) about patterns in the coding of data”
- “Saving of search results”
- “Ability to run repetitive searches”
- “Visual displays”
- “Ways of seeing connections you have recorded in the data”
- “Making reports of data, codes, coding etc.” (Richards and Morse 2007 p.85-90)

It is because of these various advantages in the data transcription, processing and analysis that Nvivo was used in this project. Without its deployment, it would have been significantly harder to tease out appropriate nodes and this almost certainly would have taken longer to achieve. Bazeley and Jackson (2013) refer to how “nodes can be structured in a branching tree system with categories, subcategories and sub-subcategories” (p.95), this is how they were used in this research. The nodes coded through Nvivo offer a unique insight in to the realm of qualitative data. As Bazeley and Jackson describe “organizing nodes into trees offers “conceptual clarity” (p.97). What it means is you can code a theme, say the CQC for instance across, a large number of interviewee transcripts. It is then possible to look at all the content coded in this node in one place with comprehensive referencing. It is then possible to develop a sub theme, say the length of time data takes, and can code this data further based on this sub group. Again the sub group data is coded logically all in one place and fully referenced.

SPSS is quite the opposite end of the social science software spectrum, compared to Nvivo, being almost solely quantitative based. If Nvivo is the Social Constructivists research tool, then SPSS is the Objectivists equivalent. But for a mixed methods researcher, following the grounded theory approach, both programmes can perform sound practical functions in unison. SPSS has many advantages such as the ability to perform statistical tests on varied

data sets easily to arrive at conclusions about quantitative data. The nature of SPSS means that relationships can be tested, correlations drawn out, data sets can be tested for normality, linear regression analysis can be conducted, and many other types of statistical analyses which are not used in this research. It makes statistical procedures very simple to implement on a data set, and so realising “what is going on?” can be significantly enhanced. The nature of the secondary quantitative research will be fully explored in chapter 5, but regarding methodological congruence, the work with Nvivo allowed themes, theories and analysis to be completed, essentially the SPSS work afterwards allowed for these themes, theories and analysis to be tested.

It is also important to acknowledge another vital area of the grounded theory method: coding. It must be stated that; “coding is linking rather than merely labelling” (Richards and Morse 2007 p.137). This means that nodes created through coding are interrelated, and the way these nodes and the codes within them show the relationships. If coding was about labelling rather than also linkages, the findings generated would be at best descriptive and undoubtedly much less analytical.

In the first instance, the type of coding applied to the data fits best under the category of microanalysis. Strauss and Corbin define this as “the detailed line-by-line analysis necessary at the beginning of a study to generate initial categories (with their properties and dimensions) and to suggest relationships among categories; a combination of open and axial coding” (Strauss and Corbin 1998 p.57). The microanalysis in this research served to generate the initial categories for nodes on Nvivo through very detailed and specific viewing of the interview transcripts. This process was relatively unstructured and free flowing. Detailed analysis was used primarily at the beginning of the process to discover categories, properties and dimensions and then uncover relationships between concepts. As Strauss and Corbin suggest; “once categories are established, analysis becomes more focused on filling out those categories and verifying relationships” (1998 p.70).

Once these nodes are created through coding and constant interaction with the data by the researcher then conceptual ordering can occur. Conceptual ordering is defined as “classifying events and objects along various explicitly stated dimensions, without necessarily relating the classifications to each other to form an overarching explanatory scheme” (Strauss and Corbin 1998 p.25). After the conceptual ordering took place it was easier to take a step back and look at the data, from more of a bird’s eye view. The aim: being to theorise from the coding, nodes, descriptions and conceptual ordering looking to develop reasons why things are occurring, explaining what is going on, why it is going on and what can potentially be done. As Strauss and Corbin suggest “a theory is more than a set of findings; it offers an explanation about phenomena” (1998 p.22). This is the objective from the grounded theory approach and this is the objective of this research. This theory also comes about through the making of theoretical comparisons, Strauss and Corbin define this process as; “an analytic tool used to stimulate thinking about properties and dimensions of categories” (1998 p.73). One of the key facets of this approach is the continuous interplay between structure and process; looking at the way things are and the way they are formed. This is achieved through inductive logic, deriving this information from the specific instances and opinions in the qualitative interviews.

Another key aspect of the grounded theory approach is “maintaining a balance between objectivity and sensitivity” (Strauss and Corbin 1998 p.53). This is something which the researcher needs to be conscious of. The very nature of the grounded theory method implies an interaction between the researcher and the data, and there is a delicate act to be carried out. It is very hard for one person to be properly objective when working on a project on their own. The idea is: that being conscious of this and striving for objectivity should result in more objectivity, even if the research is not fully objective. This is not to say that qualitative research is fully objective, merely that the subjectivity of research can be minimised by being aware of its possibility. Equally important, is the sensitivity aspect of this balance, noticing the little things in the data and not discounting things because they may seem too subjective.

Theoretical saturation is a concept used in the grounded theory approach which is hard to properly ascertain. Strauss and Corbin describe this concept as: “the point in category

development at which no new properties, dimensions, or relationships emerge during analysis” (Strauss and Corbin 1998 p.143). In reality this point may be rather artificial; there is no real way of determining whether no new dimensions may arise from data if it is analysed endlessly. Whilst the theoretical saturation point is arbitrary to an extent, it must occur as otherwise the research process would suffer. Again, acknowledging the potential for just analysing data indefinitely, in this research it became apparent that after a certain point the findings, theory and conclusions could not really be much better developed without collecting more primary data. Given the timescales of a PhD this was not an option and thus theoretical saturation was declared. Unless a research project is indefinitely funded and has no strict timescales this point of theoretical saturation is a necessary concept and serves a practical purpose.

3.2 Methodological Justification

In this research, mixed methods are being deployed, utilising both qualitative and quantitative methods. Johnson and Onwuegbuzie claim that “the goal of mixed methods research is not to replace either of these approaches but rather to draw from the strengths and minimize the weaknesses of both in single research studies and across studies” (2004 p.2). This is, in essence, the justification for conducting mixed methods research in this instance. But also, mixed methods is a more pragmatic approach given the nature of the different research objectives. On the one hand quantitative analysis is being conducted, with the philosophical justification for this type of methods coming from the positivist perspective, stemming from an objectivist epistemology. On the other hand qualitative interviews are being conducted, supported by symbolic interactionism stemming from a social constructivist epistemology. Whilst these perspectives are from polar opposite positions on the philosophical and epistemological spectrums, they pursue different research objectives (or different elements of the same research objectives) in a pragmatic fashion to ultimately increase the utility of the research. In the quantitative analysis there are objective truths to be identified, whereas in the qualitative interviews there are multiple viewpoints to be considered. Both methods can serve

to provide research with high utility as supported by varying philosophical perspectives and epistemologies.

The justification for utilising quantitative analysis comes from the theoretical perspective of positivism. For positivist philosophers such as Durkheim, Comte and Spencer, there needs to be empirical data to explain a particular phenomenon adequately. From this perspective social scientists should strive to replicate the ways in which the natural world is studied through science. Durkheim's "Rules of Sociological Method" argues under this positivist stance, that facts in the social world are no less real than those in the natural world, and that "the social scientist should adopt the same detached and inquiring stance that is characteristic of the natural scientist" (in McIntosh 2005 p.207). The quantitative analysis being deployed in this research is designed to be as objective and scientific as possible under this positivist perspective. It also seeks to determine social facts about the social world in the area of public policy.

Objective empirically verifiable knowledge differs from subjective unverifiable knowledge; this is essentially the basic premise of objectivism. From this objectivist perspective objects have meaning which is independent of any consciousness of them. Rand refers to the creation of knowledge by man and Protagoras' dictum, i.e. that "man is the measure of all things" (Rand 1967 p.8), but in reference to this, Rand is claiming the opposite of Protagoras, i.e. that man is the measure in an epistemological rather than a metaphysical sense. Below is a summary of this argument:

"In regard to human knowledge, man has to be the measure, since he has to bring all things into the realm of humanly knowable. But, far from leading to subjectivism, the methods which he has to employ require the most rigorous mathematical precision, the most rigorous compliance with objective rules and facts- if the end product is to be knowledge." (Rand 1967 p.8).

Thus, an objectivist epistemology claims that reality is in existence irrespective of the human mind. Rand argues that whilst some may believe humans perceptions of this world are constructions, this does not mean that all constructions are tarnished with a subjective brush. From this epistemology, knowledge which is sought through a mathematical-like, objective approach serves as the most legitimate type of knowledge because it can be verified and is based on logic.

From 1830-1842, August Comte outlined his “Cours de Philosophie Positive” in which he sought to explain the philosophical perspective of Positivism, stemming from an objectivist epistemology. In this explanation he alludes that once past the states of theology and metaphysics, a positive stance will be logically pursued. This positivist stance acknowledges that it is impossible to obtain absolute truth about phenomena, and merely seeks to use evidence and reason to appropriate the best answer based on this knowledge. As Comte states “the explanation of facts, thus reduced to its real terms, consists henceforth only in the connection established between different particular phenomena and some general facts, the number of which the progress of science tends more and more to diminish” (Comte 1830 p.1). The reason the quantitative analysis is supported from this philosophical position is because it seeks to make correlations, and measure trends, so as to logically pursue the research objectives and appropriate the best answer to them based on this knowledge.

Spencer had a similar philosophical vision to Comte, however Spencer championed a “System of Synthetic Philosophy” based on a mixture of deism and Positivism. Though not a Christian since his teenage years, he believed in a creator who wanted human happiness. This serves as a source of tension with Spencer’s otherwise positivist convictions about understanding phenomena and the construction of knowledge. Like Comte, Spencer supported the view that scientific laws applied equally in the physical (organic) world and the human mind and society (inorganic) (Spencer 1896). Spencer’s positivist vision argues that natural laws govern the world and are present in Biology, Psychology and Sociology. Furthermore these laws are governed by an overriding natural law: progress and evolution (influenced by Darwin). Through Spencer’s positivist guise, deploying quantitative analysis

and data analysis is a way of logically pursuing knowledge, so as to expand the number of laws applicable to the inorganic (social) world. It just so happens that the area of the social world being studied is public policy, and the laws are concerning health regulation.

This research seeks to evaluate the effectiveness of key healthcare regulators. The purpose of the quantitative element is to try and correlate, through a statistical analysis, all the secondary data obtained from the CQC, Monitor and Dr Foster. The positivist guise supports the view that no statement can be meaningful unless it can be verified. The quantitative analyses seek to determine this verification so synthetic statements about the effectiveness of the key healthcare regulators and the methodologies which they deploy can be made.

An extreme version of positivism: logical positivism originates from Moritz Schlick and the Vienna Circle as well as Hans Reichenbach and the Berlin circle in the 1920s. Logical positivism rests primarily on the idea that no statement is meaningful unless it can be verified. This empiricist stance purports that knowledge is only meaningful if there are a finite set of circumstances in which a phenomena can be investigated and hence be shown to be empirically true. Whilst this may be true to an extent, in that in a set of finite circumstances generalisations and laws that govern these circumstances can be made (and are undoubtedly true). The problem is that in the real world most sets of circumstances tend to lean more towards the infinite end of the spectrum and proving all to be the case is almost impossible. A key critic of logical positivism is Karl Popper, who claimed that the logical positivist's criteria for knowledge: verifiability, is too strong to provide any utility in the quest for knowledge. This led to Popper's criterion of falsification, which ultimately does not rest on inductive reasoning in the same way as logical positivism.

Karl Popper refers to the problem of induction. This problem questions philosophically whether inductive reasoning can lead to knowledge. This calls into question all empirical claims made in any aspect of life, based on the idea that to prove anything positively rests on an incomplete set of data. This creates problems because you cannot get objective data without a theory; and you cannot test a theory without data. Popper's hypothetico-deductive

scientific method postulates that knowledge should be constructed through falsification as Willig summarises: “to circumvent these problems, Popper proposed that instead of induction and verification, scientific research ought to rely upon deduction and falsification” (2001 p.4). This rests on the conviction that to fully construct knowledge about social trends, the opposite knowledge must be proved to not be the case. When trying to prove something is the case however many examples are given, it is logically impossible to prove anything in absolute terms. Proving something is not the case only takes one example, thus rendering it more probable to be accurate. The principle of this will be present in quantitative methods in this research, as it will be seeking to disprove a null hypothesis in the statistical analysis of the empirical data. As correlations are being measured through SPSS analysis to disprove the null hypothesis, that is; that there is no correlation between the various data sets. Under this hypothetical-deductive scientific guise the research is seeking to maximise the degree to which it is scientific in its approach.

Positivist philosophical ideals thus serve as the primary justification for the quantitative methods deployed in my research. Positivism is a philosophy which uses empirical evidence to justify knowledge through verification. This allows us to understand the social realm and the systems within it and health policy analysis represents an important social system, on which significant government funds are spent. Those of the social constructivist school of thought would, however, criticise the positivist stance for not acknowledging the subjectivity and bias of the researcher. For instance, Johnson and Onwuegbuzie claim that positivists “disregard the fact that many human (i.e. subjective) decisions are made throughout the research process and that researchers are members of various social groups” (2004 P.17). Whilst positivism is being used as reasoning to use quantitative methods, there must be awareness that this criticism holds some weight. In essence, fully objective research is a myth. In any social science research those conducting the data collection are themselves part of society, and can never have a completely neutral view of things. This does not mean objectivity cannot be strived for, but it is important to acknowledge ones relative subjectivity in the scheme of things.

The many roots of positivism, supported by an objectivist epistemology have now been outlined as support for the deployment of quantitative data analysis in social science research (although this is by no means an exhaustive list). Now the philosophical, ontological and epistemological positions supporting qualitative data collection in the social sciences are to be considered. The philosophical justification of deploying the use of qualitative interviews rests primarily on the symbolic interaction they provide. They allow a deep engagement with the perceptions, attitudes and values of the participants.

From the philosophical antirealist position it is claimed that no objective reality exists in any sense at all. All realities are constructions of multiple subjective realities, and as such antirealism supports the social constructivist perspective. Beneath is a passage which outlines briefly the antirealist position and claims that can be made through its perspective:

“Advocates of the antirealist position argue that qualitative research represents a distinctive paradigm and as such it cannot and should not be judged by conventional measures of validity, generalisability, and reliability. At its core, this position rejects naive realism—a belief that there is a single, unequivocal social reality or truth which is entirely independent of the researcher and of the research process; instead there are multiple perspectives of the world that are created and constructed in the research process.” (Mays and Pope 2000 p.50)

This serves as justification for deploying qualitative interviews in general, but it also defends their validity, generalisability and reliability. The argument is that positivist measures of validity, generalisability and reliability do not apply to qualitative methods because they seek to achieve entirely different things. The aim of qualitative research is to acknowledge the multiple viewpoints and strive to understand them, through thorough and deep analysis of interviews which respond to the participants' behaviour. This may sometimes mean that interviews are hard to compare to one another because their content varies significantly, but it will also mean rich data is obtained, from a variety of sources, illustrating the multiple perspectives present. Qualitative interviews produce a different type of data for analysis which does not rest on a positivist perspective, but antirealists argue that they can serve to glean a

reality rather than attain “the truth”. This research is seeking to understand a system which involves large numbers of multiple stakeholders. Therefore, by actually speaking to these stakeholders, the research can represent their position in the policy process, whilst acknowledging the subjectivity of their evidence.

The epistemological position of social constructivism has the conviction that there is no meaning in the world, until us as humans construct it. We are all part of society and as such our societal interpretation affects the meanings that we assign to things. This means that when trying to glean information about a complex system, which contains numerous actors, there will sometimes be differing and even opposing constructed realities of the system.

From a classical Greek philosophical perspective, the information that interviews produce can represent either “doxa” or “episteme”. By “doxa” the Greek in question: Socrates, meant that the information represents the views, experiences and opinions of those being interviewed, whereas “episteme” represents knowledge which has been proved to be valid through conversational or dialectical questioning. Kvale and Brinkmann (2009) support the argument that qualitative interviews can produce both types of knowledge, stating;

“They can elicit important descriptions and narratives of peoples experiences, narratives, hopes and dreams (the doxa), but they can also be employed as conversational ways of producing episteme, knowledge that has been justified discursively in a conversation” (p.37).

The Socratic principles of interviewing will be present in this research to some extent, in particular the element that seeks to create epistemic knowledge from the interviews. For example, questions will be asked about the interviewees’ thoughts on the current systems of health care regulation, and listening to their views on the efficiency of the system and the role they play within it. This information is doxa in its nature, but the aim is to move from listening to these opinions to seeking justification for them and questioning their views (episteme).

Hermeneutics is the study of the interpretation of texts and it is another philosophical position which supports the deployment of qualitative interviews. It is claimed that; “from hermeneutics, qualitative researchers can learn to analyse their interviews as texts and look beyond the here and now in the interview situation, for example, and pay attention to the contextual interpretive horizon provided by history and tradition” (Kvale and Brinkmann 2009 p.50). Hermeneutics will be present in the qualitative interviews being conducted, as the topic matter discussed will seek to put current regulatory activity into a historical perspective, but also to look towards prescribing future health policy initiatives. The interviews can allow an insight into the policy area, which better places any initiative recommendation, as what would be a workable solution can be discussed directly.

Pragmatism is another premise which provides support for the utilisation of qualitative interviews. Kvale and Brinkmann argue that; “from pragmatism, interview researchers can learn to focus on the practical aspects of what they are doing, on the craftsmanship of their activities, and on the issues of values and ethics raised by the use-value of their research results” (2009 p.50). This is perhaps the most compelling argument for their use in this research. The issues raised in the interviews can significantly increase the use value of the research. As previously mentioned, it is possible to interact directly with the key policy actors, meaning the scope for recommending future policy is much greater. For example; it is specifically pragmatic for future policy prescription to discuss the potential for the healthcare regulators to develop a central database, on which to data share. Actually speaking to the key actors directly will also allow policy change to come from them and protect their relative stakeholder positions.

Post-modern thought outlines the importance of understanding social relations; for example, it is claimed that; “in post-modern epistemology, there is a shift from the individual mind to relations between persons” (Kvale and Brinkmann 2009 p.53). In essence through this guise knowledge is neither inside an individual nor outside in the world in which the individual exists, it is constructed through the relationship between individuals and the outside world. Merleau-Ponty (1962) states that; “man is but a network of relations” (in Kvale and Brinkmann

2009 p.53), which summarises the post-modern epistemology. This branch is similar to social constructivism, in that it justifies qualitative interviews because they give a deeper understanding and a chance to directly engage with the network of relations that is present.

Another philosophical debate relevant for the deployment of qualitative data collection is Caplan et al.'s "two-communities" theory (1975). This postulates that social science researchers and decision makers that they research; "lack the ability to take into account the realities or perspectives of on another" (1975 p.4). This is especially relevant for this research as it is policy orientated and the interviews being conducted will be focusing primarily on the decision makers in the health policy arena. Caplan et al. observed that social science researchers consider themselves "rational, objective and open to new ideas" (1975 p.4) whereas they consider decision makers "action and interest orientated and indifferent to new ideas" (1975 p.4). Conversely, from the decision maker's perspective; they consider themselves "responsible, action orientated and pragmatic" and the academic researchers "naive, jargon ridden and irresponsible in relation to practised realities" (1975 p.4). Two way communication between researcher and researched can help to realise a mutual understanding of a policy question. This is what is wanted in this research. Honesty and openness from interviewees is being sought and it is being made completely clear that the research does not seek to jeopardise their stakeholder position in the policy process. On the contrary, the research is seeking to obtain their views to represent their position in the policy process and better understand it.

There is, however, reason to be cautious, as it is unsurprising that decision makers prefer research evidence in which they have had an opportunity to contribute to. There is a distinct possibility that the interviewed decision makers will use evidence that protects their position of authority, or even supports their own ideology or political preference. This illustrates that these factors will have to be considered when analysing findings. Evidence presented from interviewed decision makers will be subject to validation and reference checks, wherever possible, to verify the content is correct. Also, the relative subjectivity of participants (as well as the researcher) must be acknowledged throughout the research process.

A big assumption that is sometimes made concerning qualitative interview, which is often false, is that people will give you an honest reading of what they think. It takes some skill to get around this. There are lots of reasons why interviewees might not answer honestly: they want to appear rational, not emotional in their reasons for thinking or doing something. They may give what they think will be 'acceptable' answers, or their ego gets in the way. They may also have a particular interest in the outcome, e.g. they benefit from the status quo. These points are just a few of the reasons why interviewees might mislead in interviews, but whilst this is being acknowledged, this does not make their deployment unproductive. The subjectivity of data merely needs to be acknowledged. Many people will not mislead, even if some do, and the data obtained can still be rich in depth and detail.

Despite the differing ontological and epistemological positions supporting either qualitative or quantitative data collection, it is perfectly rational that using both will serve to be more pragmatic given the nature of what is being researched. The premise is that because the differing methods serve different objectives (or elements of objectives) it does not matter that they have opposing philosophical roots.

Mixed methods research is therefore the logical solution to the research questions to give the most utility to the research, as Johnson and Onwuegbuzie state; "the bottom line is that research approaches should be mixed in ways that offer the best opportunities for answering important research questions" (2004 p.17). Not only can this be achieved, but also using both qualitative and quantitative research methods can serve to minimise the disadvantages of either approach.

Caplan et al. argues that the definition of use with regard to social science research comes under three criteria:

1. Direct, specific use.
2. Enlightening use of evidence: "establishing new goals and bench marks of the attainable" and deepening understanding of a complex problem.

3. Selective strategic use. (1975: p.30)

The aim is for this research to provide utility through all three criteria. This can be achieved through the combined deployment of qualitative and quantitative research methods, obtaining differing benefits in terms of utility respectively. Ultimately, the quantitative data holds direct utility in validating the healthcare regulators attempts to accurately deploy their differing methodologies, and it is strategic in its nature due to the methodological implications for the operation of arm's length bodies as health regulators. The qualitative interviews should satisfy the enlightening use of evidence criteria as new goals and benchmarks will be discussed during the interviews. The findings of both aspects of the research should inform policy makers strategically on their specific issues. Also, the final aim is to make recommendations surrounding efficiency and the possibility of future policy recommendations, which will fit in with the enlightening use of evidence category. The argument being proposed is that without using mixed methods in this data collection, this research would ultimately have less utility. By using the two different types of data collection, there is a higher probability that the three distinct areas that utility is defined by will be fulfilled.

Without the quantitative aspect it is clear that direct use would be lessened significantly in reference to evaluating quality. Conversely without the qualitative interviews the research would fail to satisfy the conditions for enlightening use of evidence and perhaps also for selective strategic use. This demonstrates that through mixed methods deployment, more types of utility can be ascertained from the research, justifying this technique logically and pragmatically.

Mixed methods research can be critiqued for adopting a contradictory ontological position. For instance validity of qualitative research can be questioned from the positivist perspective because it is less objective and scientific. A potential retort to this is to claim; "that reliability and validity are terms that belong to the positivist paradigm, and qualitative researchers should avoid them" (Richards 2009 p.199). This is not however the stance being taken here. The positivist paradigm has a plethora of philosophical justifications and many have been

outlined as justification for the quantitative research being deployed. The point is: just because qualitative research can be less objective and scientific at times, this does not render it pointless. It can provide rich data to give a deep understanding. No research can claim complete objectivity, it is best to acknowledge ones subjectivity in the research process, and pursue the research objectives through as objective fashion as possible. Similarly just because quantitative research can yield less rich data at times or fail to represent different perceptions fully this does not mean it is unimportant. Much of the progression of public policy as a subject of academia has been fuelled by quantitative methods research and it is an irreplaceable tool in the quest for knowledge.

Often, in practice, qualitative research precedes quantitative, and is used to make the design of the quantitative research study more effective, i.e. sharpening up the questions to be asked, design of sample structure. This is very much the case in this research where the numerical data comes from the quantitative side, but the qualitative interviews make the quantitative data more effective in practice, for actual policy prescription potential and utility. Qualitative research methods are often better at eliciting real insights as to how things are, as more depth and understanding of data can be achieved

3.3 Data Collection and Analysis: Methods

3.3.1 Qualitative methods

In terms of the actual methods deployed in the qualitative side of the research, 36 interviews were carried out, across the four NHS Trusts and two CCGs, with six interviews per Trust/CCG. The providers in the sample were selected based on purposive criteria (as well as opportunistic methods to an extent); the interviewees within the specific sites were selected on the same basis. They were purposive in the sense that they had a direct link to NHS regulation from within their Trust or CCGs perspective; they were opportunistic in the sense that they were the staff members who actually agreed to be interviewed, within this remit. The purposive nature of the sample means that those who are not suitable for the research are

already eliminated and the most suitable remain; this also makes the research less time consuming. It also means that maximum variation can be achieved within the sample, by purposively choosing a wide range of variation on the key dimensions of interest. This variation allows common patterns which cut across the variations to be identified and extracted from the data. So for each Trust, for example; there are numerous levels of the hierarchy (who are involved in regulation in some way) represented in the sample. There is also some staff members who are involved primarily with CQC regulation (e.g. Quality and Safety Manager) and some involved primarily with Monitor regulation (e.g. Finance Director).

The staff members who participated in the research range significantly in terms of their hierarchical position within their organisation. Generally what happened was a key senior staff member agreed for organisational participation (such as the Chief Executive). Once this person was on board, they advised as to which other staff members would be suitable to interview, given the nature and scope of the research. This was key to the success of the data collection because having a Chief Executive involved and encouraging others to participate ensured that there were key actors involved in the interviews from each site. Participants include top level staff such as Chief Executives, Deputy Chief Executives and Executive Directors. Middle level staff members involved include Heads of Departments, Commissioners and NHS managers. The lower level staff involved in the interviews includes staff nurses. The range of participants was chosen to try and examine all aspects of regulatory behaviour. Some discussed high level concepts, others specific aspects of particular regulations. The aim of this was to target health regulation at all stages of the policy cycle to give the most informed findings as possible.

It was recognised early on in the process that qualitative interviews would be deployed to answer the research questions. It was also recognised that the quality of the interviewer can have a serious impact upon the quality of the interview, which will then impact on the entire research quality. Bearing this in mind, significant preparation was undertaken before the interviews took place. This included formal doctoral research methods training in qualitative methods. This was extremely beneficial as it not only meant qualitative techniques were

studied, but it also meant that interviews were practiced and significant Nvivo training was given. Aside from the training, the interview was also rehearsed and refined. This was with peers who acted as the participants to improve the techniques and interview skills of the interviewer. This was also carried out with (former and current) NHS staff that happened to come into contact with the researcher (prior to data collection) who were willing and suitable to assist. The NHS staff involved often had criticisms and recommendations about how to word a particular question, or specific prompts that might work. Both elements were invaluable for the research.

The style of the interviews was semi-structured, a style which fits well within the grounded theory approach:

“the use of semi-structured interviews is appropriate when the researcher knows enough about the study topic to frame the needed discussion in advance... such interviews offer the researcher the organisation and comfort of pre-planned questions, but also the challenge of presenting them to participants in such a way as to invite detailed, complex answers” (Richards and Morse 2007 p.114).

These interviews were based on an interview guide (see appendix 3), but as the interviewees varied in terms of their job and position, related to regulatory processes, this interview guide was adapted based on these factors. So for example, a Director of Finance would have more Monitor related questions, as they are the regulator for finances, but might not have many CQC related questions as they are not involved with the CQC stream of regulation. Similarly, a Quality and Safety manager would have more CQC specific questions and less Monitor based. In essence, the interviews are focusing in on the research objectives in the most practical way depending on the interviewee's position and involvement in regulatory policies. The aim of the interviews is to represent the views of the interviewees as openly and in as much detail as possible. So whilst the interview guide was an important element, guiding the questions around main themes, this was not stuck to rigidly: there was still scope for freedom and adaptability in the interview in getting the information from the interviewee. Interviewees

were given instructions to feel free to “go off on a tangent” in as relaxed a way as possible, meaning that the data obtained from the interviews was not limited by the interview guide.

Whilst the interviews were tailored to each individual to some extent at least, there were main areas which were decided to be focused upon in the interview. These came under four main areas and there was a checklist for the researcher to verify that these areas had been covered during the interview, unless there was a reason for why they had not been. These four themes emanate from the literature review. They are based on the key empirical research such as Walshe and Shortell (2004), Walshe and Phipps (2013) Nunes et al. (2011) and key conceptual papers such as Hood et al. (1998) and Trubeck et al. (2008). The four main areas or themes are outlined beneath.

1. The purpose of regulation

This came in many forms, within this the focus was on things such as; quality functions, finance functions, governance functions and competition policy.

2. The perception of the CQC and Monitor

This is in relation to the interviewees general perceptions of these bodies, issues related to them and similar perceptions. Specific issues explored include the feedback process, the age of data, replication of data collection, data coding issues and the separation of finances, governance and quality.

3. Bureaucracy

Any concerns of a bureaucratic nature, specific or general. Themes related to the overall coherence of the regulatory system.

4. Data sharing

Covering the nature of current arrangements for data sharing as well as the scope for more moving forward and whether this would be beneficial and practically achievable.

It must be noted that there are some regulators which were not focused on to the same extent as others (the CQC and Monitor). The NHS Commissioning Board for instance are not a regulator of central focus. The reason for this is that the introduction of the NHS

Commissioning Board only came after the majority of the data collection for this research had taken place (October 2012). It was considered that it was not worth putting in specific questions about the NHS Commissioning Board, because they had not really started their work yet. This does not mean however that if they were mentioned in relation to more general questions about regulation that interviewees would be steered away from talking about them, merely that they are not a specific focus of the interview questions. Regulators of health professional were similarly not focused on to the same degree as others. This decision was made because the regulation of providers and purchasers of health are the focus of this research, not professionals. Again, if these type of regulators were mentioned by interviewees anything relevant was noted. There is a need to draw a line in terms of what to include in the interview guide and this decision was taken to ensure that the data which was collected was relevant in addressing the specific research parameters i.e. providers and purchasers of healthcare.

During the interviews there were several things which were consciously present. For example:

- Clarity: in both senses; the questions and the answers. The questions being as simple, easy and short as possible and spoken distinctly and understandably.
- Calmness: being tolerant, sensitive and patient. Sometimes provocative and unconventional opinions arose; sometimes interviewees were not answering questions (or not fully answering). Remaining calm and affable is the best way of dealing with these instances.
- Steering: whilst interviewees were encouraged to discuss whatever they thought were relevant answers fully, at times it was necessary to control the course of the interview to avoid unnecessary digressions from the topic.
- Avoiding bias: interviewer subjectivity is an aspect of interviews that cannot be removed entirely, it can, and was, reduced as much as possible though. Verifying claims and interpretations, for instance, was integral. Avoiding leading questions was also very important. Prompts were an aspect that was used in the interviews, but they were only used if necessary and they were used in as neutral a way as feasible.

- The sequence of questions: firstly getting the interviewees involved as quickly as possible with some uncontroversial questions. The more controversial questions were interspersed with factual questions where possible to make the interviewee feel as though it was more of a natural conversation than an interrogation. The final question always allowed the interviewee to provide additional information that they think is relevant given the nature of the interview. They were also asked about their impressions of the interview, to allow reflection on the appropriateness of the content.

There were also a few procedures that occurred during and after the interview. The interviews were recorded and it was occasionally checked that this was working properly, and at the beginning of the interview participants were asked to state their name and job title for a sound levels check. Due to the recording of the interviews, note taking was minimal and limited to when a specific thing of interest came to light which warranted special attention. This was a conscious decision because interviewees can be put off by the interviewer constantly writing, it can make them feel that the interviewer is not paying full attention, especially if they are doing this with their head facing downwards.

The interviews were conducted face to face at the interviewee's place of work. This was decided upon as a strategy because:

1. The interviewees are more likely to agree to be interviewed in the first place. Offering to come to their place of work at a time of their convenience meant that the research was as unobtrusive as possible. This was a substantial benefit of this approach, as access and uptake of the interviews would likely have been an issue otherwise.
2. The face to face nature of the interviews allows for rapport to be developed between the interviewer and interviewee. Compared with telephone interviews, or even questionnaires, the personal nature of face to face interviews means it is likely that more revealing insights will be obtained. Also, compared with telephone interviews, face to face interviews tend to last longer, therefore revealing more useful

information. The main reason for this is that it is very easy to hang up a phone, compared with ending a conversation with someone who is right in front of you.

3. The decision to undertake the interviews at the interviewee's place of work was designed to make them feel comfortable. People are more likely to reveal things when they are comfortable in their surroundings. Offering to interview at their places of work is intended to make the interviewees feel relaxed, in an environment which they are used to.
4. The actual rooms where the interviews were conducted were private, quiet offices with no real potential distractions. This was beneficial compared to some neutral public location like a café where actually it can be quite loud and there is always the potential for someone overhearing the conversation.

All the interviews were recorded and transcribed word for word, based on these recordings (onto Microsoft Word). This data was then processed into Nvivo for analysis. The benefit of using the Nvivo software is that in the analysis of the transcripts, nodes can be developed which aids the development of themes. Specific nodes were developed, with sections of interview transcript from the relevant information related to the node coded into them. This allows the coded data in the nodes to be clearly referenced, with supporting statements from interviewees, and it is possible to see directly where this statement has come from and which interviewee it came from. The Nvivo analysis allowed themes to develop from these nodes, and these themes were further analysed and developed into the findings from the interviews, referring directly to the research objectives and allowing development into a coherent narrative on NHS regulation, based on the data. This qualitative research has led to a varied range of conclusions, which relate specifically to the primary research objectives, theoretical and practical issues, as well as recommendations.

Member validation occurred in this research during the actual interviews rather than afterwards, as often is the case. The definition of member validation is as follows:

“Also called *member check* and *respondent validation*, member validation is a procedure largely associated with qualitative research whereby a researcher submits materials relevant to an investigation for checking by the people who were the source of those materials. The crucial issue for such an exercise is how far the researcher’s understanding of what was going on in a social setting corresponds with that of members of that setting.” (Bryant 2013 p.1)

In order to verify that the data obtained in the interviews was accurate and a true representation of what interviewees were conveying, member validation checks were used throughout the interviews. This would be in a simple form such as saying “so by that you mean ____” to clarify that the interpretation of what they had said was accurate.

Another method which was considered but decided against was sending interview transcripts to participants. It was decided that it would be better to record the interviews so they could be transcribed word for word and check the meaning of the content throughout the actual interviews as described. There are numerous benefits associated with conducting a member validation, primarily related to increasing the validity; “as Lincoln and Guba (1985) observe, it can be crucial for establishing the credibility of one’s findings and can also serve to alleviate researchers’ anxieties about their capacity to comprehend the social worlds of others” (in Bryant 2013 p.2). The two-pronged usefulness certainly applies in this research, the validation checks allow the researcher to check whether specific interpretations are accurate at the time of the interview, which is helpful in terms of the subsequent analysis, but as mentioned it is also clearly useful with increasing the validity of the data in the research more generally. Usually validation checks are undertaken after the data collection stage in the research process. The reason that this was not the case in this research was to do with a few factors.

Firstly, it is asking a lot of NHS staff to participate in the research, to take between 30 minutes to an hour of their time, at work, and the feeling was that if validation checks had been attempted after the interviews the response rate would have been poor. If this indeed had been the case then the validation checks would not have served the purpose they are

supposed to. Secondly, conducting them during the interview, through checking that interpretations were correct meant that the interviews could be adjusted depending on the responses. To illustrate this here is an example from an interview with T2 Director of Corporate and Legal Affairs.

Interviewer: "Do you think there is much overlap between the functions of the CQC and Monitor from providers' perspectives?"

T2 Director of Corporate and Legal Affairs: "Yes I do, they can be asking for the same information; quality is an area where this is starting to happen."

Interviewer: "So does this mean that there is duplication of data collection with regard to quality by the CQC and Monitor?"

T2 Director of Corporate and Legal Affairs: "Yep, I would say it's not a helpful distinction to be drawn it can prove tricky for providers because extensively you have got the CQC as the quality regulator but you've got monitor increasingly moving into that territory. So in the wake of the Mid Staffs scandal, their response to that was a whole new quality governance framework which I guess it's their way of obtaining assurance that we are providing quality but as we have to attest to CQC on that slightly differently I guess you are back to where I started from, you know your busy meeting the requirements of different bodies on the same territory, it's not the most efficient use of provider's time, providing assurance on the same topic to two slightly different regulators. Question mark, yea that's a working progress. I think the Mid. Staffs enquiry the second Francis report will probably have a lot to say on that subject with implications for providers like ourselves."

Clearly here the initial question was answered and the answer is interesting if a little vague. The second question by the interviewer allows for the true meaning and interpretation to be ascertained, and in this instance the second answer is much richer in information and

confirms the interviewer's interpretation. This example illustrates the worth and benefits associated with interviewing in this style for validity.

3.3.2 Quantitative methods

With regard to the quantitative analysis, this is based on secondary data sets obtained from the CQC, Monitor and Dr Foster Intelligence Ltd. The reason for using these data sets is that these three key regulatory actors aim to quantify different but similar aspects of NHS providers, and examining the relationships between the data sets illuminates how they interact with one another. The CQC data is concerned mainly with quantifying quality, the Monitor data is concerned with primarily governance and finances and the Dr Foster data is a quality measure.

The CQC data is in the form of surveys on outpatients, inpatients, accident and emergency services and the CQCs "five key standards". Derived variables have been created on SPSS for each of these related data sets. These values are of significance, because if they accurately portray quality then they should in theory positively correlate with the HSMR score (if it also accurately portrays quality). It must be acknowledged that this is perhaps an overly simplistic view of things. All of these variables may well not correlate with one another. You could argue that outpatient surveys for instance may not correlate with HSMRs for example. The point of this exercise was to look at all the methods used by these key regulators and look at the relationships between the variables. Given the nature of the data collection and the use of SPSS to test relationships it was decided that it would not be too labour intensive to include all of these variables in the analysis. This means that the relationships between the variables can be explored in full. It may be that there is a more rational explanation for a correlation between some of the data set compared to others, but looking at all of the variables means that there is no room for missing trends which could be very interesting. Furthermore, the qualitative interviews in this research have suggested that there is a relationship between governances, finances and quality. It is therefore useful to test the correlations in this area to examine whether this is the case.

The Monitor data is related to governance and finances and again, derived variables have been created using SPSS. As mentioned, these figures are tested against the CQC data sets, but also the HSMR figures because they also represent a measure to quantify quality.

The Dr Foster data sets are based on HSMR and related data 2002-2011. The HSMR figure represents; “the ratio of the observed number of in-hospital deaths with a Hospital Standardised Mortality Ratio (HSMR) diagnosis to the expected number of deaths, multiplied by 100” (see appendix 6).

These data sets have been processed into SPSS and analysed to test normal distributions, Spearman's Rho correlations and Pearson R correlations. This statistical analysis has been extremely useful in answering the secondary research questions, which allow macro regulation to be studied (primary research objective one) and provides interesting conclusions regarding the effect of regulation on hospitals as well as assessing the methodologies the regulators deploy critically (primary research objective two).

Furthermore, linear regression analysis was conducted to take the process further and try and predict one variable from another. A model is fitted to the data and used to predict values of the dependent variable from one or more independent variables. This tool is especially useful because it allows moving forwards from the initial data that was collected.

3.4 Ethics

An important aspect of any research involving human participants is the obtaining of fully informed consent. Chadwick et al. defines informed consent:

“Informed consent means that the subject or his or her legal representative understands the nature of the study and the risks the subject will be exposed to and then makes a decision to participate free from force, fraud, deceit, duress, or other forms of constraint or coercion” (1984 p.19).

The definition is expanded upon below, with the specific elements that make up informed consent being outlined:

- “Accurate description of the research procedures and purposes must be presented in terms understandable to the potential subject”
- “A description of the risks or of any discomfort or injury reasonably expected must be disclosed”
- “A description of the benefits the subject and the scientific discipline reasonably expect from the research must be noted”
- “An offer to answer questions about any of the research procedures must be given”
- “The instruction that the subject is free to withdraw from the research at any time without prejudice must be fully explained.” (Chadwick et al. 1984 p.19-20)

In this research informed consent was obtained from all participants in the qualitative interviews, prior to their participation. The consent was obtained following the above elements to the letter. At no point was there any attempt to coerce or deceive participants, full disclosure and explanations were used and it was made clear that participation was voluntary and could be stopped at any point without prejudice, or any negative consequences for the participant.

This research has followed the appropriate ethical guidelines at all times. Ethical approval for the research was sought and obtained by the Keele Ethics Research Council (see appendix 1). This was done in consultation with Nicola Leighton, the Keele Research Governance Officer who ensured all the relevant protocol for this type of research was followed. Because this research involves participants who are NHS staff rather than NHS patients an NHS Research Ethics Committee approval was not necessary.

Interviewees were given detailed information sheets (appendix 2) which outlined key information such as why they had been chosen, what they were required to do, that they were free to stop the interview at any stage, that they would remain anonymous in the write up, and

who to contact (other than the researcher) if they were unhappy with anything. Interviewees were also given informed consent forms (also appendix 2) which they were asked to sign, if they were happy to proceed with the interview and for it to be recorded, based on the information sheet. This information sheet also requires an indication to the degree to which quotations could be used in the research, and whether or not they wanted to see these to verify before their use.

Participants were also informed of the relevant data protection and security procedures that are in place in the research. They were informed of the following:

“The only person who will have access to the data is the primary researcher (Richard McManus). Confidentiality will be safeguarded by interviewees’ responses in the research being coded in a way that makes actual participants anonymous. Data will be stored securely in a locked filing cabinet and on a password protected computer. Data will be stored in line with Keele University guidelines and the data will be retained by the principle investigator for at least five years. The longer-term arrangements are for disposing the data in a secure way.”

The letter of invitation, information sheet, consent form and interview schedule/topics were all sent to the Keele Ethics Review Panel (ERP) for their assessment. The ERP approved the research and made no recommended changes to the format of any elements submitted.

3.5 Sampling

In the qualitative side of this research a purposive or judgement sample is being used.

Barbour (2001) describes the movement in the social sciences towards this type of sample below:

“In the past qualitative research often relied on convenience samples, particularly when the group of interest was difficult to access. Purposive (or theoretical) sampling, however, offers researchers a degree of control rather than being at the mercy of any selection bias inherent

in pre-existing groups (such as clinic populations). With purposive sampling, researchers deliberately seek to include “outliers” conventionally discounted in quantitative approaches.” (Barbour 2001 p.116)

This sample is taken based on key criteria of interest. This is the best sampling method in terms of being most productive for answering the specific research questions. A framework of variables has been developed which is based on practical and theoretical considerations that have been taken. Trusts in the sample are designed to reflect the diverse circumstances in which regulators operate. This led to the development of the following criteria on which to select Trusts.

Criteria:

- Size of provider (population and number of hospitals)
- Geographical location
- Stage in FT process
- Dr Foster rating

All these factors must be proportionally represented in the sample. One of the key points for a sample to retain validity for the target population is the size of the sample. This is why the population is being limited to NHS Trusts in England.

3.5.1 Sample Profiles

Due to the necessary ethical considerations, Trusts in the sample have been anonymised, and the descriptions are consequently limited to the extent to which they cannot be identified from them.

Trust 1 (T1)

- Aspirant FT,
- Midlands,

- Single hospital Trust,
- Main provider of acute services in rural area.

Trust 2 (T2)

- Aspirant FT,
- Midlands,
- Several hospitals in Trust,
- Rural and urban mixed area.

Trust 3 (T3)

- Established Foundation Trust,
- Southern,
- Many hospitals in Trust,
- Large urban area.

Trust 4 (T4)

- Community Healthcare Trust,
- Northern,
- Mainly urban area,
- Care at home, at local health centres, community hospitals,
- Health promotion and education services,
- Works with local Trust, local council, charities, prisons, children's services and dentists,
- Works in the transitions between community care, hospital care and social care.

3.5.2 How the criteria is met

Size: The population sizes and number of services within the Trusts varies significantly, ranging from small to very big. It is impossible to be any more specific without risking the anonymity of the Trusts involved.

Geography: The sample covers good range of locations, spread across England. There is one Trust from the North of England, two from the Midlands and one from South of England. Again, to prevent anonymity being compromised the locations cannot be revealed any more specifically.

Dr Foster scores: Hospital Standardised Mortality Rates are z-scores based on the average of around 100. In the sample there is one trust below the average, one around the average, one above it, and one with no Dr Foster data. This demonstrates significant variation of HSMRs within the sample. The mean value for the scores in the sample is 96.57, which is relatively close to the 100 standardised averages that Dr Foster derives from the Z-scores.

3.5.3 Clinical Commissioning Groups

Following the publication of the Government's White Paper: "Equity and Excellence, Liberating the NHS" (2010) and the subsequent "Health and Social Care Act" (2012), significant changes have taken place in the NHS. One of the most important changes is the move towards clinical commissioning, which means that doctors and other health professionals are now much more involved in planning, monitoring and buying the NHS services that people need locally, with the view that this will result in high quality and value for money services. These services are in hospitals, health centres as well as other community settings.

Clinical Commissioning Groups (CCGs) have been established all over the country, with GPs, clinicians and managers working with commissioners to plan and buy health services for their

local population. In April 2013 these Clinical Commissioning Groups replaced Primary Care Trusts as the lead commissioners for local health services. This dramatic change in the way healthcare is purchased, half way through the research, led to a rethinking of the research sample, with the inclusion of two of these new CCGs. Consequently these CCGs are both from the same region of the country, as the sample had to be opportunistic, so the data could be collected in time. Given the fluid nature of the policy area and the barriers to gaining access for interviews, this can be considered a reasonable decision. It allowed for a better differentiated set of participants, and responded to the ever changing landscape. Whilst the fact the two CCG are opportunity sample based means they might be less generalisable to the rest of the CCGs, this does not mean that the interviews are not useful. They allow commissioners views to be included in the data analysis which was invaluable, and there was no other way for this to realistically happen. The CCGs in the sample are outlined below:

CCG1

- Midlands,
- City wide CCG.

CCG2

- Midlands,
- Rural and urban mixed area.

The premise for sampling in this purposive and opportunistic way will allow for a sample which reflects a wide range of key actors in health regulation networks to be represented. The various NHS provider Trusts in the sample have a range of different key criteria present. Within this the staff, or actual key actors provide real, practical and insightful viewpoints from which to better understand regulation and ascertain what is going on here. The two CCGs represent another viewpoint from which to consider regulation, as they commission rather than provide healthcare. Whilst they have been included in more of an opportunistic sense, this has been necessitated by the fluidity of this area of public policy, and they add true value in terms of the different viewpoints by the key actors from CCGs.

Chapter 4: Findings

The quotations used in this section are extracts from the recorded interviews that took place with key actors from the Trusts/CCGs. All participants have been anonymised with T1, 2, 3, 4 indicating which Trust they came from and CCG1 and 2 indicating which CCG they came from. Their position within their organisation is then stated so as to illustrate their viewpoint in the regulatory process. The position within their organisations of the participants in the research are summarised below.

4.1 Table: Sample Job Titles

T1	T2	T3	T4	CCG1	CCG2
Chief Executive	Chief Executive	Deputy Chief Executive	Chief Executive	Director of Quality Governance	Director of Patient Safety
Director Of Compliance and Risk Management	Director Of Clinical Quality	Director of Performance	Director of Clinical Quality	Director of Patient Safety and Quality	Head of Quality and Governance
Director of Finance	Director of Finance	Director of Corporate Services	Director of Finance	Board Member	Chief Operating Officer
Chief Compliance Officer	Director of Corporate and Legal Affairs	Head of Governance and Development	Performance Manager	Chief officer	Senior Commissioning Manager
Head of Nursing	Head Of Nursing	Head of Nursing	Head of Nursing	Commissioning Manager	Commissioning Manager
Quality and Safety Manager	Quality Manager	Quality and Safety Manager	Performance manager	Operating Officer	Operating Officer

The findings fall into fourteen sub-categories, which are divided into eight sections to make the narrative logical and progressive. The findings are presented so as best to objectively reflect the views of the interviewees in the sample, with substantial evidence backing up the claims of the findings throughout.

4.2 The Purpose of Regulation

It has become clear, throughout the interviews in this research, that the purpose of regulatory bodies can be contentious, the purpose of regulatory bodies overlaps, and the overall remit of regulators in the health sector is considered by many as too large given the resources the regulators are given.

Upon conception as a policy, creating arm's length bodies to regulate the NHS will only work if the exact purpose and remit of the body is clear, and then the arm's length body can implement the policy appropriately. Successive governments have been consistent in requiring regulators to perform more and more functions, moving the goalposts whilst creating new regulatory agencies at the same time. The CQC can perhaps be seen as a further reaching evolution of the Healthcare Commission (HC) and prior to that the Commission for Health Improvement (CHI). The purpose of the CQC far exceeds any of its predecessors. Since 2004 Monitor has existed alongside the HC and now the CQC, with a greater focus on finance and governance. But Monitor's purpose has also changed, with elements of quality aside from finance and governance also being measured by Monitor. When you also take into consideration the numerous other ALBs which operate in the NHS policy arena, this further explains why making the purpose and remit of each body becomes important. (See Conclusions section 7.1.3 for a full list of arm's length bodies).

In order to determine the key actors' views on the purpose of regulation they were asked a general question: "what do you think the purpose of regulation should be". This was then often followed up with prompts relating to service quality, finance, governance and competition. T3 Director of performance gave the answer that regulations purpose should be: "Giving assurance to the wider public that healthcare is being delivered to specific standards." This basic definition is pretty representative of the initial response from most interviewees, but when prompted more interesting views surfaced.

T2 Director of clinical quality built on this basic definition of the purpose of regulation. Their definition focuses on public assurance and basic minimum standards, it is outlined below:

“Ultimately to keep patients safe and provide public assurance that there are basic minimum standards met with regards to healthcare at the end of the day there is a large aspect of self-regulating that’s in there so I think there are huge challenges around how all of it links together, you have problems seeing the press around Morecambe and Lancaster where the CQC are doing an enquiry. They were a recent (last year) FT, and had CQC visits. So there is no doubt its quite a challenge to get it right because it’s only a snapshot when they are coming in they only see outcomes and care on that particular day. It is difficult designing the perfect system and I suppose it is about taking early warning indicators and try to create that risk profile. They do need to focus their limited d resources, we try and do that through Quality and Risk Profiles but there is no doubt that needs improving.”

T2 head of nursing claimed that the purpose of regulation was “very defined” but suggested that their issue was that they regulators did not see this clearly: “perhaps my issue is I see it more clearly than they do themselves, when it comes to quality governance there is clearly an overlap in functions I think it is clear that they defer to Monitor in the assessment of quality and that they work in partnership.”

T3 Head of governance and development similarly pointed to the idea that the CQC specifically, did not fully appreciate their own remit. When asked what they thought the purpose of regulation should be, they suggested:

“Difficult question I’m not sure the CQC fully understands its remit and purpose and it has clearly evolved over a couple of years and there is, it’s so political isn’t it, if there’s something going on the CQC respond to it the termination of pregnancy thing (about having pre signed consent forms not doing consent appropriately) but in a way maybe that’s a good way of responding an issue comes up and then they go and sort it out I was thinking more learning disabilities an immediate reaction and also a big reaction to the ombudsman’s report on care

of the elderly. Yes that was the first big inspection they did, we were slightly taken aback because they have a schedule of activity and something else is thrown in because it's suddenly become an important issue, but maybe that is an important role for a regulator to play to be able to respond to public concern in a more immediate fashion."

T4 Chief Executive argued that the CQC focuses on improvement, but should be focusing on assurance, as the buck stopped with him, rather than the CQC. This argument is summarised below:

"The CQC is quite interesting I think it the CQC is not accountable for the quality of care in my organisation, I am and what people confuse in the public is the role of the regulator in quality, but it's about assurance isn't it, I am accountable for things and people confuse the two what I would say about CQC it lost focus in terms of what it what about over the last couple of years it has spent too much time thinking about improvement instead of quality assurance. That has been compounded by Monitor becoming interested in quality, so that's led to duplication I think CQC are going to face huge challenges if they are responsible for regulating general practice and all NHS providers in the future and the only way it's going to do that well is by having a new system focusing on the assurance piece and defining how it works in its territory and others."

4.2 Summary

The purpose of regulators was found to be considered by most of the interviewees as related to public assurance. There is evidence that the CQC may not fully understand its own remit and that Monitor being involved in quality can further complicate this.

4.2.1 Competition Policy and Local Health Economies

Also linked in with the purpose of regulation is the position of competition policy, Monitor, and how this sits in the local health economies of providers. Many of these views suggested the

purpose of competition policy for Monitor is unclear and even contradictory. T4 Head of Nursing, for instance indicated:

“Again it’s a really good question I mean, Monitor being there to make sure that organisations are sound in terms of quality and finance through regulation and there’s almost a contradiction in terms there if you are registering organisations that you consider sound and then you have got a role to promote competition. You know, either you have got a free market you have not and I think the dilemma is what is the correct policy, I don’t believe the government has got a mandate for a free market for healthcare nevertheless it’s trying to reproduce a regulated competition within healthcare, but should it be? I don’t know.”

Some of the interviewees, took the view that competition policy was inherently flawed and had no place in health regulation. For example, when asked whether the purpose of regulation should be to create/restrict competition T3 Head of Governance and Development stated:

“Absolutely not. I thought Monitor were given a remit to promote competition and then it was taken away. I agree that it’s nothing to do with the CQC; in terms of a regulator in general I wouldn’t have thought frankly that it was any of their business.”

Similarly, when asked about whether Monitor should be involved in competition promotion/restriction, T1 Chief Compliance Officer stated: “I don’t think they should be... it should be about being fit for purpose really.”

Many of the interviewees did think that the extended role of Monitor was necessary, but had issues with its current implementation as a policy. T1 Chief Executive did however believe that there should be a role for Monitor in the promotion of competition between providers. But there were serious reservations expressed around the nature of competition promotion and the potential negative effects competition in the wrong type of health economies:

“In any system for there to be competition there has to be some kind of excess capacity somewhere and that capacity I don’t think we can afford. In particular health economies where you’ve got an ecosystem if you like of healthcare provision like ours, you have got to ask the question, what are the unintended consequences of competition? So I don’t think those are worked through, I think what can happen in those circumstances is that the ecosystem is destabilised and done in a kind of unthinking way, what competition can do then is undermine the core of organisations rather more quickly than people expect. I think people believe there is a margin around which you can compete but because our business is usually at the margin everything that you lose at the margin has a ripple effect into the core of your business. So can we afford competition? That’s a judgement call depending on where the health economy stands but secondly are the implications of competition thought through, there are unintended consequences that aren’t always managed, and I think there’s a role for somebody to look at that and say, does it make sense in this context or not.”

T3 Director of corporate services also pointed to the serious differences on how competition policy impacts positively or negatively within Monitor’s remit is dictated by the local health economy. Exemplifying that larger providers also feel this to be the case, they detailed:

“You have to ask how it is impacting on health economy. Price versus quality. What is objective, just price?”

T1 Director of Compliance and Risk management also believed that there was a need for an independent body that should have a purpose in relation to competition. They did not, however, necessarily believe that this should come under Monitor’s remit and also suggested that the nature of healthcare means that purely market based economics might not work. It was stated:

“I mean somebody needs to oversee processes to make sure the NHS doesn’t descend into a feeding fest of the weakest being picked off, survival of the fittest doesn’t always apply in the NHS but think there is a role to have a collaboration/cooperation process to ensure, really to

hold the ring now, more traditionally it was well the weakest will go to the wall, healthcare, I only think the economics of the market can be strictly applied to healthcare provision, and there is a patient at the centre of all that so what might seem like a very good business decision might not be in the interests of patients so I think you do need somebody, I don't think it really matters who as long as they are relatively independent of both Government and local influence to make those decisions."

T2 Chief Executive was very clear that they advocated market competition with caveats, comparing the UK healthcare market to the Canadian market. They saw problems with the prevailing arrangements. Below is a passage which summarises their views:

"Yes always, the healthcare market, structure here is very similar to the Canadian system state or provincial funding straight to state provision market structure nevertheless so as that market structure changes as it is in the UK, has been for some time the supply side is deregulated (broken up) a bit then we need to make sure that process is not avoided so there has to be regulation about standards, where the CQC comes in, there also has to be regulation about productive and competitive and avoidance of anti-competitive behaviour the issue then becomes how do you bring those two together also how you understand the healthcare market and other forms of market because you've got to strike a balance in regulation, achieving effective market competition without that being so extreme that has the other consequences of creating turbulence in the wider supply chain, of how its services that are currently delivered that are currently delivered you get this brought out, are those things compatible?"

The views of commissioners on the impact of competition policy varied between the two CCGs in the sample. Staff at CCG2 argued that the nature of the local health economy meant that competition policy had not really had an impact on their activities. CCG2 Director of Quality Governance stated for instance:

"It hasn't done much for the market locally because we haven't got any FTs and actually our local population don't seem to show very much appetite for going off the local patch. It hasn't opened up the market for us but that might be peculiar to our local area really."

However they went on to claim that: "certainly if there is a plurality of providers it can help quality." This again supports the view that competition policy can work, in theory, but this is completely dependent on the local health economy and the competition which is already inherent in the area.

CCG1 Director of patient safety and quality suggested that the "any qualified provider" aspect of competition would be an issue:

"I think with any qualified provider it's going to be an absolute nightmare for us to monitor those contracts sufficiently there will be hundreds of thousands of them, we don't have the resources and manpower to keep an eye on those contracts, so yeah if we have support from external regulators all the better."

They also claimed that competition could work in some contexts:

"It's a tricky one, I have a view around competition in the first place, if it's going to happen in the NHS it needs to be well regulated and well managed fairly, and if Monitor is the place where that can be done, fine sit it within Monitor but if we are creating competition, which I'm not saying is wrong as long as it is a level playing field for all providers then that's fine."

CCG1 Director of patient safety and quality also noted the potential conflict of interests arising from competition creation, by Monitor:

"It's tricky when they start to, there is a conflict of interests, they want providers to be viable, but on the other hand if they are encouraging competition down the road that could

undermine the financial strategy of the other provider they are regulating. I think if they start to get into market management as well as provider management it is much trickier.”

T2 Director of Corporate and Legal affairs argued that there should not be a role for market management. They were asked whether they thought competition should be part of Monitors remit, and replied:

“No I don’t. I think I would see that as a slightly different dimension at this point. As the health service is currently structured I think the main purpose of that regulation is to ensure we are meeting the essential requirements of care as we should be doing and all our legal duties as we should. The whole questions of to either promote or otherwise deal with competition is, something that’s ahead of us and new role of Monitor obviously. It is interesting isn’t it, they have a duty to promote integration to regulated competition, and you wonder whether some of those things are actually opposite and different but I would say at the moment we have very little experience of being regulated in relation to aspects of competition.”

They also went on to compare the role of the co-operation and competition panel to the new role Monitor is undertaking, although with no real conclusions:

“I suppose the closest, it’s not really regulation, there’s the Co-operation and Competition Panel which is there to act as effectively a referee for the Department of Health and Monitor and public in terms of looking at what we are doing and distorting competition or improving co-operation. They don’t really have any teeth, they can but advise ministers or monitor and they are pretty early in their life but are subsumed within Monitor. When Monitor is granted additional powers under the new bill, how that’s going to work out I would not care to predict at this point. Monitor are at a consultation at the moment on their approach to licensing providers and this is relatively new territory for NHS trusts so it’s something I think we will have to watch very carefully.”

CCG2 Senior Commissioning Manager had a different take on competition; essentially that competition should be about assurance and then competition between providers who are assured up to a certain level:

“There is a general answer, can regulatory framework support competition and the answer is yes, then you have to have faith in the regulatory framework, it’s in human nature to like stuff that is recommended whether its use a local contractor because they have been seen to be doing a good job and the applied standards that they meet. I am looking at things like to fit gas you have to be the right sort of organisation, and that applies to different levels, they don’t constrain competition there, what they do is act as assurance to the purchaser, it’s about giving a degree of assurance to the consumer, then in that sense it is about competition between people who have got the ticket, puts people who haven’t got the ticket out. I don’t see why we should be precious about health.”

This Commissioning Manager did not come from a healthcare background and interestingly thought that health regulation should not be different to regulation more generally. Referring to the suggested conflict that other interviewees pointed to it was claimed:

“I don’t see a conflict; regulatory frameworks can support competition because in other areas, you can’t compete if you don’t have the ticket, so why should health be any different. If health services are going to be much more local, responding to local need then actually they need something that says this is a local provision but it meets a certain yardstick for commissioners and consumers. Patient choice is predicated on the choice of hospital based on quality.”

T4 Chief Executive pointed to the uncertainty surrounding Monitors changing role as a regulator:

“Well Monitor had a role in, Monitors role is going to change you know clearly CQC has to have a role in registering organisations you know the basic standards so entry to the market must be like that in the new system and Monitor has a role doesn’t it in terms of it will have

two jobs for a while so it will be putting people through the FT pipeline and assuring them and then it will have its new role in the bill and part of that is about ensuring that there is sufficient competition whilst also ensuring the integration is fostered where it needs to be, so I think the role of Monitor will be uncertain for a while.”

Many consider the role of competition promotion or restriction to be a conflict of interests. It is also significant to note the importance of local health economies on the success of competition policy. Clearly in certain instances (such as CCG2) the local health economy is such that competition promotion does not work. There are simply not enough willing providers to compete. So whilst some interviewees did not disagree with the basic premise of competition and market management, the practical issues surrounding this are enormous.

4.2.1 Summary

There is significant evidence that the purpose of competition policy and Monitors role is confusing and even contradictory. Some interviewees thought competition policy should not be part of Monitors remit at all.

There are significant issues identified about competition policy in certain local health economies. If there is not already excess capacity in a local health economy, competition creation may be less likely to work. In less competitive local health economies competition promotion has the potential to destabilise providers' financial strategies.

4.2.2 Regulators remits are bigger than what they can realistically achieve

There has been evidence from staff, at varying levels of the hierarchies from all the Trusts and CCGs in the research project, which suggests the remit of both the CQC and Monitor exceeds the capabilities they have based on the resources allocated to them. When asked whether they thought that the scope of regulation had increased under the coalition government nearly all of the interviewees suggested that it had.

T1 Chief Compliance Officer claimed specifically about the CQC that: "The CQCs remit is too big with the resources they have, it's just huge, I'm not sure they can discharge it very effectively. I would not want to work for them." CCG2 Head of Quality and Governance identified similar issues surrounding the CQCs capacity problems:

(The problems are) "Really around their capacity, the reports are useful but from all the big hitting things in the press their reports are only as good as where you are in there. You can go in there and it can be great but actually that doesn't guarantee you, when the next shift come on a different set of people start, and that's why you need a broad brush of intelligence and you do need to triangulate it"

They go on to argue that with the registering of all services the CQC are going to struggle capacity wise:

"They are good but obviously they are limited really when GP practices get registered as well, how can you realistically get round these care homes, hospitals, GP practices, dentists etc. I don't know how you're going be able to, it's just getting bigger and bigger, I suppose it will be risk based. It's not just the day of the visit is it it's the preparation and the intelligence gathering all the time and the reviewing and interrogating that and focusing their efforts when they go out and physically doing it, then writing the report moderate it make adjustments, it's quite a long process for one visit isn't it!"

T3 Head of Nursing also points to the fluid nature of the health sector and the specialist knowledge of CQC staff being limited:

"The CQC have a remit that is overly ambitious by the government to ethically regulate the risk in the service, they struggle to keep a handle on the changing face of provision and the huge number of providers who are part of the market at the moment and the skills of the people being employed and their knowledge of healthcare delivery is not good enough."

With regards to Monitor there were also doubts about their ability to achieve their goals with the resources they have. T4 Chief Executive for example noted that:

“Monitor is going to have more and more trusts through the FT process, significantly more, and it doesn’t have the resources required to put some through at the moment.”

T2 Chief Executive also confirmed issues around Monitor’s capacity claiming that this had “damaged our FT application, because key things they should have been telling us were not until it was too late.” According to the Chief Executive this meant that T2 had failed in its application for Foundation status through the fault of Monitor, rather than that of the Trust.

CCG1 Director of Quality Governance points out that the CQC has tried to increase its workforce lately, but still is under the impression that they are lacking in staff given their remit as regulators:

“They have had a big recruitment drive, but I have not seen any effects from that as yet they always seem to be relatively stretched. But it is a busy environment and that is probably why the reactive stuff always seems to take precedence over the proactive, if you have got to choose you are going to pick the bits that you have absolutely got to do, so the nicer stuff will fall off the end but certainly they have had an increase recently, but they are always changing the structure around. And the regions are hard to get your head around and how they structure the inspections can be awkward. I am sure we could all benefit from better IT systems, in terms of manpower they have been stretched, I don’t know if the recruitment will work or whether they are recruiting the people they need with the right area of expertise coming in, so if they have got mental health issues are the sending someone with that background to a mental health trust for instance, that’s not a good idea because you can make assumptions about what should or shouldn’t happen”

They also point to the idea that CQC inspectorate lack specialist knowledge about particular providers. It was stated, for instance, that:

“One inspector has to cover an area and switch about between providers and types and it must be really difficult, some basic things, record keeping etc. are kind of general, but some of the other stuff will be relatively specific to where you are receiving that care so care and treatment outcomes, the way patients are treated in mental health facilities might be slightly different because it needs to be because of the mental health act or other things that providers don’t have a great deal of control over, so I’m not always sure, they are a bit jack of all trades; the inspectors.”

The CCG1 Director of Patient Safety and Quality also believed that the CQC lacked sufficient resources. They gave an example of a care home, which definitively illustrates the lack of CQC capacity to notice completely unacceptable conditions. They stated:

“The challenge they face is having enough resources you know we have seen the Panorama programmes about the atrocious care homes that they just weren’t visiting so you know, I have just been to visit a care home in my patch and I’m not too happy with what I saw, and when I reviewed the CQC reports this care home was not compliant with several of the essential standards and had an action plan in place and my concern is they have a very long time to put them in place before they are re-monitored. The original time they went in in October... and they went back in April, that’s quite a long time if you are a resident in a care home where care is completely not acceptable and yet I visited last week (June) and I wouldn’t put my relative in that care home, so I am left thinking how bad do you have to be?”

As well as resources wise they point to the reputational damage the CQC have received and the problems this causes moving forwards:

“They are really challenged with the amount of resources they have. Their history and reputation is damaged and the press did go for them, so they have a lot of reputation building to do and therefore the level of confidence, providers and others have in them is quite low, so their new Chief Executive has got a lot of work to do in restoring that, because quite honestly could you do without them, is the question I have been asking. Are there too many, is it going

change sufficiently to do the job that they need to do? Within the resources they have got I would not be at all surprised if in a couple of years they were changed to a different regulator and got rid of or replaced.”

CCG1 Chief Officer also claims that the resources CQC have at their disposal only really allows a type of “light touch” regulation:

“Given the resources they have they can only be very hands off and only intervene in a targeted way. It is probably insufficient in CQC ... the information isn’t conveniently there for CQC from the performance system you have to go and actually have a look, within their current resources they cannot do that. If they were really going to provide public assurance about the standards about meeting their minimum requirements they would have to visit many more times than they do.”

They also claim that this workload will only get worse as more and more professionals get registered with the CQC:

“They are just part of a bigger system around healthcare the whole topic around professional regulation is going to be another minefield going forward. Different professionals get regulated to varying degrees of stringency I don’t think there is coherence across the whole of professional regulation some of that will come out in the Francis 2 report. The number of providers that is going to be regulated will just go up and up GPs coming along as well, capacity issues and how close they are to the ground will probably get worse.”

4.2.2 Summary

There is consensus among interviewees that the CQC and Monitor have remits which exceed what is possible with the resources allocated. With the CQC especially this is being exacerbated by the registering of all health and social care organisations. The wide range of organisations means having appropriate specialists is very hard. Monitor does not always have capacity to put FTs through the process, even when the AFTs are ready to do so.

4.2.3 The remits of the regulators overlap

It has also become apparent, that as well as having remits that are difficult to achieve within the resources allocated, overlapping remits (between the CQC, Monitor and the NHS Litigation Authority (NHSLA) in particular) are an issue from the perspective of the regulators themselves, as well as the providers that they regulate and those who commission healthcare. The NHSLA are a not for profit part of the NHS, who “provide indemnity cover for legal claims against the NHS, assist the NHS with risk management, share lessons from claims and provide other legal and professional services” (NHSLA 2013 p.1). The issue of overlapping remits is a real problem, because it results in serious inefficiencies from the regulators’ perspectives, but also adds a significant burden of regulatory compliance for providers.

The T4 Head of Nursing claimed, for example, that:

“It’s the variety involved of services and adequately assessing it all that’s the problem. I think we are getting to the stage that we might be doing more on care assurance than we do on care delivery, there have been increases in the bureaucracy in that regulation, otherwise why have a commissioning board and still retain the PCTs, why have a board, if the members on that board are not accountable? I think the range of external assurance systems and organisations is over populated”

When asked, “Would you say health regulation operates as a coherent system and why?” the Head of Nursing replied:

“No definitely not, I suppose it feels as though there is people coming at us from all angles I just look at our organisation, a relatively new organisation, which could have 10 external organisations scrutinising us in the last year and we have probably got another 3 or 4 to come so you know, naturally, that is a phenomenal range of external investigation; a lot of clinical, professional and managerial stuff and that range of inspection doesn’t represent good value.

The sheer range of bodies and the fact that some of the standards aren't fully aligned; to me it would make more sense to have one regulator who looks at all your statutory duties."

Clearly they felt the burden of conforming to regulatory bodies (whilst necessary) was intensified by the sheer number of bodies asking for information. This is a view that was echoed by many interviewees. T4 Chief Executive backed up this claim, listing many examples:

"A Trust like ours is regulated by a number of organisations sometimes they work in partnership and sometimes they don't so we provide healthcare we work closely with children's services and we provide care in prisons so we also have inspections and regulation by Her Majesties Prison Inspectorate and Ofsted so I am saying that because I think the regulatory system is cluttered and overlaps too much so there is duplication of effort, if you add on top of that you've got the Audit Commission, the National Audit Office, our own internal audit, the SHA need additional assurance and evidence what you see is that we are often providing similar information to different regulators at the same time and that can be frustrating and a burden."

These frustrations were not peculiar to this Trust. T3 Quality and Safety Manager and Head of Governance and Development also pointed to duplication of efforts. In this case the duplication was regarding the NHSLA, their argument is summarised in the passage beneath:

"The National Health Service Litigation Authority, they are an organisation where there is a sense of duplication about them, asking slightly different questions about slightly different info. Not really a regulator, though to all intents and purposes they are our insurers they want to know that we are performing at a particular level, there are 3 levels: 1, 2 and 3. Level 1 you might get half a million of your insurance, level 2: £1million, level 3: £2million (I can't remember what it is exactly) they have 50 standards linked to CQC outcomes and you have to put a portfolio of evidence together, for particular statements and minutes, there is definitely a sense of duplication there and interestingly they don't go and talk to patients at all.

You sit in a darkened room with them and they go through your evidence with a fine tooth comb and challenge you. They are planning to look at case notes and spot checks. The difference is with the CQC they are there to ensure its safe and patients have good experience, with the NHSLA it is to try and make sure your safety processes are strong and therefore you have less litigation and less to pay out in litigation claims, it's like a car insurance company saying we are going to do an mot on your vehicle to make sure we aren't going to have to pay out. To us they are equally important and we feel we have to respond appropriately. They are actively trying to reduce risk in the health service to make it safer for patients; to some extent they do share the same aims."

T1 Chief Executive was another critic of the burden of regulation, from providers' perspectives. They claimed that the labour intensive nature of certain aspects of regulation was particularly troublesome:

"Well there is a great deal of feeding the beast that goes on and that's partly our responsibility, if the data has been collected and transmitted then if it has a purpose we should be using it, but on the other hand there is a standard flow of info that leaves the organisation quite, a lot of that can be automated so you know that's not necessarily a huge burden but then there are other areas where we can't automate they have got that kind of much more labour intensive approach to data submission. So I think we have so many feeds that leave the organisation all sorts of people who need to have all different kinds of information and it has to be sliced and diced in all these different ways of coding."

T1 Chief Executive also criticises the nature of the data collection by the numerous regulatory agencies, advocating one agreed set of data that could be used to satisfy all regulatory requirements, rather than resubmitting the same information in many slightly adjusted forms. They detailed as follows:

"Well I wonder whether, I'm sure there are dialogues which organisations like FT network for e.g. on the regulators requirements but the more that could be done to assess, I have lost

count of the number of regulators we have to deal with but it will be 30 of something like that if we have got a data stream that serves in one of those regulators why does that have to be 5% change to the margin for a regulator. Why can't we have an agreed set of data that organisations need to submit let's get that done in ways which regulators can interrogate rather than it tailored to each individual regulators' requirements. It seems much more sensible to have one data set which is capable of analysis and interpretation at a regulator level that would work better for us it's more of a burden on the regulator but arguably you would only feel that once at a regulatory level. Because you set that up once, develop the system and models. For us every increase in that, that can't be automated or made easily available means increased paperwork and that's replicated all over the system, it's just what level you are willing to have, from my point of view it's better to share than not."

T1 Chief Compliance officer also pointed out that overlapping remits between regulators had been attempted to be reduced, but this was not working due to the competitive "jockeying for position" between the regulators:

"They have tried, I'm not sure it does they have had the Concorde Act but that seems to have vanished, I still think there is duplication and probably they are all jostling for position in the regulatory area so I don't think it is very coherent, they don't actually contradict each other but they are not as streamlined as they could be. The NHSLA represents further jockeying for position"

CCG2 Chief Operating Officer offers sympathies for providers due to the crowded regulatory playing field:

"So I do think there is potential for duplication because of this covering your back kind of stuff that the Winterbourne View scandal has led to because its trial by media, so we are all kind of waiting for the next media storm and then we point the finger so we are all behaving in that in this way which leads to duplication and actually I feel very sorry for providers because every single dam regulator will want the same thing but slightly different and that's inefficient, just

think of the resources wasted in duplicating all that effort that for me is the key issue going forwards.”

CCG1 Board Member similarly emphasises the duplication of data collection by various arm's length bodies in the health sector. For instance, it is claimed:

“It's the form of data collection that's an issue, people from different organisations are asking you for the same information in different ways, if the organisation can give the data to the different organisations in a standardised form that would be better and I think that was starting to happen I don't know what it's like now on the ground. I was chair of the Local Community Health Services before it was quoted off with an arm's length with social enterprise, what we found there was we were having to put the same information into three or four different formats because people wanted to ask things in different ways, and yeah if you're doing applying for a job, you have got your cv and everything's sorted out there but they will have an application form and they are asking for the same and it's the same job as different places. Really time consuming ... and if you are doing a quality return for the CQC or Monitor for that matter, everything stops until you get that sorted out, you only have got finite resources so your team goes into that and one of the things that I have found (Alan Maynard will back me up with this bless him!) the NHS is a bit like a balloon and if you squeeze one bit, it expands somewhere else, so if you are focusing on one particular area you are not focusing elsewhere and if your focusing on getting the returns in, you are not doing other things.”

CCG1 Director of Patient Safety and Quality also recognises that from providers' perspectives the burden of information gathering and reporting is significant, and overlaps due to repeatedly being asked for the same type of data by various bodies:

“The burden in provider Trusts in providing information to commissioners and regulators is huge, and I can definitely see that from both sides, my providers tell us they report the same thing 100 times over to different people and even within my organisation I'm reporting up and I'm asked for the same thing over and over again by different people and I know they also ask

my provider for the same information that I have already asked them for and its cheeses them off, definitely a problem.”

They also point to the introduction of CCGs as adding additional confusion to this area, resulting in different fragmented bodies further overlapping in their remits:

“We have just introduced this new commissioning landscape which is just another tier of people and regulation for providers, we haven’t abolished PCTs and SHAs we just created CCGs and that’s going to be frustrating as hell for everybody, for the people in the CCGs reporting up, and for the providers who have another tier of people to report to. I came into commissioning from a provider because I thought the PCTs and SHAs were going, if had known they weren’t I might not have made the jump because obviously the reporting up is a huge bureaucracy and completely burdensome, I spend the most of my time reporting up when actually I want to be looking at the level of quality on my patch.”

T2 Director of Corporate and Legal Affairs offers a typical quote, which summarises the general feeling, i.e. that providers are subject to burdensome regulation, and the idea that the sheer number of regulators and their overlapping aims and data collection does nothing to help this burden.

“Well, there is an awful lot of information that we need to gather and assess and then provide for others. You’re probably more aware than I am of the number of different regulators there are in the territory of NHS Trusts, very large number. There’s probably a high degree of overlap actually, duplication or triplication, or whatever it’s called. But because the regulators have their own individual jobs to do then I guess notwithstanding their avowed intention to try and minimise the burden, it doesn’t really seem to work like that in practice”

They then went on to give a specific instance of this occurring at their Trust:

“You would think that if we were meeting the requirements under the CQCs essential standards of quality and safety then the evidence that we would give would then be usable in the assessment by the NHS Litigation Authority for their risk management standards, I think the NHSLA have said we will accept this type of evidence for these standards but that’s as far as it goes, so I think the general principle is there is probably a high degree of overlap and more and that it is quite a task to continue to provide information to satisfy the numerous regulators and if there was the opportunity whereby it could be aggregated in some form it would be so much better for us. I think it’s a very crowded playing field and it can be seen as a burden to those who are being regulated.”

The finding that the remits of the numerous healthcare regulators overlaps in a plethora of different areas across regulatory networks is significant. No participant whatsoever responded that they had well defined and separate roles that did not overlap, or anything remotely resembling these sentiments. This finding ties in with the later sections which discuss bureaucracy and incoherency.

4.2.3 Summary

The remits of key regulators overlap significantly. This is an issue for the regulators themselves, the organisations which they regulate, as well as the commissioners of services. The burden of overlapping regulatory remits can seriously detract from the provision of services and can be very labour intensive for providers.

4.2.4 The separation of finances, governance and quality is dubious

There is significant detailed evidence to suggest that the separation, of finances/governance on the Monitor side of things, and quality on the CQC side, creates additional complexity for NHS providers. Whilst this is the main finding of this topic, there were some participants who did not agree that the case, but the overwhelming impression was that this was an issue. Those who did not agree that the separation creates additional complexity were definitely atypical. It has also become apparent that the split (between finances and quality) is less

marked than previously the case, with Monitor now focusing on quality as well (but to a lesser extent than the CQC). All interviewees did tend to agree, that Monitor had more teeth than the CQC, partly due to past CQC scandals, and consequently finances and governance were often prioritised over quality.

CCG2 Chief Operating Officer summarises the perceived linkage between finances, governance and quality from their perspective and the Mid Staffordshire scandal. They stated that:

“So the finance does have a scope around quality so to separate them I think does make it harder, like governance, there is corporate governance but there is also clinical governance and obviously that then relates to quality so... I mean I totally accept that they are different and they can be separated in terms of infrastructure but I just wonder where will they, are the two not inextricably linked together I absolutely think they are. It's about how CQC and Monitor deliver their respective objectives but do it jointly, that was the thing with Mid Staffs, they became a FT, they were tick, tick, tick, tick, with Monitor but there was no connectivity with the CQC. It's good that somebody has a very clinical focus and somebody has a very corporate business focus but actually there has got to be a mechanism where there two are brought together because they are inextricably linked together. A good organisational structure will fundamentally impact on the level of quality in the service that it delivers, that is well known.”

They were also very passionate about this separation being detrimental to services, arguing:

“To think that they are very different is wrong fundamentally, it's about having good quality providers and services and they each play their part. I am not sure if there is that mechanism to show overall control of things which means we aren't getting what we need which is the regulation of effective providers delivering robustly and hitting clinical outcomes. They are two sides of the same coin and they are treating them as two coins.”

T1 Head of Nursing built on this point, suggesting that one regulator for both elements would be preferable from their perspective on the ground. They stated:

“Well it’s a challenging one, I would prefer to have had one regulator for health providers and I think Monitor would have done a good job for that, the CQC has got a role to play in organisations that don’t require the financial rigour that FTs have, so I see the CQC as being better on the smaller providers.”

When asked whether this separation caused unnecessary complexity, they replied:

“Oh yes, I mean I have had to increase my team recently to cope with the regulatory burden and again there are a lot of staff that have been introduced to assess quality some of the rigour with which we have to assess is very complex and I’m not sure it adds value.”

T4 Chief Executive suggested however that this separation was not real:

“It’s not quite like that, Monitor is intrusted in quality governance and its re-shifting its emphasis very strongly, if you listen to the statement by the Chief Executive he’s focusing on moving from being a financial regulator with some interest in quality, to one where they are interested in quality and cost and the assessment process that we need to be going through quality assurance framework for quality. So I think what is essential is that Monitor takes the evidence from CQC into its quality assessments rather than creating its own processes for doing the same thing, the risk that I see at the moment is that the CQC has lost credibility and unless Monitor believes the CQC to provide the right quality assurance then it will do its own process.”

The Chief Executive did however suggest that the perceived separation, (even if in reality there is not one) did lead to additional complexity for them as providers. For example saying:

“If you look at the fact that we have the NHSLA looking at quality processes the audit commission the national audit office our external auditors and Monitor it’s a ridiculously

complex picture. Organisations like mine and others are much more likely to be integrated with social care and potentially the third sector so that will need to be regulated and the regulator will need to be ready for that, the Bill provides Monitor with powers like social care and organisations, but the secondly legislations make the job for the regulator more complicated.”

T3 Director of performance also believed that there was a separation (if disjointed), and the inclusion of quality in the remit of Monitor added to the confusing situation. Their view was that:

“I suppose it is not a clean split because Monitor does cover quite a lot of quality stuff, and certainly when we give our business plan for Monitor we do need to take into account the two things together and Monitor say things like “ok you have said you think you can deliver these financial gains, what impact will that have on quality?” and so certainly within Monitor there is that read across, going back to your earlier point, duplication, that can slightly confuse who is doing what, Monitor does have a quality remit and in certain cases we know it hasn’t been as good at picking up quality issues, actually maybe it’s not split enough, potentially, in the Staffs case there was a sense that Monitor was looking to the CQC and not communicating, there is a confusion there and perhaps it comes from Monitor trying to do quality as well.”

They pointed to the issue being, if finances, governance and quality are split, there needs to be effective communication between those responsible for each respective area. It was claimed that:

“The two are absolutely inextricably linked and I suppose: do we feel that it’s such a big topic that you have to split it into finance and governance and quality and deal with them separately? In which case how you deal with communication between the two subject matters, it really is a tricky one.”

They also suggested that Monitor having an increasingly quality orientated remit was also leading to problems practically. It was stated:

“Monitor are good at what they do, there is something about they haven’t quite got going the quality side, they are kind of meddling a bit, they are not really engaging in the same way that CQC is and so if they were set up to be a regulator of FTs in their entirety, I think the confusion is that they still have that quality remit in there, because they don’t do quite well enough and their solution is to have closer links with the CQC but I don’t know whether that’s really happened. Certainly they are more alert to quality issues I agree there is confusion there but I don’t think it comes from it being Monitor finance, CQC quality, I think it comes from that Monitor having a limited quality remit, which slightly confused things.”

T3 Quality and Safety Manager was one of the few interviewees who argued that the separation of the functions was appropriate. Whilst this must be acknowledged, it may be telling that this Trust was performing extremely well on both the CQC and Monitor ratings, perhaps explaining the appreciation of the status quo. They explained that:

“My personal view is that it is appropriate and reassuring that CQC concern themselves with patient outcomes and experience and they are not worried about money or competition or politics they are very focused on the patient experience, because we are in the business of looking at patients I think it’s entirely appropriate, and good that it’s not muddled with financial and political issues. It might not be appropriate in other types of businesses but for the health service it’s the right way to do things. In terms of regulation, of course those issues come together on the ward because you are talking about how many staff nurses you can afford etc. but I think ... I’m not sure they can be brought together.”

T1 Chief Executive comes from a Trust which performs more closely to the national mean for Monitor and CQC scores, agreed that the separation does create additional complexity for providers. When posed the question about separation they replied:

“Yes I think it does, we have to look very carefully because although we talk about CQC and Monitor of course there are loads of other regulators the GMC, who look at the standard of our medical education and training, the CPA (Care Programme Approach) who regulate the pathology labs, Health and Care Professions Council who regulate radiographers, we are not short of regulators, there’s lots and lots of regulators.”

In reference to the link between finances governance and quality it was stated:

“Of course Monitor is moving into the quality arena, their registration process with FTs does have a significant amount of quality in it, but of course the governance system does require compliance with a number of standards that do have a quality dimension... I think there is already to some extent a quality dimension to what Monitor does. They will also take a feed from the CQC so if there were concerns expressed by CQC then it becomes a Monitor regulatory issue, it seems to me it would be easier if all of those issues were actually looked at in the round, 360 degree, so that the trade-offs that are inevitable between performance standards and actual sustainability, financial strength and quality and safety are brought together but there is a risk, but not always.”

When asked if finances and quality were inextricably linked together, T1 Chief Compliance officer had a different take on the issues, namely that quality was usurped by finances in terms of priorities:

“No I don’t think it is really, Monitor seems to have more weight and clout and I think it sends the wrong message. The CQC get a lot of negative publicity and it seems to be about the CQC rather than about the quality and it makes quality and safety plays second fiddle to the finances, because they should have equal weight really, whilst they are separated that makes it quite difficult to weigh it all up really.”

They also confirmed that the separation, as well as the overly crowded playing field, contributed significantly to additional unnecessary complexity:

“Oh yea trying to please two masters really, course we have the Health and Safety Executive to throw into the mix as well because they are getting more involved in regulating health, not in the same way but they come in a lot we have a lot of health and safety executive and that’s an interesting thing because they are going to start charging if they find you in breach which is interesting, NHSLA as well which is frustrating. The Health and Safety Executive are going to start charging: £100 an hour for all the time they spend on an investigation when they eventually conclude that you been in breach, so if they send you even an advisory letter as a result of it you will get charged and that could be considerable, and actually they are going to have an income target, so there is a lot of pressure on them to find you in breach because then they will get money back, it’s a perverse incentive that makes it very difficult if the CQC start following that model.”

In the end it was concluded that:

“The two absolutely are inextricably linked and we have got these things like the quality impact assessment to try and draw it all together but still it sends the wrong message that finance is the be all and end all, I know that they have put the quality indicators in the performance management regime but it’s still a bit late really, because the earlier Trusts didn’t have all those hoops, it really doesn’t feel quite right.”

T1 Director of Compliance and Risk Management argued that whilst there were some issues, post-Francis Report, things had improved:

“Again I think the changes make that better. It is actually difficult if you look at Mid Staffs for example to sometimes separate, what’s cause and what’s effect but the latest guidance for aspirant Trusts from Monitor is that every emphasis is put on quality equal to finance and there are a number of measures put into the system, so if you’re looking at cost improvement programmes there has to be quality in place in assessments and the board governors memorandum require not only that you look at it at the time you are introducing the cost improvement programme, but also subsequently that there has been no unintended

consequences. So it might all seem hunky dory on the face of it, but well actually infection rates would go up. So there are a lot more safeguards in the system, quality does come at a cost but lack of investment also impacts on quality so its two sides of the same coin and making sure you get that balance right, because you could have the perfect incident free health service but you would have to invest more in than we currently do.”

This interviewee was one of the few participants who did not see the separation as adding complexity from provider's perspectives.

“Generally no because the responsible directors, they are two separate directors so it is no more difficult, what we try to do, we involve our finance director in quality meetings and our quality director in financial meetings so you always have that kind of difficulty, I guess if its two separate and competing pressures and consistency so I don't think it does create any additional difficulties other than the difficulties that are inherent with the process.”

T2 Chief Executive was one of the most passionate of the sample in their views about the separation of quality and finances. They claimed:

“It's completely bonkers, it's absolutely loopy, it's the originating legislation which does this and you can see the original legislation plus the inability of the two regulatory organisations to cooperate. Which is to a certain extent behind the Mid Staffs piece and those organisations so it's the HC prior to CQC those organisations are likely to be criticised substantially in the Francis enquiry, I would be amazed if they weren't and some of this was personal in that the two chairs (CQC and Monitor) did not get on and so the inputs from one to the other was not strong enough and so if you haven't got the regulation function in the single building, which frankly to me is preferable, then you have the right relationship between two separate bodies, so what's the nature of the Concorde Act, interchange, how is knowledge and exchange provided that was never properly worked out as result of which they are listening to different signals. I've explained what I thought in terms of the HC now the CQC in that they weren't able to source the combination of signals that had they acted sooner, they arrived after the

bomb had gone off. Actually that's not the right metaphor because it's never a bomb with decline in the health services, it's the slow decline, incremental, so you have got Monitor listening to the financial signals so organisations will respond variously, particularly if the board isn't strong enough to make sure there's an effective reconciliation and that was a failure in Mid Staffs, reconciliation of both those sets of issues if the local organisation can't do it it's not going to get those other organisations out, they are not working together and transmitting signals."

This Chief Executive even suggested that:

"It would make it easier if regulation was in one house whether that makes it more complex or not I suppose it means that the local board has to reconcile ... If you look at what's happened Monitor is now trying to backfill the governance of quality into its assessment process. In response from the Mid Staffs type occasion, so, that's made things more complicated you've got Monitors quality governance requirements the need to respond to the CQC so you've got some duplication and some different nuances which means that yes the position is more complex than perhaps it might be."

CCG 1 Director of Quality Governance gives evidence supporting the view that from a quality perspective the separation does not make sense. They stated:

"I think its daft and again I probably would say this being a Director of Quality but actually you don't get one without the other in my view so it doesn't matter if you are performing well financially if your patients are suffering it kind of doesn't matter this is healthcare we are talking about its not a bank, actually quality has to be at the heart of everything and that they need to be looked at in whole."

On the question of additional complexity for providers they similarly support the view that the complexity is troubling in quality can consequently be ignored. For example, they detailed:

“It could lead in unfocused providers to a situation like Mid Staffs where you have providers concentrating on that their financial balance is right but not actually looking at quality, and also providers are having to separate the two things out, which actually creates complexity in reporting and that’s where duplication comes in. They are seen as two very separate things so yes I think it does create unnecessary complexity for people to get their heads round. And how do you bring it back together, so if you are assessing financial performance and quality performance where does that come back together as a performance of healthcare services.”

They also take a retrospective look at the health system, arguing that finances were previously given significant weight over quality. They described this potentially regressive policy trend:

“I think the danger is we go back to the bad old days where everything boards ever talked about (my whole life was spent in acutes) was financial and nobody ever thought about asking a question about what patients are saying about your organisation. What they got was exactly what they said in the Mid Staffs report, a complaints report which said you had 10 complaints about communication, well what actually does that mean, to someone who doesn’t deal with those complaints? Whereas, they could tell you in minute detail about their financial performance, but not what it was in relation to patients.”

CCG1 Director of Patient Safety and Quality was another who emphasised strongly that quality could suffer at the expense of focusing too much on finances. They claimed, for instance:

“What we are trying to do for our governing bodies, at the moment they are very focused on finance and performance finance for their own CCG but performance for our providers and they are not really engaged around quality because they don’t know how to be and if I was to produce an integrated finance performance and quality report I know exactly what would happen, quality would get about a nanosecond of time and level of scrutiny, they get so focused on the first two the never get to quality, or it would be glossed over so we have got

separate reports for that reason at the moment, I don't think the board are mature enough or skilled enough to say quality is equally important. If not more than performance and finance we won't integrate that report for that reason. So having bodies that have separate functions might be where they need to be because you need to make sure the emphasis is in the right place. You can look at the ambulance service for instance where performance is king that's all they did and quality didn't get a look in, and until they registered with the CQC they didn't focus on quality and you can see that if you view Ambulance Service Trust boards' reports over the years there's nothing on quality, but now its emerging and becoming more of equal status."

CCG1 Chief Officer was of the opinion that finances and quality should be looked at in the whole. They explained this view:

"In an ideal world you would want to look at them in the round and in fact that is what QIPP (Quality, Innovation, Productivity and Prevention programme) is supposed to be doing if it was more QIPP friendly you would put them together, having said that, the actual operational logistics of doing that, I don't know how practical that would be, either way you need to make sure that there is very robust intelligence sharing between the financial and quality impacts because one does have a direct impact on the other."

Complexity wise they did not see this as an issue, more troublesome from their perspective was the prioritising of finances over quality. They suggested when asked whether it made the situation more complex:

"No not really, FTs are much more worried about Monitor than the CQC generally, not sure quite why that is, but FT boards are more worried about the sanctions that Monitor can impose, they have to produce detailed assurance with regard to money and quality. They do seem to be let off the hook a lot more on the quality side."

CCG2 Head of Quality and Governance was another who pointed to clear relations between finance and quality. They made this claim with particular regard to staffing:

“There has to be a recognition that when it gets tight the fact is our biggest resource is staffing and quite often if you make your cuts around your workforce it has an impact on quality, so they are inextricably linked. However in terms of the focus that CQC have on quality and the essential standards I like that distinct focus on those very patient focused issues and you can’t get away from the fact that: with QIPPs and where they are going with finances you cannot ignore the finances and quite often when you see Trusts that struggle it’s because they had financial difficulties and they have had to make cuts and it had impacted on quality, so you cannot be siloed really.”

T2 Director of Corporate and Legal Affairs pointed to the movement of Monitor into the quality side of regulation as a potential problem going forwards. This is explained below:

“Yep, I would say it’s not a helpful distinction to be drawn it can prove tricky for providers because extensively you have got the CQC as the quality regulator but you’ve got Monitor increasingly moving into that territory. So in the wake of the Mid Staffs scandal, their response to that was a whole new quality governance framework which I guess it’s their way of obtaining assurance that we are providing quality but as we have to attest to CQC on that slightly differently I guess you are back to where I started from, you know you’re busy meeting the requirements of different bodies on the same territory, it’s not the most efficient use of provider’s time, providing assurance on the same topic to two slightly different regulators.”

4.2.4: Summary

The separation of finance, governance and quality creates additional complexity for providers being regulated. Monitor are seen by many as having more power than the CQC and this can lead to finance and governance being prioritised over quality. But Monitor’s role is changing, and focusing more on quality: this can lead to further confusion for providers.

4.2.5 Purpose of Regulation: Conclusions

These findings have centred on problems that arise through the purpose of regulation being an issue, in numerous differing ways. There are issues around competition policy, and how this is implemented in practice (if it even should be) and how the local health economies influence the effectiveness of this policy. There are issues surrounding the scope of the remits of various regulators, which have continued to increase over time without really allocating any more resources to achieve this by the government. There are also issues regarding the purpose and remits of various arm's length bodies overlapping leading to bureaucracy and inefficiencies in their implementation of regulatory policy. There are also clear problems with and stemming from the separation of finances, governance and quality.

4.3 The system is overly bureaucratic

The findings in this section focus on the nature of the regulatory systems and the associated bureaucracy. Findings presented relate to incoherence and unnecessary bureaucracy.

4.3.1 Overall Incoherence

It has become apparent that the vast majority of providers consider health care regulation to be an incoherent system. There have been a small number of interviewees who did not think this was the case, and they all came from T3, which is no real surprise considering the extremely favourable ratings and reports that the various regulators have published about T3. But in the main, including several interviewees from T3, the feeling is that health regulation operates in a way which is incoherent from providers' perspectives. This can perhaps not be regarded as surprising when it is considered that many providers have to deal with a burden of regulation from no less than 18 arm's length bodies (see conclusions section 7.1.3).

When asked whether they thought the current regulatory arrangements were coherent from providers' perspectives T4 Chief Executive said: "No, there is not enough trust between the different regulators, no this is incoherent." This reference to trust between the regulators as

contributing to incoherency in the system was shared by many, and this matter is more fully discussed in section 4.7 on data sharing.

T3 Director of performance supports the view that regulation is disjointed and lacks coherence. There is the suggestion that too many policy approaches are being sought, with reliance on the market, but then central control and regulation as well. They give evidence to support this claim:

“No. We have got regulators, we have also got contracts, and we have also got a market and all of those things, it seems that every type of policy approach that could be used, is being used in health care and I think that does detract from regulation being a coherent thing because you have regulation, contract measures, market forces and that doesn’t really feel joined up.”

In a joint interview T3 Quality and Safety Manager and the Head of Governance and Development had reflective views around the coherence of the system. A passage of the interview is below:

Head of Governance: “our personal experience of it is that it does work in that they came into the organisation and made a fair and thorough assessment of the service and picked up things that were appropriate, they didn’t come in and make a misjudgement about the organisation, and we can say that because we have inspections and are fully compliant, which is a nice place to be in, but I can imagine another Trust who have had a rocky time might have different views, but their response and exploration of the organisation has been fair and they came to appropriate views about the service.”

Quality and Safety Manager: “I agree, if our experience had been different we would be telling you probably a very different story.”

Whilst these interviewees were happy with regulatory bodies assessments of their Foundation Trust they did point out that different providers may see this differently. For example stating:

Head of Governance: “one of the main problems is around protecting people who cannot voice their concerns etc... They could come into one of our wards and talk to patients or patients’ carers and assure themselves about the patient experience, but if they go into a Dementia home or somewhere where people don’t have a voice, how do they ascertain that those people are safe or have been looked after? They are designing specific tools for gleaning info about people like that but because they are the regulator and because it’s their job to keep people safe, I think that’s a real challenge for them.”

Quality and Safety Manager: “another challenge is the reputational and credibility one, so much has gone on over the last couple of years that there is a public sense of failure about it that they have to overcome, if they aren’t credible and perceived to be doing their job it undermines the whole process of regulation.”

T1 Chief Executive was an unwavering supporter of the view that regulation was incoherent, linking this in with their previously stated views around the issue of separating finances, governance and quality. When asked whether regulation operated coherently they replied:

“No I wouldn’t. I think there really ought to be a single health regulator because then we know that regulator on behalf of the public is safeguarding standards, it would be a bit like saying that the energy companies we are going to have a regulator that looks at profitability, the prices that are charged and so on, and then a completely different regulator to look at the customer, well that’s not a rational approach to energy regulation, so why would it be a rational approach to health regulation? And because those two issues about the safety and quality on the one hand and the financial sustainability of delivering and the ability to govern that model that on the other, they seem to me to be inextricably linked whatever decision you make in one realm are bound to have an effect on another and why not bring them together and then you’ve got one set of regulators, it must be more economical to do it.”

T1 Director of Compliance and Risk Management pointed out that coherence at a high level does not necessarily translate to coherence at a local level. They replied, when asked whether regulation systems operated coherently:

“At the highest level it probably does, what happens is at local level you get lots of additional requirements being added in, so if there are local issues, by the time you end up with the requirements of the regulators, the CQUINs (Commissioning for Quality and Innovation) and the operating framework, and on it goes, with something that is, what are the priorities, the local is a touch too far because that can be run by personal prejudices and personal priorities which aren’t always based on what is the most effective things to be regulating.”

Commissioners were similarly agreed that the regulatory systems were complex and incoherent. When asked whether health regulation operates as a coherent system CCG 1 Director of Quality Governance stated:

“Not really, it probably works for the most part, but that might be more luck than judgement, the more layers of complexity you get, especially in relation to the NHS reforms, introduces more risk into a system that is already relatively fragmented. So if you have got CCGs now, if you have got the old PCT equivalents, you’re keeping SHAs all of that will become the National Commissioning Board and still other bodies all commissioning different parts of the system it is going to be really difficult for that oversight to come back together. I am not even sure that we would operate particularly well, so I don’t think the regulators do either, because they are not working with us in the way we would like them to.”

This clearly points to the 2012 Health and Social Care Act changes, and how they have added complexity into the regulatory arena. In relation to the Health and Social Care Act changes from a CCG perspective, CCG1 Board Member pointed to the complexity of regulation as debilitating at a local level, especially in terms of information sharing with commissioners. Their argument is outlined below:

“I think there are enough points of interconnection that it makes sense at a local or community level and on to commissioner the big problem is in terms of the openness of the provider organisations for commissioners, some FTs are very open and will open the books completely to the healthcare commissioners... a local example is the Healthcare Trust and the Mental Health Trust and then you’ve got aspirant FTs who won’t let you have access to anything unless you poke them in the eye or attach it to a CQUIN, just across the road at hospital X (anonymised) trying to get access to their information’s like... well why do you want it? We are bloody commissioners we are paying you to do the work that’s why we want it, trying to get the sort of granulated data is like trying to pull teeth with some organisations, but the key indicators of quality are generally there to be found and you can link up with other places... particularly the deanery because they get feedback all the time, they have got placement so you can monitor the deaneries activity as well. You know you’ve got patient information that you have got access to patient reference information. Patient reference groups are brilliant because they will supply us with things like that which you didn’t know about at all.”

CCG 1 Director of Patient Safety and Quality was also very passionate in their agreement that the regulation of the NHS was incoherent. When asked whether it was coherent they replied:

“God no. well the Mid Staffs debacle summaries that beautifully all the people scrutinising the Trust, none of which spoke to each other, none of which picked up the signs so we have got into that culture of just producing a lot of information but it is meaningless.”

4.3.1 Overall Incoherence: Summary

There is not enough trust between regulators. Incoherence is created by the separation of functions and jostling for position by regulators as well as duplication of regulatory activity. The sheer quantity of changes to the structure of the NHS exasperates this. Complexity and incoherence can impact more significantly at the local level and poor data sharing within this complex system often leads to problems in getting the right information for commissioners of healthcare.

4.3.2 Bureaucracy

Linked in with the overall incoherence of the system is bureaucracy. There has been much evidence suggested by interviewees which indicates that providers consider health regulation as overly bureaucratic. The ways they illustrate this vary from person to person and Trust to Trust but it is relatively conclusive that there are too many layers of regulation, and that the recent changes have only exacerbated this issue (see Conclusions 7.1.3 for a list of all the arm's length bodies that operate in the NHS).

T4 Head of Nursing outlined the issues facing providers in terms of bureaucracy. They stated:

"It's the variety involved of services and adequately assessing it all that's the problem. I think we are getting to the stage that we might be doing more on care assurance than we do on care delivery, there have been increases in the bureaucracy in that regulation, otherwise why have a commissioning board and still retain the PCTs, why have a board, if the members on that board are not accountable? I think the range of external assurance systems and organisations is over populated."

In answer to "what would you say are the main problems/issues that CQC and Monitor face in practice?" the Head of Nursing replied: "the sheer range of bodies and the fact that some of the standards aren't fully aligned; to me it would make more sense to have one regulator who looks at all your statutory duties."

The view that the regulatory landscape was over populated was repeated across the board. CCG2 Commissioning Manager pointed to the 2012 Health Act changes as adding an additional layer of bureaucracy. They suggested:

"We seem to have put in another level of management there was a big drive to get the management cost down in the last few years, the removal of PCTs, but once we have the clusters developed and we have a number of staff that we made redundant or they went voluntarily there were loads of jobs advertised and more people seem to be coming in the

perception now is that we have more managers now than say 2-3 years ago, that is only a perception but it certainly seems very real.”

CCG1 Director of Patient Safety and Quality reasoned that the new arrangements may mean it is more likely that important things like quality suffer as a consequence of bureaucracy. This is the idea that the burden of regulation means that providers and commissioners of healthcare are spending too much time on box ticking, and not enough on the things that really matter like providing a high quality service. Just to clarify, “box ticking” is defined by the Collins dictionary as “(derogatory) the process of satisfying bureaucratic administrative requirements rather than assessing the actual merit of something” (Collins 2013). The commissioner’s view is explained in the passage below:

“I get the impression that you are looking at the external regulators like CQC or Monitor. I thought regulation to also be the PCTs... the SHA that’s a form of regulation and we have the new landscape which has changed so other National Commissioning Board the local offices and the regional outposts which are PCT and SHAs by another name, what the danger is in this transition is that we lose sight of the really important things and don’t see the early warning signs particularly around quality because we are losing organisational memory, transitioning into new organisations with new ethos with the new set of people and skills. Our CCGs are meant to be clinically led, clinician focused, who won’t necessarily have the same skill sets as PCTs did in the past. So that’s a really dangerous place to be not just in transition but once they become authorised the following year that’s one thing. The other is we have just introduced this new commissioning landscape which is just another tier of people and regulation for providers, we haven’t abolished PCTs and SHAs we just created CCGs.”

Clearly this commissioner felt that the (2012) Health and Social Care Act had resulted in more bureaucracy and therefore less of their time was being spent doing the things they consider to be important, namely checking quality in the area they commission. They point to regulatory targets as further muddying the water; they stated:

“I want to know how many people are dying or what of and what we are doing to prevent it and patient experience is important to me and are patients getting the right level of care at the right time just because you have your operation within 18 weeks doesn’t mean it was a good experience for you and the outcome was good. You met the target but missed the point.”

This commissioner also seemed to have a general despondency around the state of affairs of the health service. They had hoped that bureaucracy would be reduced with the introduction of CCGs, but felt the opposite had occurred in reality:

“People in the health service are becoming pretty cynical now, we really did think this was going to be a different landscape, what will cripple us is this bureaucracy going up and basically how we have interpreted that is the government don’t trust the CCGs to deliver yet and they couldn’t possibly get away with getting rid of the PCTs and the SHAs they don’t trust the clinicians to deliver, yet, the whole ethos in their policy is clinicians make the decisions about their local populations because they know the needs of them best, but actually they are saying: we don’t trust you a jot because we are leaving all these extra layers in to monitor you.”

They also claimed that the information they had at their disposal from the various regulators was so complex and potentially unreliable, that it was often of little use to them as commissioners:

“If you were to ask me has the level of regulation we have improved our services my answer would be: we have more information about our services, there is a lot of complexity and there’s far too much info, which means people are struggling to make sense of what’s good and what’s bad, because we had the whole thing with Dr Foster and the HSMRs, these were forced on people and yet actually they didn’t tell you about the death rate in hospitals at all because it was much more complex than that, so there is a danger we focus on the wrong things, and can we avoid another Mid Staffs? That’s the challenge going forward isn’t it?”

T1 Chief Executive also pointed to the burden of bureaucracy as limiting the resource capacity allocated to actual service provision. They stated:

“Well I think the standard at which we are judged continues to rise and there is an enormous amount of risk avoidance from the regulators point of view and I can understand that, what that means for providers though is we face an increasingly large burden in ensuring that all of the regulators requirements are fully met. The sense I have is the regulatory burden is increasing, you can understand why, but it is and there’s a definite impact on our internal resource capability as a result.”

4.3.2 Bureaucracy: Summary

Unnecessary bureaucracy exists due to too many layers within the NHS. The sheer range of bodies is burdensome for providers, and this burden can lead to too much emphasis on “box ticking and not enough focus on actual service provision and the quality of it. Too much information from too many sources can make it hard for commissioners of healthcare to know which information is important and make evidence based decisions that are right for their service.

4.3.3 Incoherence and Bureaucracy: Conclusions

Bureaucracy and incoherence of regulatory systems are themes which in reality are present throughout all sections of these findings. In later sections specific bureaucratic elements of the regulatory system are expanded on further. The evidence in this section clearly indicates that bureaucratic elements such as the introduction of CCGs, have led to a greater burden, and more, rather than less box ticking. Clearly the government has sought to reduce bureaucracy but in reality, the view is that they have added a layer of complexity to an already incoherent system.

4.4 The CQC

There have been many issues with the CQC specifically, in practical terms related to the way they conduct data collection and analysis. When it comes to useful applications of the research findings, these issues are relatively straightforward, and subsequent recommendations would also be. Solutions to problems which are simple and straightforward are much more likely to be useful, especially when these issues have direct implications for life and death, so these findings, whilst relatively straightforward, are very significant because of this quality.

4.4.1 The age of data

The first practical issue with CQC data collection, analysis and feedback is that the age of data used is not good enough on many levels. Primarily, this refers to the data used for Quality and Risk Profiles (QRPs), the data used to assess Trusts, and the feedback of information to Trusts. This is especially important, as if the age of data is an issue, then when Trusts start to underperform it does not become obvious that this is the case, until it is too late (i.e. many additional people have been treated in an inadequate way).

Although, whilst this claim is being made, some staff from T3 did not seem to consider age of data as much of an issue as staff from other Trusts (and CCGs) did. These responses are definitely atypical and it is quite possible that the favourable ratings given to T3 by regulators may mean that they are less conscious of these sorts of problems, because if they do exist, from T3 staffs perspective, it doesn't really matter. Whereas providers who are being criticised may be more likely to notice problems with the process, as it impacts more on their reputation.

T4 Head of Nursing provided evidence which implicates the age of CQC data as an issue for providers. They specified:

“My concern is the application that you have to do if asked me are the CQC doing it right I would say no, my experience is they are very slow at applying their framework and very slow at updating their website and I would be concerned that the quality of the indicators and the evidence they are using to come to that judgement, because we are a relatively new organisation they have got very little data on us at the moment, our inspection we had resulted on good feedback on the back of that. I could sit down and I could give them some triangulation around quality. My concern is they make a judgment about a service they know nothing about... (and assume it) is accurate without exception, and there is a lack of transparency in how they come to their judgments, I would expect they should be able to address this.”

T3 Director of Performance was asked “is the age of data and feedback process an issue?” and they replied:

“So for Monitor I think it is fine. For CQC I think sometimes the information that is being used is quite out of date for some of the indicators so that will be stuff in the Quality and Risk Profiles where they are referring back to info that is quite old, sometimes a year out of date and that feels like a problem.”

The Quality and Risk Profiles were an element which many providers pointed out as particularly out of date, which essentially rendered the information useless. T1 Chief Compliance Officer, for example, claimed that:

“It’s quite frustrating sometimes because they appear to have wrong data once or twice but I could not get it put right, it wasn’t a big issue it was about a safety manager not attending a meeting, but they hadn’t attended it because it was cancelled because it snowed, so, should we have had a black mark against that indicator, I don’t think so. And it was one that came onto quite a number of different bits of the Quality and Risk Profile for some reason there doesn’t seem to be a very obvious way to challenge it.”

T1 Director of compliance and risk management claimed some of the CQC data was outdated, but this was not always their fault, as changes take time. They detailed for instance:

“Sometimes we have a CQC inspection and unfortunately they highlighted a moderate concern and that was back from October time and they have only just came back (6 months later) to make sure that the action plan has been fully operational, and during that period it had shown on our Monitor style report as a concern, however, to put thing right it does take a little while, there’s no use coming back in a couple of months and checking before it can have been completed, so it’s horses for courses really.”

T2 Chief Executive argued that regulation by the CQC was outdated, but also that they as providers are not sure what is required of them, in terms of information gathering that proves compliance with essential standards. It was said that:

“It’s very retrospective but also it’s the balance between inspection and analytical methodologies and I don’t think we quite understood something which signs off organisations as meeting a series of standards (the CQCs normal way of doing things) and ad hoc inspection and how they get that and do a mix of data and analysis co-operating to say we need to be here proactively or don’t need to be there, its predecessor the Health Commission was struggling to hit that territory as well, so we’re not quite sure how to do this yet, you could argue regulation tends to be underpowered around the developed world anyway, because it’s usually financial regulation particularly where you’ve got Bismarck based systems where 3rd party payers are often 3rd party separations the state and provision functions.”

CCG1 Director of Quality Governance was of the opinion that the CQC were very slow, but commissioners could act before CQC data was officially published. They stated:

“Yes, I think it’s slow when they go out and do a routine visit it takes them a while to publish the findings, up until that point you have no sense of what they think about a provider until months, can be a couple of months after the event, and also if there are areas where action is

needed it can be very difficult for them to get through the processes they have to go through to be able to take any action, so as commissioners we can take the action a lot more quickly in terms of, if we find an issue in a home today I can say suspend that contract I don't want anyone else going there, CQC don't have that amount of flexibility."

This commissioner did however have some startling claims about the Quality and Risk Profiles, for instance:

"Some of the QRP stuff can be going back to 2010 and earlier, so some of it can be on environment inspection scores that were done over 18 months ago it takes a little while for the data to filter through and change so you have to question if you are looking at that from a quality perspective, well is that the same as we stand today? Have things moved on?"

CCG1 Director of Patient Safety and Quality also had very strong claims around the age of Quality and Risk Profiles. The evidence they provided is beneath:

"I mean I do understand there challenges they do a snapshot visit they only see what they see on the day and they do collect other intelligence I know that, the providers' QRPs some of their data is so out of date its quite atrocious really, when I was reviewing mine at the ambulance service it completely gave wrong messages to our commissioners and other stakeholders including the public who have access to these. A. because the data was out of date and B. it was not really reflective of the work the ambulance service was doing. To be honest we took them with a pinch of salt we didn't really put much stock in them at all, and as a commissioner I don't really value those as good sources of information I think their reports, their compliance reports are much better. The QRPs are quite weak. They were using data that were several years old and particularly in the ambulance service where there has been a huge focus on improving quality then it quickly gets out of date."

CCG1 Chief Officer also agreed that the CQC data could be up to 2 years out of date. They claimed that:

“For quality for the CQC it is trickier, they can do various things based on patient feedback or complaints from patients, or safeguarding s or serious incidents, but there isn’t a regular data collection system for clients against all of their metrics as there is for the governance framework of Monitor. They have to seek that assurance in a different way. Basically this means a lot of CQC data is out of date or partially. Up to 2 years out of date if that was the last visit. Care homes, actual staff could be different, ways of operating could be different, and lots of things could change in that time. Whereas with MRSA (Methicillin-resistant *Staphylococcus aureus*) rates being fed through as part of a performance review or 18 week compliance that’s coming through all the time, it’s easy for analysts to see where things are going off track.”

4.1.1 CQC Age of Data: Summary

There have been many major problems identified with the CQC and age of data. Specifically the QRPs are a significant issue. This outdated information can also not be easily changed by providers which leads to inaccurate assessments of quality and risk. The slow nature of CQC data (especially QRPs) can mean that commissioners don’t bother using it at all.

4.4.2 The feedback process

Significantly linked in with the age of the QRP data from the CQC, the feedback process in general has come to light as a practical issue with contemporary health regulation. Many staff from providers of all different kinds made comments supporting this claim. One of the specific issues with the CQC on this point is that many aspects of the judgement framework are very subjective. The problem with this is that the subjectivity of the framework can result in classifications of quality and risk that are skewed and do not represent reality. Obviously this works in both ways, with some providers who are compliant being judged to be non-compliant and some who are non-compliant being judged as compliant. This section also links in heavily with a later section on data sharing (4.7) that develops the idea that feedback loops need to be shortened to achieve proper efficiency.

T4 Chief Executive argued that the feedback process was limited by the skill sets of those investigating, suggesting that they did not always fit the types of providers they are regulating. They claimed for instance:

“You hear a lot of chatter, I think there is a difference of question really which is have we got a cadre of CQC inspectors who understand the service? Last year 80% of them had a social care background, there’s something about how they apply that judgement and do they have the experience and ability to do so. Monitor has many people with a financial background, and then they are being asked to think about quality so there may be some grounds to the subjectivity around some of the inspectors.”

CCG1 Director of Quality Governance was asked; “what would you say are the main problems/issues that CQC and Monitor face in practice? They replied:

“The ways of information sharing and the speed at which it is shared and the responses, the length of time it takes for something to happen as a result. And just all the parts of the system recognising each other’s role responsibilities and working to those strengths. I do always feel although they are not commissioning anything they are regulating there does seem to be a parallel at least between commissioning responsibilities and regulatory responsibilities especially when you have a system where commissioners are responsible for improving quality and assurance because some of that is doing what the regulator is doing to a degree. They would say they are registering the provider as fit to operate. There is an overlap they might look like different things so one is assessing the quality and saying whether you have a clean bill of health, commissioners are working with them between those times, but it does overlap... it needs more clarity and increased collaboration... and speed. I feel sorry for them they feel a bit like they have got no teeth. They can make threats to take regulatory action but it takes too long to get anything because it feels like they are too scared of being wrong because of the challenge that might ensue.”

T1 Head of Nursing outlined their concerns from an “on the ground” level. They claimed for instance that:

“We are worried about whether or not we are compliant on key CQC standards, but we do not get enough feedback from them to tell us what exactly we need to be doing to achieve compliance”.

They also stated that “if we don’t get the appropriate information fed back to us in a timely fashion it is quite possible we will fail a key standard that we previously failed because the information isn’t there”.

CCG2 Operating Officer noted similar concerns regarding the feedback process between the CQC and commissioners. They argued that “when we have a concern about a provider there just isn’t a stream of appropriate information coming from the CQC to us; it is either too old or meaningless”. They also said that “a provider being registered with the CQC gives us no real assurance as to their quality; surely the CQC should be giving us assurance information about providers they have supposedly registered.”

4.4.2 Feedback Process: summary

The Feedback Process with the CQC can be very subjective. It is reliant on the inspectors having the right skill set and this may not be the case. There is often a long time between inspection and feedback being received which means providers cannot act. CQC registration does not have sufficient weight to be useful for commissioners in determining quality.

4.4.3 Data coding and duplication

Similarly to issues surrounding the age of data and the feedback process generally, many staff from providers identified issues with data coding (especially with the CQC and Dr Foster). Again, this is not confirmed across the board, but it seems to definitely be an issue

for smaller providers. This may well be because smaller providers are more susceptible to data coding issues as they have a greater, more pronounced impact on them, compared to larger providers.

Duplication of data collection is something else that has been identified by some staff from providers, and again it tends to be the smaller Trusts that experience this issue most. It seems likely that this is because the burden of regulation is greater for Trusts who have less staff to process the various data sets for regulators.

T4 Chief Executive suggested that duplication of data collection by the various ALBs was an issue. They claimed that:

“The format of return is different a few years ago all of the regulators signed up to a contract where they agreed to streamline all this stuff and it worked for a little while the changes in the regulatory regimes brought forward by the bill offered an opportunity to sort this out, I don’t hear much about it though.”

T1 Chief Compliance Officer points to the issues surrounding data coding and mortality data from Dr Foster Intelligence. They detailed:

“Data coding with things like mortality is an issue, we have had a couple of alerts about mortality that came through the Dr Foster system and one of them we picked up and we were way ahead of it and we knew there was a problem which was a coding issue and we were able to provide the evidence to show that to their satisfaction, but it was a huge amount of work, and I understand why they have to do it but, it’s quite frustrating sometimes, you have to spend a lot of time because it doesn’t feel like they have triangulated it, we have had another alert recently, something about obstetrics but there was other evidence that contradicts it anyway, so they don’t seem to take the whole thing in the round. So there are data coding issues with some of it.”

This point was discussed in the earlier literature review (in relation to Mohammed et al. 2009 and Francis 2013) and clearly has significant implications for the successful deployment of regulation, and for it to quantify quality effectively. This is also further developed in the secondary research which uses Dr Foster data in correlation with CQC data sets. The Chief Compliance Officer also pointed to the sensitivity of the CQC data as leading to inaccurate assessments, for instance suggesting:

“The things like the comments are quite frustrating because we get comments, I did actually speak to the CQC about this, the negative comments seem to really adversely affect the ratings so some of them, we had one indicator and it was green and then the next time it had gone red, and the only difference was we had had 4-5 more negative comments about it which doesn’t seem big, and what you don’t get is what that data source is so you can’t say oh we have got a problem there so we need to and sort it. If they are making a judgement about a problem you should at least be able to go and address the problem, so that is a bit of an issue. I did ask them about the waiting for that and I didn’t get an answer at all even though I asked him face to face.”

T1 Director of Compliance and Risk Management said that in terms of duplication of efforts, their internal systems were guilty of this. For instance they claimed that:

“There is some internal duplication with our own systems but not as far as CQC and Monitor are concerned it’s totally separate. We have the provider management report which is all the Monitor indicators, targets and performance and then we have our own strategic performance report, which duplicates a lot of that so we have been aware for some while that actually we need to refresh our own internal performance report, that isn’t really the fault of the regulators that’s down to our own internal systems.”

T2 Director of Corporate and Legal Affairs referred to the CQC standards as vague, subjective and inconsistently applied by the CQC. They stated for example:

“I think I would say that it would be nice to see the evidence that shows it is consistent from one Trust to another. Why do I say that, well interestingly, our Director of Clinical Quality, who you have met, has been involved with a network here that is run by our local area internal auditors and on behalf of their clients they have had a look at one of the CQCs standards, standard 21, and they have looked at that across the different clients as to how that has been judged by the CQC and they have extracted from different reports what they have found for different institutions for the matching records. It is quite interesting reading the different reports, what they have to say and judging whether that means they are compliant or minor concern or moderate concern and try and tease out the nuances between one being in one box and one in another box. What was crystal clear to me, someone who looks at the detail of these things, on what judgement did the fall between minor and moderate, it can look interchangeable and it's not exactly transparent to the reader as to why any one institution has found themselves in the category and how they have been judged on an objective basis. That would be influenced by the approach of the individual CQC manager, which I suppose in itself is an interesting observation, it ought to be more objective.”

T3 Director of Corporate Services however did claim that there was “less duplication and coding issues than there used to be.” But it seems apparent that duplication and coding issues remain an issue for providers and commissioners alike as the significant and varying evidence has illustrated.

4.4.3 Data Coding and Duplication: Summary

The sensitivity of CQC data coding is considered by many providers as too great, which can lead to inaccurate assessments. Some providers acknowledged that there was duplication in their own internal systems. Many providers suggest that red/amber/green risk coding was very subjectively applied by CQC inspectors.

4.4.4 The CQC: Conclusions

This section has outlined the various issues with the CQC from providers and CCGs perspectives. It is clear that the age of CQC data, specifically the QRPs is an issue for both providers and commissioners. The feedback process has also been demonstrated to be inadequate in many ways. Data coding issues and duplication of data collection are further problems associated with regulation by the CQC, especially with smaller organisations.

4.5 Monitor

Monitor have been pretty well received by the providers in this sample, and most of the positive feedback about regulation focused on them, as their financial and governance remit tends to be more clear to providers. On the negative side, some staff did consider Monitors' requirements to be relatively burdensome. There is a quote below from T3 Director of Performance which also picks up on the Monitor system being overly sensitive, and considering that he is from T3 (who have been the most positive about regulation in general) some weight has to be given to this claim. It was emphasised that:

"Obviously it can feel like a burden at times, I suppose any system that tries to get you to do things can feel like a burden, but generally I think people see it as a positive thing, sometimes some of the indicators can be seen as a bit rigid, quite black and white, so I am particularly involved with the governance side and they are a little too black and white in terms of we can be on threshold say a Cdiff (Clostridium difficile) indicator and one more case will send us into missing that indicator and amber green, the overall rating and that often feels a little too blunt an approach, I think it could be a bit more graded."

When asked whether the system was arbitrary, they stated:

"I would not say its woolly, just complex, not arbitrary, it's just sensitive and the boundaries could be more softened to a degree, so they were more sensitive to strong performance, or

strong underperformance in a particular area, whereas at the moment with Monitor in particular you are either passing or failing on an indicator, and you can be just missing on two indicators, with no impact on patient care and suddenly you are rated as amber red from the governance point of view, so in that sense its quite sensitive. So it has benefits of being quite simple, but the flipside of that is it is too sensitive to minor aberrations.”

T3 Deputy Chief Executive also referred to this, claiming the main problem with Monitor was: “the lack of a balanced and sensitive scorecard, too many early triggers that can set us off looking as if we have a problem when we haven’t.” Again emphasising the issue around Monitor related to sensitivity on the ratings which regulate providers.

However on the whole there was significantly less criticism of Monitor as a regulator than on the CQC and others. T1 Director of Compliance and Risk Management stated a typical quote about Monitor which represents the general views of the interviewees in the sample:

“I think Monitor’s a quite well defined process, probably because it started being so financed focused, it has very finance approaches and frameworks in place, which are usually pretty black and white,”

4.5 Monitor: Summary

Monitor is generally well respected as a regulator based on the interviewees in the sample. Where there are issues identified, these are generally related to the overly sensitive nature of Monitors framework. Overall though the nature of Monitor’s regulatory activity is applied consistently, which means it is easy for providers to understand.

4.5.1 The FT application

Significantly linked in with the overall theme of bureaucracy and coming within Monitor's remit as a regulator, the FT application that many aspirant FTs are going through (and FTs have gone through) is described as extremely arduous, with numerous problems being identified. It appears that the regulators lack the capacity to adequately assess Trusts for FT status, which is being exacerbated by the fact that all Trusts are being made to apply for Foundation status (despite many not wanting to or not being ready to).

The sheer number of bodies involved in this process has been identified by many as an issue, which ties in with the earlier section on the purpose of regulation and overlapping remits. Notably private companies are involved on top of the various layers of NHS regulation, which can result in costs for providers increasing through no fault of their own. Ironically, whilst purporting to result in more autonomy for providers, many in this sample considered the process and resulting FT badge to actually result in more scrutiny.

T4 Head of Nursing claimed for instance that they were: "a little concerned about the bureaucracy that has been built around the FT application." This interviewee went on to give specific examples:

"So for example in communication with us they have got no idea what we do, we have the registration process, which is not particularly transparent there must be a better way than just registering all big providers and providing so much detail about different classifications of registration mean that an organisation like us who provide so many services across a huge range of healthcare provisions its extremely difficult to make the registration meaningful, it's not a problem of assurance because we have matched our own quality framework which is completed by all the 55 services around the core standards, what I am struggling with is the effectiveness of the inspection regime and how it can possibly inspect an organisation this big."

They also went on to claim that the number of private companies involved in the FT process is unjustified and results in more scrutiny of aspirant FTs. They suggested:

“Yes it does result in more scrutiny in the application process; I don’t think its Monitor that worries me or the other stuff. When we are paying for a big regulator why on earth are we having to employ so many private companies just to show we are fit to be regulated so the amount of money that is going into external audit and external things I think messes up the process.”

T4 Chief Executive was also critical of the FT application from their perspective (they are an aspirant FT). They went on to argue that Monitors deficiencies capacity wise have damaged their own application through no fault of their own. For example they stated:

“Monitor, once you’re a FT and we are an aspirant, it requires very up to date information. Time wise I think the processes can be delayed, we are currently going through our Monitor application process involves the SHA and the gateway and then the DH, part of it we have to do due diligence processes, they got delayed by 6 months by Monitor because they didn’t provide anybody to do them, and when we submit our application to the DH in December we have no guarantees about when the application will go through, or how long it will take because they are lacking in terms of capacity.”

The Chief Executive also pointed to further issues regarding the private sector. Their argument is outlined below:

“So we are an organisation of 3000 staff who provide 65 different services they range from anything from basic things, children’s services, basic nursing supporting people who have got leg ulcers or can’t do insulin injections because they are blind or whatever it’s a very complex specialist service, with a very broad range of services and becoming a FT supports our mission to do that. We are required to become a FT because all NHS providers must be in the future and we want to be one, the aspirant process is a long journey to demonstrate that we

have the capacity to pass a series of tests and a different gateway. There are numerous assessments by Monitor, self-assessments, Department of Health the Strategic Health Authority etc. what happens is you need to prove you are fit to pass to the next stage at every stage, we have been tested by Monitor and have had to pay for external assurance to pass this particular stage several times, which is frustrating, because some of it is essential and cannot be avoided, but it seems arduous.”

The fact that they as a Trust have to pay private companies for assurance that they are giving anyway elsewhere seems ludicrous. It is not only inefficient in terms of duplication of efforts, but it is also a waste of the provider's monetary resources.

T3 Director of Corporate Services said that the main problems with regulation was that there are; “a load of Trusts at very different stages trying to get through the FT process. How do they compare one Trust to another?” in answer to their own question they stated, with a “broad brush approach.”

Bearing in mind T3 is an established FT it is important to note that they said that becoming an FT had led to more red tape, not less. Their argument is summarised beneath:

“At the beginning when we were told FT would be less bureaucracy, but now there is more bureaucracy as more FTs exist. After the Francis report now Monitor look at quality vs. finance and there is much more scrutiny than in the beginning, now we give stuff to Monitor and the SHA.”

T3 Director of Performance also gave evidence which supports this view. They suggested, for example:

“So there is more rigorous scrutiny, on those quality issues, funnily enough I think Monitor has really supported FT achievement because they do set in place an expectation that there are clear action plans and improved performance and if your performance gets worse then

there's a much more professional approach to bringing your performance back in line and that becomes quite embedded in the organisation and in that sense I think it works really well and there is an increased rigour and I think most people recognise that as a good thing. I think there is a bit of a problem even though as FTs we are meant to be regulated by Monitor part of the deal was that we don't then have to answer to SHAs but through the contract I have noticed that we are getting increasingly asked questions by SHAs often linked to contract measures but not really. So it feels like actually there is an increasing burden we have got too many masters, we have Monitor, commissioners who have the contract and the SHA is getting increasingly involved with our performance, so in that sense it feels like we are getting over regulated now."

T3 Head of Governance and Development similarly discussed the FT application process and its pitfalls, they did however remain positive about their position, which is unsurprising given their strong performance on all fronts. They stated:

"The registration process, now we are two and a half years on and we have got established relationships but if I look back we were tearing our hair out a bit with the registration process, and it was quite clear that (and I'm not sure how fully it can be thought through) you have a great big book of guidance, very difficult to make sense of, and you had to register so that was rocky wasn't it and it was a little bit scary as well because suddenly this new important regulator, and it was not easy to get answers to that because the guidance was so dense and the outcomes written in such a way it's not intuitive enough. We are used to dealing with fog but on the wards it's even more difficult to grasp, so I think there are some issues there but I think a lot of having a good relationship with them is about being confident and we are now a couple of years on in a good strong position I suspect that is where a lot of organisations aren't, this Trust is very together, it is a very confident trust, constantly growing, a can do place, that's how new initiatives are approached I think."

T1 Chief Compliance Officer represents an earlier stage in the process. They are an aspirant FT and even at this early stage they claim that: "Yeah, it's a huge amount of work and a lot

more scrutiny and external scrutiny so we seem to have been reviewed to death and Monitor haven't even got here yet." Clearly the scrutiny of becoming a FT can weigh heavily on providers, and the idea that this detracts from the day to day running of things is worrying.

T2 Chief Executive was another interviewee who pointed to the issues of the FT application process, specifically the burden it put on providers. The section beneath outlines their argument:

"It means you create a different set of requirements as well as the regulated activities as such and what you've got at the moment is the CQC but if you haven't got Monitor because you're an aspirant then you've got the intermediate tier soon to be the National Provider Development Authority next year managing this process, but they are in essence mimicking the Monitor process and adding a few things, trying to get aspiring FTs into the same environment as the FTs in addition to that, the aspirant have the application and assessment process which are significant burdens, burdens sounds negative, challenges in an environment which was threatening it does put aspirant FTs in a worse position in terms to needing to respond than current FTs. They will tell you the process with Monitor is challenging. I'm an ex FT chair, it's a lot more complex application and assessment process is much more challenging for compliance. A lot of FTs say if they applied now they would not get in."

CCG1 Director of Quality Governance had a slightly different take, perhaps not surprising due to being a commissioner rather than a provider. They claimed that FTs were less open to give information to commissioners due to the scrutiny from their perspective by Monitor. They stated:

"I think it results in less scrutiny, by the strict letter of the law it should result in less, and it should, you always get a certain set of assurance particularly the Healthcare Trust for example, we knew as a commissioner that they had just been through a very rigorous Monitor review so we had a degree of assurance around that but actually the still need to comply with

our requirements for commissioning although they don't need to, we still want them to do that, because they get a lot more freedom if they are an FT. I am not sure how sustainable that is going to be in the new world either if there is an opt out clause to not tell local commissioners things because you are an FT, how can commissioners plan and buy services properly without having the data to do so which then impacts on patient safety experience and effectiveness which might then impact on CQC. Whist ever freedom is a good thing, it needs to be freedom from the things that don't really matter as much that don't impact on decisions that are being made on the wider health economy. Commissioners are often having trouble getting information out of Acute FTs because they do not have to provide it in the same way due to being regulated by Monitor."

This commissioner also believed that the FT process detracted from the day to day running of aspirant FTs. For example they said:

"I saw the massive amount of work the Trust had to put in to get that FT equivalent status and I just think with a lot of this does it distract people from the everyday running and care. And is there a better way that we can get the same outcomes without the bureaucracy and the stuff that goes around it? Putting together information for several processes or systems for one incident must distract from every day running of things and core business."

CCG1 Director of Patient Safety and Quality referred to Mid Staffordshire, the FT application process in that instance and the problems that it created. They believed that:

"In terms of regulation you only have to look at Mid Staffs and every other Trust is doing the same thing at the moment the focus on what's the here and now what has to be done immediately, so for authorisation for an aspirant FT they will focus on getting through FT and we saw in Mid Staffs that was at the detriment of quality, they focused on the finance because to get through FT you must balance the books you must also have performance in order but the emphasis was on finance at the detriment of quality and that is repeated over and over again, and whilst we all say we are learning the lessons from Mid Staffs, I can see that in all

the contracts of major aspirant FTs that is exactly what they are doing, they are trying to make cost improvements and that means taking staff out or getting rid of expensive staff who are their eyes and ears and expertise, trying to balance the books where they can and taking beds out of the system which may be a good thing, not always. It is so difficult and whilst we have to save money and become more efficient, they have been tinkering around the edges really there isn't a whole health economy approach although we talk about QIPP you know everybody's doing it in the short term everybody's doing it from year to year and so these directives or regulatory standards often cause problems."

T2 Director of Corporate and Legal Affairs outlined the limitations of not yet being a FT from their perspective. They claimed it affected the Trust in a number of ways, for example:

"The very fact that under a FT arrangement there is built in into the governance of a FT a voice at the table for the patient and the public. It puts extensively the patient into a very different position where they are in relation to a non FT you know we would establish a council of governors, the majority of governors would be elected by the public, patients they have rights and responsibilities in relation to the Trusts business so I think that accountability in an FT arrangement gives an opportunity for the public and patients to have increased influence than might otherwise be the case at one level."

This director also argued the lack of "FT badge" meant that they were limited in several ways. For instance:

"It impacts on the way the trust operates and legally there are certain things we can't do as a non FT that might be a constraint on what we want to do, so some of the business propositions we might want to pursue, maybe we have to wait until we are an FT. There is a further dimension which is less tangible, the FT thing is not an end in itself it simply provides an opportunity to do things differently, financially in terms of involvement of patients and other stakeholders and then to have a voice that bites the governance of trust and I think we know that it's effectively the FT badge is a marker of sound governance. So for us to not be in that

club is like we are not in the premier league for organisations. So it's not a good place to be. Why does that matter? Well we don't want an arrangement where another might take on responsibility for our Trust maybe from outside this patch, and might sort making decisions about the future services for patients in this area would be much better for, we think the people that we serve if the management was on the patch, accountable to them and responsive to their needs and requirements."

T3 Director of Corporate Services claimed that the FT process at their Trust (before they were an FT) had led to more rather than less bureaucracy. They stated for example: "at the beginning when we were FT it would be less bureaucracy but now there is more bureaucracy as more FTs exist." They also claimed that the increased quality remit for Monitor meant that there was "increased scrutiny", despite the rhetoric around purported autonomy.

4.5.1 The FT application: Summary

Monitor is identified by many interviewees as lacking in the capacity to put aspirant FTs through the FT process, which can delay getting FT status for providers despite their best efforts to achieve it. Many see the FT process as a burden for aspirant FTs, it can impact on the day to day running of providers of healthcare and take energy away from this. The use of private companies for assurance in the FT process was also questioned by many of the interviewees.

4.6 Regulating smaller providers: care homes

In response to the Francis Report, Health Secretary Jeremy Hunt has recently stated that bureaucratic box ticking when it comes to health regulation "cannot be the solution", in terms of the reforming the NHS to ensure that standards that are expected by the NHS hospitals are maintained and serious service failures do not occur. On the CQC specifically Hunt states; "at

the moment, failure to meet CQC standards simply does not have enough consequences for the management of a hospital” (National Health Executive 2013). The issue is that many of the recommendations made by Francis (290 in total) represent cultural change within NHS organisations rather than merely structural. But what about smaller NHS commissioned organisations such as care homes which are visited significantly less frequently by the CQC than hospitals? Populations around the world are rapidly ageing. Therefore, the performance of these types of organisations has increasingly important practical implications for health regulators. If the CQC is failing at large, supposedly flagship Foundation Trusts (such as Mid Staffs) due to prioritising monetary efficiency over quality and safety (fuelled by austerity measures) then this type of regulatory culture can only bode badly for care homes. This research focuses on care homes because of these reasons: they are of paramount importance to society. But not only that, care homes are a topic which came up in a large number of the interviews, particularly the ones with commissioners, which further justifies their inclusion in the findings of this research.

The CQC has the mammoth task of the registration and regulation of all health and social care in England. Recent UK scandals in health and social care homes like Winterbourne View (Bristol), Hillcroft nursing home (Lancaster) and Ash Court (London) have highlighted the serious service failures to provide quality services and respect for patients (Independent 2012). So what is going wrong? Interviews with commissioners at Clinical Commissioning Groups (CCGs) strongly suggest that what is being asked of the CQC is far greater than what is feasible given the staff numbers and resources allocated for this task. The main issue the commissioners, in this sample, have highlighted with care homes specifically is that the CQC is very slow to respond, and the process is overly bureaucratic. The first thing to note here is the regularity and frequency of visits to care homes is not sufficient. The consensus is that the CQC are “reactive rather than proactive” and can result in important things going unnoticed.

CCG2 Commissioning Manager was significantly involved in the commissioning of care homes in their local patch. Their take on the regulation and monitoring of these homes was damning:

“Am I allowed to use the word bureaucratic? The whole system is overwhelming and bureaucratic with a certain amount of questionable value, the reason I say it because I use one experience in the last twelve months, last winter we had a particularly demanding capacity across the system and we had to put a lot of people into nursing or residential homes from an Acute Trust there were a few questions over one or two of the nursing homes they were not under formal investigation but there were one or two concerns anyway, some of my colleagues then said I don’t think we should be using those homes because they are in question at the moment my argument was, well they have got CQC registration, CQC haven’t deemed it appropriate to withdraw their services in the homes, so why should we? The answer came back they don’t actually guarantee safety or quality within those homes, now I thought the CQC would have a clue in the title, but I was told well they don’t actually guarantee quality so if they don’t fulfil a basic requirement like that what are they there for? From a purely personal and cynical view I do not value it. The care homes that we use, they have registration, but I don’t personally check that.”

It seems that for this commissioner the CQC registration of care homes was meaningless as it did not mean that these homes were fit for purpose.

As an exercise the ten nearest care homes in this commissioner’s local area on the CQC website (on 03/05/13) were examined, to see when they were last visited and what they had found. All ten providers had been registered with the CQC, and all the services that had been checked were deemed to be fulfilling all the essential standards, on the face of it, a seemingly positive situation. Upon further scrutiny however, it becomes apparent that this is not really the case. Three of the care homes that had been registered (in Nov 2011, Jan 2012 and May 2012) had not been checked at all, and one of the care homes was last checked in August 2011. If even in this very small regional sample there are three care homes that have never been checked for “standards you have the right to expect” (CQC 2013ii) you can see why serious service failures are happening, you can also see why the commissioner took no assurance from this registration.

Of further concern is the length of time that care homes which are deemed non-compliant with essential standards are given to remedy the situation. This is illustrated by an example given by CCG1 Director of Patient Safety and Quality:

“I have just been to visit a care home in my patch and I’m not too happy with what I saw, and when I reviewed the CQC reports this care home was not compliant with several of the essential standards and had an action plan in place and my concern is they have a very long time to put them in place before they are re-monitored. They originally went in in October (and realised the care home was not compliant) and then they went back in April (to check if they were), that’s quite a long time if you are a resident in a care home where care is completely not acceptable and yet I visited last week (June) and I wouldn’t put my relative in that care home, so I am left thinking how bad do you have to be?”

In this situation eight months after being judged to be failing on compliance the commissioner themselves still considered this care home to be failing on compliance. If this is the case where the CQC has actually intervened, it does not bode well for care homes that have not even been checked, (despite being registered) of which there are hundreds.

When asked what the main challenges the CQC face moving forwards were, CCG2 Chief Operating Officer argued it was “around their capacity” and elaborated about the degree to which the “ad hoc” visits made to care homes even detect failing to meet minimum standards:

“You can go in there (the care home) and it is great, but actually that doesn’t guarantee you when the next shift come on a different set of people begin and that’s why you need a broad brush of intelligence and you do need to triangulate it”

They also argued that there are significant limitations around capacity, which contribute to the failure of properly providing assurance on care homes and smaller organisations:

“They (The CQC) are good but obviously they are limited really when GP practices get registered as well, how can you realistically get round these care homes, hospitals, GP practices, dentists etc. I don’t know how you’re going to be able to, it’s just getting bigger and bigger, I suppose it will be risk based. It’s not just the day of the visit is it it’s the preparation and the intelligence gathering all the time and the reviewing and interrogating that and focusing their efforts when they go out and physically doing it, then writing the report, moderating it, making adjustments, it’s quite a long process for one visit isn’t it! You are left with that “CQC were in” and they were, but you can only glean so much from what you see in a day, to me it’s one part in a tool box really it’s not the be all and end all.”

If the inspection element of CQC with regard to care homes is part of the tool box then perhaps the commissioners themselves are the other tools. They are clearly accountable for the services that they commission, but the worry is that they see the CQC information about a care home on their patch, which states there are no issues and then do not visit the service themselves to assess quality. The fact is, one visit at a care home up to 18 months ago does not give the CQC a full picture of what is going on, and basing their risk assessments on this may have dangerous knock on effects. But now, recently authorised CCGs can act a lot more quickly than the CQC and suspend contracts if they find issues in care homes they are not happy with. Whether this always results in less serious service failure or not will become apparent along the line. Relying solely on commissioners to guarantee all care homes are safe seems to not fit in line with the rhetoric of the CQC being the main regulator for quality in health and social care.

CCG1 Director of Patient Safety and Quality suggested that regulation and inspection was of vital importance, especially when it comes to care homes. They claimed for instance:

“Clearly if you allowed the hospitals to self-regulate we just wouldn’t see the level of improvement that we would need and we have seen that in the care homes for e.g. where there haven’t been regulations and some absolute atrocious conditions, so yea I think it’s

absolutely essential. And it gives them that level of legitimacy and authority to question and challenge and publishes your data as a provider open to the scrutiny of the general public.”

They also suggested that politicising issues in healthcare made things more complex especially with regard to the closing down of services. They stated:

“The problem is when politicians get involved in healthcare and that’s a talking point at the moment for e.g. when you want to close a service or a hospital which is the policy of the government at the time, locating to centres of excellence or expertise and then you have your local MP saying we don’t want this hospital to close because our local population thinks it’s wonderful when actually it’s the most dangerous place and actually you wouldn’t go there yourself unless you were dying! So politicians muddy the water and should keep right out of healthcare.”

One of the other issues with care homes specifically is that the quality of care in homes varies very quickly with small staff numbers and high staff turnover, meaning that serious service failures can quickly arise, even when relatively recent checks have been made.

In a fluid area of health policy reform, competition policy is something which can be brought into the quality debate with regard to care homes. Monitor’s current line on competition policy is that they are “preventing anti-competitive behaviour” after the initial 2012 Health Act was watered down. But interviews with commissioners and providers in this research suggest that competition policy having an effect is dependent on having a large population to cater for and many providers being there already. Areas where there are far more health services of all kinds are a good example of where a commissioner can change the service provider without increasing cost or harming quality.

There are some areas where for practical reasons it is hard to ensure there is competition among providers. In rural areas there are far fewer providers meaning competition is minimal. In areas with large densely populated areas of deprivation there are often only one or two

local providers and a real reluctance of the population to seek healthcare elsewhere. When it comes to care homes the situation is exacerbated by the fact that as the demographic of the residents is primarily old people, who are even more reluctant to “shop around”. Because it is necessary to keep care homes local, so as to fit the needs of the local population without shipping them away from their families and friends, this can mean a real headache for commissioners in terms of competition. Whether anti-competitive behaviour prevention works for large providers or not, it cannot be relied on to ensure the standards of care homes.

CCG1 Director of Quality Governance pointed to some of the regulatory issues facing care homes, suggesting that responsiveness was an issue from their perspective. They claimed that:

“I have a clinical background in nursing and midwifery and came into this role out of clinical practice, my portfolio within the commissioning group covers a multitude of things and one of those things is care homes. So not traditional providers as you would perhaps be thinking in terms of big hospitals, but actually providers who deliver or we commission care for who are funded by the NHS. So a lot of my experience in the care home sector with the CQC hasn’t always been that positive, the reasons for that are they are sometimes quite slow to respond its quite a bureaucratic process for them to get anything done, despite being the regulator they seem to have to jump through a myriad of hoops to be able to take any action against a provider and they are quite reactive certainly, after Winterbourne and all the problems last year with the learning disability home they had a bit of a roasting in terms of their lack of responsiveness they seem to have upped their standards to a point where it would be impossible to get a clean bill of health from them.”

CCG 1 Director of Quality Governance outlined care homes as the most significant area of risk in the regulatory system. They stated: “the people that are at risk is predominantly the care home area. That is being paid for by NHS funds it’s not necessarily going to an NHS provider but it is still NHS money and care”.

If the CQC is not ensuring hospitals bear the consequences of non-compliance, then it seems inevitable that non-compliance in smaller organisations (which are not visited by them or at best very rarely are) will go unnoticed until it is too late. Care homes look after some of society's most vulnerable people, most of whom are old. The UK population, like most of the world's, is getting older and older in its demographic, it seems probable that care homes will feature highly in the health policy arena, as ensuring standards of care and protection for harm for patients should be paramount.

4.6 Care Homes: Summary

Many interviewees claimed that CQC regulation does not guarantee quality in care homes. CQC checks of care homes are so irregular that the information is very rarely current, some care homes have never been checked. Interviewees suggested that when issues are identified the length of time it takes for change to be implemented is very long. Providers and Commissioners alike agreed that the CQC lack capacity to register and check all smaller providers like care homes. All of this is exacerbated by small staff numbers and high staff turnover in care homes.

4.7 Data sharing is underdeveloped

One of the biggest themes that have arisen through these interviews is that increased data sharing, in line with better information age e-governance, would benefit the NHS. This has been something that all providers in the sample agreed that was not currently in place and definitely needs to be improved. Many referred to the aims of the Concorde Act which are desirable, but not yet being realised fully.

This finding ties in with many others such as; bureaucracy, overlapping remits, data collection issues and the feedback process generally, the age of data, the separation of finances and

quality and even the FT application issues to some extent. The relations between the CQC and Monitor are seen by many as a power game, and the data sharing that should exist is underdeveloped in terms of the systems they use as well. This finding links in significantly with the neo-pluralist theory of many competing key actors as shaping policy, and their competing interests resulting in inefficiencies due to their undefined and overlapping remits as regulators. The separation of finances and quality, and then Monitor being focused on quality to some extent, seems to further influence the way the regulators see one another. If they are both regulating separate issues then this makes them see one another as unrelated, and data sharing suffers. If they are regulating separate things to some extent, but have overlapping remits in terms of quality, then this makes them see one another as competitors and results in less data sharing.

T1 Chief Executive states that “sunlight is the best disinfectant” and the T3 Deputy Chief Executive says “I don’t see any value in putting information in silos, if its public information then it should be shared”. Every staff member at every level of the management structure has agreed that data sharing between regulators, as well as data sharing between the regulators and the providers themselves (the feedback process) is not working in the way it should be. When it comes to mortality rates and serious service failures, if information is not being shared often and regularly between the CQC and Monitor (and other regulators), and if the information obtained by the CQC and Monitor is not being fed back to providers in an open and timely way, then these things will inevitably be more likely to occur. This links in with the idea of feedback loops, and in essence to root out these inefficiencies the feedback loop needs to be shortened. Data sharing initiatives are something which would shorten feedback loops in many ways, and all the staff in the sample agreed that due to the systems in place with the CQC, Monitor and Trusts QRPs, could be practically achievable.

CCG2 Head of Quality and Governance argued that they had tried to share information with their local CQC manager, and suggested that they did have a good relationship with them. The passage beneath summarises the relationship:

“We have been quite open in sharing information because she (their local CQC manager) came back to us and asked if we would mind sharing with her our findings so she could use them alongside her own evidence, so it is just further intelligence really to just triangulate with what she had got. And certainly, very recently our Acute Trust has a visit from the CQC, an unannounced two day visit, and when I read the report it is quite obvious to me that they have been reading board papers, the local press, they are well aware of what commissioner... its quite clear that they use some of the things that we have found in previous routine reports and are included in our reports to board to give them a fuller picture, so I think that we know they are there, we know if we have high level concerns we would go there, normally most of the time we can sort things out at a local level with the Trust ... they did a visit 12 months ago to our local hospital and asked us if we had any capacity for our team to go in and visit with them and I was one of them who went on the visit with them and they dispatched us off to particular wards to try and get individual patients and ask certain questions of staff and check some records for them, so I think locally we have got a good relationship.”

They did mention however that they were lacking in “formal mechanisms” and said that “I wouldn’t want to give you the impression that we see them every month of anything like that” So whilst they felt a good relationship had been developed, they saw the system of information sharing as regressive. They suggested for instance that:

“If you take risk registers for example which I have been discussing this morning the PCT that I was in, we had got a web based system people where sat at their desks and could report accidents when that all got joined together that all went, and we are now on an excel spread sheet, so to me that all feels a bit retrograde.”

The introduction of CCGs into the system may have contributed to the regression of data sharing systems in the NHS. When asked “What would you say are the main problems/issues that CQC and Monitor face in practice?” T4 Head of Nursing replied:

“I suppose what we lack is the ability to benchmark effectively and I could see that increased data sharing would be a good way to do that it’s again in a commercial market you would start to question actually is it to our commercial advantage and it would depend on who and how the data was being shared, I would not like to think there was a lot of data out there on our organisation when our competitors don’t have to report in the level of detail we have to. It puts us at a commercial disadvantage so it needs to be clear whether it is free market or not.”

So clearly from providers’ perspectives, if data sharing is going to work effectively and not damage their position then we come back to the role of competition policy needing to be properly defined in this context.

T4 Chief Executive suggested that the public should be able to access the information that is already out there about providers on some kind of easily accessible central database, which they could rely on. They stated:

“Yeah I mean it would be wonderful if the public could access information, which I think it can but in a more readily available format. The same information being used by the main regulators would be great. I don’t see why it couldn’t be practically achieved, the practical consideration that’s an issue is the relationships and the coherence.”

This Chief Executive also suggested that the relations between the CQC, Monitor and Commissioners were often minimal, and not enough sharing of information was taking place. They detailed:

“They don’t always feel like the system leaders at the top across the commissioning boards and the regulators are working together to make the system work, they don’t seem to be talking about it much and that may be because it’s not public, it may not. If they aren’t talking how can the system work?”

When asked whether they thought there was scope for increased data sharing between the various healthcare regulators T3 Director of Performance responded: “absolutely, if we didn’t have to keep providing the same information to different people it would make things better.”

T1 Chief Executive was another interviewee who firmly believed that data sharing was underdeveloped, and that becoming more transparent could only be good for the quality of providers. Their argument is summarised below:

“I think personally that sunlight is the best disinfectant, the more of this that be made transparent between the regulators and the organisations they are regulating the better, because then there are no surprises we have got full transparency and then there’s no excuse, everyone knows where we are... we know if the info that’s being held is incorrect or improperly interpreted one the one hand, or if those signals that are being sent through and triangulated at a regulatory level have meaning for us... we should know and we should be acting on those, it’s further assurance if those information strands are brought together and reflected back to us because we can then use that and assess our own place in the system. I would be in favour of more transparency and much more evidence.”

Also on data sharing, they pointed to the potential for more standardised data flows being shared between regulators as having significant implications in terms of being able to reduce the burden of regulation from providers’ perspectives, freeing up more time for the actual day to day running of things rather than repeated “box ticking”. They claimed for instance:

“I have lost count of the number of regulators we have to deal with but it will be 30 or something like that if we have got a data stream that serves in one of those regulators why does that have to be 5% change to the margin for a regulator? Why can’t we have an agreed set of data that organisations need to submit? Let’s get that done in ways which regulators can interrogate rather than it tailored to each individual regulators’ requirements... it seems much more sensible to have one data set which is capable of analysis and interpretation at a regulator level that would work better for us. It’s more of a burden on the regulator but

arguably you would only feel that once at a regulatory level because you set that up once, develop the system and models. For us every increase which can't be automated or made easily available means increased paperwork and that's replicated all over the system, it just what level you are willing to have, from my point of view it's better to share than not."

T1 Director of Compliance and Risk Management described the shared aims of providers, commissioners and regulators as being enhanced by increased data sharing between all parties concerned. They argued that:

"The whole point is we are all trying to do the same thing which is the best and safest services for patients and certainly in other organisations where there has been data sharing it has helped... a completely different perspective: with social security sharing things with tax revenue and customs - that helped prevent fraud, with health if there were clearer routes for information, because we produce an awful lot of data and it disappears and turns up as a Dr Foster HSMR or whatever and it's not always clear, who has got the information and where it's going to, that's probably as much our fault because there is so much information coming in that comes into different portals, they did set up a health observatory to try and bring that all together: that didn't really work, there's no easy... yes if you did this... maybe with the new structures it might work better but it is about that two way communication which is critical really."

When questioned as to their perception of the relations between Monitor and the CQC they described an unusual picture, where both are seeking to protect their own interests. Their response to the question was:

"Monitor have been there a long time and have got a very established world view, I think Monitor see CQC as interlopers on their turf and not terribly well organised, possibly they feel it was some sort of punishment for Mid Staffs. There doesn't from our low level seem to be a great deal of contact between Monitor and CQC, or communication or joint working."

T2 Chief Executive was asked whether they thought that there was more scope for data sharing between the various regulators and they replied: “yes enormously, the very idea that they don’t is abhorrent isn’t it?”. They also believed that this would reduce the replication of data collection and that this would be “reasonably practical” if there was “some kind of central data repository, a data warehouse, on a cloud”

CCG1 Director of Quality Governance was another interviewee who pointed to data sharing as an important issue. For instance when asked: “what would you say are the main problems/issues that CQC and Monitor face in practice?” they suggested:

“The ways of information sharing and the speed at which it is shared and the responses, the length of time it takes for something to happen as a result. And just all the parts of the system recognising each other’s role responsibilities and working to those strengths.”

They elaborated on the importance and need for better data sharing systems, to reduce duplication or triplication of data collection by the various regulators. The evidence from the interview is below:

“Our providers, particularly now around reportable incidents, in terms of CQC so they have to report to NPSA (National Patient Safety Authority) they also have to report serious incidents to commissioners they then need to report them to CQC and need to have talks together, I imagine it’s an inevitable nightmare, better data sharing within the rules and remits of the Data Protection Act cannot be anything but helpful. It must be frustrating to report things in three or four different ways. Certainly our independent sector treatment centre if it’s got an incident that needs reporting it needs to report it to us, it might need to report it as a serious incident, that’s one set of systems, it will need to report to the NRLS (National Reporting and Learning System) it will need to report to the DH, and then it will need to tell CQC as well, the amount of different people they have to tell, 5 completely separate systems.”

Below CCG1 Board Member discusses the implications of the current lack of good, reliable, up to date information flow.

“Yeah I think one of the things that often happens is you provide the data to the regulator and then you get nothing back which usually means we must be alright, so yes definitely feedback. They used to do stars, or rankings which were, they used to attach money to as well which was another one, they got out of fashion politically because if stars started going down then the government is going: “what are you doing?” But certainly there should be a lot more tie up between those involved in quality assurance, both within the organisations, within the deaneries, the colleges of nursing as well and in the commissioners, and the role of CQC should be as an assurance on that, the same way as the National Commissioning Board is meant to be saying: right, how are these CCGs commissioning? Let me do a quality assurance that the work is being done properly, and if we are getting into trouble let’s go down and see how we need to react and should it be taken over by somebody else? It should be a high level high cloud layer, if they start coming down to the local level then you get what happens every time a cloud comes down to local level: you get fog, that’s the way I see it.”

The realm of data sharing is significant in this research. All the participants in the interviews gave evidence as to why the current systems are limited and many gave ways in which they could be improved. This section is further developed in the conclusions (section 7.6).

4.7 Data Sharing: Summary

Increased data sharing would benefit the NHS significantly. All interviewees agreed that data sharing remains underdeveloped. A large proportion of interviewees claimed that data sharing between the CQC and Monitor was very limited. This links in with neo-plural theory, where many competing actors jostle for power. Similarly many interviewees suggested that data sharing between regulators of healthcare and providers was poor. Both data sharing between regulator and regulator, and between regulators and providers is lacking in formal mechanisms. Some interviewees even claimed that some data sharing systems were less advanced than they had been previously. Also the information made available to the public could be in an easier to understand format.

There is significant scope for increased data sharing, all interviewees agreed that increasing data sharing was desirable and had the potential to reduce duplication and the burden of regulation. They also all agreed that this was practically achievable.

4.8 Positives about regulation

This research seeks to evaluate the regulatory systems in the NHS in England and as such it is not surprising that problems and issues with regulation have been identified. If you look at any system with a critical eye it very likely that you will come up with negative criticisms.

When you look at standards in the NHS since regulation was conceived of as a policy, the evidence suggests that the service has improved over this time (and this is confirmed to some extent in the secondary quantitative research chapter 5 section 5.4.1). Setting targets and using punitive measures for service which is below the expected standards is a driver of efficiency. There has been praise for the way Monitor conducts itself, being metrics driven and clear about what it requires governance and finance wise. Whilst the CQC generally have been more criticised than Monitor, the individual CQC managers and their relationships with

staff have often been praised. Furthermore, many have identified regulation as a driver of standards in the NHS.

T2 Head of Nursing argued that elements of both CQC and Monitors regulatory activities were appropriate and helpful for them as providers. They claimed for instance:

“They are doing some really good things and that standards set by the CQC are right, and I particularly like Monitors quality governance framework financial framework. Monitor have been really careful to minimise the requirements of data collection, I don’t think we are doing anything for Monitor that we wouldn’t want to be doing for ourselves.”

T3 Director of Performance also praised Monitor and their work; they claimed that they assisted in certain areas. It was stated:

“I deal mostly with Monitor, I don’t have much to do with the CQC, for Monitor I would say it provides a very demanding type framework from which we need to operate from the point of view of Monitor I would say most of the time it’s quite sensible regulation, they are things we should be getting right and so I think the regulation can actually help us deliver better patient care, because it keeps us very focused on specific things. To a certain degree we appreciate the framework it can provide. I would say Monitor works pretty successfully.”

T3 is an example of an organisation which is performing well on the standards published by the CQC and Monitor. The Quality and Safety Manager there put a lot of this down to their good relationship with their CQC manager. They claimed:

“He fosters a collaborative approach so what I don’t mean is a friendly chummy relationship but he is open, you feel you can pick up the phone and call him, also if he has some worrying data on the Trust that he is obliged to investigate he will call us and then we can help him with his investigations. So I feel that’s it’s a good relationship that protects patients because there is an open and transparent relationship between the Trust and the regulator, and whenever

he comes into the Trust, because people are prepared he gets a good response from staff, so they are not frightened of him and he feels he can come in whenever he needs to, so he comes in to do inspections but he also comes in and talks to staff. He has recently been to the matrons meeting, he has helped us run workshops, and come in and talked about what his role is and the role of the CQC is, so there is a slight education component with his relationship with the trust, which is very helpful.”

Also, despite the significant criticisms in this research around the QRPs, T3 Quality and Safety Manager had a different view of them. They argued:

“Yes, I think our experience of working with them in inspections is that we did find a team of inspectors to be a little intrusive in the delivery of patient care but we were able to feed that back to the inspector and he took note of that and normally the inspections are not particularly intrusive. Back to the question of perception, in my dealings with the CQC, not just the inspector, but other inspectors and the Quality and Risk team is that they are responsive and they respond to requests reasonably quickly, they have got better, initially they were dreadful, the information on the website was wrong, and getting it changed took months and months... But they have definitely got quicker and they are better at it, the way in which they behave and run their inspection... I have found them to be very professional, knowledgeable and receptive to feedback... my experience of working with them is that they are a good regulator.”

This Trust is perhaps the exception to the rule in this instance. Whilst it is good that the QRPs are working well in this area, the vast majority of interviewees from other providers suggested that the QRPs were extremely unresponsive and not up to date.

T3 Head of Governance and Development further elaborates on the good relationship this Trust has with their CQC managers:

“I think it is fostered that good relationship by the fact that we have had, it must be four, good inspections. It has sort of fed on itself a little bit and there is a lot of hard work done across the Trust to get the compliance monitoring done, to be aware of problems. Our experience of them has been quite reasonable and when they come in to do inspections in the main they have seemed knowledgeable, the questions have been relevant.”

CCG2 Head of Quality and Governance was also positive about the commissioning landscape and the involvement of clinicians moving forward. They stated:

“What we are waiting for now is we are rearing to go, certainly in CCGs there is an energy and enthusiasm there really is an engagement with clinicians that we haven’t had before from my perspective in quality... it’s brilliant and you can see the difference from clinician to clinician communication makes. Much more willingness when they talk to each other and it’s a different conversation really than from clinician to manager, we had clinicians involved in PCTs before but we didn’t have this level, now most of the time that’s really positive, they are learning, some bits of the structures that aren’t in place that haven’t restructured and become leaner, don’t quite get how lean we are and how our expectations have changed, we are trying to be a different being than a PCT we are trying to be a CCG that is clinically led patient focused that can do things differently, that isn’t bureaucratic”

T1 Director of Compliance and Risk Management was another interviewee who was had praise for the regulators. They claimed that “I think they have been quite separate under the new Health and Social Care Act their roles and responsibilities are going to change and I think there will be more alignment and I think that’s as good thing, a sensible step forward really.”

They also pointed to the idea that regulation has driven up standards over time, and whilst it has its issues and limitations, it is necessary and beneficial. They claimed for instance:

“I’m not a sort of regulation basher because I have worked in the NHS for 26 years, in this organisation when I first started here, I saw people who had been on waiting lists for 9 years so it needed some sort of grip taking of the way health care was provided because it was a very poorly regulated business, so there was a need as a taxpayer to see it was run more efficiently, and I think we did all of that but it’s important to not lose sight: that sometimes you have to spend money to provide a good quality service.”

T2 Chief Executive had a similar view that it has developed and helped over time. They summarised:

“It’s evolving, regulation in health is new, inspection and regulation is completely new, it has just over a 10 year history but if you look at where CHI was versus where we are now it’s come on a long way, it was very crude 10 years ago, it’s better than that, but it still hasn’t worked out where it goes.”

4.8 Positives about regulation: Summary

There has been significant praise for Monitor: it is clear and metrics driven, which providers of healthcare like. Many CQC staff and managers have also been praised at an individual level. Whilst there are numerous reasons and evidence presented related to the deficiencies associated with the regulation of health care in England it is important to acknowledge that regulation is not and inherently “bad” thing.

Whilst it is impossible to say what would have happened without regulation of health care over the past 30 years, the general feeling of interviewees is that it has had a positive impact on quality. Whilst regulation cannot be working 100% effectively in all areas, the identification of unsafe care and subsequent action to remedy this must surely have driven up standards in extremely poor providers even through the limited “safety net” aspects.

4.9 Findings: concluding thoughts

This research has led to a wide range of findings about various aspects of regulation. In line with the research objectives these have been of both a specific (micro) and general (macro) nature, covering a range of policy, political and economic concepts. Full conclusions arising from these findings will be discussed in detail in chapter 7, linked in with the quantitative side of the research (chapter 5) and the case study of Basildon and Thurrock NHS Trust (chapter 6). These conclusions are then used to make recommendations and develop inductive theory about regulation in the health sector. This theory: “Feedback loop theory of regulation” (section 7.8) has been created based on the information contained within these interviews, the secondary quantitative work, as well as the case study. It aims to explain what is going on, why this is occurring and what can be done about it.

Chapter 5: Secondary quantitative research

5.1 Introduction

Health regulation is an area of English public policy which involves a plethora of different bodies operating independently of one another with the purported aim of monitoring standards, ensuring minimum standards are met, and providing assurance for the public and government. These standards differ somewhat in their exact focus, the CQC being primarily based on quality and safety measurements. Monitor focuses on finances and governance (although quality is also becoming part of their remit). These two organisations are “arm’s length” bodies, but also of significance in this arena are Dr Foster Intelligence, who are a private public partnership that publish annual hospital guides based on quantitative measurements.

The purpose of the secondary quantitative research is to ascertain whether regulation generally is having a positive effect on service provision as well as what the relationship between the data collected by these bodies is. The rationale for testing whether the effect of regulation is positive is obvious; it costs money, time and effort, does it work? The rationale for testing the relationships is that providers who score well on quality measures should also be experiencing fewer deaths compared to what would be expected. They should also be the providers who are performing well in terms of finances and governance. Some units will just be well managed, and some badly managed, and this will permeate all aspects of what they do. If there is no relationship between these data sets, then surely something is going wrong; i.e. does the various regulatory monitoring and scrutiny actually measure what it sets out to measure? More than that, if finance and governance scores are negatively correlated with quality scores then financial austerity or overly emphasising governance may actually harm quality.

5.2 Secondary Aims/Research Questions

1. Has the overall average of Hospital Standardised Mortality Ratios (HSMRs) increased or decreased during the period 2002-2011?
2. Is there a statistically significant correlation between HSMRs and CQC data on quality?
3. Is there a significant correlation between HSMRs and Monitor data on finances and governance?
4. Is there a significant correlation between CQC data on quality and Monitor data on finances and governance?
5. To ascertain using linear regression whether it is possible to predict the values of the CQC and Monitor data sets based on the HSMR data set.

5.3 Research Methods

5.3.1 The data sets explained

The data in this analysis is secondary and is extracted from a range of sources from the CQC, Monitor and Dr Foster Intelligence. The CQC data comes in the form of whether or not a provider is currently compliant with the five main “key standards”, and surveys of outpatients, inpatients and accident and emergency departments. The five key standards the CQC measure for each provider are:

- ‘Standards of treating people with respect and involving them in their care
- Standards of providing care, treatment & support which meets people's needs
- Standards of caring for people safely & protecting them from harm
- Standards of staffing
- Standards of management’ (CQC, 2013)

For each provider it is assessed whether they are meeting all five key standards when last checked. It also will indicate whether at least one standard was not being met requiring

improvements, or whether at least one standard is not being met and enforcement action is being taken. Each provider in the sample has been given a score of 0-5 depending on how many of the five key standards are being met upon last inspection.

The CQC surveys on outpatients, inpatients and accident and emergency departments are based on a core of evaluative questions assessing the patients experience at their respective department. These questions are “core” in the sense that they are those questions where results are available from every Trust. The questions are scored on a scale from 0-10 where 0 represents a considerable scope for improvement and 10 refers to the most positive patient experience. These results are also based on standardised data because it is known that views can relate to certain demographic characteristics, and in these surveys the data has been standardised by age, gender and method of admission (emergency or elective). In the sample each provider has been given an overall score out of ten for each survey which is based on the mean for all the other questions in the survey.

The Monitor data is assigned a risk rating for finance and governance taken from their Foundation Trust directory. The risk rating for finance ranges from 1-5 where 1 represents the highest risk and 5 represents the lowest risk. This rating is derived from four financial criteria; achievement of plan, underlying performance, financial efficiency and liquidity.

The governance rating comes in four categories: red (likely or actual significant breach of terms of authorisation), red/amber (breach of terms of authorisation), amber/green (limited concerns surrounding terms of authorisation) and green (no material concerns). This overall rating is derived from; performance against national measures, third parties, mandatory services, board statement factors and other factors.

The Dr Foster data is taken from their annual hospital guides based on HSMRs. The HSMRs represent the “ratio of the observed number of in-hospital deaths with a Hospital Standardised Mortality Ratio diagnosis to the expected number of deaths, multiplied by 100”. This data is based on patients who were involved with an emergency spell with a primary dominant

diagnosis of any of 56 Clinical Classification Software (CCS) groups. The HSMR basket of CCS groups accounts for approximately 80% of all in-hospital deaths in England. It must be made clear that the mean HSMR is not necessarily 100 each year. This is because they are based on expected number of deaths which are derived from logistic regression, adjusting for factors to indirectly standardise for differences in case-mix. Simply put, total actual deaths divided by total expected deaths times 100 equal the HSMR. So if total actual deaths are the same as total expected deaths then the HSMR score will be 100. The way that these expected numbers of deaths are calculated is extremely complicated (please refer to appendix 6 for a fuller explanation).

Data was obtained from Dr Foster Intelligence on HSMRs for all the available years since data collection began. In terms of actual data that is available this means the results are based on the years 2002 to 2011 (available at www.brianjarman.com). Whilst there have been two subsequent hospital guides published these do not include the raw HSMR figure and so have had to be omitted from the analysis.

5.3.2 The Methods

The aim of this research is to use statistical techniques to answer the research questions based on this secondary data. This involves deployment of Excel to collate and synchronise these data sets into one manageable and comparable data set. This information has then been processed into SPSS where relationships and trends can be teased out.

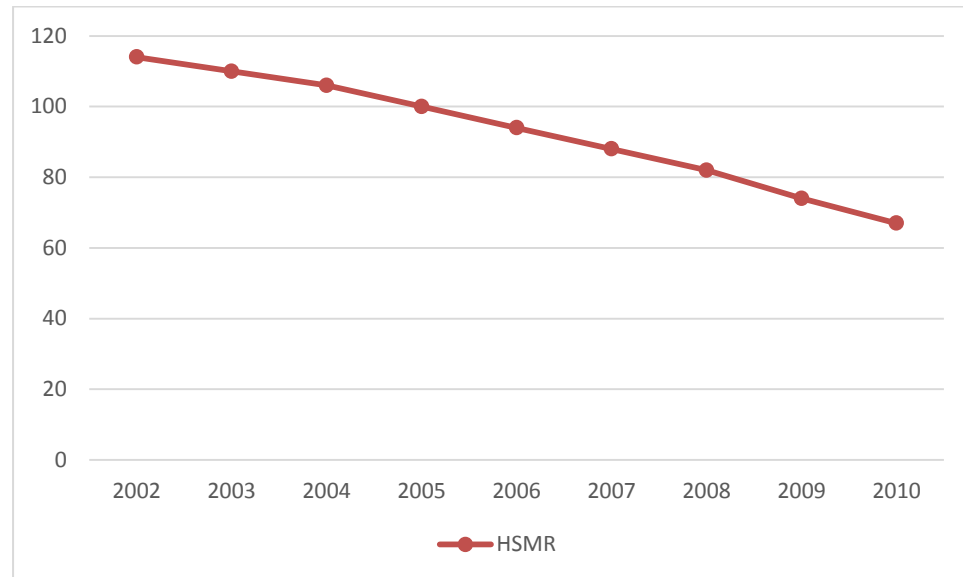
5.4 Findings

5.4.1 RO1: Has the overall standard of Hospital Standardised Mortality Ratios (HSMRs) increased or decreased during the period 2002-2011?

HSMRs in NHS Trusts in England over the period of 2002 to 2011 have consistently gone down. In total the reduction has been by 41.74%, an average of 4% each year, this is displayed in chart 5.1 beneath. This means that using the HSMR measure, less people are

dying compared to how many are expected to in 2011 compared to 2002 and can be considered an improving situation, if HSMRs are an accurate measure.

Chart 5.1: Hospital Standardised Mortality Ratios in England 2002-2011



5.4.3 RO3: Is there a statistically significant correlation between HSMRs and Care Quality Commission (CQC) data on quality?

In order to correlate the HSMRs and CQC data sets it first has to be determined whether or not the data is normally distributed. This was initially done using SPSS to create a histogram of the frequencies (with a line of normal distribution). These visual representations of the frequencies compared to a normal distribution show that some of the data looks normally distributed and some does not. Due to the inconclusive nature of the histograms (as is always the case) they have been omitted from this thesis. The HSMR and outpatient histograms show the data roughly fits the normally distributed line. The CQC five key standards, accident and emergency and inpatient survey histograms suggest that perhaps this data is not normal as it does not fit the projected normal frequency lines.

In order to test normality further (and more effectively) Skewness and Kurtosis is calculated for the variables frequency distributions, this is shown in output 1. Skewness represents deviation from symmetry in a data set. Kurtosis is a measure of whether the data is peaked or flat relative to normal distribution.

Output 1: Skewness and Kurtosis for HSMRs and CQC data

		DR F	the CQC 5 key standards	CQC Accident and Emergency overall	CQC outpatient overall	CQC inpatient overall
N	Valid	145	145	139	140	140
	Missing	28	28	34	33	33
Mean		99.89	4.504	6.701	8.751	5.819
Skewness		-.694	-2.400	-7.190	-.427	-7.766
Std. Error of Skewness		.201	.201	.206	.205	.205
Kurtosis		.434	6.210	71.248	-.283	79.235
Std. Error of Kurtosis		.400	.400	.408	.407	.407

The thresholds of normality for the purposes of this research for Skewness and Kurtosis are from -2 to 2. By this definition, the Dr Foster HSMR data does not look significantly different from a normal distribution, and neither does the CQC outpatient survey data. This information supports the visual evidence on normality. This means that a standard Pearson's correlation can be measured to determine the relationship between the two variables. The Skewness and Kurtosis for the CQC five key standards, accident and emergency and inpatient surveys however do not fit the criteria for normally distributed data, which means that instead a Spearman's Rho correlation coefficient is necessary. Output 2 illustrates the Pearson's correlation between the HSMRs and the CQC outpatient survey. This indicates a very small positive correlation, but no correlation at even $P > 0.05$ (two tailed). It is therefore likely that there is no significant relationship between HSMRs and the CQC outpatient survey data sets.

Output 2: HSMR and CQC Outpatient Pearson correlation coefficient

		DR F	CQC outpatient overall
DR F	Pearson Correlation	1	.166
	Sig. (2-tailed)		.054
	N	145	135
CQC outpatient overall	Pearson Correlation	.166	1
	Sig. (2-tailed)	.054	
	N	135	140

Outputs 3, 4 and 5 illustrate the Spearman's Rho correlation coefficient between HSMRs and the CQC surveys for which the data is not normally distributed.

Output 3: Spearman's Rho correlation for HSMRs and Accident and Emergency surveys

			DR F	CQC Accident and Emergency overall
Spearman's rho	DR F	Correlation Coefficient	1.000	.124
		Sig. (2-tailed)	.	.154
		N	145	134
	CQC Accident and Emergency overall	Correlation Coefficient	.124	1.000
		Sig. (2-tailed)	.154	.
		N	134	139

The HSMR and accident and emergency data (output 3) shows a very small positive correlation. There is no significant correlation at $P > 0.05$ (two tailed). It is therefore almost certain that there is no relationship between HSMRs and CQC accident and emergency survey data sets.

Output 4: Spearman's Rho correlation for HSMRs and inpatient surveys

		DR F	CQC inpatient overall
Spearman's rho	Correlation Coefficient	1.000	-.073
	DR F		
	Sig. (2-tailed)	.	.402
	N	145	135
	Correlation Coefficient	-.073	1.000
	CQC inpatient overall		
	Sig. (2-tailed)	.402	.
	N	135	140

Output 4 shows that there is a very small negative correlation between the HSMR and inpatient data, but there is no significant correlation at $P > 0.05$ (two tailed). It is again extremely likely that there is no correlation between the HSMR and CQC inpatient data sets.

Output 5: Spearman's Rho correlation for HSMRs and the five key standards

		DR F	the CQC 5 key standards
Spearman's rho	Correlation Coefficient	1.000	.006
	DR F		
	Sig. (2-tailed)	.	.947
	N	145	138
	Correlation Coefficient	.006	1.000
	the CQC 5 key standards		
	Sig. (2-tailed)	.947	.
	N	138	145

Output 5 displays no correlation whatsoever at any level of significance between the HSMR and five key standard data sets. This clearly demonstrates that there is no relationship between HSMRs and the CQC five key standards.

5.4.4 RO4: Is there a significant correlation between HSMRs and Monitor data on finances and governance?

In order to test whether the Monitor data sets are normally distributed, frequency histograms with normal curves on (for comparison) have been created. Again these are omitted from the research paper due to their inconclusive nature. The finance histogram illustrates that the frequencies are slightly skewed with more falling on the right hand side, tailed off to the left. It is unclear whether this Skewness is within the normal range. The governance histogram shows edge peak distribution due to the high numbers of ones and fours on the governance scores. Based on the visual representation it appears that the governance data set is unlikely to be normally distributed. The frequency histograms show deviations from the normal line but these could still be within the realms of normality. The Skewness and Kurtosis of the data is therefore worked out, this is displayed in output 6.

Output 6: Skewness and Kurtosis for Monitor finance and governance scores

	Monitor Finance Scores	Monitor Governance Scores
N Valid	86	86
Missing	87	87
Mean	3.02	2.95
Skewness	-1.002	-.667
Std. Error of Skewness	.260	.260
Kurtosis	1.472	-1.149
Std. Error of Kurtosis	.514	.514

These figures show the data can be treated as normally distributed, as the Skewness and Kurtosis are both within the threshold of -2 to 2. This means that to measure the correlation a Pearson's correlation coefficient test is deployed (outputs 7 and 8).

Output 7: HSMR and finance Pearson correlation

		DR F	Monitor Finance Scores
DR F	Pearson Correlation	1	.016
	Sig. (2-tailed)		.892
	N	145	76
Monitor Finance Scores	Pearson Correlation	.016	1
	Sig. (2-tailed)	.892	
	N	76	86

Output 7 indicated that there is no significant correlation at $P > 0.05$ (two tailed). This suggests that there is no relationship between HSMR and Monitor finance data sets.

Output 8: HSMR and governance correlation

		DR F	Monitor Governance Scores
DR F	Pearson Correlation	1	-.034
	Sig. (2-tailed)		.769
	N	145	76
Monitor Governance Scores	Pearson Correlation	-.034	1
	Sig. (2-tailed)	.769	
	N	76	86

Output 8 indicates that there is a very small negative correlation but not a significant correlation at $P > 0.05$. This also suggests that there is no relationship between the HSMRs and Monitor governance data sets.

5.4.5 RO5: Is there a significant correlation between CQC data on quality and Monitor data on finances and governance?

It has already been established that the CQC data for outpatients and the Monitor data for governance and finances is normally distributed. It has also been established that the CQC data for the five key standards, inpatient surveys and accident and emergency surveys is not normally distributed. On this basis the outpatient survey and Monitor data sets has been tested using Pearson's correlation coefficient (output 9). Similarly the five key standards, inpatient surveys and accident and emergency surveys have been tested against the Monitor data using Spearman's Rho correlation coefficient (output 10).

Output 9: Outpatient and Monitor Pearson's correlation coefficient

		CQC outpatient overall	Monitor Finance Scores	Monitor Governance Scores
CQC outpatient overall	Pearson Correlation	1	-.046	-.050
	Sig. (2-tailed)		.699	.673
	N	140	74	74
Monitor Finance Scores	Pearson Correlation	-.046	1	.617**
	Sig. (2-tailed)	.699		.000
	N	74	86	86
Monitor Governance Scores	Pearson Correlation	-.050	.617**	1
	Sig. (2-tailed)	.673	.000	
	N	74	86	86

** . Correlation is significant at the 0.01 level (2-tailed).

Output 9 illustrates that there is no correlation between either Monitor finance or governance scores and the CQC outpatient surveys at even P.0.05 (two tailed). This suggests that there is no relationship between outpatient and finance data, or outpatient and governance data.

Output 10: Spearman's Rho correlation coefficients for Monitor data and CQC data sets which are not normally distributed

Correlations			the CQC 5 key standards	Monitor Finance Scores	Monitor Governance Scores	CQC inpatient overall	CQC a and e overall
Spearman's rho	the CQC 5 key standards	Correlation Coefficient	1.000	-.065	-.169	.056	.063
		Sig. (2-tailed)	.	.579	.144	.509	.461
		N	145	76	76	140	139
	Monitor Finance Scores	Correlation Coefficient	-.065	1.000	.540**	.045	-.028
		Sig. (2-tailed)	.579	.	.000	.706	.814
		N	76	86	86	74	74
	Monitor Governance Scores	Correlation Coefficient	-.169	.540**	1.000	.066	-.180
		Sig. (2-tailed)	.144	.000	.	.575	.125
		N	76	86	86	74	74
	CQC inpatient overall	Correlation Coefficient	.056	.045	.066	1.000	.448**
		Sig. (2-tailed)	.509	.706	.575	.	.000
		N	140	74	74	140	139
	CQC a and e overall	Correlation Coefficient	.063	-.028	-.180	.448**	1.000
		Sig. (2-tailed)	.461	.814	.125	.000	.
		N	139	74	74	139	139

** . Correlation is significant at the 0.01 level (2-tailed).

Output 10 indicates that the Monitor data on finance and governance is correlated at a significant level. The correlation coefficient between finances and governance is positive, 0.617 at a significance at $P > 0.01$ (2-tailed). This data may suggest that attempts by Monitor to measure these variables are more of a box-ticking process, due to the significant correlation. It may be the data has little relevance when it comes to actual quality in terms of service provision and safety.

There are positive correlations between the Monitor and CQC data, but there is however no correlation of significance at $P > 0.05$ (two tailed) between the Monitor financial data and any of the CQC data sets (which are not normally distributed). There is also no correlation of significance at $P > 0.05$ (two tailed) between the Monitor data on governance and any of the CQC data (which are not normally distributed).

5.4.6 RO6: To ascertain using linear regression whether it is possible to predict the values of the CQC and Monitor data sets based on the HSMR data set.

Using linear regression it is possible to attempt to predict one variable from another, the dependent variable (outcome) is predicted using a model based on the independent variable(s) (predictors). So measuring the Pearson correlation coefficients previously allowed to measure the relationships between variables, but regression allows this to be taken a step further and say for example; what is the impact of increasing a CQC standardised score by one on the HSMR for a provider? The assumption being that if the measures accurately portray quality then a score of better by one on the CQC data set should result in a decrease of a certain amount on the HSMR, because the CQC measures the provider to be safer and then therefore less people die there.

As linear regression is a parametric test it requires data that is normally distributed. Consequently not all the CQC data sets are suitable for this analysis. The CQC outpatient surveys however, as previously discussed do fit the criteria of normality. The main assumption associated with linear regression is that of heteroskedasticity; which means in general terms, differences in variances. This refers to the observations of the variance of the residuals in the analysis not being consistent or constant across the predictor variable so the predictive power of the regression analysis should be roughly equal from low levels of the X value to high levels of the X value. This is tested using a histogram of the residuals of the dependent variable, is also tested using a normal probability plot. Also to test this, the Z predictor variable at X and the Z predictor variable at Y to create a scatter plot, this can be analysed for heteroskedasticity.

As earlier described there is a Pearson correlation coefficient of .166 between the Dr Foster HSMR and CQC outpatient data sets. This is a very small positive correlation which is not significant at even $p > 0.05$. Output 11 summarises the linear regression model for HSMRs and outpatient surveys.

Output 11: Linear regression model for HSMR and outpatient surveys model summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.166 ^a	.028	.020	9.621

a. Predictors: (Constant), CQC outpatient overall

b. Dependent Variable: DR F

The R score replicates the Pearson's correlation coefficient. The R square score shows that 2.8% of the variability in HSMR can be explained by the scores on the outpatient surveys. So this is not a meaningful predictor, and it accounts for a miniscule amount within this. Taking sample size into account SPSS has adjusted the R squared to .020 which means that more realistically only 2.0% of the variance can be explained by the outpatient surveys, a relatively trivial difference, but this negates the predictive nature of the relationship even further. Output 12 is the ANOVA table related to the linear regression.

Output 12: ANOVA table for linear regression**ANOVA^a**

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	349.452	1	349.452	3.775	.054 ^b
	Residual	12311.541	133	92.568		
	Total	12660.993	134			

a. Dependent Variable: DR F

b. Predictors: (Constant), CQC outpatient overall

This essentially tells us whether the correlation of 0.166 is significant. There is an F value of 3.775 and a significance of .054.

Output 13: Coefficients with 95% confidence intervals**Coefficients^a**

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	35.820	33.039		1.084	.280	-29.529	101.169
1 CQC outpatient overall	7.334	3.774	.166	1.943	.054	-.132	14.799

a. Dependent Variable: DR F

Output 13 illustrates the coefficients with 95% confidence intervals. The standardised Beta score is the same as the correlation coefficient, as is the statistical significance based on the t distribution. So it is known that the correlation is not statistically significant at $p > 0.05$. We now know that because unstandardised Beta is 7.334 if you increase CQC outpatient survey score by one then we expect a 7.334 increase in HSMR for the provider.

The confidence intervals of 95% for Beta illustrate that there can be no real certainty around this because both the constant (intercept) and CQC outpatient scores range from the negative (-29.5 and -0.132) to the positive (101.2 and 14.8). So actually, if 95% confidence intervals are applied the 7.334 increase in HSMR per one unit increase in outpatient survey is between -0.32 and 14.8.

Output 14: Residual statistics**Residuals Statistics^a**

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	95.96	104.02	99.99	1.615	135
Residual	-28.890	21.110	.000	9.585	135
Std. Predicted Value	-2.499	2.496	.000	1.000	135
Std. Residual	-3.003	2.194	.000	.996	135

a. Dependent Variable: DR F

Output 14 is a table for Residual Statistics which are used to check heteroskedasticity. As the residual values for the mean is zero, the histogram looks normally distributed, and the normal P-P plot (output 15 see appendix 9) looks to be relatively straddling the regression line, so heteroskedasticity is present. Furthermore the scatter plot (output 16 see appendix 9) between regression standardised residual and regression standardised predicted value is like a bird's nest i.e. there is no associated pattern with the error of the variables, which confirms the heteroskedasticity of the data.

5.5 Conclusions

5.5.1 RO1: Has the overall average of Hospital Standardised Mortality Ratios (HSMRs) increased or decreased during the period 2002-2011?

The overall average HSMR for England has decreased by an average of 4% per year during the period 2002-2011. With a consistent year on year reduction, the total decrease was 41.74%.

What exactly does this mean?

It means that if we are to believe that the Dr Foster HSMRs are true representations of the ratio between how many people die compared to how many people should die at hospitals, then less people are dying now in hospitals verses how many should die, compared with all the previous years when data has been collected.

The problem is that there are reasons which means the data coding techniques of Dr Foster may not be valid and true representations of mortality rates. Mohammed et al. (2009) published an influential paper titled "Evidence of methodological bias in hospital standardised mortality ratios: retrospective database study of English hospitals". This paper is heavily critical of HSMRs as an accurate measure, due to the coding and risk predictions that make them up. This article goes on to conclude that "variations in hospital standardised mortality ratios from Dr Foster Unit reflecting differences in quality of care are less than credible" (2009 p.228). Thus it is possible that this decrease in HSMRs over time does not truly represent an improvement of hospital quality.

In Appendix 9 of the Francis Enquiry (vol. 1) there is a detailed review of mortality statistics produced by two Harvard academics. This also points out that there is no fully reliable method for quantifying health care quality. It is stated:

“We accept that there is no single, perfect mechanism for assessing health care quality. We also agree that every statistical quality monitoring algorithm, including Dr Foster, should be critically examined by experts to determine its validity.” (2010 p.440)

There is, however, significant evidence in this paper which means that Dr Foster HSMRs should not be ignored or written off completely due to the methodological flaws. The conclusion on HSMRs is as follows:

“The HSMR is a summary figure, designed to give an overview of mortality within a Trust, and we accept it will hide a considerable number of differences in the risk profiles across different factors in the model, but we do not see why this should decrease the value of the HSMR as a summary figure used in conjunction with other measures”. (2010 p.442)

Specifically referring to the Mohammed et al. (2009) research it is stated:

“We are disturbed by the final sentence summarising the author’s conclusions: “In other words, quality of care should remain innocent until proven guilty”. This is a hospital-centric admonition, but certainly not one that would be acceptable to most patients or to the regulators entrusted with ensuring the quality of their care.” (2010 p.446)

Despite the disclaimers by Mohammed et al. (2009) (which were in effect discussed by Francis) it still raises the question: could HSMRs even at the time of The Mid Staffordshire NHS Foundation Trust debacle (2005-2009) not have shown trends over time, or hospital to hospital, as cause for worry? This could perhaps be considered as a middle way between Mohammed’s purism and the view that Mid Staffordshire did indeed have 1,200 deaths too many. It is possible to concede HSMRs do not show the whole picture, but they do certainly show an important part. The Francis report into the failures at Mid Staffordshire has identified there were three types of data at the time that should have signalled the issues. This could not have helped matters, in terms of Mid Staffordshire being authorised as a Foundation Trust (which are supposed to be models of best practice). The three warning signs should have

come from HSMRs, CQC (or Healthcare Commission previously) data and Monitor data. The balance of hard versus soft data has evidently not been right and the mechanisms for triangulating the three types of data needs to be enhanced, if these failures are to be avoided.

Clearly Mid Staffordshire has been an example where HSMRs increasing was not noticed quickly enough and resulted in far too many people dying. This deficiency still remains a wide concern, as there are 14 Trusts which have been identified by the Department of Health as having over than expected death rates and one of the main possible causes is medical staffing levels.

The NHS Commissioning Board has identified the Trusts, following the publication of the Francis report, they are as follows: North Cumbria University Hospitals, United Lincolnshire Hospitals, George Eliot Hospital, Buckinghamshire Healthcare, Northern Lincolnshire and Goole Hospitals, The Dudley Group of Hospitals, Sherwood Forest Hospitals, Medway, Burton Hospitals, Colchester Hospital, Tameside Hospital, Blackpool Teaching Hospitals, Basildon and Thurrock University Hospitals and East Lancashire Hospitals. (2013 p.1)

Bearing the validity of the HSMRs in mind, the fact that they have been measured by Dr Foster Intelligence to be decreasing over the measurable period is good. Whilst cause and effect of this reduction of HSMRs over the period cannot be fully ascribed, the fact that they are going down and not up is good.

5.5.3 RO3: Is there a statistically significant correlation between HSMRs and CQC data on quality?

There is no significant correlation between HSMRs and any of the four CQC quality related data sets. This means that at least one of the two variables is not accurately measuring what they are supposed to: portraying quality in a useful way.

This is based on the rationale that; if safety and quality outcomes in hospitals are measured accurately, then this should correlate with the amount of people dying there compared to how many should die (if measured accurately). Based on the discussion previously on HSMRs it is assumed that these do represent quality to some extent at least. If we accept that HSMRs at least “give an overview of mortality” then the CQC data may not be properly represent quality in its measurements.

The five key standards include safety, care, respect, staffing and management. It must be the case that these sorts of measures, if accurate, would correlate with HSMRs. They do not however at any level of significance. The CQC accident and emergency, outpatient and inpatient surveys all do not correlate with HSMRs. These are national surveys, which are undertaken periodically over hundreds of locations. It again seems logical to assume that if these measurements accurately portray quality they would correlate with the HSMR (even with the HSMR critique considered). If these things are not obtaining the information they are supposed to, information which is relevant on quality and relevant for the regulation of hospitals for policy makers, then different techniques for data collection in this area should be deployed. It is possible that the CQC rely too heavily on “soft” data on quality such as surveys, observations and self-reported information. HSMRs are based on actual numbers of people dying this can be considered “hard” data on quality (criticisms on the expected death algorithm considered). If the soft data sets collected on quality do not accurately portray quality, this renders the whole process pointless. If quality is not measured with hard data it seems inevitable that if providers in England deteriorate, the CQC may not notice.

5.5.4 RO4: Is there a significant correlation between HSMRs and Monitor data on finances and governance?

All the logic seems to point to there being an inextricable link between finances and governance on the one hand and quality on the other. But based on the data sets, it seems that neither governance nor financial scores positively or negatively correlate with HSMRs. In this case the evidence on finances and governance are less likely to be unreliable. Many of

the elements of the Monitor weightings on risk are quantifiable variables which are not open to interpretation (as with some of the CQC and Dr Foster data). Returns surpluses and liquidity ratios, for example, are unlikely to be false. The lack of correlation between HSMRs, finances and governance shows that it is quite possible to be performing well financially and governance wise, but be performing poorly HSMR wise. The converse is equally true.

It is perhaps disappointing that there is no correlation. If organisations which were performing well financially and are effectively governed performed favourably on their HSMR score, then this would add clout to the argument that the work of Monitor was driving up standards. There is, however, another argument that the Monitor assessing regime is merely a box ticking process. If we are to doubt the reliability of the Monitor data at quantifying finance and governance robustness then perhaps there is an inseparable link between quality and finance, as well as quality and governance, but this is not clear from the data because the nature of Monitor regulation is bureaucratic and does not measure what it is supposed to.

5.5.5 RO5: Is there a significant correlation between CQC data on quality and Monitor data on finances and governance?

There is no significant correlation between the CQC and Monitor data sets. The reasons discussed previously explain why the CQC data may not accurately quantify quality, which may explain the lack of correlation. But equally it may be that quality does not actually correlate with either finances or governance.

5.5.6 RO6: To ascertain using linear regression whether it is possible to predict the values of the CQC and Monitor data sets based on the HSMR data set.

The linear regression between the CQC outpatient surveys and the Dr Foster HSMRs was revealing in several ways. The model predicts that for an increase in the CQC outpatient survey of one unit, there will be an increase in HSMR by 7.3. This is very troublesome because it is the opposite of what would be anticipated to be the case.

It is logical to assume that a better score for quality based on outpatients surveys would be a predictor for how many people die and that as the outpatient scores increase (get better) the amount of people dying will decrease (improve). The fact that the converse is true suggests that there are serious limiting factors with the methodologies deployed by the CQC in their outpatient surveys, and there may well be issues with the HSMRs also (as has been discussed already). The 95% confidence intervals do illustrate that the figure of 7.3 may not be entirely accurate, but with a range of -0.132 to 14.8 it is appropriate to suggest that the opposite of what should be occurring is almost certainly occurring: as scores for outpatients improve, scores for death rates worsen, seriously limiting the validity and usefulness of the data sets involved.

5.5.7 What does this all mean for the arm's length bodies and their effectiveness at positively influencing health policy?

The fact is: there are reasons to doubt all attempts of quantifying quality in any capacity. There are important lessons to be learnt for the NHS in England as well as internationally. Many countries around the world deploy regulation of a similar nature in (some capacity at least) and these countries should take note of the trends of the NHS in England. There are certainly many deficiencies associated with the current regulatory regime in English health policy, which have been confirmed by the lack of the data sets to correlate with one another. If arm's length bodies are not measuring what they are supposed to the service is likely to suffer. There is an overreliance on "soft" rather than "hard" data, which limits the effectiveness of regulation. There is also too much "box ticking" which has no value to health policy, and actually creates additional bureaucracy.

A tempting conclusion may be that the composite regime of health regulation in England is having a neutral effect on quality at best. There is approximately no evidence of any link between providers graded highly by regulators and the normalised deaths among their patients. Indeed, it could be argued that the cost of the regulation, both in the regulators and servicing their requirements in the providers, uses resources which could be better allocated

elsewhere. But this may be too superficial a view. The existence of the regulatory bodies, and the public visibility of their findings, may be exerting an overall upwards pressure on service quality, and this may be why the HSMR figures have decreased consistently over the time period 2002-2011. This possibility cannot be assessed through the kind of analysis contained in this paper as cause and effect of the changes in HSMRs cannot be ascribed. What can be determined though is that there is no relationship between the CQC, Monitor and Dr Foster datasets.

5.6 Evaluation

One of the obvious criticisms of this part of this research is that the data is not the author's own. This is something which comes with the nature of these types of research questions, in that the researcher is attempting to assess the relationships between data sets that are not their own. This does bring the question of reliability of these data sets, but that is what is being investigated, and cannot be avoided.

A further criticism of this research is that there is some missing data in the data sets, there is, however always a reason for this. For instance, some of the Dr Foster historical HSMR data is missing in some of the early years, when their remit was less than it now is. Furthermore the Monitor data sets are only for Foundation Trusts, as that is who they regulate, and therefore it has been compared to the corresponding data for Foundation Trusts, not all providers. There is also the issue of Trusts merging into one another or closing down completely, which means there is not information for all years for all providers. That being said these missing values have been taken into account in this quantitative analysis and the number of missing values is minimal.

Chapter 6: Case Study - Basildon and Thurrock NHS Foundation Trust and The Keogh Mortality Review (2013)

6.1 The Keogh Mortality Review (2013)

The 2013 Keogh Mortality Review offers further substantial evidence that supports the findings of this research surrounding bureaucracy and the failure of the various health regulators to properly share information as well as their methodological deficiencies. 14 NHS Trusts are identified (following Mid Staffordshire) in the review; pointing to high death rates, mortality and weekend deaths. This provides significant support for the view that regulation has associated deficiencies, particularly because one of the 14 identified in this report was Basildon and Thurrock.

One of the main reasons Basildon and Thurrock is of particular significance, is that it is an example which involves a great number of regulatory healthcare regimes, showing their interaction with the Trust, and with one another, over many years. This is the main reason why it has been included as a case study in this research. The outcome of this interaction has not been positive. In 2009, the CQC were responsible for conducting research to assess the Trusts quality in many ways, such as their annual health check. Dr Foster Intelligence was responsible for making public the degree to which mortality rates had increased beyond the national average. Monitor was subsequently required by the CQC to send in a task force to remedy the situation. The fact that these three regulatory bodies feature heavily in this case study allows a deeper understanding of their effectiveness in their respective roles, with reference to a specific micro-regulatory example of their associated deficiencies.

In 2009 Basildon and Thurrock University Hospitals NHS Foundation Trust was heavily covered by the media due to emerging scandalous headlines concerning its care. It is an example of a hospital which was classified as “good” and “excellent” by the CQC, and then given the worst overall patient safety score by Dr Foster in its hospital guide published weeks later. It is revealing to examine how the two bodies arrived at such differing ratings for the hospital, through extensive scrutiny of the methodologies they used to arrive at these ratings.

6.2 Basildon and Thurrock in 2009: The CQC

Prior to the worst Dr Foster HSMR rating it received in 2009, the CQC rated Basildon and Thurrock as “good” for overall quality of services in 2008/09. This compares to “excellent” in 2007/08, “fair” in 2006/07, and “good” in 2005/06. This overall score compiled by the CQC measures a range of areas including safety of patients, cleanliness and waiting times (CQC 2009 I p.1). In 2009, this Trust fell into the same category as 48.2% of Trusts (good) and appeared to be better than average in terms of the services it provided for consumers of health care.

In relation to meeting the core (basic) standards set out by government, Basildon and Thurrock was categorised as “almost met”. This is because the Trust complied with 42 of the core standards but not C07a and c - Governance or C21 - clean, well designed environment (CQC 2009 II p.1). The Governance standard that Basildon did not meet was met by 93.3% of all Trusts and the clean, well designed environment standard was met by 87.8% of all Trusts.

The CQC stated that there existed a poor overall system of clinical governance, corporate governance and risk management practices within the trust (CQC 2008/09 I p.2). There were a number of reasons for this statement. The CQC was concerned that the Trust was not doing enough to reduce the rates of mortality, or monitor these rates in any great detail. Accident and emergency accountability and working relationships were unclear, due to no operational policies for staff reference. Poor medical workforce planning did not ensure enough accident and emergency consultants, as well as middle grade staff, to support the quality of care to patients. There was a lack of clear leadership in accident and emergency and a lack of consistent senior medical input (CQC 2008/09 I p.2). Nursing care concerns arose due to audits and significant patient complaints. There was a lack of systems in place to monitor and evaluate actions taken for assurance purposes (CQC 2008/09 I p.3). There were also concerns at board level relating to the sustained focus on quality of care and outcomes, especially in relation to clinical care.

The inspectors raised concerns, related to both clinical governance practices and capacity

issues in coping with the size of the medical take. This resulted in lengthy transfers to critical care, general capacity problems and difficulties in finding appropriate beds (CQC 2008/09 I p.3). Significant concerns came to light in reference to the design of the hospital. Privacy and dignity were not protected adequately and child friendly areas were minimal. The CQC recommended that the rebuilding work within accident and emergency should be pursued as a matter of urgency as the report letter made clear that the accident and emergency environment is poor (CQC 2008/09 I p.3).

Significant criticism of the arrangements for children in the accident and emergency department were levied. It was claimed that inspectors reported that children did not appear to be treated any differently than adults (CQC 2008/09 I p.3). The accident and emergency department was further criticised for its lack of adherence to hygiene procedures. This was described as an on-going problem, especially relating to infection control and prevention guidance.

In relation to the core standard C21 (clean, well designed environment) the CQC argued that; a number of lapses have been identified for this standard which, when taken together, constitute a significant lapse (CQC 2008/9 II p.2). These lapses included as previously mentioned; poor hygiene procedures, problems with accessibility of services when the hospital was busy, significant capacity issues, leading to the use of unsuitable settings for treatment. Again, problems with the accident and emergency department concerning privacy and confidentiality; patients were being cared for on trolleys, which were positioned in dedicated spaces around the edges of the major area. When all the spaces were full, additional patients are positioned in the centre of the room (CQC 2008/9 II p.2).

It is worth noting, that on both these basic standards which the CQC decided that Basildon and Thurrock has not met, the Trust itself reported no problems. On the contrary, the Trust reported in its self-assessment submitted to the CQC that it was conforming to the national core measures. This clearly emphasises the scope for self-administered assessments of performance being unreliable. It was only through further inspection that the CQC decided

that Basildon and Thurrock was not meeting the basic standards. The Trust's Internal Auditors independently checked the evidence relating to six core standards (C1a, C2, C8b, C11b, C13c and C15b) and the 47 related elements and provided 'adequate assurance' that the Trust had in place sufficient evidence to support the self-assessed compliance level.

These internal auditors mentioned are Essex and Southend LINK. Essex and Southend LINK are a Government funded organisation that seeks to improve health and social care in their area. In this internal assessment they justify why each area is considered compliant with national core standards. C07a and c - governance are excluded from the justification element of the report with no explanation whatsoever.

The statement explaining why they considered themselves compliant for C21 - clean, well designed environment states: public awareness of the importance of cleanliness has been raised over the past few years. The report regarding their visit in December did not make good reading when headlined in the local press. The Chief Executive did make a response putting in context the hospital's commitment and progress on hospital acquired infections: "the LINK has been assured that the remedial actions have been accepted. The issue is one which is perpetually with the hospital and needs continual monitoring by all involved. We are pleased to hear that Executive Directors do walk the floor with clinicians checking that standards are being maintained." (CQC 2008-09 I p.5)

Another interesting factor to this internal self-assessment is the number of overview and scrutiny committees used to validate the self-assessment. The maximum the CQC allows is ten. Basildon and Thurrock used only one, Essex County Council, and the depth of the committees review was superficial at best: it only amounts to one paragraph which is critical of the nature of the process it is itself involved in. It states:

"For some time, the Committee has had concerns about the usefulness of this exercise. As the results are not published until October, any data is then at least six months old (and often older). The Committee also feels that it has now established robust and adult relationships

with all the health bodies in Essex. As a result, any issues of concern are raised as soon as they arise and are dealt with in a constructive way locally and immediately. Should the Committee ever have major concerns which could not be resolved; it would raise these with the national regulatory body at the time and not wait for an end of year 'sweep up'." (CQC 2008-09 I p.15)

In terms of the existing commitments that Trusts are already expected to be compliant with Basildon and Thurrock was categorised by the CQC as mostly met (CQC 2009 II p.1). This was due to there being one existing commitment indicator which was not met; patients waiting longer than three months (13 weeks) for revascularisation. 94% of Trusts achieved this level.

In the national priorities assessment Basildon and Thurrock achieved a good rating (CQC 2009 II p.1). This was despite the Trust underachieving on two measures; stroke care and participation in heart disease audits. Furthermore the Trust failed on 18 week referral to treatment times. Only 3.6% of all trusts failed on this measure (CQC 2009 II p.1), showing that the Trust was in a minority who were struggling in this area.

With regard to its financial management the CQC gave Basildon and Thurrock University Hospitals Foundation Trust a rating of excellent. (CQC 2010 III p.1) This had been the case for the four previous years and there is no evidence to suggest that this was inaccurate.

In the CQCs analysis of Basildon and Thurrock's control and prevention of diseases, the Trust was found to be conforming to the required levels of protection for patients (CQC 2010 IV p.1). This was therefore an area in which the Trust was performing well.

In the CQC section which analyses Basildon and Thurrock's children's hospital follow up services, a lot of problems were outlined. For instance, there are many areas where targets were consistently not met (CQC 2010 V p.1). Of the nineteen children's service indicators that were measured ten were classified as consistently low performing and a further three were classified as deteriorated (CQC 2010 V p.1). Clearly the children's services at Basildon and

Thurrock were considerably poor in their quality, even despite previous warnings.

The CQC also conducted outpatient and inpatient surveys. For these surveys they measured the responses to be around average when compared to other Trusts. (CQC 2010 VI p.1)

Therefore these results were not a particular cause for concern.

In conclusion, it is very hard to see how the CQC arrived at their “good” rating for Basildon and Thurrock in 2009, prior to the Dr Foster HSMR publication. This cannot be emphasised enough. There were issues identified in the following:

- Governance - poor overall system of clinical governance, corporate governance and risk management practices within the trust.
- Clean, well designed environment – CQC identified as failing
- The Trust was not doing enough to reduce the rates of mortality, or monitor these rates.
- Failure on accident and emergency accountability and working relationships.
- Poor medial workforce planning.
- Nursing care concerns arose due to audits and significant patient complaints.
- There were concerns at board level relating to the sustained focus on quality of care and outcomes, especially in relation to clinical care.
- Concerns, related to both clinical governance practices and capacity issues.
- Lengthy transfers to critical care, general capacity problems and difficulties in finding appropriate beds.
- Privacy and dignity were not protected adequately and child friendly areas were minimal.
- Significant criticism of the arrangements for children in the accident and emergency department.
- Accident and emergency department was criticised for its lack of adherence to hygiene procedures.
- CQC found the Trust not to be meeting: patients waiting longer than three months (13 weeks) for revascularisation.
- Stroke care and participation in heart disease audits.
- CQC found the Trust to be failing on 18 week referral to treatment times.

The issues that have been outlined at the Trust were significant, across a number of areas, and they even specifically mention a concern around mortality rates. This supports the view that the methods used by the CQC at the time did not succeed in capturing quality and risk at Basildon and Thurrock. It is amazing to think that all these things were known to the CQC but they still rated the Trust as good in 2009.

6.3 Basildon and Thurrock in 2009: Dr Foster

Three weeks after the CQC judgement Dr Foster's annual hospital guide was published. The hospital guide published by Dr Foster in 2009 indicates that; Basildon and Thurrock University Hospitals NHS Foundation Trust had a mortality ratio 31 per cent above the national average (Dr Foster Hospital Guide 2009 p.4). Using a set of indicators and a z-scoring methodology, Dr Foster assessed all NHS acute trusts across a range of safety indicators and assigned a banding and score based on their performance (Dr Foster Hospital Guide 2009 p.10). On this scoring system Basildon and Thurrock came last out of all the trusts who gave data.

In 2009 the Basildon and Thurrock University Hospitals NHS Foundation Trust told Dr Foster that, for at least one NPSA alert, they would not be compliant in the next six months with staffing levels and recruitment (Dr Foster Hospital Guide 2009 p.11). In 2009 Basildon and Thurrock University Hospitals NHS Foundation Trust had experienced consistently high HSMRs for the past five years currently had a mortality ratio 31 per cent above average that year. The overall patient safety score for Basildon and Thurrock was 0, the worst score from any trust (Dr Foster Hospital Guide 2009 p.15).

In the patient safety section on Basildon and Thurrock in the hospital guide; overall death rate, death rate for emergency admissions, death rate for heart attack patients, compliance with National Patient safety guidelines were all measured by Dr Foster to be below expected. The remaining nine safety measures in the report for Basildon and Thurrock were all in line with expected rates. This scoring equates to a banding of one for Basildon and Thurrock (the worst banding) and an overall patient safety summary score of zero (the worst result of any

trust). In terms of clinical effectiveness, the trust scored one below expected in the proportion of day-case patients end up staying longer for treatment. The patient experience indicators are all in line with expected levels.

Dr Foster arrives at the patient safety score for each trust based on a whole range of different statistical tests on different factors. The first measure is as follows: based on the recommendation from the Healthcare Commission (2009), relative risk-based indicators were transformed thus: $z = 2(\text{"observed"} - \text{expected})$. Rates were transformed by subtracting the mean value for the rate then dividing by its standard deviation. Categorical data (e.g. yes or no questions) were mapped onto a scale between 2.5 and +2.5. Before aggregating, all z-scores were capped at ± 3 to stop a single extreme value dominating the aggregate score.

(Dr Foster 2009 p.34)

They then used these Z scores to produce aggregated Z scores ranging from high to low. As is appropriate with Z scores (also called standardised scores) they then subtracted them by the mean value and then multiply them by the standard deviation, so they behave like Z scores. They then used Bayesian ranking to remove the likelihood of the associated degree of uncertainty affecting overall data analysis and rankings. These relative risk indicators come from numerous procedures and treatments and measure how the Trust is doing compared to the national average as well as using the yes or no responses to questions to influence these scores. In 2009 the only crude ratio used by Dr Foster was the staff/bed ratio and this will be kept fixed as it is within a hospitals control (Dr Foster 2009 p.35).

To ensure the robustness of the statistical ranking through Z scores they state: "To ensure this was sufficient, we ran the procedure for an additional 50,000 iterations and verified that the trusts in the top and bottom 10 remained unchanged for each domain indicator" (Dr Foster 2009 p.35).

The scores are then given a median rank and then these ranks are adjusted to fit within 0 and 100 (100 being the best). This is how Dr Foster arrived at their score of 0 for Basildon and

Thurrock University Hospitals Trust. The banding it received, of one (on a range of one to five) reflects the degree of uncertainty in the overall Z score. Some Trusts will have received a low score but not a particularly low banding; this is due to their being more chance that data errors or anomalous results. Evidently this is not the case for Basildon and Thurrock as it received the worst score in both the rank and the banding.

6.4 Basildon and Thurrock in 2009: Monitor

In 2009, after the publication of the Dr Foster HSMR scores, Monitor entered the picture. Progress at Basildon and Thurrock is reported to have been assessed very closely by Monitor. In 2010 Monitor claimed that “the Trust has systematically and substantially improved its performance in key areas of quality which were the cause of concern to the CQC” (Monitor 2009/10b p.67).

The CQC escalated its concerns (which coincide with Dr Foster Hospital Guide publication) to Monitor, and in November 2009 Monitor found the Trust to be in significant breach of the following terms of authorisation and intervened under S52 of the National Health Service Act (2006).

Monitor has been substantially involved with Basildon and Thurrock since the 2009 intervention. This has involved regulatory enforcement action in 2009, and periodic updates of the Trusts performance in terms of finance and governance.

6.5 Basildon and Thurrock in 2013: Conclusions

Since the intervention by Monitor in November 2009 the Trust has received related visits, reports or correspondence from Monitor, the Care Quality Commission, the Health and Safety Executive, the East of England Strategic Health Authority, the NHS South West Essex Primary Care Trust, the Nursing and Midwifery Council and East of England and London Deaneries. (Monitor 2009/10b p.112)

Bearing in mind the significant regulatory actions taken by Monitor and the CQC in 2009, as well as the Dr Foster identification in that the provider had experienced consistently high mortality figures for the preceding five years, it is fair to describe this as a Trust where a lot has gone wrong. A lot of effort has been made by the arm's length bodies operating in the arena to point this out, and remedy the situation. See the table below which illustrates the timeline:

Table 6.5: Basildon and Thurrock: Regulatory timeline 2005-2010

	2005	2006	2007	2008	2009	2010
CQC/HC rating	Good	Fair	Excellent	Good	Good	
CQC/HC Finance rating	Excellent	Excellent	Excellent	Excellent	Excellent	
Dr foster HSMR	Higher than average	Higher than average	Higher than average	Higher than average	Higher than average	
Monitor					Found Trust in significant breach	Claimed significant improvements

The fact that the Keogh Review in 2013 has also identified Basildon and Thurrock as a provider who is suffering from high mortality rates suggests that there are definite limitations to the effectiveness of the arm's length bodies (NHS 2013). This illustrates the deficiencies of the regulators to regulate effectively, because if the regulation was effective then a Trust such as Basildon and Thurrock who have been subject to such intense scrutiny have not got favourable mortality rates then something is not working. The fact is: in 2009 when Dr Foster identified high mortality rates, they were saying Basildon and Thurrock were the worst offenders at the time, and had been performing poorly mortality wise for five years. The CQC and Monitor have attempted to use their regulatory powers to improve the situation at Basildon and Thurrock, they have been checking data in the various ways they do, randomly conducting "ad hoc" inspections periodically since 2009 (even though they are not ad hoc or random because they are risk based).

How a Trust, which is under so much scrutiny by all three key regulatory actors identified in this research (the CQC, Monitor and Dr Foster), can still be failing on the same measure of quality that it has been since 2004, nearly a decade ago, is baffling. This specific example gives clear evidence for the deficiencies associated with the regulation of health providers in England that are identified in the qualitative interviews in this research. If something does not change in the way regulation is conceived and implemented in the NHS then there is no real reason why in another decade there will not be another review commissioned by the government which identifies that mortality rates are “too high” at Basildon and Thurrock NHS Foundation Trust

6.6 What does this case study tell us about the findings in chapter 4 and 5?

- This case study illustrates the finding from the qualitative interviews that regulators of NHS providers do not share enough information with each other (findings section 4.7).
- It exemplifies that there are significant limitations of the reliability of regulators methodologies, especially the CQC. This relates to findings in chapter 4 (section 4.4) as well as from chapter 5 (section 5.4).
- It shows how internal self-assessments can fail to pick up quality issues.
- It demonstrates it is possible to be judged as financially sound yet to still have major quality issues elsewhere. This links in with chapter 4 (section 4.2.4) which discusses the separation of finances and quality.
- It proves that mortality rates still have a place in determining quality. Despite some of the disclaimers (Mohammed et al 2009 for example) mortality rates were key in identifying issues in this case study. This is linked to chapter 5 significantly (quantitative research including HSMRs).

Chapter 7: Overall Conclusions and Recommendations

This chapter is drawing overall conclusions. It is argued by Strauss and Corbin that literature when, “used as an analytical tool ... can foster conceptualization” (1998 p.53). It is on this basis that a literature review was conducted prior to the data collection in the research, despite traditional grounded theory method advocating not doing this. It is similarly on this basis that the relevant literature is being used to further conceptualise, give evidence for and support the conclusions in this section. This research project began in 2010 and data collection finished at the end of 2012. Much of the research which is discussed in this section was published between 2010 and 2013 as this area of health policy has been subject to significant scrutiny in this period. This literature gives support to many of the findings in this research and assists in developing wider theory around what is going on and why this is occurring.

This section seeks to relate the findings from the primary and secondary research directly to the various research objectives, drawing wider conclusions, recommendations, discussion and presenting “feedback loop theory of regulation”.

7.1 Research Objective 1: Critically assess the regulation of NHS providers in England (macro level).

7.1.1 The purpose of regulation: what is going on here?

In the critical assessment of regulation of NHS providers in England, many of the problems that became apparent in the findings from the qualitative interviews in this research, are related to the fact that the purpose of regulation is contentious in several ways. It is clear that when arm’s length bodies are created to regulate a sector, their exact purpose needs to be well defined and appropriate if they are to effectively implement their powers. Many of the issues identified in this research, stem from the definition and purpose of various regulators (CQC and Monitor particularly). Equally pertinent is the finding that their remit is ever expanding, and probably beyond what they as regulators can achieve resource wise.

The CQC role as a regulator is defined as: “the independent regulator of all health and social care services in England”. They purport that “our job is to make sure that care provided by hospitals, dentists, ambulances, care homes and services in people’s own homes and elsewhere meets national standards of quality and safety.” (CQC 2013). The CQC functions are outlined in the following paragraph:

- “Setting standards of quality and safety that people have a right to expect whenever they receive care.
- Registering care services that meet our standards.
- Monitoring, inspecting and regulating care services to make sure that they continue to meet the standards.
- Protecting the rights of vulnerable people, including those whose rights are restricted under the Mental Health Act.
- Listening to and acting on your experiences.
- Involving the public and people who receive care in our work and working in partnership with other organisations and Local groups.
- Challenging all providers, with the worst performers getting the most attention.
- Making fair and authoritative judgements, supported by the best information and evidence.
- Taking appropriate action if care services are failing to meet the standards.
- Carrying out in-depth investigations to look at care across the system.
- Reporting on the quality of care services, publishing clear and comprehensive information, including performance ratings to help people choose care.” (CQC 2015)

This seemingly all-pervading purpose of the CQC clashes starkly with the purported remit of Monitor. Monitor’s role is defined as “regulating health care providers and commissioners”, another seemingly comprehensive remit. They also refer to their main duty; “to protect and promote the interests of patients” (Monitor 2013), which is also vague and omnipresent. The segment beneath is taken from their website, and describes their specific functions.

“Licensing providers:

In carrying out our sector regulator role, Monitor licenses providers of NHS services in England. The licence is our key tool for regulating providers of NHS services. Monitor and NHS England have joint responsibility for setting prices for NHS-funded services in England. We are working together to design an NHS payment system that delivers affordable, quality care and better outcomes for patients.

Cooperation and Competition:

Monitor's focus in this area is to make sure that any competition in the health sector is fair and that it operates in the best interests of patients.

Supporting the continuity of services:

Monitor supports commissioners by ensuring that patients can continue to access the care they need if a health care provider fails.

Enabling integrated care:

Monitor has a duty to consider how it can enable or facilitate the delivery of integrated care for patients where this would improve quality of care or improve efficiency.” (Monitor 2013)

Given the definitions and functions which Monitor and the CQC have, it is perhaps unsurprising that significant overlap exists in their implementation of regulation. The problem is that this overlap results in significant unnecessary bureaucracy, for both providers and commissioners of healthcare. From providers' perspectives the burden of having to demonstrate compliance with numerous regulators on very similar territory is great. Aspirant FTs, for example, are regulated quality wise primarily by the CQC and have to cope with the burden of CQC regulation. Conforming to registration processes, quality and risk profiling, ad hoc inspection and surveys for instance, are a few of the on-going procedures for aspirant FTs. At the same time, they have to conform to Monitor's FT application process, not only providing evidence that they are soundly run financially and in terms of governance, but now Monitor also make quality checks. Not all aspirant FTs have huge numbers of staff numbers,

and conforming to the CQC and Monitor regulation can seriously detract from the day to day running of things.

Competition policy is a specific concern from the perspectives of both providers and commissioners of healthcare. Monitor currently describe their function regarding what they term “cooperation and competition” as; “To enable us to carry out our role relating to safeguarding choice and preventing anti-competitive behaviour which is against patients' interests, Monitor has established a cooperation and competition directorate.” (Monitor 2013 ii)

Monitor has a number of powers which they use to “protect choice and prevent anti-competitive behaviour” They can for instance:

- “Apply and enforce sections of the provider licence related to integrated care and choice and competition;
- Apply and enforce the Procurement, Patient Choice and Competition Regulations and relevant sections of the Responsibilities and Standing Rules;
- Apply and enforce provisions of the Competition Act 1998 and the Treaty on the Functioning of the European Union that prohibit anti-competitive behaviour; and
- Make market investigation references under Part 4 of the Enterprise Act 2002 to the Competition Commission.” (Monitor 2013 ii)

They also provide the Office of Fair Trading with advice on matters relating to mergers involving foundation trusts. (Monitor 2013 ii)

Whether competition policy should even be part of Monitor's remit is disputed by many providers and commissioners in this research. There is also vast evidence in the interviews which expresses concern over how effective competition policy can be in certain health economies. For competition policy to work, excess capacity is required within a local health economy, the fact is: in many local health economies there is not excess capacity, and to try and artificially stimulate competition is expensive. Monitor's role regarding competition policy

is therefore likely to be far less successful in particular local health economies, and the unintended consequences of this policy may be negative, and undermine the core of organisations. Competition policy and market management are clearly now part of Monitor's remit, and with the potential conflicts of interests, issues with local health economies and unintended consequences, and this policy arena a potential turbulent area moving forward.

A further finding of significance is that the remit of the regulators is overzealous given the resources allocated. This is especially true for the CQC, whom are now responsible for registering all providers of healthcare, but have not seen an increase in their resources that reflect this gargantuan task. The CQC's financial statement (see appendix 7), for instance indicated that their net expenditure for 2011/12 was £60,949,000. Compared to the previous year 2010/11 their net expenditure was £59,005,000. This 3.29% increase is clearly not dramatic and when inflation is also taken into account for this period, which was between 3% and 5.2% in 2010-2012 (Inflation 2013), this further illustrates that the CQC have not had any additional spending to finance their increased remit as regulators. The CQC is responsible for registering over 20,000 care homes, over 10,000 GP practices and "regulating all aspects of health and social care". There are currently listed 304 junior staff and 61 senior staff employed at the CQC, when all these factors are considered it is reasonable to consider their responsibilities as greater than their remits as regulators.

Monitor offers a similar picture financially (see appendix 8). Monitor's net expenditure for 2011/12 was £15,538,000. This compares to £14,771,000 net expenditure in 2010-11. This represents a slightly higher increase in net expenditure of 5.19% but clearly when the inflation rates are again taken into consideration, the increase is negligible, especially when Monitor's remit and purpose has expanded greatly.

Another significant finding in the qualitative interviews was that the separation of finances, governance and quality is perceived by many as adding additional complexity for providers. This split is clearly less clean cut as previously, now Monitor does have a quality remit, which many interviewees considered as further complicating things from their perspective. The vast

majority of interviewees also perceived Monitor as having “more teeth” than the CQC, as a consequence of previous reputational damage the CQC has suffered from scandals such as Mid Staffs. This lack of CQC clout has had dangerous unintended consequences, and many of the interviewees in the qualitative interviews suggest that finances and governance regulation is prioritised, to the detriment of quality regulation.

The majority of interviewees argued that quality, finances and governance are inextricably linked and whilst it is not necessarily wrong to separate the bodies that regulate these functions, they are not tied together as they should be, by linkages between the CQC and Monitor. Many did however see the separation as inherently flawed and argued the burden of regulation on providers was exacerbated by this separation.

A conceptual issue with regulation is whether arm’s length bodies are actually operating independently of government. When the key actors in these interviews were asked whether they thought the health regulation bodies operated independently from central government only around a third thought that this was the case. This demonstrates how quasi-autonomous arm’s length bodies are often perceived by providers of healthcare as simply pursuing the aims of central government, but in a way which alleviates the responsibility and blame by this artificial “separation”. This is significant, because if arm’s length bodies merely represent projected rather than actual autonomy from government then the premise for them operating is being contradicted.

7.1.2 Discussion: Why is this occurring?

The CQC seem to be an organisation which is set up to fail. It is working based on a sound premise, but the expectations of them as an ALB are unrealistic and ill defined. ALBs like OFSTED are perceived as successful because their purpose is well defined and realistic given the resources at their disposal. So on the question of; what is the CQC’s role? There are several answers that muddy the water. On the one hand they are perceived as the regulator of all health care provision in England. On the other hand they are perceived as a

safety net regulator only for basic standards. Then they have responsibility for registering Trusts, taking over from the HC this was probably realistically achievable, but then the introduction of thousands GPs, care homes, dentists and other providers of healthcare made the registration timescales unrealistic and also devalued the worth of the registration. Interviewees in this research expressed that CQC registration did not mean a service was safe, and if this is the case then the registration must be insignificant as a tool for quality assurance.

With Monitor the issue is more political. Competition policy is a hotly contested concept and time will tell if it is successful. The basic premise again is relatively sound; creating and promoting competition may be able to increase competition in terms of price and quality and therefore drive efficiency. The issue is that this premise does not seem to be a universal truth. This research suggests that certain health economies do not have the relevant structures for competition as a viable option.

Neo-pluralist theory suggests that there are many key actors among which power is relatively widely distributed. In the Health sector there are around 26 arm's length bodies operating currently depending on the definition applied (see conclusions 7.1.3 for a full list). In terms of power, it therefore must be the case that it is widely distributed between these bodies. There are clear differentiations between the purposes of these bodies but there is also large scope for overlap. The CQC, Monitor, and Dr Foster for instance are all involved with quantifying quality in some form.

There is significant wider research evidence which support the conclusions in this research, which give greater weight to them. Gash et al. (2010) for instance make the point that arm's length bodies fail when there is no clarity over their role. Walshe and Phipps (2013) argue that the function of the CQC is that of a safety net regulator in that they are looking to prevent very poor care rather than quantifying care beyond this. They also exemplify evidence which suggests that regulatory enforcement action is symbolic, and that in practice enforcement action is always trivial. The Department of Health (2013) have suggested that the introduction

of Chief Inspector will alleviate this, wanting this individual to be more than a safety net regulator; this effectiveness will need to be monitored, because this task is surely enormous. The Health Committee (2013) report that Monitor and CQC roles create confusion and lead to duplication of efforts. Timmins (2013) present evidence which demonstrates that the CQCs remit is greater than their resources. Timmins (2013) is also critical of the worth of competition policy being deployed, and concludes that there is no evidence that it actually works. Walshe and Shortell (2004) whilst focusing on the US offers very similar conclusions to this thesis and supports many of the conclusions, especially due to it using qualitative interviews of healthcare providers.

The evidence presented in this research, along with the listed contemporary studies of the NHS and regulation, suggests that the concerns of earlier theorists on regulation are being realised. Baldwin and Cave (1999) argued that regulations purpose needs to be clear and legitimate. The Better Regulation Taskforce (1999) suggested that regulation should be accountable, consistent, transparent, targeting and proportionate. Hood et al. (1998) makes the point that a main problem identified with regulation is that there is a lack of clear central responsibility. Trubeck et al. (2008) also argued that capacity and implementation deficits are present in the regulation of healthcare.

7.1.3 Bureaucracy: what is going on here?

Weber famously claimed that “experience... tends universally to show that the purely bureaucratic type of administrative organization... is, from a purely technical point of view, capable of attaining the highest degree of efficiency” (1947, p.337). This view shows a stark contrast to those of the interviewees in this research, who tend to view bureaucracy as something which is inherently bad. This is because they view bureaucracy as inefficient. Weber noted that people thought this back in 1947, suggesting that “however much people complain about the evils of bureaucracy it would be sheer illusion to think for a moment that continuous administrative work can be carried out in any field except by means of officials working in offices. The whole pattern of everyday life is cut to fit this framework” (1947 p.337).

In this seminal text Weber outlined six major principles of bureaucracy, which are explained briefly beneath:

1. A formal hierarchical structure – each level in the hierarchy controls the level below and is controlled by the level above. This formal hierarchy is the basis for central planning and decision making.
2. Management by rules – this allows decisions made at high levels to be consistently applied at lower levels.
3. Organisation by functional specialty – work should be carried out by specialists and organised into units based on these specialisms.
4. An “up-focused” or “in-focused” mission – If a mission is up-focused then the organisation reports to the stockholders or board. If the mission is in-focused then this means it is to serve the organisation itself, i.e. to make profits, gain market share etc.
5. Purposely impersonal- the idea is that all employees should be treated equally, as should all customers, not influenced by individual differences.
6. Employment based on technical qualifications. (p.340)

Based on these principles of bureaucracy, it is fair to say that a bureaucracy is capable of being efficient. It is also easy to see why people regard bureaucracy as a negative trait of an organisation. Essentially the negative sense exaggerates each of these conditions. So rather than a formal hierarchical structure a bureaucracy might be considered an overly hierarchical and rigid structure. Rather than management by rules a bureaucracy might be considered an overreliance on rules at the expense of efficiency. Inside organisations employees experience red tape and negative by-products of bureaucracy and this is why bureaucracy is conceived of as a negative thing. Bureaucracy can result in policies which are not responsive to individual circumstances; rules can be applied inappropriately and inflexibly. Bureaucracy can be described as anti-innovation, in that the rigid application of rules can prevent anything “outside the box” being considered. Niskanen (1971) refers to the problem of bureaucrats being self maximisers, in line with economic and rational choice theory: “the beginning of wisdom is the recognition that bureaucrats are people who are, at least, not entirely motivated by the general welfare or the interests of the state” (in Culyer 1980 p.36)

Lipsky refers to “street level bureaucrats” who make policy through two related aspects “they exercise wide discretion in decisions about citizens with whom they interact. Then, when taken in concert, their individual actions add up to agency behaviour” (in Culyer 1980 p.13).

The evidence in this section clearly indicates that bureaucratic elements such as the introduction of CCGs, have led to a greater burden, and more rather than less box ticking. Clearly the government has sought to reduce bureaucracy but in reality, the view from providers is that they have added a layer of complexity to an already incoherent system.

This is not surprising given the vast number of ALBs that operate in the health policy arena. The list below illustrates as coherently as possible the interaction between these regulators and providers, and it is not a pretty picture with massive overlap, repetition and bureaucracy present. * Indicates where quality overlap exists between ALBs.

Regulatory Arm's Length Bodies:

- CQC*
- Monitor*
- NHS Confederation*
- NHS Trust Development Authority*
- Healthwatch England*
- Human Fertilisation and Embryonic Authority
- Human Tissue Authority
- Medicines and Healthcare Products Regulatory Agency

Public Welfare Arm's Length Bodies:

- Alcohol Research UK
- Public Health England*
- NHS Commissioning Board Special Health Authority*
- National Treatment Agency for Substance Misuse

Professional Regulators:

- The General Medical Council
- Nursing and Midwifery Council
- General Dental Council
- The Health and Care Professions Council*
- Medical Research Council*
- The National Institute for Health Research*

Central Services to the NHS Arm's Length Bodies:

- NHS Business Services Authority
- Health and Social Care Information Centre*
- NHS Blood and Transplant
- NHS Institute for Innovation and Improvement*
- NHS Litigation Authority*

Standards Arm's Length Bodies

- National Institute for Health and Clinical Excellence*
- Professional Standards Authority for Health and Social Care*
- Medicines and Healthcare Products Regulatory Agency

That is 26 regulators in total operating within the healthcare market in England. There are obvious reasons for having certain specialist regulators as the degree of professionalism in healthcare and medical science. But there are large numbers of regulators which replicate the same or similar functions.

A significant finding from the qualitative interviews which adds to the bureaucracy is that there is not enough trust between the various regulators which adds to the burden of “box ticking” and bureaucracy for providers. Many interviewees pointed to the regulatory framework as not being “joined up” and there is much evidence to suggest that the government doesn’t fully

understand the purpose of regulation, which in turn leads to large numbers of (often overlapping) goals being pursued by numerous bodies which is bureaucratic in itself, but also puts an extremely large burden on providers in terms of conforming to these numerous ALBs.

The Oxford dictionary (2013) definition of bureaucracy is: “excessively complicated administrative procedure”. If this negative definition is applied to the sample in this research then every participant referred to bureaucracy in some capacity. Every interviewee suggested at least one procedure which would benefit from becoming more simplified. Often synonymous with “red tape” bureaucracy is more frequently represented by the key actors as too many requests for the same information or repeated data collection of a similar if not identical nature.

The issue of bureaucracy in NHS regulation is not a new one. In 2009 the NHS Confederation issued a report which outlined the need for several key reforms related to bureaucracy in the NHS specifically related to regulation. The key recommendations identified in 2009 included things like:

- “The government should consider rationalising regulators, auditors, inspectorates and accreditation agencies;
- The Government should streamline the work of regulators, auditors, inspectorates and accreditation agencies;
- The NHSIC (NHS Information Centre) should establish a web portal by 2013 to facilitate improved information sharing;
- The CQC should work with other parts of the system, including securing cooperation between the various agencies;
- Providers should have the right to challenge agencies which ask for the same information that has been requested by others.” (NHS Confederation 2013 p.7)

The NHSIC is now the HSCIC. Government policy has followed a trend of bringing health and social care closer together and the HSCIC can be seen as an example of this: it publishes statistics which are related to social care, public health and the NHS.

In 2013 the NHS Confederation issued a further discussion paper “Information overload: Tackling bureaucracy in the NHS” which details evidence which corroborates the findings of this research regarding bureaucracy in the regulation of the NHS. For example, it was demonstrated in the qualitative interviews, that providers and commissioners perceived the Health and Social Care Act 2012 changes regarding CCGs as introducing more risk and complexity into an already fragmented system. The NHS Confederation identifies the number of commissioning organisations as increasing similarly, adding to the bureaucracy. They claim “211 CCGs are proposed to replace 152 PCTs. Inevitably, this will mean there are more transactions and thus more reporting, accountability and feedback mechanisms” (p.3).

Also in the 2013 paper, they give support to the claims of commissioners and providers in this research concerning the increasing burden of regulation. It claimed for instance that: “A significant increase in the complexity of system architecture, post-reform, will potentially make it far more burdensome for commissioners and providers to consult on local decisions. There will be more layers of organisations that may need to be involved in a decision” (p.4)

The finding that this burden exists and is increasing from providers and commissioners perspectives is worrying, because it is inevitable that if regulation is overly burdensome, then the actual business of commissioning and providing a high quality service will suffer. There is significant other supporting research around the notion suggested by the interviewees; that bureaucracy leads to duplication and inefficiencies in the NHS. The Health Committee (2013) argues for instance that Monitor and CQCs roles lead to confusion and duplication for providers of healthcare. Walshe and Shortell (2004) offers significant supporting evidence for this conclusion, emphasising the costs of compliance with regulation in the USA. Nunes et al (2009) is another international empirical piece of research which emphasises the information asymmetry which exists in the UK and Portugal in health regulation systems.

The NHS Confederation (2013) also levy the claim that recent reforms to the health service add to the already substantial bureaucracy, and that providers cannot challenge requests for information which inevitably leads to duplication. This burden reduces the time that can actually be spent on the day to day running of core services, a claim repeatedly suggested by provider key actors in this research.

7.1.4 Discussion: Why is this occurring?

Power (1997) claimed that in regulation audits become rituals of verification. A more accurate statement now would be; regulation audits become rituals of verification which are repeatedly implemented, do not properly quantify what they are supposed to, and detract from the providers' capacities for delivering their service. All the evidence suggests that this phenomenon remains present in the regulation of the NHS caused by in part the inherent bureaucratic processes and also related to the purposes of regulators being ill defined and unrealistic.

Bevan and Hood (2006) suggest that previously, star ratings under CHI looked like they were improving but actually this just represented gaming; where data collection became about making it look like there had been improvements, but actually there had been none. There is danger that the bureaucracy of compliance with regulation seriously impacts on providers capacities. Combine this with the information that regulators present not being accurate and it makes no sense. Information regulators collect must be meaningful and simple for providers to conform to, for it to have a positive impact on service provision. Paton (2006) gives evidence that suggests there are significant internal politics involved in the NHS between the different departments and ALBs. This can also be seen as part of the reason for the bureaucracy. Poor relations between the CQC and Monitor have been suggested by key actors from providers in this research which further supports the view that bureaucracy in the form of duplication is exacerbated by the fact that there is not a holistic approach by ALBs.

A large part of why this is occurring relates to the previous conclusion; that the purpose of regulation is often poorly defined and overlapping. The roles of numerous bodies overlapping

in terms of trying to quantify quality in some capacity inevitably lead to unnecessary bureaucracy. This is very inefficient because not only does the repeated attempts to measure the same thing represent duplication from a government spending perspective, but more importantly, because this burden of regulation on providers limits their capacity for normal operations (especially in the case of smaller organisations).

7.2 RO2 Evaluate the effectiveness and reliability of the regulatory regime and their activities (micro level).

7.2.1 The CQC: what is going on here?

The findings of this research have identified various issues with the CQC from providers' and CCGs' perspectives. It is clear that the age of CQC data, specifically with QRPs, is an issue for both providers and commissioners. This is a particularly concerning finding because the QRPs are integral in CQC regulation. The CQC define QRPs below:

"QRPs are a tool used by providers, commissioners and our own staff to monitor compliance with the essential standards of quality and safety. Each organisation has a profile which contains information from a number of sources. We then analyse this information to identify areas where the organisation may not be meeting standards. Currently only NHS QRPs are shared with providers and commissioners. They help in assessing where risks lie and can play a key role in providers' own internal monitoring as well as informing the commissioning of services." (CQC 2013 ii)

The fact that numerous providers and commissioners in this research identified QRPs as being up to two years out of date is significant. This means that where the CQC may have a provider listed as compliant with meeting standards; in reality this provider may have not been meeting these standards for a very long time. Similarly frustrating for providers, when they have been identified as failing to meet standards on the QRPs, and have made subsequent efforts to remedy this, it is quite possible that this will not be recognised for a very long time. The fact is, with organisational information of quality and risk, the information is only

meaningful for a certain length of time. There are so many variables that influence the performance of providers, and these can change massively over short periods of time. When the structural changes to the NHS (from the 2012 Health and Social Care Act) are also taken into consideration, this enormous reorganisation changes many of the variables. Bearing this in mind, the finding that QRPs are often significantly out of date renders them near useless as a tool for adequately assessing quality and risk.

This research has also found the CQC feedback process to be inadequate in many ways. The feedback process is limited by the skill sets of the particular CQC inspectors. Often the inspectors regulating specialist providers do not have the specialisms necessary for adequately assessing these providers, and consequently the feedback for provider is insufficient.

The key CQC standards are another area where many providers consider the feedback to be limited. Providers are expected to conform to these key standards, but there is much evidence to suggest that these key standards are subjective, and providers do not get enough information and feedback from the CQC to ascertain whether or not they are compliant. Again this has clear implications, which suggest that this severely limits their deployment. Firstly, their subjectivity limits their use; in terms of they may not consistently be applied from Trust to Trust. Secondly, when providers are found to be non-compliant with a standard, the lack of feedback seriously limits the ability of the provider to change this.

There is also substantial evidence provided by NHS commissioners at CCGs in this research which identifies smaller providers as being a specific issue for the CQC. There are so many smaller organisations such as care homes that are subject to CQC registration and regulation that they are not properly monitored even at a basic safety net level. Commissioners in the research stated that they did not use CQC data sets on these smaller organisations because there was no point, it actually gave no reassurances over quality, and they preferred to check these organisations themselves as often as possible. If the CQC are failing to properly

quantify quality in the many ways outlined at larger providers like NHS Trusts it is inevitable that the thousands of smaller organisations will be even harder to manage.

7.2.2 Discussion: Why is this occurring?

There is lots of contemporary research evidence which supports the conclusions of this research. Walshe and Phipps (2013) for instance purport several CQC deficiencies which are identified in this research, arguing that there was a limited effectiveness of QRPs, a lack of expertise, inconsistency and no evidence to support CQC regulation style. Walshe and Shortell (2004) also offers support to the claim that regulation is fraught with methodological issues, such as having up to date information in regulatory systems.

Nuffield Trust (2013) offers more supporting evidence, claiming CQC registration timescales were unrealistic, and are also very critical of the QRPs. They also identify that the CQC does not indicate whether providers are good, excellent etc. beyond basic standards. This confirms the findings regarding the meaningfulness and significance of QRP data illustrated in this research. The Institute for Government (2012) suggests that information needs to be accessible, relevant, timely, contextualised and proportionate these three criteria certainly apply to the CQC and the issues identified in this research.

Barder's (2009) research on feedback loops suggests that when a feedback loop is short it is efficient. The feedback loop between the CQC and providers in terms of the QRPs is very long. Data being up to 18 month old as suggested in this research by key actors elongates the feedback loop. The accuracy of QRPs also comes under question by key actors which further complicated the feedback loop. The inefficiencies associated with the QRP feedback loop essentially make it worthless. There is no point in having unreliable information on services from up to 18 month ago.

Power (1997) referred to rituals of verification; it appears that QRPs as a function of CQC regulation fit this description. Department of Health (2013) proposes that they want the CQC to be more like OFSTED where it is no surprise there exists a short feedback loop between

OFSTED and schools where information exchange is much more efficient. This premise is further developed in the latter “Feedback Loop Theory of Regulation”.

7.2.3 Monitor: what is going on here?

Most of the Monitor specific findings in this research centre on the FT application process. Many key actors from aspirant FTs and FTs emphasised that the FT application can be a burden for providers and requires diverting a lot of their manpower to this, which can detract from the day to day running of things. This research also suggests the FT application process is not transparent enough, making the burden on providers even greater. Furthermore limitations with Monitor capacity wise have been identified by one Trust as derailing their FT application, as Monitor were not ready for the registration in the timeframe they had previously suggested.

Another finding of significance regarding the FT application process is the use of private companies for assurance, which can be expensive for providers. It is hard to see why this is justified, if Monitor is responsible for regulating FTs and aspirant FTs, then requiring these organisations to get external assurances by private companies (which they have to pay) seems superfluous. This is not only inefficient in terms of duplication of efforts, but is also a waste of the provider’s limited monetary resources.

The basic premise of creating FTs is that they have more autonomy, are not directed by government, have more freedom for decisions and are more accountable. The idea is that these factors mean that FTs compared to NHS Trusts are subject to less bureaucracy and red tape. There is much evidence in the findings of this research which disputes this claim, and even suggests that the converse is true: getting and maintaining FT status results in more bureaucracy and red tape.

Many key actors at FTs and aspirant FTs claimed that they were now subjected to increased scrutiny and that many of the FT guidelines are difficult to make sense of. Added to this,

aspirant FTs have to conform to both Monitor and CQC regulations which makes the burden for aspirants even greater. Clearly the additional scrutiny of becoming a FT can have a large impact on providers, making regulation increasingly burdensome, which can limit the amount of time these providers have to focus on important current tasks, like the day to day running of their organisation.

There is much wider contemporary research and evidence which supports the findings in this research. The Health Committee (2013) for instance concluded that there has been a greater focus on finances over quality and that this supports the views of the numerous key actors who declared that regulation focused overly on finances and less on quality. Timmins (2013) is also extremely critical of Monitor's competition policy and its worth.

7.2.4 Discussion: Why is this occurring?

Again, a lot of the issues concerning Monitor are to some extent derived from their purpose being poorly defined and overly ambitious. Monitor is primarily concerned with finances and governance but is also concerned with quality. Monitor's role as a financial and governance regulator of healthcare is one thing, but then Monitor is also responsible for the authorisation of all FTs, and it does not make sense to authorise FTs who are failing on quality and safety measures, so consequently Monitor has this under its remit by default. The compulsory authorisation of FT status is a task that Monitor are obliged to undertake, but for aspirant FTs the dual burden of conforming to Monitor and CQC regulations is large.

The evidence from the qualitative interviews points to there being an inextricable link between finances, governance and quality. But the quantitative data illustrates that neither governance nor financial scores positively or negatively correlate with HSMRs. The conclusions in this section are necessarily tenuous due to the nature of these relationships. It can only really be said that these data sets are not correlated, not really why this is the case. It could be the case for instance that finance scores simply do not correlate with HSMRs, and neither do governance scores. This would disprove the premise extracted from the qualitative interviews

in this research; that finances, governance and quality are inextricably linked together in a relationship. It could also be the case however that the lack of correlation is because the Monitor scores for finance and governance do not accurately portray finance and governance as they intend on doing. If this were the case it could be quite possible that finances, governance and quality are inextricably linked together however due to methodological issues in the quantifying of finances and governance the correlation does not emerge.

The fact is, it cannot be fully ascertained what is going on in this instance, and the conclusions around this are therefore more tentative. The speculation is that either there is no relationship between the variables, or the Monitor methods are methodologically flawed. It is recommended that future research is conducted to more fully evaluate critically the methods which Monitor deploys in their work on finance and governance ratings.

7.2.5 Dr Foster: what is going on here?

The main conclusions regarding Dr Foster are derived from the secondary research and concern HSMRs. Firstly, HSMRs have improved (reduced) over the period 2002-2011 which is a positive (if HSMRs do accurately portray mortality). Secondly the quantitative analysis suggests that there are no correlations between HSMRs and any of the CQC survey data sets for Accident and Emergency, Outpatient, Inpatient and five key standards. If the HSMRs and CQC data sets both properly quantified quality as they are supposed to then there would be a strong positive correlation, because a poor HSMR would equate to poor CQC scores and vice versa. The fact that there is no correlation suggests that, either the various CQC data sets, the HSMR scores, or both are inaccurate flawed attempts to operationalise quality and safety.

There is a lot of literature which supports the view that HSMRs are flawed in what they measure. Mohammed et al. (2009) for example are extremely critical of HSMRs and refute their accuracy. Taylor (2013) gives evidence of earlier HSMR issues, suggesting that ever since the conception of some kind of standardised mortality ratio, there have always been issues. The Francis Report (2013) is also very critical of HSMRs as a measure. Kennedy

(2001), Jacques (2013) and Freemantle et al. (2013) also offers significant evidence which supports the conclusions around mortality rates: HSMRs, SHMIs and even other mortality indicators like QUORUM. All this research suggests that any effort at quantifying mortality measures is marred with methodological limitations. The Department of Health (2013) acknowledges that whilst it has some worth, mortality data of this nature needs to be used with care.

Following the 2010 Steering Group for the National Review of the hospital Standardised Mortality Ratio, The HSCIC has been commissioned by the Department of Health to produce and publish the SHMI. The SHMI is described by the HSCIC below.

“The Summary Hospital-level Mortality Indicator (SHMI) is an indicator which reports on mortality at trust level across the NHS in England using a standard and transparent methodology. It is produced and published quarterly as an official statistic by the Health and Social Care Information Centre (HSCIC) with the first publication in October 2011.

The SHMI is the ratio between the actual number of patients who die following hospitalisation at the trust and the number that would be expected to die on the basis of average England figures, given the characteristics of the patients treated there.” (HSCIC 2015)

The SHMI is by no means a flawless solution. But it may offer a way of monitoring mortality in a way which is less methodologically limited. The SHMI is something which should be used by regulators in conjunction with a range of other sources to ascertain quality.

7.2.6 Discussion: Why is this occurring?

Essentially the basis for HSMRs is not a perfect measure of quality. The fact that it involves predicting how many people should be dying based on the demographics, socio-economic conditions and characteristics of the population means that there is scope for inaccuracy.

There is strong evidence for there being methodological bias in HSMRs in England as exemplified by Dr Foster Intelligence.

Whilst the Mohammed et al. (2009) study has been criticised, the main conclusions appear to be confirmed by the evidence in the quantitative section of this research, i.e. that “The Dr Foster Unit hospital standardised mortality ratio is derived from an internationally adopted/adapted method, which uses at least two variable (the Charlson comorbidity index and emergency admission) that are unsafe for that case mix adjustment because their inclusion may actually increase the very bias that case mix adjustment is intended to reduce” (p.1). The fact that this HSMR methodology is an internationally adopted method is of further concern, because of the inherent flaws at properly quantifying the mortality ratio, meaning that this flawed methodology is the prevailing status quo around the world despite these limitations.

7.3 Research Objective 3: To compare methodologies used by the regulatory bodies for rating and regulating NHS Trusts in England and assessing the impact of this on service provision.

7.3.1 Methodologies: What is going on here?

The secondary quantitative analysis has many implications concerning the third research objective. The quantitative research implies that the value and accuracy of many of the CQC, Monitor and Dr Foster data sets may be limited. The quantitative analysis suggests that there may be reason to doubt all the data sets, but the wider research (such as Francis 2013, Kennedy 2001, Jacques 2013, Freemantle et al. 2013 and The Department of Health 2013) suggests that HSMRs might not mean exactly what they are supposed to, but they do represent death rates to some extent at least. Consequently, the lack of correlation between HSMRs and the other data sets (that aim to quantify quality) does suggest that they do not properly quantify quality. Therefore the CQC outpatient surveys, inpatient surveys, accident and emergency surveys and checking of the five chosen key standards are of limited value,

because they do not properly quantify quality. These CQC methodologies are thus likely inappropriate, however determining why they are inappropriate is more speculative.

The several qualitative research interviewees alluded to the CQC being overly reliant on “soft data” such as surveys. There is also much evidence presented in the qualitative research which suggests that the remit of the CQC is unrealistically wide ranging, and it is quite possible that this explains the ineffectiveness of the five chosen key essential standards at quantifying quality. Most importantly it must be noted that if these measures the CQC deploy are methodologically flawed then it is a waste of time and effort doing this. The quantitative data analysis also suggest that if there are relationships between finances and quality and governance and quality (as the qualitative interviews purport) then the Monitor data sets on finances and governance should also to be doubted, because they do not correlate with the HSMRs either. Methodologically speaking, there are numerous reasons that regulation may be failing to do what it supposed to, across the board, for all the key actors in the regulation of health care in England.

There has also been significant evidence outlined in the findings from the qualitative interviews in this research that suggests there have been issues from providers' perspectives with the coding of data in terms of both the CQC and Dr Foster. Whilst this was not universally agreed as being an issue, the many key actors who did identify this type of methodological issue suggested that issues arose primarily due to overly sensitive categorisation or out of date information.

A theme which reoccurred over and over in the findings from the qualitative research is the age of data as a methodological issue with the CQC Quality and Risk Profiles. Up to 18 months out of date, this information is methodologically flawed as data of such an age is essentially rendered useless. The premise of such data is that the QRPs are the basis of whether further inspection by the CQC is needed. The QRPs give a profile of a provider and a brief glance at the quality of the provider and the associated risk of something going wrong there. The age of the data is such an issue that commissioners say they do not even bother

using these QRPs. The methodological issues surrounding the QRPs are so significant that they are not useable, meaningful data

Also identified as a methodological issue in the qualitative interviews was the view of many key actors: that there is a greater focus on finances over quality. This finding suggests that for Aspirant and FTs conforming to Monitor's financial regulatory framework, this focus is much more greatly weighted than any regulatory frameworks focusing on quality. This finding is very significant because a vast part of why arm's length bodies operate as organisations is supposedly for quality assurance, even Monitor the financial regulator have a quality remit as FTs are obliged to be of a minimum quality standard, particularly because once given the FT status, they are then supposedly more autonomous. If finance is prioritised over quality in the way that is prevailing, then organisations will be authorised as FTs due to their financial statements being favourable, but the lack of focus on quality in the organisations will mean that FTs operating autonomously will be of variable quality and subject to less scrutiny.

There is significant contemporary literature which backs up the findings from the qualitative interviews and quantitative data analysis alike. Walshe and Shortell (2004) offers very similar conclusions to this research. The Nuffield Trust (2013) is a further study which is very critical of CQC QRPs. When all the evidence presented in the qualitative interviews in this research in line with the contemporary studies evaluating regulation and the NHS is taken into consideration it is appropriate to suggest that under the current arrangements the QRPs are a flawed methodology. They are supposed to be a risk based way of regulating, obtaining a little information which is not particularly intrusive or a burden for a provider which then means the CQC can judge whether more checks are necessary. The problem is the QRPs do not give a clear picture of risk because they are flawed in the ways identified. Whilst the deficiencies in QRP accuracy and timeliness persist they remain an ineffectual methodology applied by the CQC which does nothing positive towards service provision. It could be argued that even worse than this, the burden of QRPs for provider's means that they are actually damaging service provision due to the extra resources which providers of healthcare have to dedicate towards conforming to such registration. Power (1997) claimed that arm's length bodies

become “rituals of verification” whereby bureaucrats who are part of a system implement checks in a way that is merely “box ticking” and protecting the status quo. Unfortunately currently QRPs represent one of these rituals; they do not have enough accuracy or meaningfulness to be of any real use to anyone.

There is similarly significant research evidence that supports the conclusions in this research regarding HSMRs. Mohammed et al. (2009), Kennedy (2001), Jacques (2013), Freemantle et al. (2013), The Department of Health (2013), and The Francis Report (2013) all suggest that HSMRs are an imperfect measure of death rates (and other methods like SHMIs are also flawed). Despite this however The Francis Report and The Department of Health (2013) argue that they do mean something about death rates. The flaws of the methodology lead to the lessened value of HSMRs and if a more accurate way of quantifying death rates was deployed, and then the scores would be more influential. If the CQC, for instance, sees under the current format that a particular provider is performing poorly on their HSMR score, they may not take regulatory action because of the discrediting of the HSMRs scores. However, actually this is very dangerous, if the HSMRs are meaningful then the CQC may not be taking regulatory action despite this being necessary, the discrediting of the methodology simply means the scores may not be taken seriously. SHMIs do to some extent improve on the limitations of HSMRs, but even these must be treated with caution as they do not show the full picture about mortality and must not be viewed alone.

7.3.2 Discussion: Why is this occurring?

Methodologies deployed by health regulators seek to quantify a variable. Whatever the exact nature of this variable it comes under one of three main wider variables: the quality of the service provided the financial performance of the provider, or the quality of the governance structures within the organisation. Measuring any one of these variables is extremely difficult. To properly ordinalise these concepts is a process fraught with problems.

For the CQC: is quality related to quantitative or qualitative data? How often does this data

need to be checked or obtained? What criteria make up the quality of a service? These questions are not easily answerable. For Monitor, how do you ascertain whether finances and governance are robust without giving sufficient attention to quality? For Dr Foster how do you properly quantify accurately how many people are dying at a provider hospital compared to how many people should be dying? Again these are very tough questions to tackle.

In reality any methodology deployed by an ALB aiming to quantify the variables of quality, finances and governance is going to have limitations because of the many issues in ordinalising these concepts. Take the CQC data sets, it is easy to see why the CQC might think that conducting surveys of outpatients, inpatients and accident and emergency departments would be a good way to check and compare the quality of the providers that they regulate. If the surveys are very positive then the providers are doing well, if they are negative then they are not. The different types of surveys should allow for the areas which are performing best within each provider to be compared, and problems identified. In reality however it seems (for whatever reason) this data does not mean this. It is quite possible that the nature of the surveys does not lend itself to quantification of quality.

For instance the accident and emergency survey focused on patients who attended a major accident and emergency department; in this survey the response rate was 38% with 46,000 participants (CQC 2013i). On the surface that response rate does not sound like an issue, but actually around two thirds of the population did not respond. Why this is the case could be any number of reasons: maybe they just don't want to fill out the forms, maybe they are incapacitated, or maybe they are dead. It is very likely that a certain type of population member is more likely to participate than another. In surveys of things like customer satisfaction, the response rate is highest among those customers who were either very happy with or absolutely hated a product. This is perhaps unsurprising because having an extremely positive or extremely negative experience of consuming something is logically going to give a more pronounced opinion of this consumption. This is a limiting factor in the deployment of these types of surveys too, because the same principle applies; the most likely patients to want to give their opinion are those whom are have a strong opinion. A further complicating

issue in the health sector however is that extremely poor health service provision leads to things such as people dying or becoming incapacitated as a consequence. These patients cannot fill out the patient survey forms. Bearing this in mind patient surveys apparent lack of usefulness is perhaps explained.

The five key essential standards are not surveys, however and therefore cannot be explained in such a way as population anomalies (as with the CQC survey data). The measurement of the five essential standards fails to quantify quality because of two reasons: firstly they are not properly measured, and two they are not measured often enough. The failure of key standards to correlate with any other data on quality of service must mean that this data is inaccurate. It is perhaps the case that “box ticking” prevails, because the CQC has such limited resources and therefore these key standards being ticked does not mean anything about the safety and quality of a provider. The conformity with the five key standards can be data which is as old as the QRPs (18 months old) and therefore may not represent what is prevailing at a provider quality wise currently.

The mortality figures are another limited methodology that is deployed. They are inherently flawed because of the nature of prediction being imperfect. The HSMR equals the number of expected deaths versus the number of actual death times 100 for example. It is known (presumably) the number of actual deaths at any one hospital, it is not known however exactly how many “should” occur at each provider to be “normal”. The way this is worked out is based on a vast array of factors. Expected number of in-hospitals deaths is derived from logistic regression, adjusting for factors to indirectly standardise for differences in case-mix. The list for which adjustments are made for is beneath:

- Sex
- Age on admission (in five year bands up to 90+)
- Interactions between age on admission (in five year bands up to 90+) and Charlson co-

- Superspell: a group of spells linked by transfer
- morbidity score
- Admission method (non-elective or elective)
- Socio-economic deprivation quintile of the area of residence of the patient (based on the Carstairs Index)
- Diagnosis/procedure subgroup
- Co-morbidities (based on Charlson score)
- Number of previous emergency admissions
- Year of discharge (financial year)
- Palliative care (if any episode in the spell has the treatment function code 315 or contains ICD10 code Z515 in any of the diagnoses fields)
- Month of admission
- Source of admission (Dr Foster 2013)

These adjustment factors are the limiting factor in the HSMR score. This is because many are contentious, the Charlson score for instance has been demonstrated to be inaccurate (Mohammed et al. 2009, Francis 2013), the Carstairs index is also a limited way of measuring socio-economic deprivation for instance because it is very simple and it is not considered a good measure of rural deprivation because owning a car may be essential for living in a rural area however poor you are (ISD Scotland 2012).

The deficiencies associated with the QRPs are vast. They are very out of date (up to 18 months) and they are barely even used by commissioners featured in this research because they mean so little. As a lot has been said about them already this will remain brief. Why are the QRPs so methodologically flawed? The most straight forward answer is the CQC are spread too thinly and therefore the QRPs cannot be meaningfully enacted by them. The fact that the QRPs do not properly represent quality or risk means that as a methodology they are destined for failure. This problem is inherent to the failings of all the methodologies: they do not properly operationalise the variable that they seek to.

7.4 RO4 To discuss and explore the political, economic and policy orientated ideologies that underpin the various regulation regimes involved in the NHS.

7.4.1 Regulation theoretical underpinnings: What is going on here and why is this occurring?

Cope and Goodship (1999) identify regulation of public services as rising in line with rising new public management trends (p.6), and ALBs follow the unusual objectives of centralisation and decentralisation at the same time. New public management based policy initiatives seek to simultaneously “centralise the making of policy strategy (especially policy goals and policy budgets) increasingly in the hands of the core executive at the heart of government, embracing a closely-knit network of senior ministers and civil servants (such as those in the Prime Minister’s Office, Cabinet Office and Treasury)” (Cope and Goodship 1999 p.6-7). There is reference to separation of “steering from rowing” and a decentralisation of “a plethora of rowing agencies” that are controlled from “the steering centre” (p.7). Centralised leadership steers ALBs that are decentralised in their delivery of regulatory functions. The passage beneath summarises the simultaneous centralisation and decentralisation:

“Central steering agencies (such as central government departments) increasingly, both directly and indirectly, regulate local rowing agencies (such as executive agencies, local authorities and quangos) by setting policy goals for rowing agencies to achieve, fixing budgets within which rowing agencies must operate, awarding contracts (or quasi-contracts) to competing rowing agencies, appointing the “right” people to head up rowing agencies to do the “right thing”, and establishing regulatory agencies (such as the Audit Commission) to monitor the performance of rowing agencies (Clarke and Newman, 1997). NPM seeks to enhance the capacity of steering agencies to manage rowing agencies within their jurisdiction. It is all about managerial surveillance - the ability of steering agencies to monitor and direct rowing agencies more effectively, and within rowing agencies the ability of managers to control workers more effectively. The regulation of public services is thus central within NPM. The rise of NPM thus represents a very significant push towards the rise of the regulatory state.” (Cope and Goodship 1999 p.6-7).

It is perhaps strange to talk about decentralised centralisation, by definition a contradiction in terms. What appears to be a prevailing trend is decentralised policy delivered by regulatory ALBs, which are operating within a remit and resource allocation which is determined centrally. Cope and Goodship also argue that this can decentralised centralisation can be explained because:

“Regulation can be seen as a manifestation of mistrust by the centre of those agencies providing public services locally (Power, 1997, pp.134-138). As a result, such regulation, though joining-up government, is not based on mutual collaboration but more on enforcement imposed from the centre.” (1999 p.11).

Clinical Commissioning Groups are another important policy direction to assess. They rest on the premise that moving the budgets for healthcare provision to GPs and clinicians should provide more evidence based practice and fewer bureaucrats and managers spending healthcare budgets for the local populations. In reality it appears whilst there is more emphasis on clinical evidence, many of the same people work for CCGs who previously worked for PCTs and the reorganisation has wasted time and money with no real impact, other than to slow progress down. The introduction of CCGs as well as The National Commissioning Board is perceived by many key actors featured in the interviews in this research as adding an additional layer of bureaucracy and complexity to an already overly bureaucratic and complex system.

Competition policy is another area where political ideology determines the decisions made and what directions to follow. Free market ideology purports that by following the principles of the private sector efficiency will prevail. NPM supports this idea, suggesting the public sector be made more like the private sector to gain these efficiencies pushed by competition. A more left wing viewpoint would suggest that the public sector is inherently different from the private sector and that there is no place for competition policy within the public sector. In reality in the health sector, this research has demonstrated that competition policy in a creative sense can only work under certain conditions. Artificial competition does not work in certain small health

economies due to the size making competition creation either: unrealistic, expensive or simply ineffectual due to the services not being taken up by the public.

Neo-pluralism is another reoccurring theme related to health regulation. In the health sector there are a plethora of regulatory agencies operating at the same time with similar and often overlapping aims. This can be explained through a neo-plural viewpoint, because the numerous key actors in the field share the power. Based on principles of rational choice theory, these key actors seek to operate under self-maximising and self-preserving ideals and the retaining of power can be seen as one of the main limiting factors of these organisations. The quest for retaining the fragmented neo-plural distribution of power means that inefficiencies such as duplication and bureaucracy are inherent to the system. Collaboration rather than competition is certainly something to consider, in a system such as healthcare regulation, where the number of bodies operating at arm's length in some capacity is so numerous.

7.5 Data Sharing: what is going on here?

The realm of data sharing is massively significant in this research. The decision to put this section after each individual research objective had been discussed in turn was made because the conclusions around data sharing apply to at least three of the four research objectives. Data sharing has both macro and micro implications for health regulation. It also has significant methodological implications.

All the participants in the interviews gave evidence as to why the current systems are limited and many gave ways in which they could be improved. E-governance is seen by providers and commissioners alike as potentially hugely beneficial in terms of assisting in the regulation of the NHS in a plethora of ways. Improving the capacity of data sharing systems between various regulators, as well as between regulators and providers has the potential to alleviate at least to some extent many of the associated regulatory deficiencies outlined in the findings of this research. Bureaucracy could be reduced, the overlapping remits of regulators could be

lessened, data collection issues and the feedback process could be improved, the age of CQC data feeds could be lessened, and the FT application could be made less burdensome.

Better data sharing has the potential to vastly reduce the burden of regulation for providers, therefore freeing up time for staff to focus on actual provision of their services rather than jumping through hoops repeatedly for regulators. It also has the potential to significantly increase efficiency of the regulators themselves, reducing data collection repetition and making it much clearer when serious service failures are occurring. Increasing data sharing systems would make regulation more joined up, less complex and more transparent.

Many of the interviewees in the research consider the relations between the CQC and Monitor specifically as minimal as they both try to protect their position as regulators. There is much evidence that suggests that because they see one another as treading on each other's toes they are not keen to share information about providers. It appears that they both want to operate separately and independently because they want to appear useful in their own right as regulators. The problem is that because of this, proper data sharing simply does not occur and the implications of this limit the effectiveness of both as regulators. Information being siloed in this way has been demonstrated to detract from the functions of both regulators, in this research and in wider examples (Mid Staffs and Basildon and Thurrock). The most effective feedback loops are those which are short, the lack of data sharing between health regulators seriously lengthens the feedback loops in healthcare regulation, which inevitably leads to the effectiveness of this regulation being limited.

There is vast evidence which supports the notion of increasing data sharing in the public sector to reduce inefficiency and increase transparency. Bellamy and Taylor (2003), Cabinet Office (2008), CST (2005), Chissick and Harrington (2004), and Timmins (2013) all support increased data sharing to increase transparency and efficiency, therefore supporting the views of the key actors taken from the qualitative interviews of this research.

As mentioned previously Barder (2009) discusses the merits of short feedback loops for efficiency. Trubeck et al. (2008) refers to the “information deficit” present in the current regulatory systems. The Nuffield Trust (2013) gives evidence which suggests that whilst there is lots of information available about providers of healthcare, this information is not easily available in one place. Nunes et al. (2011), Nunes (2009) and Walshe and Shortell (2004) all offer empirical international research evidence which support the notion of information asymmetries in healthcare regulation systems.

A central repository upon which all health regulators could deposit information on NHS providers surely seems like a logical solution to all these issues. This would be transparent, available for all to see, as a Chief Executive of a provider suggested: “sunlight is the best disinfectant”, transparency is clearly an objective which is universally aspired to. With greater transparency the likelihood of serious service failure would also be greatly reduced. The Francis Report (2013) outlined the many issues concerning Mid Staffordshire relating to the CQC, Monitor and Dr Foster Intelligence and the lack of communication between these ALBs. One of the most concerning aspects to The Francis Report (2013) findings was that all three ALBs had data about Mid Staffordshire which gave reason to doubt the quality of care at the organisation, but there was no alignment of the various data set. There are obvious parallels between this and the case study used in this research: Basildon and Thurrock. Clearly a central database or better data sharing would have been extremely useful both instances. It would have been clearly visible in one transparent place that the Trusts were failing on a wide variety of measures aimed at quantifying quality. This would have been identified in a much more timely fashion.

A central database would also have the scope to dramatically reduce data collection duplication. If Monitor, for example, wanted some information about the accident and emergency department of an aspirant FT that they were registering, they could simply check the CQC accident and emergency section of the central database and decide whether to collect additional data based on the data that already exists, rather than just collecting the data regardless.

7.5.1 Discussion: Why is this occurring?

As a Chief Executive in the qualitative interviews aptly suggests about health regulators; “the very idea that they don’t (share information between one another) is abhorrent isn’t it?” When the potential advantages of increased data sharing are considered it is hard to disagree with this statement, so why does it not happen? Neo-pluralist theory suggests that power is widely distributed among key actors. As previously discussed, this seems a realistic proposition with regard to the regulation of NHS providers in England, where there exists a plethora of regulatory bodies whom all exert varying degrees of power over the providers. Also previously mentioned is the idea that these ALBs operate in slightly different but often similar territories, related to their conceived purposes as regulators. Three key ALBs who could and should be sharing information between one another are the CQC, Monitor and Dr Foster Intelligence. It has been argued by the Francis Report (2013) that had this occurred, the scandal at Mid Staffordshire would have been much more manageable and less severe. All three of these ALBs have some part of their purpose related to the quantifying of quality, and this can perhaps be seen as why they do not share information, rather than what it should be seen as: why to share information.

Organisations such as ALBs tend not to be politically popular, ever since the 1918 Haldalare Review, successive governments have been trying to get rid of as many as possible of these more colloquially termed (as the media tend to refer to them in a negative sense) QUANGOs. There is good reason to monitor and remove unnecessary ALBs. If they provide no particular function, repeat a function which is performed by another ALB, or perform an unnecessary function, then they are a waste of taxpayer’s money. However in reality this task is hard, because organisations tend to have a way of rationally pursuing their own survival. Which can be explained by rational choice theory applied to a neo-plural sector: many key actors where power is widely distributed seek to justify their existence, budget and power through their activities.

Take an example: the Potato Council; in 2009 the Tax Payers' Alliance listed this ALB as one of the 100 QUANGOs that needed to be removed (Horticulture Week 2013). With a budget of £6million per annum, the Potato Council represents a seemingly straightforward body to simply remove: the government decided that it is not performing a function which is necessary and costs taxpayers money. This is in reality not the case, however, in 2015 the Potato Council remains operating as an ALB "committed to supporting the British potato industry" (Potato 2013). This example clearly illustrates that removing ALBs is far from straightforward. If a simple regulator of potatoes with a relatively small budget in a very specific area cannot be easily removed then it is easy to see how removing larger ALBs with more power is difficult.

When the Potato Council example is considered it is unsurprising to see how the CQC, Monitor and Dr Foster intelligence aim towards self-preservation. From their perspective, they get a grant from the government (or a payment in the case of Dr Foster) once a year to finance their continued operations. This payment is based on them performing their purpose in a way which benefits citizens, through continued monitoring and inspection of the NHS provided services. It is easy to see why these bodies are therefore reluctant to collaborate, and share information, because they see their functions as overlapping and they want to prove that they are the "best regulator" and therefore most deserving of the governments continued financial support. This continued financial support keeps the ALB as a power exerting force in the health policy arena and more importantly (from their perspective) it keeps those employed by the body in a job.

It is straightforward enough to see the logic of not enhancing data sharing based on neo-pluralist notions of power and rational choice ideas of self-preservation and budget maximisation, but this does not mean it is either right or inevitable. There is a good argument to suggest that increasing data sharing in this realm would actually increase the worth of the three regulators, with the collective being worth more than the three separate individual bodies. So the enormous benefits of the data sharing could be present; better transparency, more timely data, more rounded assessments, less duplication and the rest. But at the same

time the CQC, Monitor, and Dr Foster are all portrayed in a much more positive light because of exactly these reasons. Power being distributed among key actors in the regulatory arena and these key actors pursuing self-preservation should not be a barrier to increasing data sharing between them; it is not in the interests of anyone involved in the process.

7.6 Recommendations

7.6.1 Recommendations: specific recommendations from key actors

Many of the staff in varying levels of the hierarchy from providers in the sample came up with their own recommendations concerning the delivery of regulatory functions. These included many areas of regulation, and a selection is presented here in line with additional recommendations based on the findings and conclusions in this research.

The first recommendation suggested by a key actor in this research is that there should be one overall regulator for finances, governance and quality to reduce duplication and bureaucracy. T4 Head of Nursing proposed when asked: “what would you say are the main problems/issues that CQC and Monitor face in practice?” that the answer was: “The sheer range of bodies and the fact that some of the standards aren’t fully aligned; to me it would make more sense to have one regulator who looks at all your statutory duties.” This proposal of having one overall controller of regulatory functions or purposes has clear implications in terms of reducing duplication, the burden of regulation for providers, bureaucracy, poor data sharing and inefficiencies.

Another recommendation that has been proposed by a key actor in this research, is that the remit of the CQC in particular is made evaluated and redefined. T4 Chief Executive describes in the passage beneath how the CQC should focus on its main function as a safety net regulator, because it simply does not have the capacity for any more than this given the resources at its disposal:

“Monitor is going to have more and more trusts through the FT process and significantly more, and it doesn’t have the resources required to put some through at the moment. The CQC is quite interesting I think it the CQC is not accountable for the quality of care in my organisation, I am and what people confuse in the public is the role of the regulator in quality, but it’s about assurance isn’t it, I am accountable for things and people confuse the two what I would say about CQC it lost focus in terms of what it what about over the last couple of years it has spent too much time thinking about improvement instead of quality assurance. That has

been compounded by Monitor becoming interested in quality, so that's led to duplication I think CQC are going to face huge challenges if they are responsible for regulating general practice and all NHS providers in the future and the only way it's going to do that well is by having a new system focusing on the assurance piece and defining how it works in its territory and others."

This is an apt recommendation because there is much evidence in this research to suggest that the CQC is failing at implementing basic safety net regulatory functions such as the QRP, essential standards, registration of services and survey information (inpatients, outpatients, and accident and emergency). If it cannot adequately perform these basic functions due to lack of capacity combined with poor methodologies as identified in this research then it seems unlikely to be able to go beyond the function of safety net regulator.

Another recommendation stems from the 2012 Health and Social Care Act restructuring of the NHS, with the introduction of CCGs. CCG2 Commissioning Manager identifies a potential conflict of interests for GPs:

"It is quite difficult, we are in a situation now where we have got GPs that are with commissioners and providers, the conflicts of interest that naturally fall out of that are huge. So therefore we need some sort of regulation to ensure that all the GPs and GP practices we are working with are aware of their conflicts but also I think senior managers as well need to be aware of those conflicts, this is very difficult because I see evidence of GPs recommending certain services to be commissioned and then they could potentially delivering those services, so feathering ones nest... and I can naturally give evidence of that, I am not prepared to now but there is evidence of that going on which concerns me, I mean I have been around the health service for 38 years I have seen a lot of changes, I have seen GP fundholding in the 90s that was criticised as being a postcode lottery, this what we have now the CCG working, I think is a lot more controversial. Simply because of the amount of financial gain that could be seen by GPs, we are in a very dangerous ground at the moment so regulation is going to be absolutely paramount."

This potential conflict of interests with GPs is very concerning. This commissioner was not prepared to give specific evidence on the record for fear of being considered a whistle blower in the NHS, where they argued there was a “blame culture” and suggested “it would not be good for me... I could lose my job”. The fact that when people working in the NHS can see glaring issues right in front of them but are not confident enough to point these things out, it is inevitable that issues will remain present in services under this type of culture.

To truly make progress aside from the particular issue of GPs potential conflict of interests (despite this being an important contradiction of CCGs that needs to be considered) perhaps of more concern is the resistance of those working in the NHS to be transparent about problems they see for fear of losing their job. Whistle blowers root out problems in organisations such as the NHS, and if the staff are afraid to do this because of the culture of the organisation, many problems and inefficiencies will persist. So whilst the commissioner makes a specific recommendation about the potential for a conflict of interests needing to be monitored, equally pertinent from this statement is the recommendation that the NHS needs to experience a culture change. Otherwise when staff see things which require attention such as this, if they are too scared to tell someone about it, problems are inevitable. There is a website and phone line created since this research was undertaken (wbhelpline.org.uk) and a report by Francis (2015) called “Freedom to Speak Up”. In this report the vast majority of findings centre around the fact that cultural change is needed in the way whistle blowers are perceived in the NHS. Recommendations also relate to a new national officer for NHS whistle blowing and whistle blower guardians at every hospital. It is also important to point out that this report is not a public inquiry; individual cases are not considered. It is not a magic bullet either cultural change takes time and a lot of effort and the response to this report has been varied. NHS whistle blower Dr David Drew who was dismissed in 2010 after raising concerns about poor standards of care at Walsall Manor Hospital claimed for instance that the report was “no help to those who have suffered” and would have a “further deterrent effect on staff raising concerns” (Independent 2015).

7.6.2 Recommendations: based on evidence in findings and analysis within this research

1. The purpose of the various regulators and their exact remits need to be better defined

For regulation to work in the healthcare sector it needs to be clear who is responsible for what and why. Overlapping aims need to be removed or bodies that overlap on functions need to be transparent and freely share information with one another. For example, under the current arrangements Monitor and the CQC have overlapping quality remits with regard to aspirant FTs and FTs. It needs to be clear who is responsible for monitoring quality in these organisations and if it is both of them, then data sharing capabilities need to be better developed.

2. Competition policy needs to be clear and even then may be unsuccessful in some local health economies

There is much evidence which suggested that to pursue competition promotion as is being done currently will not work. Artificially creating competition in smaller health economies and other types such as densely populated urban areas of deprivation are resistant to new service uptake, and often do not have the demand of structures in place to support competition.

If competition policy is to remain part of Monitors remit, it needs to be applied after considering each individual health economy so ascertain whether it is viable or whether it will be a waste of time, money and effort.

3. There needs to be less unnecessary bureaucracy and duplication of efforts.

Bureaucracy, box ticking, rituals of verification and duplication of data collection are all phenomena which exist in the current regulatory health policy arena. They seriously waste time, money and effort. Reducing unnecessary bureaucracy by better defining aims so as to

not overlap is as previously discussed is clearly one way of achieving this. Another is going back to T4 Head of Nursing's recommendation that regulation should all be in one house, if all the various regulatory agencies operating in the health sector are not going to be merged into one "super regulator" then data sharing is again of paramount importance. The potential for better data sharing systems for reducing these phenomena is so great and must be realised if regulation is to remain a system in which a plurality of regulators operate.

4. Regulators need to use appropriate methodologies to measure quality.

The numerous limitations associated with methodologies in this research necessitate their evaluation and changes in their implementation by regulators. QRPs, essential standards, surveys, finance scores; governance scores and HSMRs have all been illustrated to be imperfect in fully quantifying what they are supposed to. Methodologies deployed by healthcare regulators needs to be evidence based and proven to ordinalise the variable in question otherwise there is no point the methodologies being used at all, as the data may be meaningless.

7.7 Feedback Loop Theory of Regulation

This theory is inductive, in that it has been grounded in the data analysed in this research. Feedback Loop Theory of Regulation builds on Owen Barder's concept of Feedback Loops in economic transactions and develops a similar explanation of regulatory systems, with wide reaching consequences. In Barder's (2009) paper entitled "Beyond Planning: Markets and Networks for Better Aid" he develops the notion that foreign aid to developing nations could be vastly improved. To do this it is argued that there should be a much greater focus on the results of this aid rather than the inputs. Barder reflects on a specific issues with development aid: "there is a broken "feedback loop" connecting the intended beneficiaries and decision makers" (2009 p.3). The recommendation that stems from this conceptualisation is that:

"By investing in greater transparency and accountability of aid agencies, making more use of market and network mechanisms and closing the feedback loop we can change the context in which aid agencies operate and make faster progress on reducing poverty" (2009 p.5).

This theory of regulation takes the same basic premise of feedback loops and applies them to regulation. Regulation is a set of functions regarding a sector which are implemented by a body which is "arm's length" in some capacity i.e. not under the explicit control of central government. The exact nature of the function varies from sector to sector and from regulator to regulator as does the degree of true autonomy from government.

One of the most important factors in determining the overall success of a regulator (or at least perceived success) is what this function (or functions) is/are. There are several elements which determine the perceived/actual success of a regulator related to the initial purpose:

1. The purpose or function(s) of the regulator is realistic, given the amount of resources allocated to the regulator.
2. The purpose or function of the regulator is clear and cannot be misunderstood or misinterpreted.

3. The purpose or function is unique to the regulator, and is not replicating or overlapping with the work of another body.
4. The purpose or function of the regulator does not negatively impact upon those subject to the regulation. I.e. The burden of regulation does not render it superfluous.
5. The methodologies deployed are appropriate.
6. The nature of the associated feedback loop of information is short.

The first factor: the purpose being realistic is particularly poignant based on the findings and conclusions of this research. Having an unrealistic set of aims means that the likelihood of perceived failure is inevitable, the casing point here being the CQC. If the aim is vast, such as the regulation and registration of all health and social care in England then the amount of resources must reflect this.

Comparing the CQC, who are often portrayed in the interviews in this research as an unsuccessful regulator to OFSTED who are often portrayed as a model of best practice in them, it seems extremely obvious, given the resources allocated to each, why one is more successful than the other. OFSTED has a similarly vast remit (like the CQC) their remit is to “inspect and regulate services which care for children and young people, and those providing education and skills for learners of all ages” (OFSTED 2013). The resources allocated to each regulator are extremely different, in 2012 the CQCs net expenditure was around £60million (Parliament 2013) compared to OFSTEDs £160million (Parliament 2013 ii). Staff numbers present a similar story with the CQC employing 61 senior staff members and 304 junior staff, compared to OFSTEDs 443 Her Majesty’s Inspectors (senior) and 1948 Additional Inspectors (junior). Clearly whilst the two bodies share a relatively similar purpose, the resources allocated to each varies significantly and goes a long way to explaining their relative perceived success.

The second factor: the purpose of the regulator being clear also has clear links to the qualitative findings and conclusions in this research. In this specific instance Monitor’s role as the financial regulator has led to Monitor becoming involved in competition policy, where there

is resistance to this and it is dubious whether this policy works. Monitor are perceived by the majority of the interviewees as successful in their financial regulatory function, but the inclusion of competition promotion makes providers more negative in their appraisal. Not having an agreed upon purpose which is clear and can only be interpreted in one straightforward way has also been a factor which has resulted in the CQC coming under much criticism. In essence the CQC is really a safety net regulator which is concerned with minimum standards. Many however perceive their role to be about quantifying “good”, “excellent” et cetera and therefore are disappointed when this does not materialise.

The third factor: the function being unique and non-overlapping has also arisen through the findings and conclusions of the qualitative side of this research. Repeating functions inevitably results in inefficient regulation. This means that the purpose is superfluous in the sense that it seeks to answer a question which has already been answered. But not only that, the labour and economic cost of repeating a regulatory function means it is unsurprising that organisations who have purposes which overlap are not perceived as successful.

The fourth factor: a minimal burden of regulation for those who are regulated again stems from the findings and conclusions of the qualitative side of this research. Where the burden of conforming to regulations is large, the impact of the service regulated is great. This has been illustrated in this research to distract from the general running of things in smaller providers of healthcare especially. This does not mean “light touch” regulation is being advocated per se, more that regulation is successful where it is as unobtrusive as possible. This can be simple things such as designing regulatory function to coincide with internal assessment activities to reduce the burden. It can be a mere lack of asking for the same information in numerous different formats. It can be better information sharing practices being deployed to reduce the burden. Without seeking to be vague, it depends on the organisations and sector involved, and normally depends on common sense approach to enforcing a purpose or function.

Whilst the discussed factors related to the purpose of regulation have much bearing on the overall success of a regulator, there are other key factors which are separate, and also have

a large impact on the perceived success of a regulator. The fifth factor for instance: the methodologies deployed by a regulator must be based on evidence and proven to achieve what they set out to. There is significant evidence from both the qualitative and quantitative elements of this research which demonstrates that untested or unjustified methodologies such as HSMRs, QRPs, CQC key standards and CQC surveys do not achieve what they set out to, in the sense that they do not ordinalise the variable they want to. Methodologies must be justified and tested to ensure rigour and simply that they measure the thing they are supposed to. Flawed methodologies are wrong in the sense that the function of the regulator is not being achieved, but more than that, they can also have huge implications for those who are regulated.

In relation to the sixth factor, a large part of regulation in every sector is some kind of reassurance over quality of the service which is regulated. Feedback loops operate in quality reassurance mechanisms the same way they operate in the private sector. In the private sector the question of “what works?” is answered very quickly through the short feedback loop present; the purchase of goods resulting in an equilibrium price which reflects this. Products which are poor are not purchased, and products which are good are purchased. In the public sector however there is no transaction in the same way, public services are consumed in some sense but they have been paid for by taxation rather than individual transactions as in the private sector. This means that regulation agencies are often created to give assurances over quality and essentially recreate the feedback loop of information which is present in the private sector.

Every deficiency which has been identified in this research with regard to the regulation of NHS providers in England is extending the feedback loop in some way, which results in a long and convoluted feedback of information. Because there are too many agencies attempting to feedback information the loop is fragmented. Because of poorly implemented methodologies such as the QRPs the information is very old which means the feedback loop can be up to 18 months old. Other flaws with methodologies such as the CQC five essential standards, surveys, and HSMRs mean that even when information is obtained this may not truly quantify

quality. A lack of transparency and properly developed data sharing capacities between regulatory agencies such as the CQC, Monitor and DR Foster Intelligence means that getting all the information which has been obtained into one quick feedback loop is again disrupted, and politicised changes to the purpose and remit of regulators amplifies this.

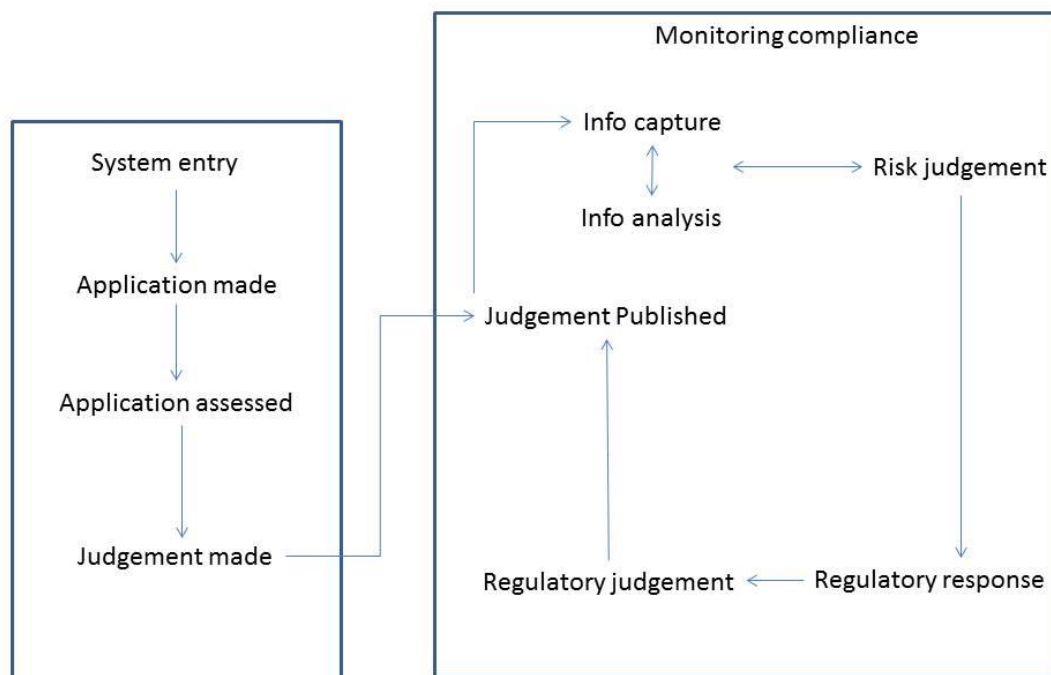
Again comparing the health sector to the education sector where OFSTED are perceived in interviews as a model of best practice for regulation, in education the feedback loop is much shorter. OFSTED are solely responsible for artificially creating the feedback loop of quality in schools. Compared with the fragmented nature of health regulation this feedback loop is much simpler, and OFSTED are better financed and have a bigger workforce to achieve their remit. Effectively the issues present regarding data sharing between various fragmented agencies is removed completely because the feedback loop has one overall controller.

ALBs created to provide assurance information concerning public sector services operate efficiently when the artificially created feedback loop of data is short and accurate. In the pursuit of regulatory excellence policymakers need to create appropriate methodologies and agencies who process information quickly implement them to create a feedback loop which is available and meaningful. If feedback loops in the public sector do not do this then they will be unsuccessful because quality is a concept which can change quickly and have large implications for the population which it serves. Long fragmented and unnecessarily bureaucratic feedback loops operating in the public sector mean inefficiencies persist.

Below is a model which effectively summarises the regulation of NHS providers in England. This can be seen as the feedback loop which is artificially created by the regulators. Looking at the feedback loop it is easy to see why it is so fragmented, and there are specific issues with elements of the feedback loop noted on the model. It is important to point out that the “system entry” aspect of the model can have more than one meaning. It can mean entering the system in a way that applies to all providers of healthcare: CQC registration. It can also mean entering the system in the sense of FTs i.e. a Trust applies to become an FT and

enters the secondary level of the system in this way. After this initial entry, the processes within the system are however the same.

7.7.1 NHS Feedback Loop: Model of Provider Regulation



Problems with the model:

1. **System entry:**

In a basic CQC registration sense: the CQC has not registered all providers of healthcare, so many never enter the model. The CQC has targets related to registration and publishes some related data. In quarter 1 2013/14 the percentage of registration applicants processed was 83% going down to 75% in quarter 2 (CQC 2014 v). This is against a target of 90%. It is impossible to quantify how many providers never enter the system, because if they have not entered the system they cannot be counted. The CQC do themselves acknowledge that they are behind on this task (CQC 2014 v) so it is inevitable that many providers remain unregistered.

In an FT sense: FT application is often encouraged by the Department of Health when Trusts are not ready or do not currently want the FT status. Furthermore not all

Trusts are FTs. This means that many never enter the chain into monitoring compliance at the secondary level.

2. Information capture and analysis:

The regularity and timeliness of this stage of the process varies vastly based on numerous variables. Smaller providers inevitably end up being monitored less than bigger ones. The observations of this kind are supposed to be risk based, but in practice they appear very haphazard. The fact that information capture and analysis is so inconsistent means that the feedback loop is fragmented and cannot be relied upon, compared to if there were assurances around the regularity of this aspect.

Information capture and analysis can also be of contestable quality for the various methodological reasons already outlined. This clearly disrupts the feedback loop as the information within it is not always accurate. All the subsequent processes: the risk judgement, the regulatory response and judgement can therefore be flawed.

The feedback loop of regulation in the NHS is clearly long and convoluted. All the specific regulatory deficiencies disrupt the loop of information further. The more simple and quick a feedback loop is the higher it's utility. In the private sector the market provides a short quick feedback loop based on the consumption of goods. In regulation, the feedback loop is more artificial but that does not mean the same idea does not apply. For regulatory feedback loops to effectively convey something meaningful about the public service they wish to regulate, simple, quick, short and accurate feedback loops must be present.

7.8 Who Regulates the Regulators?

The title of this research includes a question: who regulates the regulators? The answer to this question is not straightforward. You could say in a sense no one regulates ALBs in the NHS. They are supposed to be independent bodies who implement a specific function independently from central government. You could say that the level and degree of malpractice in NHS regulators and ALBs (as identified in this research) illustrates they are not subject to scrutiny or regulation.

On the other hand regulators and ALBs are regulated in another sense. The extent to which they are actually independent from central government is contestable. Their budgets and objectives are set by central government so the Department of Health clearly influences the behaviour of regulators in the NHS. There is an argument that ALBs only exist to depoliticise policy implementation and in reality they are doing what the Department of Health want and the separation is tokenistic. So in a sense you can say that regulators in the NHS are regulated by the Department of Health and central government.

Another way of look at it is to say that regulators are regulated by other sources like the public, the media and social media. Media in the UK frequently criticises the government, public services, the NHS, regulators and ALBs. The public has access to social media which is unlike anything ever previously known. Julie Bailey, a whistle blower related to Mid Staffordshire is a good example. She has a twitter account with thousands of follower (JulieBailey@CuretheNHS). She has a website (www.curethenhs.co.uk) which is also designed to share critiques about the NHS, the regulators involved and specifically Mid Staffordshire. So in a sense, the public and mass media regulate the regulators in the NHS in England.

The role of academia must also not be understated. This Economic and Social Research Council funded research has focused on the regulators of the NHS in England. There is a plethora of other research and commentary about this and related issues outlined in the

literature review. Researchers into these topics can be considered regulators of sorts, in that we are seeking to evaluate the concepts, activities, methodologies, success and implementation of regulators.

This thesis also started with a hypothesis: “In the health sector there are micro and macro deficiencies present in regulatory systems”. Based on the evidence presented in this document, proved by the inductive Feedback Loop Theory of regulation this hypothesis is accepted. All the evidence from all aspects of the research: qualitative, quantitative and the case study, suggests that there are micro and macro deficiencies present in regulatory systems. These deficiencies need to be a focus point for policy makers, because the implications of these deficiencies are vast and significant for society.

Chapter 8: Evaluation

8.1 Benefits and Limitations of Qualitative Interviews

8.1.1 Power Asymmetry

Interviews entail an asymmetrical power relation. Research interviews are very different from standard everyday type conversations between to equal parties in terms of power. Kvale and Brinkmann claim, for instance that; “the interviewer has scientific competence, he or she initiates and defines the interview situation, determines the interview topic, poses questions and decides which answers to follow up, and also terminates the conversation” (2009 p.33). The fact that the interviewer is the one who determines or controls so many aspects of the interview means that it is inevitable that they enjoy more power than the participant.

The first reason why qualitative interviews entail an asymmetrical power balance is that qualitative interviews represent a one way dialogue. This is a facet of qualitative interviewing that significantly increases power asymmetry in the relationship. It is the role of the interviewer to ask one directional questions and it is the role of the interviewee’s to answer these questions. The entire focus of the interview is directed towards the interviewee and as such this means that the position of the interviewer and interviewee are very different in relation to power. Kvale (2006) describes the unnatural nature of a research interview in comparison to normal conversations; “far from the reciprocal change of questioning and answering in a spontaneous conversation or a philosophical dialogue” (Kvale 2006 p.484).

The interview is an instrumental dialogue. In qualitative research interviews, the content of the interviews is designed to fit in with the researcher's aims and objectives. Rather than a conversation in which both parties objectives are pursued, research interviews are an instrument of the researcher. This instrument serves as “a means for providing the researcher with descriptions, narratives, texts – to interpret and report according to his or her research interests.” (Kvale and Brinkmann 2009 p.33) It is also argued that due to the nature of interviews being a conversation in which one party has a clear objective to gain from it that to

refer to them as dialogues is misleading in itself. Kvale 2006 purports this opinion because a dialogue is defined as; “a joint endeavour where egalitarian partners, through conversation, search for true understanding and knowledge” (p.33). Whilst acknowledging this, dialogue is referred to in this evaluation as a more appropriate term is not available.

Another reason why power imbalances can surface is because the interview may serve as a manipulative dialogue. It is possible but not necessarily the case that interviews may involve an element of deception from the researcher. In this research a manipulative dialogue does not exist, as all participants were fully briefed as to the nature of the interviews, with the aims of the research being clearly visible on the information sheet.

Another aspect of interviews which influences power relations dramatically is that there exists a monopoly of interpretation in the relationship. As Willig (2001) states: qualitative researchers “are interested in how people make sense of the world and how they experience events” (p. 9). Any research involving an interview is subjective in its nature due to the fact that only one person is deciding how to interpret findings and decide exactly how to portray these experiences of events. The researcher determines which interview passages to code for analysis and also decides how to analyse these coded findings. Despite the best efforts of any researcher trying to remain completely objective, the researcher “retains an exclusive privilege to interpret and report what the interviewee really meant” (Kvale and Brinkmann 2009 p.33) and there is no real way of ensuring this is always done effectively. Due to the nature of language and expression it is often the case that people misunderstand other people’s statements for a variety of reasons (cultural, social, language barriers, interpretation of gestures, regional dialect).

Richards and Schwartz (2002) offer further support for this notion and claim that “the interpretive nature of qualitative research means that the published results are only a version of “the truth”, and the validity of the findings must be judged in relation to the care with which the data were analysed” (p.136). Fossey et al. (2002) similarly acknowledge that, “it is important to consider the extent to which the qualitative research report reflects the

perspectives of those it claims to represent” (p.743). Fossey also recommends using direct quotations from interviews, involving the interviewees in the interpretation process and allowing interviewees to give feedback on the interpretations made as methods which can minimise the monopoly of interpretation that exists. Using these techniques can validate claims made by the interviewee in their interpretation, which can only result in research which is higher in validity and accuracy. The problem is that these methods may not be realistic when very high numbers of interviews are being conducted, and even if they are deployed, the monopoly of interpretation still exists because one person still has the final say on how to interpret evidence. As Kvale (1984) puts it; “extensive, complex and little structured interview material lends itself to be read like the devil reads the bible, selecting and interpreting interview statements according to one’s own preconceptions or prejudices” (p.190), and the monopoly of interpretation present means that this is more likely.

Many of the factors influencing power relations have been analysed but another important point to consider is the effect of these power imbalances on the interviewee. Power relations tend to position the interviewer in the position of power, but this can lead to efforts seeking to retain counter control from interviewees. Enosh and Ben-Ari (2009) refer to this as “deflection and power games” (p.129) in which interviewees either refuse to answer questions or deflect their answers, choosing to focus on topics other than those questioned about. Enosh and Ben-Ari claim that this tends to happen when the perceived reality of the interviewee differs from that of the interviewer, and deflection and power games ensue (2009 p.130).

There may be a monopoly in interpretations, instrumental and manipulative dialogues but the factor that puts the interviewee in the driving seat is that it can never be fully ascertained as to whether they are telling the truth. You can ask for evidence to back up interviewees’ claims but in reality there is no completely reliable method for verifying some claims. As discussed there are many reasons why the interviewer is in a position of power compared to the interviewee, and the interviewee may not like this. This may result in dishonest answers in the interviews. There may be other reasons for dishonesty in interviews, such as the interviewee may have personal reasons like; they want to appear rational, not emotional in their reasons

for thinking or doing something. Similarly, they may give what they perceive as “acceptable” answers, or their ego gets in the way. Another reason may be that they have a particular vested interest in the outcome. For example, they may benefit from the status quo and hence seek to answer questions in a way which preserves it. Another example is present in Nunkoosing (2005), in which a student is interviewing older men about health related behaviour and associated activities undertaken. One of the interviewees has made the claim that they visit the gym every day. The interviewer in question has serious doubt that this actually is the case due to the man’s overweight physical appearance, but aside from actually monitoring the man constantly there is no real way to decide whether he is being honest or not. It is quite possible that the claim is true, but it is also quite possible that it is a fabrication designed to make him feel better about himself and impress the interviewer. These are but a few examples reasons why interviewees may lie, and not revealing information is just as much of an issue. There is no way to know if an interviewee is giving short answers to questions genuinely or because they do not wish to be judged on the answers. Either way, the initial position of the interviewer in the position of power can quickly change if the interviewee pursues counter control in any of the ways discussed.

A further argument which comes from Caplan et al. is the “two-communities” theory. This thesis argues that there exists a power imbalance in interviews conducted by academics on decision makers because both parties “lack the ability to take into account the realities or perspectives of one another” (Caplan et al. 1975 p.4). Caplan observes that social science researchers in the public policy realm consider themselves: “rational objective and open to new ideas” (p.4) yet consider decision makers “action and interest orientated, indifferent to new ideas” (p.4). On the other hand decision makers being interviewed consider themselves “responsible, action orientated and pragmatic” and the academic researchers “naïve, jargon ridden and irresponsible in relation to practiced realities” (p.4). The issue here is that because both parties fail to fully take into account the perspectives of one another, battles for power can ensue. The problem for the interviewer is that the interviewees can withhold information or lie because they want to protect their relative stakeholder position in the policy network. This is an example of what was previously mentioned: preserving the status quo. Conversely,

the problem for the interviewees (who are decision makers or part of a policy network) is that their job may be put in jeopardy if they reveal certain information, and consequentially may be punished. Hence, Caplan et al. highlight the ebb and flow of the power struggle in the specific context of qualitative interviews which involve decision makers in a policy network.

There are many feminist writers who champion qualitative interviews over quantitative surveys as a way of obtaining information from women in particular. This is argued to be the case because; “whereas the linear thinking of men may be captured by questionnaires, soft qualitative data come closer to the female life world” (in Kvale 2006). The feminist justifications for such a claim rest on the premise that women are more likely to offer real insights when they are in a situation based on reciprocity, corroboration and intimacy (Ribbens 1989 p.580). Whilst this may be the case to some extent, this does not mean that interviews involving women are free from power imbalances. As Ribbens duly notes: “feminist writers have been in danger of developing romantic myths about research” (1989 p.580), in reference to the idea that qualitative interviews with women alleviate the associated problems with quantitative surveys. The fact that interviews may be more suited to obtaining information which is rich in content from women does not mean that power imbalances in the interviews are no longer present. The numerous reasons discussed are just as applicable to women as they are men, and consequently power relations remain a significant issue in interviews with women.

Another important factor which influences the power relations between interviewer and interviewee is the geographical location of the interview. Initially this seems like an inconsequential aspect of interviews and power, but on closer inspection it can dramatically change the perceptions and attitudes of those involved. Authors who have noted the influence of location on power include Elwood and Martin (2000) who state that at “any given location, is a setting for a variety of social, political, and economic activities and relations that operate at and through multiple scales” (p.650). This is something which is influenced by a plethora of factors and there is no real answer as to how to conduct interviews in a neutral environment. For example, a public policy researcher may be conducting interviews on health care

consumers, and decides to conduct them at a hospital. This may lead to the interviewees regarding the interviewer as someone who represents hospital and its interests and the answers given may reflect this. As Hewitt (2007) states “participants are less likely to criticise professional groups that are represented by the researcher” (p.1150) and conducting the interviews at the hospital may extenuate the likelihood of this occurring. With this in mind the researcher might consider conducting interviews at interviewees’ homes. This may lead to interviewees becoming reluctant to divulge too much information because they have a stranger in their house and feel defensive due to this. An alternate strategy is to conduct telephone interviews. This also has many issues attached because interviewees are much more reluctant to divulge information or even participate in the interview due to the impersonal nature of the situation. Conversely, these various sites offer various advantages. The hospital is a public place which may offer neutrality. The private home may lead to the interviewee feeling at ease and in their comfort zone. The telephone interview offers convenience for both interviewer and interviewee. This leaves a tough decision for interviewers because any location has advantages and disadvantages. Elwood and Martin (2000) conclude that there is no site which is free from factors which imbalance power fully and that the most important thing is to acknowledge the power dynamics that any particular location provides and consider this acknowledgment in analysis (p.656).

The last factor contributing to power imbalances to be discussed is researcher identities.

Hewitt (2007) notes importantly that “very few studies give such detailed descriptions of the researchers’ personal qualities (age, class, appearance, and status), which allow the reader to evaluate the validity of claims regarding conceptual bias” (p.1150). It seems obvious that “who the interviewer is” will influence their interactions with interviewees, and Nunkoosing (2005) also notes this point, advising interviewers “cannot pretend that their status, race, culture, and gender and their interviewee’s status, race, culture, and gender do not influence what can be said, how it is said, and what can be written about” (p.699). Similarly, Tang (2002) acknowledges the issues with researcher identities persist from a feminist perspective, claiming that “while power dynamics are at work in peer interview(s), the woman interviewer and interviewee’s perceptions of each other based on differences in social, cultural and

personal backgrounds have an impact on the power relationship in the interview” (p.704). The problem with researcher identities as a factor which is influential in power relations is that there is little that can be done if the researcher is working on their own. They cannot change their identities, so there is no obvious solution other than to acknowledge that it will affect the way the interviews are conducted and take this into consideration. But this also has issues, because there is no precise formula to calculate how researcher identities influence interviewee responses and the effects will vary from person to person.

In any discussion surrounding power asymmetries it is also imperative to consider the arising ethical implications for researchers. As always important consideration must be paid to vulnerable groups in interviews, and this can arise due to some of the reasons for power imbalances that have been outlined. As qualitative interviews often involve open ended questioning another ethical issue arises which is identified by Nunkoosing (2005) who notes that whilst consent is sought prior to interviews in open ended interviews, “the stories being narrated are constructed in the moments of the interviews to the extent that neither the interviewers nor the interviewees can predict the details of what is going to be discussed in advance of the event” (p. 700). This poses an additional ethical issue because information may surface that compromises the perceived autonomy of the interviewee or some other issue relating to their experiences.

Whilst this evaluation has focused on the many reasons for power asymmetry, attempts can be made to reduce power relations and these are now to be discussed. One example comes from Kvale (2006) who states that; “some interview researchers attempt to reduce their dominance over their research subjects, such as by giving their interpretations back to the interviewees for validation in the form of “member checks” as an attempt to obtain consensual knowledge” (Kvale 2006 p.5). There are many potential barriers to this attempt at balancing power, for instance the interpretations researchers make may be critical in their nature and the interviewee may have an emotional barrier to criticism. Therefore the fact that an interviewee disputes an interpretation may not mean it is necessarily false. This claim is supported by Riessman (1993) who “advocates asking for participants’ views on an

interpretation offered by the analyst” but at the same time “explicitly rejects the idea that the analyst’s intellectual independence should be abdicated or eroded by taking participants’ opinions as an authoritative judgement of the veracity or value of the interpretation” (in Yardley 2000 p.221). Fossey et al. refers to the validation of qualitative research claiming that; “informed by the empirico-analytical paradigm, is best evaluated against its own aims: accurate and objective measurement and the generalisability of the findings to a population beyond the study context” (p.726). So the general consensus among academics is that findings are more accurate when they can be validated in some way, but the problem is that validation is often not possible. As previously mentioned, member checks were present in this research. They were made during the interviews rather than afterwards. This meant that by simply validating an interpretation during the interview validity of the interpretations could be increased without having to ask the interviewee to actually read through the entire transcript after the interview.

Karnieli-Miller, Strier and Pessac (2009) make the recommendation that to reduce power imbalances between interviewer and interviewee “disclosure and authenticity” (p.280) must be present in qualitative interviews. This remedy for the power asymmetries is present in this research as illustrated by the information sheet and consent form (appendix 2).

The overriding conclusion is that power imbalances are most certainly present in qualitative interviews. What is less conclusive is who can be considered to be in the position of power. The majority of the reasons for power imbalances stem from the dialogue of the interview and inevitably put the interviewer in the position of power. Conversely, efforts for counter control and issues surrounding truth and authenticity of interviewees put them in the position of power. The main recommendation that can be gleaned is that these factors need to be noted in analysis. Whilst some measures can be taken to reduce power asymmetries, such as validating interpretations from the interview, these measures are by no means problem free. Power relations and asymmetries are an inevitable aspect of qualitative interviews, but whilst this is acknowledged, there is still significant worth to their deployment as rich and comprehensive information can be obtained in a way that no other research method can

provide.

8.1.2 Interviews and Qualitative Research

Aside from power relations in interviews there are numerous other strengths and weaknesses associated with the deployment of interviews and qualitative research methods in the social sciences. It is argued for example that: “given the temporary nature of the exchange, the respondent may have little motivation either to participate in the first place or to give complete and accurate answers” (Chadwick et al. 1984 p.108-109). This is an issue which cannot be completely alleviated, steps can be taken to increase the likelihood of complete and accurate answers, such as building a good rapport between interviewer and interviewee, but it is still possible that this will occur. This point is exacerbated by the fact that it is not always known to the researcher when this is occurring.

Another point that Chadwick et al. make criticising qualitative interviews as a method is that:

“It is almost always necessary to buttress central questions with supplementary probes which guarantee, to some extent, that even taciturn respondents will provide the essential minimum of detail... Probe questions often yield the underlying essentials that a poorly constructed interview schedule might miss entirely.” (Chadwick et al. 1984 p.118).

Again this is an issue in a sense, but can be combated in another. Probe questions can glean details not originally divulged and a well-constructed interview schedule makes this less necessary. The problem again is that it is not always known when an interviewee is intentionally avoiding a topic or providing monosyllabic answers and they cannot be forced to do otherwise if they do not want to.

There are also numerous strengths associated with the deployment of qualitative research methods; Chadwick et al. suggest for instance that:

“A major advantage of qualitative research is that it often involves the observation of behaviour in its “natural setting”. Allegedly, a researcher’s understanding is increased because he or she deals with the subjects in their world, and not in an artificial one created by the researcher.” (Chadwick et al. 1984 p.211)

It is certainly true that qualitative research tends to focus on participants experiences in the real world rather than in a constructed experimental or quantitative environment. It is also argued that this gives a “depth of understanding” (Chadwick et al. 1984 p.211) that is not present in quantitative research, which is especially relevant when evaluating key actors in regulatory networks. Another significant advantage of the qualitative method is its flexibility: “its flexibility in that it allows a researcher to be surprised... the apparent tangent often turns out to be the main line of future research” (Chadwick et al. 1984 p.212). This flexibility allows for revelations which are not constrained by the method and whilst this is less focused at times the flexibility has vast advantageous implications for the overall usefulness of findings and conclusions.

8.2 Benefits and Limitations with Quantitative Analysis

The fact that the quantitative analysis in this research was a secondary analysis of data that was not the authors own has associated benefits and limitations. In terms of advantages, this is much cheaper and less time consuming than generating new data, and findings are generated more quickly. Glaser (1963) describes a further advantage of such research: “the independent researcher subjects the data and interpretations to the critical judgement of an “outsider” who has nothing to lose, and may with impunity disagree with the “majority view” about what the data mean” (in Chadwick et al. 1984 p.262).

In terms of the associated disadvantages of secondary research: the main disadvantage is that the quantitative data was limited some ways outside the control of the researcher. For example the Dr Foster hospital guide did not publish results for two of the years in the time period being assessed. They have given assurance that this was due to legitimate reasons,

but with secondary research the researcher is at the mercy of the secondary data. Another general disadvantage of such research is that the quality of the data cannot be verified as it is not owned by the researcher. This does not really hold weight in this instance, however, as it is impossible to examine the data sets of arm's length bodies without the ownership being this way.

8.3 Practical Issues:

The size of a sample is always integral to the generalisability of research. The sample in the case of the qualitative interviews was of a non-probability based nature. The aim of this is to make the findings theoretically relevant rather than merely statistically random. It is also certain that a probability sample was not feasible given the nature of this research. This is because there was no necessity for Trusts and CCGs to participate and access had to be carefully negotiated. The purposive nature of the sample does however reflect a diverse range of the selected dichotomies.

As mentioned, access was a significant barrier in this research. One Trust, who shall remain nameless due to the anonymity arrangements, agreed to participate in this research and sent through all the relevant documentation to prove this. They then, when contacted, claimed that they were no longer willing to participate, and abruptly hung up. This type of occurrence was thankfully a rarity in this research. Upon further inspection, it became apparent that the Trust has (since agreeing to participate) been subject to regulatory enforcement action by the CQC. It therefore seems extremely likely that their reasons for pulling out of the project were related to this action. It is possible that they did not want to be subject to additional scrutiny, by the researcher, perceiving the research as judgemental in some sense. It is equally possible that due to the regulatory action, they simply no longer wished to participate due to the burden of such regulatory action: they were too busy. In any event, this did not detract from the range of providers in the sample, which as suggested, fits the purposive criteria.

Anonymity is another practical issue which holds relevance in this research. Anonymising participants definitely made them much more likely to participate in the first place, and also made them much more likely to give views which were insightful. Had they not been anonymous, they may have been less likely to give what might be considered controversial views. This is supported by the earlier section which described an interviewee holding back specific information for fear of being considered a whistle blower. On the negative side the anonymous nature of the Trusts and CCGs as well as interviewees means that it is not clear exactly where the data is coming from. But this issue is minimised because there are descriptions about the Trusts and CCGs and all the participants' job titles are clearly indicated. The quotes used in this research still clearly reflect the views of the key actors, and these views are contextualised by the descriptions and job titles (see table 4.1 p.114).

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Appendices

Appendix 1: Ethical approval

8 December 2011

Mr Richard McManus

30 Pilgrims Lane

Bugbrooke

Northants

NN7 3PJ

Dear Richard

Re: 'NHS Regulation: Getting the most from Health Care'

Thank you for submitting your revised project for review.

I am pleased to inform you that your project has been approved by the Ethics Review Panel.

If the fieldwork goes beyond the date stated in your application (September 2012) you must notify the Ethical Review Panel via Michele Dawson.

If there are any other amendments to your study you must submit an 'application to amend study' form to Michele Dawson. This form is available from Michele (01782 733588) or via <http://www.keele.ac.uk/researchsupport/researchethics/>

If you have any queries, please do not hesitate to contact Michele Dawson in writing to m.dawson@uso.keele.ac.uk

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Yours sincerely

M. D. Dawson

PP

Dr Nicky Edelstyn

Chair – Ethical Review Panel

CC RI Manager, Supervisor

Appendix 2: Information Sheet and Consent Form

Study Title: NHS Regulation: Getting the most out of Health Care.

Aims of the Research

- ☐ To critically assess the regulation of NHS Trusts in England (macro-level);
- ☐ To focus on case studies of eight NHS Trusts and evaluate the effectiveness and reliability of the regulatory regime and their activities;
- ☐ To compare methodologies used by the regulatory bodies for rating and regulating NHS Trusts in England and assessing the impact of this on service provision;
- ☐ To discuss and explore the political, economic and policy orientated ideologies that underpin the various regulation regimes in health care.

The content of the interview surrounds the nature and degree of assessments carried out by regulatory bodies and the representation of the position of the interviewee in this process.

Key areas to be focused on include:

- The nature of self-assessments,
- The methods used by the various bodies and whether it is adequate in assessing performance,
- The individual Trusts experience of the respective regulators (has compliance been unnecessarily bureaucratic etc.),
- The potential for replication of data collection by the various bodies,
- The scope for potential data sharing practices to be developed between regulators.

Invitation

You are being invited to consider taking part in the research study: NHS Regulation: Getting the most from Health Care. This project is being undertaken by Richard McManus as part of my PhD research.

Before you decide whether or not you wish to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is unclear or if you would like more information.

Why have I been chosen?

You have been chosen because of your position at your respective NHS Trust and the interaction between yourself and regulatory bodies that exists. There are around 60 interviews of this nature being conducted in total. I am interviewing staff from six Trusts around the country.

Do I have to take part?

You are free to decide whether you wish to take part or not. If you do decide to take part you will be asked to sign two consent forms, one is for you to keep and the other is for our records. You are free to withdraw from this study at any time and without giving reasons.

What will happen if I take part?

You will be asked a series of questions concerning your experience of health regulation. This interview is expected to last around 30 minutes and will take place at your work place.

If I take part, what do I have to do?

Simply answer the questions to the best of your ability.

What are the benefits of taking part?

You will be assisting in the evaluation of NHS regulation by representing your personal opinions and views on these matters.

What are the risks of taking part?

There are no risks to taking part in this research.

How will information about me be used?

The information collected will be used to evaluate the work of health care regulation in England. My aim is to represent the views of those I am interviewing in my thesis, and draw wider conclusion from this data.

Who will have access to information about me?

The only person who will have access to the data is the primary researcher (Richard McManus). Confidentiality will be safeguarded by anonymising interviewees' responses in the research.

Data will be stored securely in a locked filing cabinet and on a password protected computer

Data will be stored in line with Keele University guidelines and the data will be retained by the principle investigator for at least five years.

The longer-term arrangements are for disposing the data in a secure way.

Who is funding and organising the research?

Joint funded by The Economic and Social Research Council and Keele University.

What if there is a problem?

If you have a concern about any aspect of this study, you may wish to speak to the researcher who will do their best to answer your questions. You should contact Richard McManus: r.m.mcmanus@ilpj.keele.ac.uk. Alternatively, if you do not wish to contact the researcher you may contact Calum Paton (supervisor): c.paton@hpm.keele.ac.uk

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:-

Nicola Leighton

Research Governance Officer

Research & Enterprise Services

Dorothy Hodgkin Building

Keele University

ST5 5BG

E-mail: n.leighton@uso.keele.ac.uk

Tel: 01782 733306

CONSENT FORM**Title of Project:** NHS Regulation: Getting the most from Health Care**Name of Principle Investigator:** Richard McManus**Please tick box**

- | | | |
|---|--|--------------------------|
| 1 | I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. | <input type="checkbox"/> |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time. | <input type="checkbox"/> |
| 3 | I agree to take part in this study. | <input type="checkbox"/> |
| 4 | I understand that data collected about me during this study will be anonymised before it is submitted for publication. | <input type="checkbox"/> |
| 5 | I agree to the interview being audio recorded. | <input type="checkbox"/> |

Name of participant	Date	Signature

Researcher	Date	Signature

CONSENT FORM**(For use of quotes)****Title of Project: NHS Regulation: Getting the most from Health Care**

Name of Principle Investigator: Richard McManus

Please tick box

- | | | |
|---|--|--------------------------|
| 1 | I agree for any quotes to be used | <input type="checkbox"/> |
| 2 | I don't want any quotes to be used | <input type="checkbox"/> |
| 3 | I want to see any proposed quotes before making a decision | <input type="checkbox"/> |

_____	_____	_____
Name of participant	Date	Signature

_____	_____	_____
Researcher	Date	Signature

Appendix 3: Interview Guide

*Please note: this is a qualitative interview style and as such, questions sometimes vary from the interview guide dependant on the responses, and subsequent follow up questions. The questions in this guide represent the main areas the interview is structured around.

Introduction

I want to ask you some questions about your personal interaction with health regulators. Please be aware that the interview is being recorded, but that all answers will be treated confidentially with all responses remaining anonymous. I want to encourage open ended responses to the questions so please do not hold back, I am seeking to represent your views based on your respective position in the regulatory process. If you are happy to continue please read the information sheet and sign the written consent form.

1. How would you describe your perception of health regulation from your perspective, in particular in relation to the CQC and Monitor?
2. Do you believe that external CQC and Monitor regulation works effectively, doing what it should and how it should? Why? Is the age of data collected and the feedback process an issue? Are replication and data coding issues you would agree exist? Is your relationship with your CQC manager a good one?
3. What do you think the purpose of external regulation should be?
 - To improve service quality?
 - To improve finance/governance?
 - To create/restrict competition between providers? Should this be Monitors role?

4. What is your opinion of the separation of financial/governance and quality functions between the CQC and Monitor?
 - a. Is it appropriate?
 - b. Does it create additional complexity for providers?
 - c. Are the two not inextricably linked together?
5. When the CQC and Monitor monitor compliance they undertake information capture and analysis, how often would you say this happens? Is this appropriate?
6. Stage 1 in the CQC judgement framework involves determining whether there is enough evidence to make a judgement about compliance, would you consider this subjective from person to person or provider to provider?
7. In stage 2 in the CQC judgement framework checking whether the evidence demonstrates compliance with regulations is informed by “what is reasonably practical”, what do you consider this to mean? Subjective?
8. What is your opinion of the overseeing of your activities by the National Commissioning Board? Has it been satisfactory? Any issues?
9. Would you say health regulation operates as a coherent system? Why?
10. What would you say are the main problems/issues that CQC and Monitor face in practice?
11. Do you think that increased data sharing between regulators would be beneficial in terms of reducing replication of data collection?
 - a. What about between regulators and providers?
 - b. Could this be practically achieved?

15. Is there anything else you feel you can add about the topics we have discussed?

If you have any questions or information you think of after the interview please do not hesitate to email/call me, my details are on the information sheet. Thank you very much for participating in this interview.

16. Additional contacts. Is there anyone from either of your CCG who you think would be suitable or willing to participate in an interview for my research?

Appendix 4: Financial metrics: Monitor

Financial criteria	Weight (%)	Metric to be scored	Rating categories				
			5	4	3	2	1
Achievement of plan	10	• EBITDA* achieved (% of plan)	100	85	70	50	<50
Underlying performance	25	• EBITDA* margin (%)	11	9	5	1	<1
Financial efficiency	40	• Net return after financing** (%)	>3	2	-0.5	-5	<-5
	20	• I&E surplus margin net of dividend (%)	3	2	1	-2	<-2
Liquidity	25	• Liquidity ratio*** (days)	60	25	15	10	<10
<div>Financial risk rating is weighted average of financial criteria scores</div>							

* EBITDA: Earnings before interest, taxes, depreciation and amortisation. EBITDA (and other financial metrics) may be adjusted by Monitor for any 'one-off' non-recurring revenue, costs or 'investment adjustments'.

** Defined as (I&E surplus less PDC dividend, interest, PFI financing and other financial lease costs) divided by (total debt + total balance sheet PFI and finance leases + taxpayers' equity). The full definition can be found in the Monitor's quarterly and annual templates.

*** The liquidity ratio is defined as cash plus trade debtors (including accrued income) minus (trade creditors plus other creditors plus accruals) plus unused, committed and available working capital facility where there is no outstanding event of default (up to a maximum of 30 days and excluding overdraft agreements) expressed as the number of days operating expenses (excluding depreciation) that could be covered.

Appendix 5: Governance metrics: Monitor

84. Where NHS foundation trust plans are subject to further analysis as part of the annual plan review, the annual plan risk

a review of governance at the NHS foundation trust.

Diagram 11: deriving the governance risk rating

Monitoring	Service performance score	Governance risk rating												
1. Performance against national measures	<ul style="list-style-type: none">National indicators set out in Appendix BApplicable to all foundation trusts commissioned to provide servicesDeclared risk of, or actual, failure to meet any indicator = + 0.5-1.0Three successive quarters' failure of a 1.0-weighted measure (see Diagram 12): red rating and potential escalation for significant breach	<table><tr><th>Service performance score of...</th><th>Governance Risk Rating</th></tr><tr><td>< 1.0</td><td>Green</td></tr><tr><td>≥ 1.0</td><td rowspan="2">Amber-green</td></tr><tr><td>< 2.0</td></tr><tr><td>≥ 2.0</td><td rowspan="2">Amber-red</td></tr><tr><td>< 4.0</td></tr><tr><td>≥ 4.0</td><td>Red</td></tr></table> <p><i>Risk ratings applied quarterly and updated in real time</i></p>	Service performance score of...	Governance Risk Rating	< 1.0	Green	≥ 1.0	Amber-green	< 2.0	≥ 2.0	Amber-red	< 4.0	≥ 4.0	Red
Service performance score of...	Governance Risk Rating													
< 1.0	Green													
≥ 1.0	Amber-green													
< 2.0														
≥ 2.0	Amber-red													
< 4.0														
≥ 4.0	Red													
2. Third parties	<p>Care Quality Commission¹ <i>Following non-compliance with essential standards</i></p> <ul style="list-style-type: none">Major impact on patients = +2.0Enforcement action = +4.0 <p>NHS Litigation Authority²</p> <ul style="list-style-type: none">Failure to maintain, or certify, a minimum published CNST level of 1.0 or have in place appropriate alternative arrangements: +2.0													
3. Mandatory services	<ul style="list-style-type: none">Declared risk of, or actual, failure to deliver mandatory services: +4.0													
4. Other board statement failures	<ul style="list-style-type: none">If not covered above, failure to either (i) provide or (ii) subsequently comply with annual or quarterly board statements (see Appendices C and D)													
5. Other factors	<ul style="list-style-type: none">Failure to comply with material obligations in areas not directly monitored by MonitorIncludes exception or third party reportsRepresents a material risk to compliance													
		<p>Override applied to risk rating</p> <ul style="list-style-type: none">nature and duration of override at Monitor's discretion												

¹ Monitor will not score more than once for multiple CQC compliance actions. Any changes to risk ratings arising from CQC actions will be applied immediately (not quarterly).

² Where an NHS foundation trust has a CNST level of 0 due to a transaction and can demonstrate a plan to achieve a minimum level of 1, Monitor will not apply a score to the trust's risk rating.

Appendix 6: Dr Foster HSMR metrics

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Metric

The ratio of the observed number of in-hospital deaths with a Hospital Standardised Mortality Ratio (HSMR) diagnosis to the expected number of deaths, multiplied by 100.

Numerator

Denominator superspells with method of discharge as death (DISMETH=4, 5)

Denominator

Superspells containing an emergency spell with a primary dominant diagnosis of any of the 56 CCS groups that comprise the HSMR basket.

HSMR basket: **CCS Number CCS Group Name**

2	Septicemia (except in labour)
12	Cancer of oesophagus
13	Cancer of stomach
14	Cancer of colon
15	Cancer of rectum and anus
17	Cancer of pancreas
19	Cancer of bronchus, lung
24	Cancer of breast
27	Cancer of ovary
29	Cancer of prostate
32	Cancer of bladder
38	Non-Hodgkin's lymphoma
39	Leukaemias
42	Secondary malignancies
43	Malignant neoplasm without

	specification of site
55	Fluid and electrolyte disorders
59	Deficiency and other anaemia
68	Senility and organic mental disorders
100	Acute myocardial infarction
101	Coronary atherosclerosis and other heart disease
103	Pulmonary heart disease
106	Cardiac dysrhythmias
107	Cardiac arrest and ventricular fibrillation
108	Congestive heart failure, nonhypertensive
109	Acute cerebrovascular disease
114	Peripheral and visceral atherosclerosis
115	Aortic, peripheral, and visceral artery aneurysms
117	Other circulatory disease
122	Pneumonia
125	Acute bronchitis
127	Chronic obstructive pulmonary disease and bronchiectasis
129	Aspiration pneumonitis, food/vomitus

130	Pleurisy, pneumothorax, pulmonary collapse
131	Respiratory failure, insufficiency, arrest (adult)
133	Other lower respiratory disease
134	Other upper respiratory disease
145	Intestinal obstruction without hernia
148	Peritonitis and intestinal abscess
149	Biliary tract disease
150	Liver disease, alcohol-related
151	Other liver diseases
153	Gastrointestinal haemorrhage
154	Noninfectious gastroenteritis
155	Other gastrointestinal disorders
157	Acute and unspecified renal failure
158	Chronic renal failure
159	Urinary tract infections
197	Skin and subcutaneous tissue infections
199	Chronic ulcer of skin
224	Other perinatal conditions
226	Fracture of neck of femur (hip)
231	Other fractures
233	Intracranial injury

237	Complication of device, implant or graft
245	Syncope
251	Abdominal pain

Data Source

SUS – CDS

Statistical methods

□ Logistic Regression: Expected number of in-hospitals deaths derived from logistic regression, adjusting for factors to indirectly standardise for differences in case-mix.

Adjustments are made for:

- o Sex
- o Age on admission (in five year bands up to 90+)
- o Interactions between age on admission (in five year bands up to 90+) and Charlson co-morbidity score
- o Admission method (non-elective or elective)
- o Socio-economic deprivation quintile of the area of residence of the patient (based on the Carstairs Index)
- o Diagnosis/procedure subgroup
- o Co-morbidities (based on Charlson score)
- o Number of previous emergency admissions
- o Year of discharge (financial year)
- o Palliative care (if any episode in the spell has the treatment function code 315 or contains ICD10 code Z515 in any of the diagnoses fields)
- o Month of admission
- o Source of admission

□ Relative Risk: The ratio is calculated by dividing the actual number of deaths by the expected number and multiplying the figure by 100. It is expressed as a relative risk, where a risk rating of

100 represents the national average. If the trust has an HSMR of 100, that means that the number of patients who died was exactly as it would be expected taking into account the standardisation factors. An HSMR above 100 means more patients died than would be expected; one below 100 means that fewer than expected died.

□ Control Limits: Control limits tell us the range of values which are consistent with random or chance variation. Data points falling within the control limits are consistent with random or chance variation and are said to display 'common-cause variation'; for data points falling outside the control limits, chance is an unlikely explanation and hence they are said to display 'special-cause variation' – that is, where the trust's rate diverges significantly from the national rate.

Data points falling above the upper 99.8% binomial control limit are said to be significantly 'higher than expected', data points falling below the lower 99.8% binomial control limit are said to be significantly 'lower than expected', otherwise 'within expected range'.

Appendix 7: CQC Finances

Statement of Comprehensive Net Expenditure for the year ended 31 March 2012

		2011/12	2010/11
Note		£000	£000
Expenditure			
Staff costs	3	94,153	70,241
Depreciation	4	11,340	12,473
Other Expenditure	4	37,544	56,308
Impairment of Assets	4	6,403	67
		149,440	139,089
Less Income			
Income from Activities	6	(85,987)	(80,062)
Other income	6	(2,504)	(22)
		(88,491)	(80,084)
Net Expenditure for the financial year		60,949	59,005

<http://www.official-documents.gov.uk/document/hc1213/hc04/0482/0482.pdf>

Appendix 8: Monitor finances**Financial position**

Monitor's net expenditure for the year was £15,538,000 (2010-11: £14,771,000).

Staff costs represent 90% of net expenditure at £13,914,000 (2010-11: £10,712,000).

Other operating costs include property, consulting and office expenses.

Grant-in-aid of £15,700,000 was received during the year of which £197,000 was applied to the purchase of fixed assets. Net assets at 31 March 2012 were £1,579,000 (31 March 2011: £1,417,000). In 2011/12 Monitor recharged all expenditure in relation to preparing for the transition to our new functions, as detailed in the Health and Social Care Act 2012, to the Department of Health, this totalled £7,744,000, of which £170,000 was applied to the purchase of fixed assets.

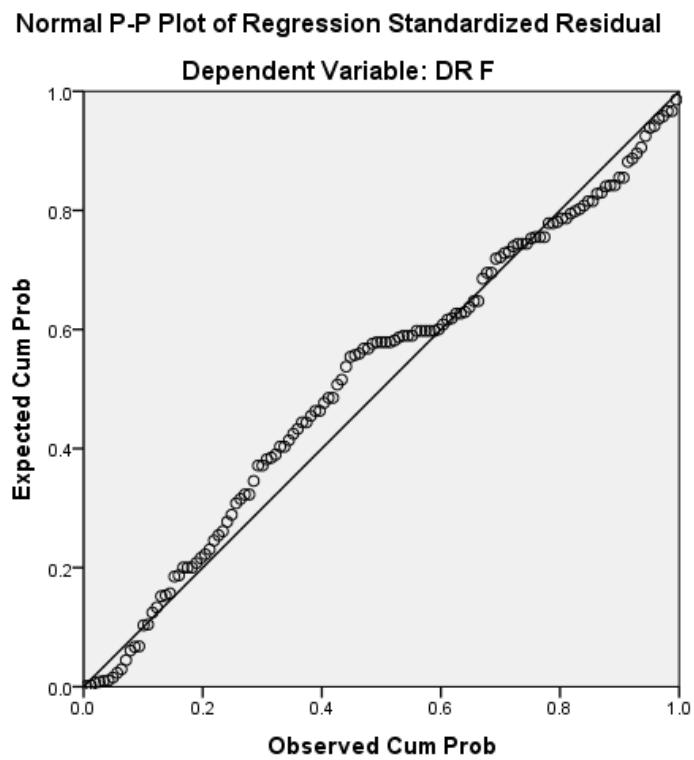
A comprehensive review of Monitor's activities and performance against business objectives during the year is set out on pages 3–59 of this report.

Dr David Bennett

Chair and Interim Chief Executive

3 July 2012

<http://www.monitor-NHSft.gov.uk/sites/default/files/Annual%20Report%20-%20corrected%20-%20180712.pdf>

Appendix 9: Additional Statistics Diagrams**Output 15**

Output 16

