Review of the regulation and governance processes of independent hospital entities in England and New Zealand

England: Jean Long and Anne McCarthy
New Zealand: Jackie Cummings and Grant Hannis

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List of abbreviations

ACC	Accident Compensation Corporation
AHB	area health board
ALOS	average length of stay
CCG	clinical commissioning group
CCMAU	Crown Company Monitoring Advisory Unit
CHE	crown health enterprise
CNS	central nervous system
CPI	Consumer Price Index
CQC	Care Quality Commission
DHB	district health board
DoH	Department of Health
GP	general practitioner
HCP	healthcare plans
HFA	Health Funding Authority
HHS	hospital and health services
HRD	Health Reform Directorate
MMP	mixed member proportional
MoH	Ministry of Health
NGO	not-for-profit or non-governmental organisation
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIPB	National Interim Provider Board
OECD	Organisation for Economic Co-operation and Development
PCT	primary care trust
PFI	private finance initiative
PHC	Public Health Commission
RCSI	Royal College of Surgeons in Ireland
RHA	regional health authority
RPI	Retail Price Index
SOE	state-owned enterprise
UL	University of Limerick

Executive summary

Purpose

The purpose of the review is to present information describing the establishment and regulation of, and governance for, foundation trusts in England and New Zealand. The review was undertaken to inform the legislative framework establishing, regulating and governing independent hospital entities (or trusts) in Ireland.

Methods

The search methods employed in this study comprised systematic, targeted and informed searches. Systematic searches of the PubMed database were undertaken, using a set of criteria and parameters which allows for the establishment of a static framework and the feasibility to repeat the search using the same criteria. Targeted searches are defined as examination of websites of interest to the study. These include the Google search engine and other named websites. Details are provided in the main body of this report.

Findings

After extensive searching, we present the findings of two of three countries (England, New Zealand and Scotland) that transformed public entity hospitals into independent entities. The findings from Scotland are not presented, as the experience is not well documented.

Case history: England

Introduction

Healthcare in England is funded through general taxation, is universally available and free at the point of delivery. The UK healthcare market is subject to European and national law, which prohibit anti-competitive behaviours such as cartels or taking a dominant position.

Regulation framework and governance of healthcare in England (What was put in place and why?)

The principle contemporary Acts determining health-related governance in England are the: National Health Service Act (2006, consolidating 1990 and 2003 Acts), the Health and Social Care Acts of 2008 and 2012, and the National Health Service (Procurement Patient Choice and Competition) (no 2) Regulations of April 2013.

Legislation covering healthcare governance in England deals with the roles and responsibilities of National Health Service (NHS) trusts and NHS foundation trusts (providers), and clinical commissioning groups (CCGs) and the Commissioning Board (purchasers); the Commissioning Board is now titled 'NHS England'.

Trusts are public bodies and, as legal entities, have a financial autonomy not permitted to State bodies. The degree of autonomy varies between trust types, reflecting their independence in law. The NHS foundation trusts have greater managerial and financial independence and are responsible to Parliament, not the Minister of Health, as is the case for NHS trusts. Originally, the NHS was managed by regional and central government hierarchies. These were replaced by a more market-driven ethos in 1990, and since 2004 foundation trusts function within a regulatory framework whose ethos allows profit-making and requires cost-effective service delivery. This transformation of State bodies to independent legal entities has occurred over a 24-year period, with the most prominent transition points being the establishment of NHS trusts (in 1990) and the establishment of foundation trusts (since 2004) between 14 and 24 years later. However, Allen *et al*. 2012 maintain that foundation trusts do not fulfil all the criteria to be classified as mutual trusts, as the members cannot distribute the surpluses and do not own the capital infrastructure and, in the event that the foundation trust fails, the membership cannot distribute the assets among the membership – the assets return to the state.

In line with the establishment of foundation trusts, Monitor was established to provide governance oversight for foundation trusts.

Monitor was established in January 2004 to assess, authorise and regulate NHS foundation trusts in England. It is funded by the Department of Health (DoH) and reports directly to Parliament. The Health and Social Care Act 2012 made changes to the way healthcare is regulated in order to strengthen the manner in which patients' and other users' interests are promoted and protected. Monitor's role has changed significantly since 2012, as it has taken on a number of new responsibilities. Monitor is the sector regulator for healthcare, which means that it regulates all providers of NHS-funded services in England, unless exempt under secondary legislation. Monitor's main duty is to protect and promote the interests of patients. It does this by promoting the provision of healthcare services that are effective, efficient, and economic, and maintains or improves their quality.

Monitor's regulatory functions include: licensing healthcare facilities; regulating prices; enabling integrated care; safeguarding cooperation and competition (based on quality rather than price); and ensuring continuity of services. Monitor retains its old function with respect to foundation trusts and has five new regulatory functions.

The Conservative-Liberal Coalition Government published the Health and Social Care Act 2012, which abolished the remaining bureaucratic hierarchical arrangements of the NHS in England and transformed the NHS into a regulatory body. Strategic Health Authorities (SHAs) were replaced by the NHS Trust Development Authority and NHS England. Primary Care Trusts (PCTs) were abolished and replaced by NHS England and consortia of CCGs (approximately 221 general practitioner (GP) groups in 2013). Davies' (2013) consideration of the Health and Social Care Act 2012 highlights two concerns with respect to CCGs' skill sets: one is their knowledge of specialist secondary care and the other is their skills with respect to procurement and contractual law. These groups are akin to the district health authorities and GP fundholding in the early 1990s and the subsequent PCTs. Davies maintains that CCGs will need to hire or contract experts to complete this work and these experts are likely to be former staff from the PCTs. In addition, she questions whether accountability will be weakened, as the responsibility for procurement decisions will be transferred by the CCGs to their hired experts.

Establishing foundation trusts (What was achieved?)

Monitor examines corporate and financial data to assess whether an NHS trust is ready to become an NHS foundation trust. The depth and the validity of measures reported have evolved since the establishment of the first foundation trusts in 2004. However, broadly speaking, NHS trusts applying for foundation trust status have, from 2004 to 2012, been assessed under the following three criteria:

1. Is the trust well governed?
2. Is the trust financially viable?
3. Is the trust legally constituted?

Since April 2013, the newly established NHS Trust Development Authority has undertaken a more rigorous baseline assessment process, comparing a range of governance indicators (in the corporate, financial and clinical domains) against a baseline standard to assess the readiness or not of an NHS trust for foundation trust status. These indicators are monitored through its oversight and escalation process. The process has five numeric measures where '1' indicates that there were no identified concerns, and '5' indicates that formal action is required. The indicators are based on Monitor's three assessment criteria for the transfer from NHS trust status to NHS foundation trust status, as outlined above.

With regard to the NHS Trust Development Authority's process to assess the readiness or not of an NHS trust for foundation trust status, in March 2014 there were six NHS (hospital) trusts where formal action was required (escalation score 5), and which were undergoing a series of interventions to improve their governance and their ability to provide high-quality care. In the same period there were 27 NHS trusts assessed as having material issues (escalation score 4).

Since April 2013, Monitor has been responsible for economic regulation and governance of the healthcare sector in England. The role Monitor has played with respect to both NHS trusts and NHS foundation trusts has broadened since its establishment in 2004, and reflects the new requirements of the 2012 Act, which include assessment, licensing, monitoring and regulation. Monitor's *Guide for Applicants* provides NHS trusts with information on how to achieve foundation trust status.

Successful applicants for NHS foundation trust status are authorised and licensed. In some instances, authorisation is deferred or other alternatives, discussed below, are sought. At the end of January 2014 there were 99 NHS trusts that had not been either established as foundation trusts or merged with existing foundation trusts. Of the 99 trusts, 62 provided acute hospital services.

Monitor has used a competence framework to monitor established foundation trusts on a quarterly basis between 2004 and 2013. Following this quarterly assessment, it assigns a code to the domains of corporate governance and finance; this may be: green (no concerns), amber (some or moderate concerns), red (serious concerns) or pairings of these codes. Where foundation trusts fail their quarterly assessment process, a series of pre-defined, corrective steps is put in place to restore adequate governance. Temporal trends show that the level of success for foundation trusts varies. The proportion classified as having some, or many, serious governance concerns was 35% in 2012/13, and the proportion classified as high risk with respect to their financial status was 46% in Q4 2012/13. At the end of 2012/13, 19 (13%) of the 145 foundation trusts remained in significant breach of their authorisation or licence. All 19 had to undergo remedial action such as the establishment of contingency planning teams, the appointment of new chairs, and the development of turnaround plans.

The competency framework was replaced by a risk-based system of regulation in late 2013. The risk-based assessment measures the foundation trust's ability to sustain itself into the future (continuity) and the degree of concern about how the trust is run (governance); the governance measure takes account of quality using assessments from the Care Quality Commission (CQC). There are four continuity-of-service-ratings, where '1' is very serious risk of failure to continue its service, up to '4' where there is no risk of failure. There are two governance ratings – green, which indicates no evident concerns or red, which indicates concerns.

In March 2015 the competency framework found that a large proportion of NHS foundation trusts had serious governance concerns and financial difficulties:

1. A total of 23.7% of NHS foundation trusts were deemed to have a serious risk of continuity failure, and 34.3% had governance concerns or were under review to deal with past governance concerns.

2. Thirty-three (21.7%) of 152 foundation trusts were subject to special enforcement actions by Monitor, and a further nine (5.9%) were the subject of an investigation by Monitor.

This monitoring system indicates that the governance, quality of care, financial situation and sustainability of foundation trusts are monitored closely and that immediate action is taken to deal with concerns. Despite the extensive monitoring, a large minority of NHS foundation trusts are at risk of not being able to continue to provide services.

Effectiveness of economic regulation and governance on both foundation and NHS hospital trusts in England (What was its effect?)

Regulation (impact of change)

At present there is no evaluation of Monitor's regulatory function. The Government's proposed evaluation of Monitor's effectiveness as a regulator will be based on the newly determined measures of cooperation, integration, quality, cost and competition. The measures are endorsed as indicators of healthcare productivity. Improved productivity has been promoted by each government since 1991 as the beneficial outcome of market competition in healthcare. However, some experts have argued that a beneficial effect of competition on healthcare productivity and, more particularly, healthcare quality remains contested.

Governance (impact of changes)

Monitor's impact on foundation trusts has been assessed in numerous ways, taking account of various expected outcomes. These include: the impact of Monitor's processes of assessing NHS trusts' suitability for foundation status and its assessment of foundation trusts' compliance with its authorisation up to 2013, and its healthcare provider licence since 2013. External research groups examined the evolution of foundation trusts with regard to their internal development and their relationship with the wider civil and political framework in which they functioned.

Frontier Economics (2009) reviewed Monitor's impact on the development and governance of foundation trusts. The nine selected foundation trusts examined were reported to have effected a saving of £271-£389 million. Frontier Economics reported that Monitor's regulatory regime resulted in: a direct improvement in financial governance and discipline, boards becoming more commercially aware, and improvements in specific quality indicators (for example, a reduction in MRSA rates, as well as a reduction in waiting times).

In 2010, Monitor analysed regulatory breaches by foundation trusts and the ensuing recovery actions the trusts were required to undertake in order to effect good governance. Effective recovery actions were identified as: development of a long-term corporate and financial strategy, the undertaking of business planning with potential commissioners, and regular, independent third-party reviews of the board.

A 2012 study by Allen *et al*. used three years of quantitative longitudinal data to describe and compare governance practices for four foundation trusts which were considered to be representative of other foundation trusts. The data were interpreted as foundation trusts compared with NHS trusts, and foundation trusts demonstrated more business-like practices, a self-reliant ethos among board members but less so among the clinical directors, and awareness as autonomous agents. Foundation trusts were also reported to be more cost aware, a practice apparent in the drive to reduce service costs, and in the growing and re-investment of surplus to improve income and expand and develop services. The nature of the relationships between the trust, other healthcare service providers or purchasers, and Monitor was also observed. Greater competition with other hospitals was reported, as was some friction between the foundation trusts' boards and Monitor.

Allen *et al*. (2012) also examined the membership of four foundation trusts and reported that, although membership had increased during the study, it comprised approximately 4% of the population served by the foundation trust in 2009. Foundation trusts are not directed by Government. Therefore, they have greater freedom to decide, with their governors and members, their own constitution, strategy and the way services are run. Anyone who lives in the area, works for the trust, or has been a patient or service user there, can become a member of an NHS foundation trust. Members can stand for election to the council of governors. The council of governors works with the boards of directors, which are responsible for the day-to-day running of the foundation trust, to ensure that the trust delivers high-quality care and plays a role in helping to set the overall

direction of the organisation. Allen *et al*. (2012) reported that the main positive effect of local membership and the governors' structure was that it increased responsiveness and gave legitimacy to the services provided by the foundation trust. However, there was no evidence that the governors' structure influenced the foundation trusts' strategic planning.

In late 2013, the Comptroller and Auditor General examined whether Monitor's regulation of NHS foundation trusts had been effective. It found that the growth in risk in the foundation trust sector may put unsustainable pressure on Monitor's capacity to regulate trusts in difficulty, or on the trusts' capacity to maintain continuity of services. Historically, Monitor has used mainly retrospective performance measures in assessing risk, but it strengthened its approach in October 2013. Monitor's interventions have helped trusts in difficulty to improve. Monitor's influence has been less effective where the cause of the trust's difficulties relate to underlying issues in the local health economy. Overall, the Comptroller and Auditor General reported that Monitor has achieved value for money in regulating NHS foundation trusts.

A report for the Nuffield Trust (Jones and Charlesworth 2013) assessed the overall financial position of the NHS in England and identified financial pressures, one of which is private finance initiatives (PFIs). It found that the total bill for PFI repayments had increased by nearly £200 million in just two years, from £459 million in 2009/10 to £628.7 million in 2011/12. (These amounts only apply to NHS trusts in England). The report's authors stated that PFI deals have become problematic for three major reasons: they usually have very high interest rates; they impose much higher debts on the taxpayer than the actual value of the infrastructure they originally helped to build (in 2011 the taxpayer owed £121.4 billion to pay for infrastructure which was only valued at £52.9 billion); and they often include expensive maintenance and service contracts which charge the public purse vastly inflated fees for performing simple tasks. The Nuffield Trust report also highlighted specific NHS trusts which have to spend a particularly large proportion of their overall budgets on servicing PFI schemes. In England, there were seven trusts where PFI repayments accounted for more than 5% of total revenue in 2013. The report also emphasised that interest repayments on PFI debts are mostly up-rated using the Retail Price Index (RPI) measure of inflation, which tends to be higher than other measures, such as the Consumer Price Index (CPI).

Lessons learned

England: Lessons learned

- It takes time, legal intervention and rigorous assessment and monitoring to establish independent hospital entities from state hospitals: 24 years in the case of the NHS in England, and the process is still not complete.
- A regulator is required to assess and monitor foundation trust applications and foundation trusts themselves, once established.
- A detailed application and assessment process is required for applicant NHS trusts that wish to become foundation trusts.
- A detailed legal contract, or a licence and a continuous monitoring process are required, so that the regulator can hold the foundation trust to account.
- On the one hand, successful foundation trusts demonstrated improved financial governance and discipline, saved money, had more commercially aware boards and improved quality. In addition, the public had a say in local healthcare services.
- On the other hand, approximately one-third of the established foundation trusts had/continue to have serious governance and/or financial problems despite rigorous oversight, and these require serious intervention by the regulator.
- Some foundation trusts compromised quality of care in order to meet financial targets.

- Quality-of-care measurements were only introduced as part of the assessment and monitoring criteria in 2009, following some serious incidents.
- PFIs have become a serious drain on hospital resources and remain a barrier to some NHS hospital trusts becoming NHS foundation trusts.

Conclusion for England

1. It is clear that preparing public hospitals to be independent entities, and maintaining them as such, requires a rigorous process including an annual licensing process, continuous monitoring and an independent organisation to provide oversight.

2. It should also be noted that, despite the rigorous procedures, 34.3% of NHS foundation trusts had governance concerns and 23% had serious continuity (financial) risks in March 2015.

3. Evaluations of the oversight procedure indicated that quality-of-care measurements were necessary alongside governance and financial measures, and these were only included after some serious incidents in 2009.

4. The introduction of competition based on quality with set prices rather than competition based on price in 2012 is an interesting measure.

Case History: New Zealand

During the 1990s, New Zealand established independent hospital entities ('crown health enterprises' or CHEs) as part of a series of major reforms of its publicly financed healthcare system. In 2000, these reforms were overturned. The purpose of this review is to provide an overview of the rationale for establishing CHEs and of the evidence of the impact of CHEs during the 1990s, and the subsequent rationale for reversing the reforms.

New Zealand introduced radical reforms of its publicly financed healthcare system in 1993. These reforms were introduced in response to concerns over inefficiencies and lack of responsiveness from publicly owned hospitals, and an overemphasis on hospital services to the detriment of primary healthcare services, resulting in overall poorer health, higher cost services, and inequalities in health. This review focuses on an assessment of the reforms in terms of their impact on improving the performance of publicly owned hospitals.

The reforms involved the introduction of a 'purchaser-provider' split. Four geographically based regional health authorities (RHAs) were established as standalone purchasers holding a single, integrated budget for all health and disability services. Publicly owned hospitals were converted into 23 CHEs to be run along business lines, including returning a surplus to central government. RHAs would contract for services, including from CHEs; they could also contract with private hospitals and allocate resources as they best saw fit across preventive, primary, and secondary healthcare (hospital) and disability support services.

The reforms were highly unpopular. Significant concerns were raised about the high cost of implementing the model over a very short time period (two years); about the anticipated high ongoing transaction costs arising from contracting processes; uncertainties about whether the model would result in the expected efficiency gains, and whether these gains would offset the costs of the reforms. Central government sought a 'low-impact' start to the reformed model, in order to alleviate concerns about the impact of the reforms on publicly owned hospitals, and also in response to a lack of information on which to base contracting and resource allocation decisions. Contracting proved extremely difficult in the early years (1993 to 1995). CHEs ran significant deficits for many years, in part due to low fees offered by the RHAs, which in turn resulted in central government having to allocate additional resources to the system. Overall, the reforms failed to generate the gains that had been expected.

In 1996/1997, changes were made to the model. These changes included amalgamating the four RHAs into a single Health Funding Authority (HFA), and changing CHEs into hospital and health services (HHSs), with HHSs no longer having to earn a surplus, and with expectations of a more collaborative set of arrangements. Following a transitional year, while the HFA was being established, the HFA finally commenced operations in 1998.

In late 1999, there was a change of Government. The model was overturned from 2001 onwards, with the re-amalgamation of purchasing and hospital provision into 21 (now 20) district health boards (DHBs). Aspects of the 1996/1997 purchasing model continue to this day, however, with DHBs contracting with independent, privately owned primary healthcare and community providers for a range of services.

Enablers and barriers

Key enablers supporting the CHE reforms included:

- When they were established, CHEs were placed on a sounder financial footing (including through the writing off of debt).
- Over time, the reforms generated improved information on costs and volumes of services delivered.

Key barriers hampering the CHE reforms included:

- The lack of consultation on, and lack of support for, the reforms as a whole, coupled with the high cost of the reform processes themselves, thus making it difficult for the Government to fully implement the reforms as expected.
- Major reforms take a considerable period of time to implement and to bed in, and can be very costly to implement.
- There were highly unrealistic expectations of efficiency gains among health decision-makers, and of how the proposed model would work in practice in the New Zealand setting. In particular, a lack of competition and a focus on ensuring access to services in a country with a widely dispersed population and many small population centres with no private hospital service provision meant that many CHEs had a monopoly over the delivery of a wide range of services; consideration should have been given at an early stage as to how the model would work in practice in such circumstances.
- The poor financial position of CHEs prior to their establishment, resulting from lack of funding in the previous decade, coupled with strong public support for CHEs, led to ongoing concerns about the financial position of CHEs, and therefore a lack of public confidence that services would continue to be available.
- A lack of clear analysis and information on the likely impact of the reforms on publicly owned hospitals was also evident; public concern over potential privatisation was another factor that led to a lack of support for the model.
- The lack of information available to support purchasing in the early days made negotiations and pricing difficult.
- A highly legalistic approach to contracting led to adversarial relationships and high ongoing transaction costs, thus further undermining the model.
- With a lack of general support for the reforms, the Government hampered the ability of the model to deliver gains by creating a 'low-impact' environment, which prevented significant change and suggested to purchasers and providers that there was a lack of commitment to seeing reforms through, and that this would mean significant change in service delivery patterns.

Lessons learned

Key lessons learned included:

- Health sector contracting relationships took some time to mature in New Zealand.
- In New Zealand, health sector reforms that emphasised the business and efficiency aspects of healthcare provision were profoundly unpopular.
- High transaction costs and pressure to use resources to deliver services also hampered the development of strong contracting processes.
- The introduction of additional co-payments was also politically fraught In New Zealand.
- Acute hospitals in rural New Zealand were generally natural monopolies, implying that market strategies based on competition were unlikely to succeed.
- The failure to properly monitor quality of care, and build quality into contracts, also hampered reforms.

- The failure to adequately monitor efficiency limited New Zealand's ability to assess a key aspect of the performance of the New Zealand health sector.

New Zealand conclusion

Although it is widely acknowledged in the literature that the 1990s purchaser-provider reforms failed to meet their objectives with respect to hospital services, there are diverging views as to whether this was due to the reforms not being implemented fully or appropriately, or whether the New Zealand model itself was flawed.

1. In conversations about the reforms, some experts argue that once the single, national HFA was established, relational contracting developed and a less legalistic approach was taken to contracting; moreover, the purchaser-provider reforms had the potential to deliver gains in the longer term – in particular by putting pressure on CHEs to perform (even if they held monopoly positions), and by enabling RHAs to allocate increasing resources to primary healthcare settings, thus potentially generating improved overall value for money. However, by the time the HFA was fully established and was up and running (in January 1998, i.e., six and a half years after the announcement of the reforms), the financial and political costs of the reforms had been significant, and the gains had been insufficient for many.

2. An alternative view is that the New Zealand model itself was totally flawed. Here, the arguments are that: political factors are impossible to remove from decision-making within a system where the largest proportion of spending comes from the Government and where New Zealanders hold ministers to account for the performance of the health system – meaning that a single, national purchaser is never truly independent; transaction costs would remain high with any contracting system; there is only ever likely to be very limited competition between publicly owned and privately owned hospitals, given the dispersed and small New Zealand population; the separation of purchasing and provision creates too much uncertainty for hospital providers in terms of longer-term planning, and too little flexibility to respond to short-term issues.

3. Some experts continue to argue for a return to a purchaser-provider split model, suggesting a re-establishment of a HFA in New Zealand. The main reasons for this seem to be to enable a purchasing authority to use a formal contracting process to make efficiency gains within hospitals, but also to allocate resources to primary healthcare providers, with an increased focus on wellness rather than sickness. As yet, however, there does not seem to be any real appetite among the main political parties for health reform or restructuring, given the expected high financial costs of reform and the likelihood that significant reform would divert attention for several years to health service restructuring issues, as opposed to the current key health issues the health sector faces.

Purpose of the review

Future Health: A Strategic Framework for Reform of the Health Service 2012-2015, published in Ireland in November 2012, details the actions required to deliver on the health reform agenda outlined in the current Programme for Government.(1) *Future Health* commits to the changes proposed in a step-by-step manner based on good evidence. While the overall approach to reform will be informed by the experience of other countries and best practice, the system as a whole will be uniquely Irish. The reforms are designed to increase the quality of care for patients, where quality refers not only to patient outcomes but also to the cost of achieving those outcomes. Delivery of the first phase of the transition process for health structures has already commenced through the publication of the Health Service Executive (Governance) Bill 2012.(2) The Bill provides for the abolition of the board of the Health Service Executive (HSE) under the Health Act, 2004 and the establishment of a directorate structure with strengthened accountability arrangements between the Department of Health (DoH) and the HSE.

The establishment of hospital groups was committed to in *Future Health: A Strategic Framework for Reform of the Health Service 2012-2015* (1), which was approved by Government in November 2012 and is a key building block in delivering on the Programme for Government commitment to fundamentally reform our health services. It is intended that the hospital groups will, in time, qualify as independent competing hospital trusts as the DoH progresses towards Universal Health Insurance. Following Government approval, the Minister for Health, James Reilly published two reports in May 2013: the "Report on *The Establishment of Hospital Groups as a transition to Independent Hospital Trusts" (3)* (known as the Report on Hospital Groups), and "*Securing the Future of Smaller Hospitals: a Framework for Development" (4)* (known as the Smaller Hospitals Framework).

The reorganisation of acute hospitals into a small number of groups, each with its own governance and management, will provide an optimum configuration for hospital services to deliver high-quality, safe patient care in a cost-effective manner. It will allow integration and improve patient flow across the continuum of care. Each grouping includes a primary academic partner, which will stimulate a culture of learning and openness to change within the hospital group. Smaller hospitals will be supported within the hospital group in terms of education and training, continuous professional development, the sustainable recruitment of high-quality clinical staff and the safe management of patients with deteriorating and complex conditions.

Seven hospital groups have been established on a non-statutory administrative basis as follows: (i) Royal College of Surgeons in Ireland (RCSI) Hospitals (Dublin North East); (ii) Dublin Midlands; (iii) Ireland East; (iv) South/South West; (v) Saolta University Healthcare Group (West/Northwest); (vi) University of Limerick (UL) Hospital Group (Midwest) and (vii) Children's Hospital Group. Primary legislation will be required in due course to give full effect to the introduction of Hospital Trusts. While *Future Health* (1) sets the broad trajectory for reforming the system, it was always made clear that an incremental approach to implementation would be taken. *Future Health* (1) specifically referred to a "reform-learn-reform" approach being taken to the process, which would enable the DoH to make impromptu changes to the proposed approach while simultaneously making progress towards the final structures and delivering tangible improvements.

Pending the enactment of legislation, the implementation of hospital groups will progress in a phased manner, which will provide for devolved decision-making, fostering flexibility, innovation and local responsiveness, while also adhering to prescribed national service objectives and standards. Phase II of the Health Reform Programme, as set out in *Future Health* (1), provides for the dissolution and replacement of the HSE with the introduction of a formal purchaser/provider split, the establishment of a healthcare commissioning agency and a range of provider agencies, including hospital trusts. This is a complex health reform programme and it is essential that

the hospital trust legislation is developed as part of the overall process, and that the appropriate structures are in place in advance of the formal establishment of trusts.

The DoH will progress the significant body of work necessary to facilitate the transition from hospital groups to hospital trusts. It will set out the high-level overarching policy to guide overall hospital services reorganisation from a national standpoint to inform and complement the plans of the hospital groups, and will provide guidance on the definition of a hospital trust in an Irish context. The hospital groups and their respective strategic plans will be rigorously reviewed against criteria to test their suitability to proceed to become hospital trusts. The review of hospital groups will be completed before trusts are legally established and, if changes prove necessary, these will be made with Government approval when hospital trusts are being formed.

The purpose of the review is to present information describing the establishment and regulation of, and governance for, foundation trusts in England and New Zealand. The authors examined a number of countries to determine if they had created independent hospital entities from state-owned enterprises and the only other country that had was Scotland. Scotland is not covered in this review, as the process to establish foundation trusts was the same as in England, but there was not enough documented information to determine why they were disestablished.

The research questions were:

- Describe the process (including regulation and governance) of creating public independent entities from State-owned health infrastructure, in particular hospitals, in England and New Zealand.
- Describe the effectiveness or lessons learned from the process and the associated adaptions made over time.

Methods

Methods: England

The search methods employed in this study comprised systematic, targeted and informed searches. Systematic searches comprised examination of the PubMed database using a set of criteria and parameters that allow for the establishment of a static framework and the feasibility to repeat the search using the same criteria. Targeted searches are defined as examination of websites of interest to the study. These include the Google website and other named websites (in particular, regulator, commissioner and provider websites). However, these websites are live and dynamic and these searches cannot be replicated. Informed searches are defined as the retrieval of articles or papers identified as being of interest from the outputs of PubMed and website searches.

The systematic searches comprised:

- Logic and parameters searches of PubMed reported in Table 1
- Keyword search of the legislative databases reported in Table 2.

The targeted searches comprised:

- National organisations' websites examined, as presented in Table 3.

Findings from these systematic searches were used to identify the government and other relevant bodies listed in Table 3. The websites for these bodies were subsequently searched for relevant material and the material presented represents the information provided by the website owners. The screening of papers, reports, and legislation, coupled with the organisation of such materials for study inclusion, reflect the iterative findings of the researchers rather than the findings from a predetermined search approach with inclusion and exclusion criteria.

Table 1 PubMed search criteria and number of identified, screened and retrieved references

UK
PubMed was searched using the following logic for UK (England): ("delivery of health care"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of health care"[All Fields] OR "healthcare"[All Fields]) AND ((("england"[MeSH Terms] OR "england"[All Fields] OR "england"[All Fields]) AND ("social control, formal"[MeSH Terms] OR ("social"[All Fields] AND "control"[All Fields] AND "formal"[All Fields]) OR "formal social control"[All Fields] OR "regulation"[All Fields])) OR (("england"[MeSH Terms] OR "england"[All Fields] OR "england"[All Fields]) AND ("economics"[MeSH Terms] OR "economics"[All Fields] OR "economic"[All Fields])) OR (("england"[MeSH Terms] OR "england"[All Fields] OR "england"[All Fields]) AND ("Governance (Oxf)"[Journal] OR "governance"[All Fields])))
No. of references identified N=6861
No. of references screened by title N=6861
No. of references screened by abstract N=135
No. of references cited 18

Table 2 Keyword search of legislative databases

UK
The UK legislative website www.legislation.gov.uk/was searched using the 'advance search' facility 'keywords in content' and the keywords 'regulation and health', 'regulation and economic', "governance and economic" individually and combined the year range '1990 to 2013' type (of legislation) 'primary' on 2 May 2013 This site was set up on 15 August 2010.

European Commission legislation covering competition http://eur-lex.europa.eu/

Table 3 Government and other relevant bodies

UK
National Audit Office http: http://www.nao.org.uk/
Department of Health https://www.gov.uk/government/organisations/department-of-health
Monitor https://www.gov.uk/government/organisations/monitor
Care Quality Commission http://www.cqc.org.uk/
Clinical commissioning groups http://www.datadictionary.nhs.uk/data_dictionary/nhs_business_definitions/c/clinical_commissioning_group_de.asp http://www.england.nhs.uk/wp-content/uploads/2012/06/ex-comm-pc.pdf
NHS England (NHS Commissioning Board) and NHS Commissioning Assembly http://www.england.nhs.uk/ http://www.england.nhs.uk/ourwork/part-rel/assembly/
NHS Trust Development Authority http://www.ntda.nhs.uk/about/
NHS trusts and foundation trusts http://www.datadictionary.nhs.uk/data_dictionary/nhs_business_definitions/nhs_business_definitions.asp http://www.legislation.gov.uk/ukpga/2003/43/contents www.legislation.gov.uk/ukpga/1990/19/contents

Methods: New Zealand

The search methods employed in this study comprised systematic, targeted and informed searches. Systematic searches of the PubMed database were undertaken using a set of criteria and parameters that allow for the establishment of a static framework and the feasibility to repeat the searches using the same criteria. Targeted searches are defined as examination of websites of interest to the study. These include the Google search engine and other named websites. However, these websites are live and dynamic, and the searches cannot be replicated. Informed searches are defined as the retrieval of articles or papers identified as being of interest from the outputs of PubMed and website searches.

The systematic searches comprised:

- Logic and parameters searches of PubMed, reported in Table 4
- Keyword searches of the legislative databases, reported in Table 5
- Keyword and time parameters of Google Scholar, reported in Table 6.

The targeted searches comprised:

- National and international organisations' websites examined, as presented in Table 7.

The websites for these bodies were subsequently searched for relevant material, and the material presented represents the information provided by the website owners. The screening of papers, reports, and legislation, coupled with the organisation of such materials for study inclusion, reflect the iterative findings of the researchers rather than the findings from a predetermined search approach with inclusion and exclusion criteria.

It should be noted, however, that as the focus of this New Zealand review is on events that took place during the 1990s, a period when websites did not operate as efficiently as they do today, the emphasis in the review is based on the knowledge of the authors and material published in journals and known grey literature.

Table 4 PubMed search criteria and number of identified, screened and retrieved references

New Zealand
PubMed was searched using the following logic for New Zealand: ("delivery of health care"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of health care"[All Fields] OR "healthcare"[All Fields]) AND ((("new zealand"[MeSH Terms] OR "new zealand"[All Fields] OR "new zealand"[All Fields]) AND ("social control, formal"[MeSH Terms] OR ("social"[All Fields] AND "control"[All Fields] AND "formal"[All Fields]) OR "formal social control"[All Fields] OR "regulation"[All Fields])) OR (("new zealand"[MeSH Terms] OR "new zealand"[All Fields] OR " new zealand "[All Fields]) AND ("economics"[MeSH Terms] OR "economics"[All Fields] OR "economic"[All Fields])) OR (("new zealand "[MeSH Terms] OR " new zealand "[All Fields] OR " new zealand "[All Fields]) AND ("Governance (Oxf)"[Journal] OR "governance"[All Fields]))))
Number of references identified N= 2888
Number of references screened by title N= 143
Number of references screened by abstract N= 143
Number of references cited N= 40

Table 5 Key website search of legislative databases

New Zealand
Details of New Zealand's legislation can be found at: http://www.legislation.govt.nz/ An archive of New Zealand Legislation as enacted before 2008 can be found at: http://www.nzlii.org/nz/legis/hist_act/ The main legislation governing the health sector during the 1990s was the Health and Disability Services Act 1993. This can be found at: http://www.nzlii.org/nz/legis/hist_act/hadsa19931993n22304/ Amendments in 1995 to dissolve the Public Health Commission can be found at: http://www.nzlii.org/nz/legis/hist_act/hadsaa19951995n84384/ Amendments in 1998 to establish the Health Funding Authority and Hospital and Health Services (replacing regional health authorities and Crown Health Enterprises, respectively) can be found at: http://www.nzlii.org/nz/legis/hist_act/hadsaa19981998n74384/

Table 6 Keyword search in Google database

New Zealand
Keywords 'Health Reform New Zealand 1990s' were searched on 1 June 2014. These yielded approximately 465,000 hits. The first 200 hits were screened. Most of these overlapped references found in the earlier searches.

Table 7 Government and other relevant bodies

New Zealand
Ministry of Health: www.moh.govt.nz
Commerce Commission: www.comcom.govt.nz
OECD: www.oecd.org
Commonwealth Fund: www.commonwealthfund.org
European Observatory: http://www.euro.who.int/en/about-us/partners/observatory

Findings

Case history: England

History and background of the NHS

Helderman *et al*. (2012)(5) wrote that the history of the English National Health Service (NHS) illustrates the complexities of moving from government (in the 1940s) to governance (in the 1990s). Throughout this time, the NHS has been free at the point of delivery and funded by taxation; hospital specialists are salaried employees, whereas GPs are independent contractors to the NHS. The private sector's contribution to acute care is small. In essence, there have been three different organising principles underlying policies for, and organisation of, the English NHS: a regional hierarchy until 1991, the regional hierarchy was replaced with a market from 1991 onwards, and the development of regulation for purchasers and providers commencing in 2002 with the establishment of the Commission for Health Insurance. The shift in 1991 was associated with an attempt to redefine the Government's responsibility away from delivery of healthcare to two different responsibilities: as insurer (to provide universal coverage for a service free at the point of delivery) and for providing a system of contracted delivery (to ensure good access to high-quality local services). The absence of a market prior to 1991 meant that the NHS could function without detailed information on costs or prices whereas a market-based health system requires detailed costing.

The overriding objective of the creation of the NHS in the **1940s** was to tackle inequitable access to health services, which was dependent on ability to pay, and also to reduce the inequitable distribution of GPs. Nothing was done to correct the inequitable distribution of hospitals at that time; indeed, the situation was exacerbated by the organisational structure of the NHS and its system of incremental budgeting. The NHS of 1948 comprised four distinct parts. There were two classes of hospitals: the voluntary teaching hospitals became privileged NHS teaching hospitals, governed by a board of governors directly accountable to the Minister of Health; other hospitals were governed by hospital management committees and organised into 13 (later 14) Regional Hospital Boards. Community health services remained with local authorities.

The **1974** reorganisation sought to tackle weaknesses of the 1948 organisational design, namely the privileged status of teaching hospitals and the separation of hospitals from community health services. Teaching hospitals were brought into the structure of 14 new regional health authorities and 90 area health authorities, which were responsible for social services and contracting with GPs. Area health authorities had two responsibilities: running hospital and community health services, as well as planning to meet the needs of their populations. A new planning system aimed to develop services (for the disabled, mentally ill, the elderly) that had been neglected by constraining expenditure on acute (hospital) services. From 1977 a new system of resource allocation was implemented for allocating the total budget for England on an equitable basis to different populations.

Subsequently, key elements of the 1974 reorganisation were dismantled by successive Conservative administrations: area health authorities were replaced with smaller district health authorities; and the principle of 'consensus management', which had required each member of health authority management teams to agree on decisions, and was designed to give consultants and GPs the power of veto, was abandoned following the introduction of general managers. In the early 1980s there was criticism of the Department of Health and Social Security for its lack of an effective system of governance by the Public Accounts Committee. The Department responded to this by developing the first set of NHS performance indicators.

The **1991** internal market sought to correct three weaknesses of the 1974 organisational design: chief officers were allowed to manage acute hospitals, which had been undermanaged; health authorities were enabled to

develop their role as planners of health services of populations, which had been seen as secondary to their role as managers of the delivery of hospital and community health services; and incentives were created for providers within the system through the introduction of a policy known as 'money follows the patient'. The internal market separated providers from district health authorities, which became 'purchasers'; providers became NHS trusts independent of health authorities (but directly accountable to the DoH). The 14 regional health authorities, established under the 1974 reforms, were abolished and subsumed into the DoH.

The innovation with the greatest potential for effective purchasing was GP fundholding, which was introduced in 1991; GPs opted to become purchasers of diagnostic and elective services and managed budgets for these services and their own prescribing costs, but that potential was realised by a few fundholders only. As part of the policies of the internal market new types of audit were introduced into the NHS. The Audit Commission undertook these audit studies, until this function passed to the Commission for Healthcare in 2004. Evaluations of the 'internal market' showed that it failed to develop as hoped, or to achieve its intended objectives. Some of the obvious problems were, arguably, due to the attempt to replace a hierarchy with a provider market without an adequate system of regulation.

From **2002**, the Labour Government sought to develop a regulator system to enable the provider market to work more effectively. However, it had been elected in 1997 on the promise to abolish the concept of both provider competition (which had failed to develop in the 1990s) and GP fundholding (on the grounds that this had created a two-tier NHS). The Labour Government retained the purchaser/provider split and initially sought a 'third way' between 'command and control' and a market. It introduced two important institutions to regulate how care was provided.

1. Firstly, the National Institute for Clinical Excellence (NICE) was created. NICE makes recommendations, based on assessments of cost-effectiveness, as to whether (mainly new) treatments ought to be made available for the NHS. This regulator aimed to end the perceived problem of 'postcode rationing'.

2. Secondly, an independent regulator of quality of care in the NHS, the Commission for Health Insurance, was created. The Commission has since been subject to two reorganisations (subsequently known as the Commission for Healthcare and later as the Care Quality Commission). These reorganisations were in response to a number of cases of scandalously poor quality of care that had gone on for a number of years with no corrective action being taken.

From 2000, the Government sought to resolve the problem of managing the NHS with neither a market nor a hierarchy using a system of performance management based on 'star ratings'. This distinguished those NHS organisations that performed well, and would be granted 'earned autonomy', from those that performed poorly, which were subject to extensive monitoring. This system was highly effective at tackling the problem of long waiting times for access to care that had beset the NHS since 1948. The rationale for the shift in emphasis from targets to markets as the preferred mode of governance of the NHS from 2002 was driven by a belief that a system based on targets could only improve NHS performance from appalling to mediocre, whereas if the objective were a high-performing NHS, then only markets could achieve that; there was no supporting evidence provided for this assumption. So, from 2002, the Government developed the idea of provider competition with both NHS and private organisations in delivery. The Commission for Health Insurance, which was designed to regulate the NHS, was replaced by the Commission for Healthcare, which was responsible for regulating quality of care in both the NHS and independent providers. In 2009, the Commission for Healthcare was, in turn, replaced by the Care Quality Commission (CQC), which is responsible for regulating the quality of providers of health and social care. According to Helderman *et al*. (2012), there has been a dramatic shift in the role of the quality regulator. The Commission for Health Insurance was seen as the regulator responsible for delivering

quality improvement; at the time, there was no market that aimed to do this. The Commission for Healthcare was in an ambiguous position, being responsible for quality improvement and also, in effect, a regulator of providers eligible for entry into the NHS market. For the CQC that ambiguity has been removed; its role is only the regulation of providers. Unlike its predecessors (the Commission for Health Insurance and the Commission for Healthcare were funded by the Government for regulating the NHS) the CQC charges all providers a registration fee.

The Labour Government also created a new status for high-performing NHS trusts, independent of the DoH. These are NHS foundation trusts, which are subject to approval and regulation by a regulator, Monitor. The Government also created Independent Sector Treatment Centres, which were intended to create a private sector market that delivers value for money and that provides diagnostic and elective services. Providers of healthcare services now include NHS trusts, NHS foundation trusts, Independent Sector Treatment Centres and private providers. During the period 2002-2010, the hierarchical arrangements were that 10 Strategic Health Authorities had oversight of purchasing by PCTs (about 150) and by the NHS trusts that had not become foundation trusts. Three key regulatory functions remained with the DoH: the allocation of resources to purchasers; the setting of hospital prices at standard national tariffs; and the principles and rules of cooperation and competition.

The Conservative-Liberal Coalition Government published a White Paper in **2010** titled *Liberating the NHS*, which proposed the abolition of the remaining bureaucratic hierarchical arrangements of the NHS in England and the transformation of the NHS into a regulatory body. Strategic Health Authorities were replaced by the NHS Trust Development Authority and NHS England. PCTs were abolished and replaced by NHS England and consortia of CCGs (approximately 221 GP groups in 2013). The remaining NHS trusts were to become, or be taken over by, NHS foundation trusts or private operators by April 2014; this has not been achieved at the time of writing. NHS England regulates purchasing and allocates resources to GPs and specialist services. Monitor has become the economic regulator and is setting the tariffs. The CQC continues to regulate quality. A new independent consumer champion, HealthWatch England, informs patients of quality of care in the various institutions. NICE provides national guidance and advice to improve health and social care.

The commissioning models in the NHS between 1991 and 2015 are presented in Table 8.

Table 8 Commissioning models in the NHS since 1991

Period	Purchasers	Secondary care providers	Choice of provider exercised by
1991-95	192 district health authorities and GP fundholders	NHS trusts (which became independent from district health authorities between 1991 and 1996)	District health authorities and GP fundholders
1996-98	District health authorities reduced and renamed 100 health authorities and GP fundholders	NHS trusts	100 health authorities and GP fundholders
1998-02	100 health authorities and 481 primary care groups from 1999, decreasing to 303 primary care trusts by 2002. Primary care groups replaced GP fundholders.	NHS trusts	100 health authorities
2002-06	303 primary care trusts and Practice-based commissioners from 2005	NHS trusts and NHS foundation trusts – NHS trusts could apply for authorisation as NHS foundation trusts from Monitor from 2004 onwards. Strategic health authorities must prepare and approve applications to Monitor.	Primary Care Trusts and Practice-based Commissioners from 2005
2006-10	152 Primary Care Trusts in conjunction with practice-based commissioners	NHS trusts, NHS foundation trusts and independent treatment sector providers	Patients choose and book from local menus in 2006, from Extended Choice Network in 2007; then on the basis of 'free choice' in 2008 and the NHS as preferred provider from 2009 onwards. Primary Care Trusts with Practice-based Commissioners
2012 onwards	National Health Service Commissioning Board (known as NHS England) Clinical care commissioning groups	NHS trusts until end of 2014, NHS foundation trusts and independent treatment sector providers. NHS trusts can apply for authorisation (now known as a licence) as NHS foundation trusts from Monitor from 2004 onwards, but must meet the requirements of NHS Trust Development Authority.	It is not clear how patients choose their acute hospital service.

The current organisation of the NHS is presented in Figure 1.

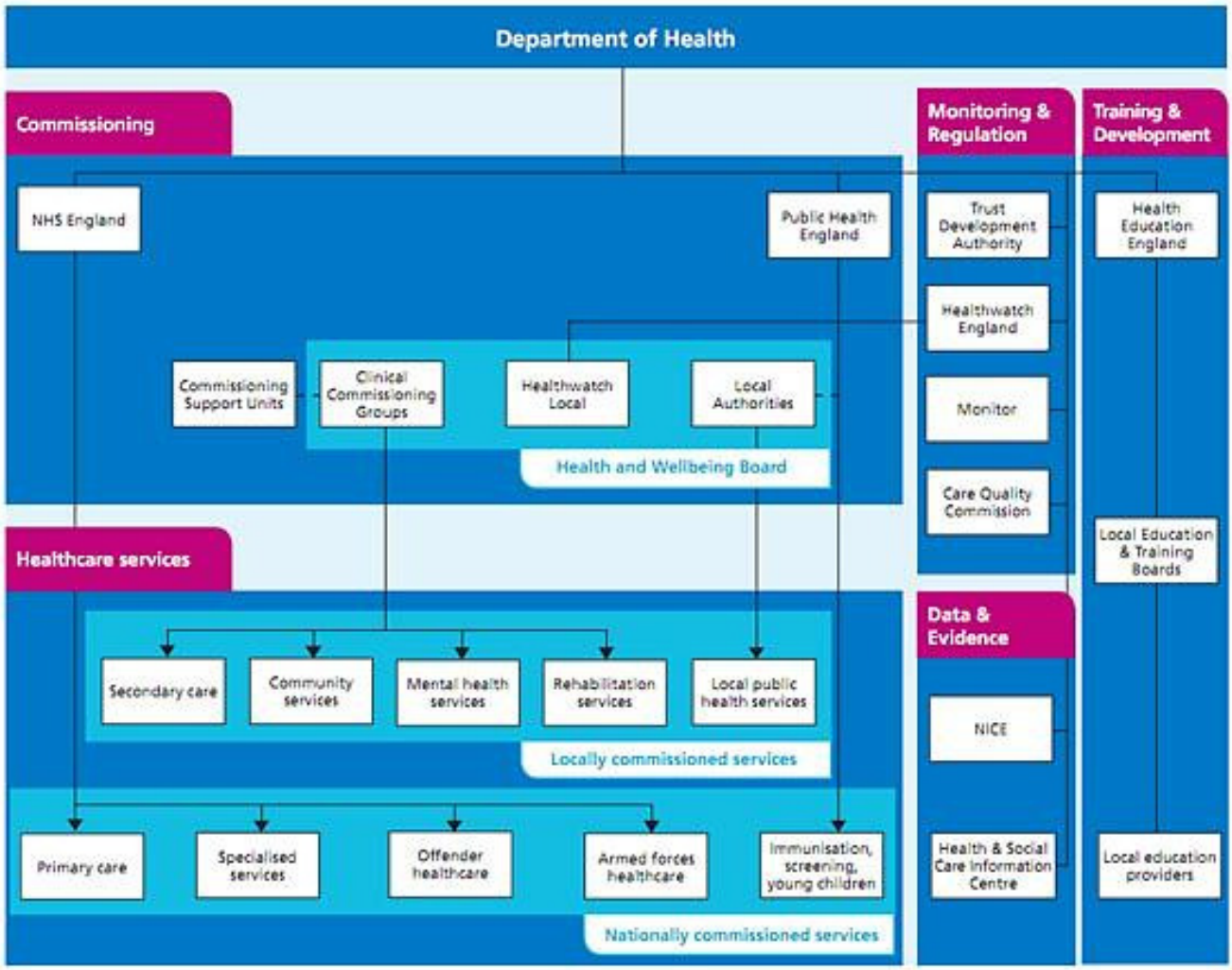


Figure 1 Organisation of the NHS under the **Health and Social Care Act 2012**

Legislation covering the governance of healthcare (including NHS trusts and NHS foundation Trusts)
There are five healthcare laws that deal with aspects of governance in NHS trusts and NHS foundation trusts in England. These Acts, which were introduced between 1990 and 2012 and coincide with the major political reforms, are:

- National Health Service and Community Care Act of 1990 (6), which separated the purchaser and provider roles in the NHS. It established NHS trusts and Fundholder GPs.
- Health and Social Care (Community Health and Standards) Act 2003(7), which established foundation trusts, Monitor and the Commission for Healthcare
- National Health Service Act 2006 (England) (8), which consolidates all previous health Acts into one Act and covers Monitor's governance role.
- Health and Social Care Act 2008 (9), which established the Care Quality Commission and disbanded the Commission for Healthcare.
- Health and Social Care Act 2012 (10), which established Monitor as an economic regulator, the National Health Service Commissioning Board (NHS England), clinical commissioning groups and a public health and social care information centre. It also stated a requirement for integrated healthcare around the service user.

It is thought that foundation trusts may come under the Companies (Audit, Investigations and Community Enterprise) Act 2004. (11) Table 9 gives a brief summary of each of the six Acts.

Table 9 Legislation covering governance of healthcare in England

Identified legislation	Brief summary
National Health Service and Community Care Act of 1990(6) www.legislation.gov.uk/ukpga/1990/19/contents	An Act to make further provision about health authorities and other bodies constituted in accordance with the National Health Service Act 1977; to provide for the establishment of NHS trusts; to make further provision about the financing of the practices of medical practitioners; to amend Part VII of the Local Government (Scotland) Act 1973 and Part III of the Local Government Finance Act 1982; to amend the National Health Service Act 1977 and the National Health Service (Scotland) Act 1978; to amend Part VIII of the Mental Health (Scotland) Act 1984; to make further provision concerning the provision of accommodation and other welfare services by local authorities and the powers of the Secretary of State in line with the social services functions of such authorities; to make provision for, and in connection with, the establishment of a Clinical Standards Advisory Group; to repeal the Health Services Act 1976; and for connected purposes. NHS trusts and Fundholder GPs were introduced under this Act.
Health and Social Care (Community Health and Standards) Act 2003(7) http://www.legislation.gov.uk/ukpga/2003/43/contents	An Act to amend the law about the NHS; to make provision about quality and standards in the provision of health and social care, including provision establishing the Commission for Healthcare Audit and Inspection and the Commission for Social Care Inspection; to amend the law about the recovery of NHS costs from persons making compensation payments; to provide for the replacement of the Welfare Food Schemes; to make provision about appointments to health and social care bodies; and for connected purposes. Foundation trusts and Monitor were introduced under this Act.
Companies (Audit, Investigations and Community Enterprise) Act 2004 (11) www.legislation.gov.uk/ukpga/2004/27/contents	An Act to amend the law relating to company auditors and accounts, to the provision that may be made in respect of certain liabilities incurred by a company's officers, and to company investigations; to make provision for community interest companies; and for connected purposes. It is thought that foundation trusts may come under this Act.
National Health Service Act 2006 (England) (8) www.legislation.gov.uk/ukpga/2006/41/contents	An Act to consolidate certain enactments relating to the health service after the devolution of government in Scotland and Wales. It reiterates the provisions in the 1990 and 2003 Acts. Part 1 Promotion and provision of the health service in England Part 2 Health service bodies Chapter 1 Strategic health authorities Chapter 2 Primary care trusts Chapter 3 NHS trusts Chapter 5 NHS foundation trusts Part 3 Local authorities and the NHS

Identified legislation	Brief summary
	Part 4 Medical services Part 5 Dental services Part 6 Ophthalmic services Part 7 Pharmaceutical services and local pharmaceutical services Part 8 Family Health Services Appeal Authority Part 9 Charging Part 10 Protection of NHS from fraud and other unlawful activities Part 11 Property and finance Part 12 Public involvement and scrutiny Part 13 Miscellaneous Part 14 Supplementary
Health and Social Care Act 2008 (9) www.legislation.gov.uk/ukpga/2008/14/contents	An Act to establish and make provision in connection with a Care Quality Commission; to make provision about healthcare (including provision about the NHS) and about social care; to make provision about reviews and investigations under the Mental Health Act 1983; to establish and make provision in connection with an Office of the Health Professions Adjudicator and make other provision about the regulation of the healthcare professions; to confer power to modify the regulation of social care workers; to amend the Public Health (Control of Disease) Act 1984; to provide for the payment of a grant to women in connection with pregnancy; to amend the functions of the Health Protection Agency; and for connected purposes.
Health and Social Care Act 2012 (10) www.legislation.gov.uk/ukpga/2012/7/contents	An Act to establish and make provision about a National Health Service Commissioning Board and clinical commissioning groups and to make other provision about the National Health Service in England; to make provision about public health in the UK; to make provision about regulating health and adult social care services (through Monitor); to make provision about public involvement in health and social care matters, scrutiny of health matters by local authorities and cooperation between local authorities and commissioners of healthcare services; to make provision about regulating health and social care workers; to establish and make provision about a National Institute for Health and Care Excellence; to establish and make provision about a Health and Social Care Information Centre and to make other provision about information relating to health or social care matters; to abolish certain public bodies involved in health or social care (including NHS trusts); to make other provision about healthcare; and for connected purposes.

Figure 2 provides an overview of the regulation, governance and organisation of the health services in England following the 2012 Act.

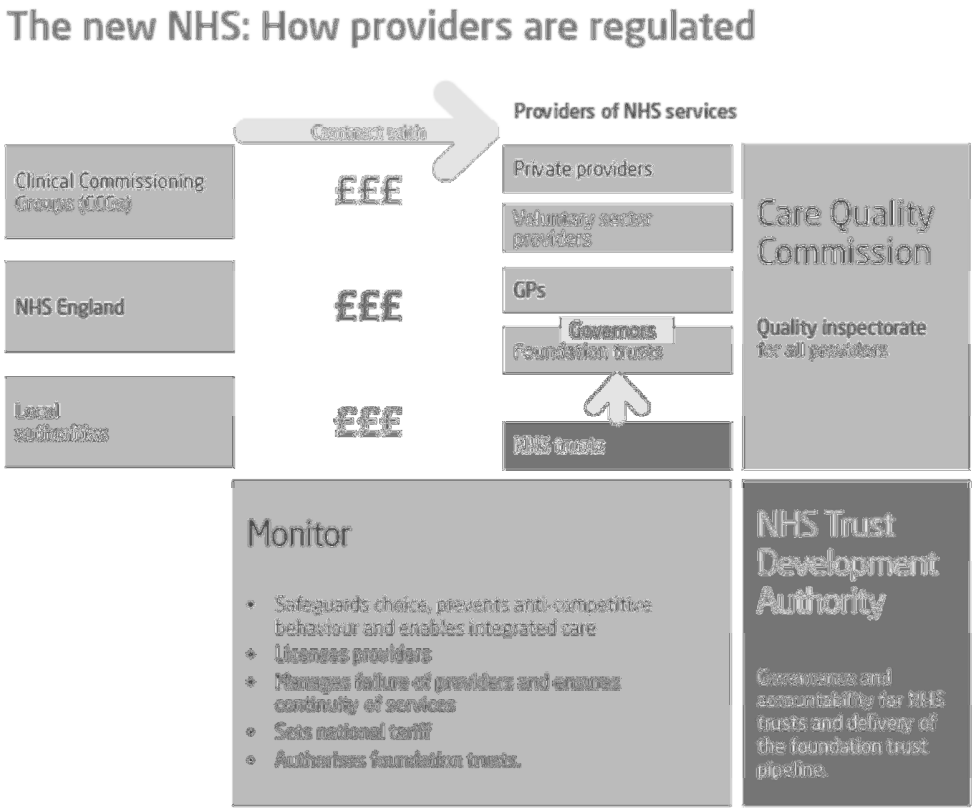


Figure 2 Organisation of the health services in England under the Health and Social Care Act 2012[12]

Provision of publicly-funded healthcare in England

The healthcare providers in England comprise NHS trusts, foundation trusts, independent sector treatment centres (which provide elective surgery for NHS patients), and a small number of other private providers (such as homecare organisations). There are specific corporate, clinical and financial governance requirements for NHS trusts and foundation trusts.

A trust is a public body corporation, which is allowed to manage finances in a manner not permitted to state bodies.

An NHS trust in England is a legal entity, set up by order of the Secretary of State under section 5 of 'The National Health Service and Community Care Act 1990'.(6) The performance of trusts was originally managed by regional health authorities (up to 2002) and then by strategic health authorities (2002-2011); currently, performance is managed by the NHS Trust Development Authority which is ultimately responsible to the DoH. NHS trusts may act as healthcare providers and provide hospital services, community services and/or other aspects of patient care, such as patient transport facilities. Each trust is headed by a board comprising executive and non-executive directors, and is chaired by a non-executive director. Non-executive directors are recruited by open advertisement. The National Health Service and Community Care Act of 1990 introduced the concept of NHS trusts (13) in order to allow separation of commissioning (purchasing) and delivering (providing) services. This split was introduced to create competition between services, so as to reduce cost and increase efficiency. The NHS trusts included hospital, community and mental health services and had day-to-day decision-making devolved to them, but they could not make a profit and could provide only limited private healthcare. The strategic management function of the NHS trusts was initially the role of regional health authorities who were subsequently replaced by strategic health authorities, and more recently the NHS Trust Development Authority. The NHS trust, rather than the NHS, employed all staff working in the trust and was responsible for the trust's assets, liabilities and finances. It no longer had crown immunities (i.e., since its inception it could be prosecuted under criminal law). Initially, the NHS trusts were commissioned by district health authorities, and later by primary care trusts and commissioning care groups, to provide services to patients based in a specific geographical (catchment) area. The Health and Social Care Act 2012 states that all NHS trusts will be required to become foundation trusts (or become part of a foundation trust) as soon as is clinically feasible, ideally, by April 2014. It has taken more than 20 years (2004 to 2014) to transform NHS trusts into foundation trusts and many of the authorised foundation trusts (46% in Q4 2012/13) have difficulty meeting the financial requirements set by Monitor. The April 2014 deadline has passed and not all NHS trusts have become foundation trusts.

An NHS foundation trust in England is a type of NHS trust which is an organisation in its own right or a legal independent entity. Foundation trusts were established under the Health and Social Care (Community Health and Standards) Act 2003(7) and latterly consolidated in the National Health Service Act 2006.(8) Two other important Acts facilitating the establishment of foundation trusts are the National Health Services Act 1977 (14) and the Interpretation Act 1978 (15). There are also a number of other acts that play a subsidiary, but important, role. Numerous individual disestablishment and establishment laws (not described here) were enacted to facilitate the legal status of foundation trusts. These aforementioned Acts underpin the main aspects of the original authorisation contract (Appendix 1) or licence (Appendix 2), which establishes foundation trusts as separate legal entities with the ability to self-manage, which includes raising finance and taking responsibility for any debts accrued; the authorisation contract was replaced with a licence under the Health and Social Care Act 2012. (10) Foundation trusts (13) (16) are classified as mutual structures akin to co-operatives, where local people, service users, patients and staff can become members and governors, and can hold the foundation trusts to account. These entities are independent of the NHS and have a constitution. However, Allen *et al*.

(2012)(17) found that foundation trusts do not fulfil all the criteria to be classified as mutual trusts as the members cannot distribute the surpluses, do not own the capital infrastructure and, in the event that the foundation trust fails, cannot distribute the assets among the membership. Foundation trusts provide hospital, mental health and ambulance services and have a clearly defined range or basket of health services that they provide. These trusts were created to devolve decision-making from central government to a local organisation and to communities, while providing and developing healthcare according to core NHS principles, which are free care, based on need and not ability to pay. Foundation trusts are not directed by Government, so they have greater freedom to decide, with their governors and members, their own constitution, strategy and the way services are run. In addition, they can retain their surpluses and borrow to invest in new and improved services for patients and service users. Anyone who lives in the area, works for the trust, or has been a patient or service user there, can become a member of an NHS foundation trust. Members can stand for election to the council of governors. The council of governors works with the board of directors, which is responsible for the day-to-day running of the foundation trust, to ensure that it delivers high-quality care and plays a role in helping to set the overall direction of the organisation. Councils of governors are expected to focus on ensuring that NHS foundation trusts listen and respond to the needs and preferences of stakeholders, especially local communities. The NHS foundation trusts are accountable to:

- Their local communities, through their members and governors
- Their commissioners, through contracts
- Parliament (each foundation trust must lay its annual report and accounts before Parliament)
- The Care Quality Commission, through the legal requirement to register and meet the associated standards for the quality of care provided
- Monitor, through the NHS provider licence

Each foundation trust has a strategic business plan and prepares an annual report and audited accounts for Monitor. The foundation trust's financial plan contains strategies to ensure financial viability, prudential borrowing and a contingency fund to deal with unforeseen situations. In 2004, Monitor was established to assess and register foundation trusts, and subsequently, to monitor and evaluate corporate and financial governance. In 2009, the Care Quality Commission (CQC), which was established under the Health and Social Care Act of 2008, became the regulator of healthcare and adult social care quality in England. The CQC assesses compliance with national health (quality) standards, and registers those services that comply. There is a suite of detailed documents providing legal, corporate and financial guidance for foundation trusts, and detailing the requirements and expectations of Monitor. These statutory authorities are important arms-length bodies with a high degree of corporate, financial and clinical expertise, and they provide guidance to, and oversight of, foundation trusts. Transforming state-owned entities into independent legal entities in England has taken 24 years and this was completed in a two-stage process. In the early 1990s all NHS health services were established as legal entities owned by the DoH; between 2004 and 2013 the majority of health services were established as independent foundations 'owned' by their governors. However, if these entities should fail, the state rather than their members will take back the assets and decide how to redistribute them.(17)

Private and voluntary organisations can be licensed to provide healthcare. In 2010-11, 4.8% of the NHS budget was spent by private and voluntary providers.(18)

The initiative to establish independent sector treatment centres was designed to provide extra capacity to the NHS and reduce waiting times for elective surgery.(19) The programme had two phases. Phase one, launched in 2003, was contracted to deliver up to 170,000 completed medical consultant reviews or episodes annually over five years, at a cost of £1.6 billion. Phase two, launched in March 2005, was expected to provide 420,000 elective procedures and an additional two million diagnostic procedures annually, over five years, at an estimated cost of around £4 billion (£3 billion for elective procedures and £1 billion for diagnostics). In July 2007,

24 centres, provided by seven for-profit companies, were operational. Pollock (19) reviewed their effectiveness in 2008 and concluded that the centres did not provide adequate information to the National Office for Statistics to enable an accurate review of their value and effectiveness to be completed.

Purchasing of publicly-funded healthcare in England

Over the past decade, the role of commissioning, as a key driver of quality, efficiency and outcomes for patients, has become increasingly important to the health system in England.(20) At its simplest, commissioning is the process of planning, agreeing and monitoring services. However, securing services is much more complicated than securing goods and the diversity and intricacy of the services delivered by the health services is unparalleled. Commissioning involves a wide number of activities, ranging from the health-needs assessment for a population, through the clinically based design of patient pathways, to service specification and contract negotiation or procurement, with continuous quality assessment. There is no single geographical area across which all services should be commissioned: some local services can be designed and secured for a population of a few thousand, while for rare disorders, services need to be considered and secured nationally.

Prior to the Health and Social Care Act 2012, primary care trusts (PCTs) assumed responsibility for purchasing acute services, primary care services, community-based services, and additionally in some instances, purchasing mental health services. Special commissioning groups purchased hospital and rare disease services. The NHS classifies a clinical commissioning group (CCG) as an organisation that is responsible for implementing the commissioning roles as set out in the 2012 Act.(21) CCGs are formed from groups of general practices that are responsible for commissioning most health and care services for patients. All GPs providing care on behalf of the NHS must be members of a CCG, although their level of involvement is not specified. Each CCG must have a governing body of at least six members. The board of the group must contain other healthcare professionals (one nurse and one consultant-level doctor) working alongside the GPs, a finance director and two lay people (of whom one has financial expertise). The boards of the CCGs are responsible for commissioning the majority of NHS services for patients within their local communities. The CCGs must publish constitutions which contain a section on discharging their functions.(18) They have a duty to work with local authorities in relation to health and adult social care, early years' services, and public health. GPs have been allocated the purchasing role as they provide primary medical care and are gatekeepers for referral to, and use of, other NHS services. Policy-makers expect that if the GPs are responsible for the CCG budget, they will make better decisions about the use of NHS resources and this will prevent overspending. The CCGs are not responsible for commissioning all services (for example, specialist services and rare disease services). They have the flexibility to decide which of their allocated commissioning activities they undertake themselves or choose to buy in from external organisations.(18) Since 2012, 211 CCGs have replaced 151 PCTs and now manage most of the NHS commissioning budget. CCGs are not be responsible for contract compliance, but are focussed on local priorities and supporting continuous development; it seems from the literature that contract compliance is managed by NHS England. (22)

NHS England (formerly the NHS Commissioning Board) is the regulator for the CCGs. The regulatory process comprises legal elements, such as public procurement law, and NHS regulations such as ensuring patient choice and preventing anti-competitive practices. Each CCG must submit a commissioning plan (based on the views and needs of the population) to the regulator and is subsequently assessed on how well it achieved the plan's objectives.(18) The assessment criteria for CCGs are:

- Are local people getting good quality care?
- Are patient rights under the NHS Constitution being promoted?
- Are health outcomes improving for local people?
- Are CCGs commissioning services within their financial allocations?

- Are conditions of CCG authorisation being addressed and removed, where relevant?
- Are CCGs ensuring that information is appropriately used to drive change?

Davies' (18) consideration of the Health and Social Care Act 2012 highlights two concerns with respect to CCGs' skill sets: one is their knowledge of specialist secondary care and the other is their skills with respect to procurement and contractual law. In addition, Davies raises the issue of who will complete and monitor the contracts. Davies maintains that CCGs will need to hire or contract experts to complete this work and these experts are likely to be former staff from the PCTs. She then questions the extent of the savings to be made by replacing PCTs with CCGs, as the procurement and contract experts will need to be hired and paid at consultancy rates. In addition, she questions whether accountability will be weakened as the responsibility for procurement decisions will be transferred by the CCGs to their hired experts.(18)

The NHS Commissioning Assembly(23) is the community of leaders for NHS commissioning. It was set up to create shared leadership nationally and locally, to co-produce national strategy and direction, to embed principles for working together to create a common voice for commissioners, and to connect leaders both within the NHS commissioning system and beyond. It comprises the clinical leaders from all CCGs in England, together with the broad body of senior leadership from NHS England.

In April 2013, NHS England was established, with an overarching role to ensure that the NHS delivers better outcomes for patients within its available resources and upholds and promotes the NHS Constitution. As a single national organisation, NHS England is responsible for ensuring that services are commissioned in ways that support consistency not centralisation, with an emphasis on consistency in ensuring high standards of quality across the country. NHS England works through its national teams, and 27 local area teams, to discharge these responsibilities.

NHS England, an independent body at arm's length from the Government, plays a key role in the Government's vision to modernise the health service, with the key aim of securing the best possible health outcomes for patients by prioritising them in every decision it makes. NHS England commissions:

- Specialised services and services for rare diseases
- GP contracts (the CCGs commission other primary care services)
- Offender healthcare
- Health services for members of the armed forces

The NHS commissioning system(22) previously comprised PCTs and specialised commissioning groups. While NHS England has 27 area teams, it is a single organisation operating to a common model with one board. Most of the NHS commissioning budget is now managed by 211 CCGs. The NHS England publication *Securing excellence in commissioning primary care* sets out the operating approach for primary care commissioning, including clinical, dental, optical and pharmaceutical services. The document does not define clinical services, but it is most likely that it includes medical, nursing and therapy services.

Accountability for publicly funded health care

Davies'(18) review of the Health and Social Care Act 2012 found that the Secretary of State's ability to set the direction of NHS-funded healthcare is limited to a set of carefully delineated powers which include:

- an annual mandate to NHS England concerning its functions for the coming year
- directions to Monitor when an NHS trust or foundation trust fails.

However s/he can alter the annual mandate of NHS England if:

- the NHS England board agrees to the revision

- there is a general election
- exceptional circumstances occur

The Secretary of State cannot intervene directly in the activities of CCGs or those of any type of provider and s/he cannot issue directions in relation to competition issues. Despite the limitations on her/his powers, s/he remains responsible to Parliament for the overall performance of the NHS. Davies (18) considers that the provisions mentioned above allow the Secretary of State to distance her/himself from accountability for any failures in, or harm caused by, NHS commissioners or services.

Table 10 Timeline identifying major NHS reorganisations (to introduce governance and regulation) and associated legislation, 1988-2013

YEAR	ACTION	ACT
1988	PRIME MINISTER MARGARET THATCHER (CONSERVATIVE PARTY) MAKES THE SURPRISE ANNOUNCEMENT OF AN NHS REVIEW ON THE TELEVISION PROGRAMME PANORAMA.	
1989	THE WHITE PAPER, WORKING FOR PATIENTS (NHS REFORMS), PROPOSES TO INTRODUCE A SPLIT BETWEEN PURCHASERS AND PROVIDERS OF CARE, GP FUNDHOLDERS AND A STATE-FINANCED INTERNAL MARKET, IN ORDER TO DRIVE SERVICE EFFICIENCY.	
1990	CREATION OF AN INTERNAL MARKET SEPARATE PURCHASERS AND PROVIDERS CREATION OF NHS TRUSTS	NATIONAL HEALTH SERVICE AND COMMUNITY CARE ACT 1990.
1994	THE NUMBER OF REGIONAL HEALTH AUTHORITIES IS REDUCED TO EIGHT.	
1997	LABOUR COMES TO POWER AND PUBLISHES THE WHITE PAPER, THE NEW NHS: MODERN, DEPENDABLE.	
1998	THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE) IS ESTABLISHED.	
1999	GP FUNDHOLDING IS ABOLISHED; NEW PRIMARY CARE GROUPS ARE ESTABLISHED.	
2000	THE NHS PLAN – A 10-YEAR MODERNISATION PROGRAMME OF INVESTMENT AND REFORM.	
2001	THE COMMISSION FOR HEALTHCARE IMPROVEMENT IS CREATED – THE FIRST ORGANISATION TO FORMALLY ASSESS THE PERFORMANCE OF NHS HOSPITALS.	HEALTH ACT 1999
2001	THE NHS PLAN IS FORMALISED THROUGH LEGISLATION.	THE HEALTH AND SOCIAL CARE ACT 2001
2001	INTRODUCTION OF THE HOSPITAL STAR RATING SYSTEM.	
2002	DISTRICT HEALTH AUTHORITIES ARE REPLACED BY STRATEGIC HEALTH AUTHORITIES (SHAS) AND PRIMARY CARE TRUSTS (PCTS). THE CONCEPT OF FOUNDATION TRUSTS IS INVESTIGATED.	
2002	THE REDISTRIBUTION OF POWER FROM REGIONAL HEALTH AUTHORITIES INTO STRATEGIC HEALTH AUTHORITIES (SHAS).	NATIONAL HEALTH SERVICE REFORM AND HEALTH CARE PROFESSIONS ACT 2002
2003	ALLOW FOR THE ESTABLISHMENT OF FOUNDATION TRUSTS AND MONITOR AND INTRODUCTIONS OF QUALITY AND STANDARDS IN HEALTH AND SOCIAL CARE	HEALTH AND SOCIAL CARE (COMMUNITY HEALTH AND STANDARDS) ACT 2003.
2004	THE FIRST 10 FOUNDATION TRUSTS (FTS) ARE ESTABLISHED, WITH CONTROL OVER THEIR BUDGETS AND SERVICES.	
2004	THE HEALTHCARE COMMISSION TAKES OVER FROM THE COMMISSION FOR HEALTHCARE IMPROVEMENT.	
2004	THE GOVERNMENT OUTLINES PLANS FOR INVOLVING GP PRACTICES IN COMMISSIONING HEALTH CARE SERVICES THROUGH ITS 'PRACTICE-BASED COMMISSIONING' POLICY	
2005	THE GOVERNMENT ACCELERATES THE TIMETABLE FOR THE INTRODUCTION OF PRACTICE-BASED COMMISSIONING THROUGH THE PUBLICATION OF THE REPORT: COMMISSIONING A PATIENT-LED NHS.	
2006	STRATEGIC HEALTH AUTHORITIES (SHAS) ARE REDUCED FROM 28 TO 10. THE NUMBER OF PRIMARY CARE TRUSTS (PCTS) FALLS FROM 303 TO 152.	
2007	THE CONSERVATIVE PARTY OUTLINES ITS VISION FOR THE FUTURE OF THE NHS IN THE WHITE PAPER: NHS AUTONOMY AND ACCOUNTABILITY: PROPOSALS FOR LEGISLATION.	
2008	HEALTH MINISTER, LORD DARZI, LEADS WHAT BECOMES KNOWN AS THE 'NHS NEXT STAGE REVIEW' AND OUTLINES HIS 10-YEAR VISION FOR THE NHS IN THE REPORT, HIGH QUALITY CARE FOR ALL.	
2009	THE NHS CONSTITUTION IS PUBLISHED, OUTLINING A REVISED SET OF RIGHTS AND RESPONSIBILITIES FOR PATIENTS AND STAFF.	
2009	A NEW HEALTH AND SOCIAL CARE REGULATOR, THE CARE QUALITY COMMISSION (CQC), IS CREATED.	
2009	NHS CHIEF EXECUTIVE SIR DAVID NICHOLSON, WARNS THE NHS TO PREPARE FOR THE NEED TO RELEASE UNPRECEDENTED EFFICIENCY SAVINGS OF BETWEEN £15 BILLION AND £20 BILLION BETWEEN 2011 AND 2014.	
2010	THE ROBERT FRANCIS INQUIRY REPORT INTO MID-STAFFORDSHIRE NHS FOUNDATION TRUST IS PUBLISHED.	
2010	FOLLOWING TALKS BETWEEN THE CONSERVATIVE AND LIBERAL DEMOCRAT NEGOTIATORS, THE COALITION AGREEMENT IS PUBLISHED.	
2010	"THE EVENTS AT MID-STAFFORDSHIRE WERE A TRAGIC STORY OF TARGETS BEING PUT BEFORE CLINICAL JUDGEMENT AND PATIENT CARE." ANDREW LANSLEY, SECRETARY OF STATE FOR HEALTH (2010) SECRETARY OF STATE FOR HEALTH, ANDREW LANSLEY MP, ANNOUNCES A PUBLIC INQUIRY INTO MID-STAFFORDSHIRE NHS FOUNDATION TRUST.	
2010	THE WHITE PAPER, EQUITY AND EXCELLENCE: LIBERATING THE NHS IS PUBLISHED.	
2011	THE HEALTH AND SOCIAL CARE BILL 2010/11 PROPOSES SIGNIFICANT REFORMS TO INCREASE THE INFLUENCE OF GPS ON COMMISSIONING, INCREASE COMPETITION AND ABOLISH STRATEGIC HEALTH AUTHORITIES (SHAS) AND PRIMARY CARE TRUSTS (PCTS).	
2012	FOLLOWING NEARLY 18 MONTHS AND THOUSANDS OF AMENDMENTS, THE HEALTH AND SOCIAL CARE BILL IS PASSED.	HEALTH AND SOCIAL CARE ACT 2011
2012	AS SET OUT IN THE HEALTH AND SOCIAL CARE ACT 2012, THE GOVERNMENT PUBLISHES OBJECTIVES AND EXPECTATIONS FOR THE HEALTH SERVICE IN ITS FIRST MANDATE TO THE NHS COMMISSIONING BOARD.	
2012	THE GOVERNMENT ANNOUNCES NEW FUNDING REFORMS FOR CARE AND SUPPORT, BASED ON RECOMMENDATIONS MADE IN 2011 BY THE DILNOT COMMISSION.	
2013	THE 'NEW' NHS COMES INTO BEING AS RESPONSIBILITIES SHIFT TO BODIES CREATED BY THE 2012 HEALTH AND SOCIAL CARE ACT. MONITOR'S CURRENT ROLE IS EXTENDED TO COVER REGULATION NHS TRUST DEVELOPMENT AUTHORITY IS ESTABLISHED REPLACING SHAS NHS ENGLAND (NHS COMMISSIONING BOARD) IS ESTABLISHED CLINICAL COMMISSIONING GROUPS ARE ESTABLISHED REPLACING PCTS. REMAINING NHS TRUSTS TO BECOME FOUNDATION TRUSTS, OR BE MERGED WITH OTHER FOUNDATION TRUSTS, OR BE DISESTABLISHED AND SERVICES TO BE RELOCATED TO ANOTHER FOUNDATION TRUST, OR BE SOLD OFF TO PRIVATE SECTOR	

Organisations involved in establishing foundation trusts
The Health and Social Care Act 2012 states that all NHS trusts will be required to become foundation trusts (or become part of a foundation trust or part of a private sector service) as soon as is clinically feasible, ideally, by April 2014 (although this deadline has passed). Monitor's website provides a web page (24) and an application guide (25), which provides NHS trusts with information on how to become a foundation trust. In addition, the Monitor website recommends that applicant NHS trusts seek assistance from the NHS Trust Development Authority as it is responsible for deciding when an NHS trust is ready to apply for foundation trust status or become part of another foundation trust or other organisation. (26)

The authors of this review have summarised the three guidance documents mentioned in the preceding paragraph. However, they recommend that persons working on a day-to-day basis to create independent entities from hospital groups should read these documents in full, as they contain some well-worked-out processes and procedures which could not be adequately represented in a summary overview.

NHS Trust Development Authority's role in establishing foundation trusts
The functions of the NHS Trust Development Authority include:

- Performance management of NHS trusts including planning, oversight and escalation (or intervention in the event of concerns or failure)
- Management of the pre-application period for foundation trust, merger or acquisition
- Assurance of clinical quality, corporate and financial governance and risk in NHS Trusts through oversight, personal development programmes and capital investment
- Assurance of the right leadership through appointments to NHS trusts' boards and reviewing board members' performance

The NHS Trust Development Authority (27) (which replaced the Strategic Health Authorities) published a strategy document titled *Delivering high quality care for patients: the accountability framework for NHS trust boards.(26)* The framework sets out a clear set of rules under which the remaining NHS trusts should operate, underpinned by clear principles that should guide their judgement, both on day-to-day decisions as well as on the long-term strategic ambitions. It also describes how the framework's expectations are to be delivered, setting out how the Authority works with NHS trusts on a day-to-day basis, how it assesses the progress NHS trusts are making and how it provides the development support each organisation needs in order to meet challenges. The Authority reports that its ambition remains a simple one as it seeks to create an environment that enables NHS trust boards to deliver high-quality and sustainable services for the patients they serve.

The accountability framework described five responsibilities which are planning, oversight, development and support, approval, and enhancing sustainability. Each responsibility is presented in a separate chapter.

The NHS Trust Development Authority reports that the first action in the process for delivering high quality care is to have a clear and unambiguous plan for the short-, medium- and long-term ambitions of each NHS trust board. The Authority's commitment is to ensure that planning guidance for the year ahead is always delivered in a timely manner, in order to allow NHS trust boards as much time as possible to plan how they will deliver improvements in the year ahead. The Authority published a plan titled *Toward high quality, sustainable services: planning guidance for NHS trust boards for 2013/14* (28), which set out the expectations for what the remaining NHS trusts were expected to deliver in 2013/14, and how the NHS Trust Development Authority supports them to achieve high-quality and sustainable care for the patients and communities they serve. All NHS trusts are expected to submit a final operating plan at the beginning of each financial year. Their plan will set out how they will meet the expectations described in the planning guidance for the respective year. The Authority assesses

the level of risk to non-delivery of services based on its review of an organisation's plan. Risks to delivery of quality are assessed by comparing recently published annual performance targets against indicators, examining responses to the quality checklist in NHS trusts' operating plans, and a qualitative assessment of risk-based assessment by the CQC. The risk to financial delivery is assessed using indicators including bottom-line income and expenditure position; actual efficiency compared to the plan, splitting recurring/non-recurring costs; and forecasts of the underlying revenue position compared to the plan for the year. This integrated risk assessment is a key determinant of the nature of the Authority's interaction with the organisation from the start of the year.

The oversight model (26) assesses the impact the NHS trust's performance is having on the quality of care that patients receive and, where necessary, intervenes when things do not go well. This model describes how NHS trusts can expect to be assessed by the NHS Trust Development Authority, and how they can expect to be held to account for what they have promised to deliver with respect to outputs, outcomes and quality. The metrics the Authority measures against give a clear understanding of how well an organisation is delivering, the strength of the governance arrangements that sit beneath the NHS trust's approach, and the rigour applied to delivering a sustainable business plan. The oversight model is designed to align as closely as possible with the broader requirements of NHS trusts, such as the monitoring requirements of commissioners and regulators. The access metrics replicate the requirements of the NHS constitution, the outcome metrics are aligned with the NHS Outcomes Framework and the mandate to the NHS Commissioning Board. The framework also reflects the requirements of the CQC and the conditions within the Monitor licence such as pricing, competition and integration, which NHS trusts are required to meet. Finally, the structure of the oversight model reflects Monitor's proposed new Risk Assessment Framework and includes calculation by the Authority of shadow Monitor risk ratings for NHS trusts (similar to those calculated for foundation trusts). In this way, the Authority seeks to align its approach, wherever possible, with that of other organisations and to prepare NHS trusts for the foundation trust environment. The core objectives of the oversight model are to ensure that all NHS trusts in England:

- Provide safe, high-quality care, that ensures a positive experience for patients
- Achieve agreed measures of financial performance
- Make progress towards a sustainable organisational form, either as a standalone foundation trust or as part of another organisation

Every month, the Authority monitors in-year delivery against plans and against key indicators including quality, governance and finance (Table 11), as well as progress towards a sustainable organisational form (Table 12). The Authority also presents general quality and governance for all institutions (Table 13) and it presents specific quality and governance indicators for acute hospitals (Table 14), mental health, community trusts, and ambulance trusts.

Table 11 Routine financial indicators of the NHS Trust Development Authority (England) (26)

Parameters	Indicators
Hospital-specific measures	• Adjusted surplus finance margin • Reference cost index for each procedure excluding excess bed days • Unit costs day cases • Unit costs non-elective inpatients (unplanned admissions or visits) • Unit costs elective inpatients (planned admissions or visits)
Income and expenditure	• Bottom-line income and expenditure position • Year-to-date actual income and expenditure compared to plan • Forecast income and expenditure compared to plan
Efficiency	• Actual efficiency compared to plan split into recurring and non-recurring costs • Year-to-date actual efficiency comparing recurring and non-recurring costs to plan • Forecast efficiency comparing recurring and non-recurring costs to plan
Revenue (mainly recurring)	Forecast underlying revenue position compared to plan for the year
Capital (mainly non-recurring)	Forecast year-end charge to capital resource limit compared to plan
Support required	• NHS trust accessed a triple bottom line report or public dividend capital for liquidity during 2013/14 • NHS Trust is in receipt of distress financing

Table 12 Measures of progress towards foundation trust status using financial indicators (England) (26)

Parameters	Indicators
Monitor Compliance Framework	1 – Earnings before interest, tax, depreciation and amortisation achieved (% of plan) 2 – Earnings before interest, tax, depreciation and amortisation margin, % 3 – Net return after financing, % 4 – Income and expenditure surplus margin net of dividend, % 5 – Liquidity ratio days Combined (1 to 5) Financial Risk Rating
Monitor Risk Assessment Framework – Continuity of Services	1 – Liquidity days 2 – Capital services capacity Combined (1 and 2) Risk Rating

Table 13 Routine quality and governance indicator for all institutions (England) (26)

Category	Example indicators
Clinical standards	• A&E consultant cover 24/7 • Emergency paediatrics consultant rota 24/7 • Obstetrics consultant cover 24/7 • Midwife cover 24/7
Staff satisfaction	• Staff survey – friends and family test, material changes • Staff survey – staff satisfaction, material changes
Board capability and capacity	• Board observations • Board Governance Accountability Framework • Monitor Quality Governance Framework
Licence terms	• Choice, competition and integration terms (self-certification)

Table 14 Routine quality and governance indicators specifically for acute hospitals (England) (26)

Category	Indicator
Care Quality Commission concerns	• Warning notice • Civil and/or criminal action
Access metrics	• Referral to treatment waiting times for non-urgent consultant-led treatment within 18 weeks – Admitted patients to start treatment within a maximum of 18 weeks from referral, 90% – Non-admitted patients to start treatment within a maximum of 18 weeks from referral, 95% – Patients on incomplete non-emergency pathways (yet to start treatment) should have been waiting no more than 18 weeks from referral, 92% – Number waiting for over 52 weeks (not clear which group the number refers to) • Patients waiting for a diagnostic test should have been waiting no more than six weeks from referral, 99% • Cancelled operations: number (%) of cancelled patients re-booked within 28 days • Urgent operation: number (%) of patients being cancelled for the second time • Mean (average) elective inpatient waiting times • Accident and Emergency wait: patients should be admitted, transferred or discharged within four hours of their arrival at an accident and emergency department, 95% • Cancer waits: two weeks – Maximum two-week wait for first outpatient appointment for patients referred urgently with suspected cancer by a GP, 93% – Maximum two-week wait for first outpatient appointment for patients referred urgently with breast symptoms (where cancer was not initially suspected), 93% • Cancer waits: 31 days – Maximum one-month (31-day) wait from diagnosis to first definitive treatment for all cancers, 96% – Maximum 31-day wait for subsequent treatment where that treatment is surgery, 94% – Maximum 31-day wait for subsequent treatment where that treatment is an anti-cancer drug regimen, 98% – Maximum 31-day wait for subsequent treatment where the treatment is a course of radiotherapy, 94% • Cancer waits: 62 days – Maximum two-month (62-day) wait from urgent GP referral to first definitive treatment for cancer, 85% – Maximum 62-day wait from referral from an NHS screening service to first definitive treatment for all cancers, 90% – Maximum 62-day wait for first definitive treatment following a consultant's decision to upgrade the priority of the patient (all cancers), no operational standard set
Outcomes metrics	• Venous thromboembolism risk assessment: (number and % of admissions) • Thrombolysis (for chest pain patients) within 60 minutes counted from first call for assistance • Rapid access (not defined) chest (pain) clinic • 30-day emergency re-admissions (number and % of discharges) • Incidence of MRSA • Incidence of Clostridium Difficile • Incidence of eColi + MSSA • Medication errors causing serious harm (as a number and proportion of all medication errors and all discharges) • Admissions of full-term babies to neo-natal care (as a number and proportion of all births at full term) • Caesarean sections rate • Number of, and incidence of, maternal death • Summary Hospital Mortality Index: month, quarter and year • Hospital Standardised Mortality Ratio • Harm-free care (incidence of pressure sores , falls, urinary tract infection as a consequence of catheterisation and venous or pulmonary thrombosis) • Response to patient safety alerts • WHO surgical checklist compliance • Serious incidents • Never events (preventable mistakes) (number and type)
Third-party reports	Any relevant report including safeguarding alerts, serious case reviews, ad hoc reports from MPs, General Medical Council, Ombudsman, Commissioners, and litigation
Quality governance indicators	• Patient satisfaction (friends and family) • Mixed-sex accommodation, minimise breaches • Patient and carer voice • Complaints • Board turnover rate: month, quarter and year

Category	Indicator
	• Staff turnover rate: month, quarter and year • Staff sickness/absence rate: day, month, quarter and year • Proportion of temporary staff (as a proportion of all staff) by clinical and non-clinical categories • Registered nurse: bed ratio • % nurses registered nurses versus enrolled nurses • % staff appraised

The **escalation** model (26) provides a clear understanding of what the NHS Trust Development Authority needs to do when NHS trust boards fail to deliver on the ambitions they have set themselves. The progress of NHS trusts' achievements against their planned targets determines what kind of relationship they can expect to have with the Authority. Where delivery is on plan, interactions focus more on the NHS trust's journey towards a sustainable organisational form (foundation trust). Where delivery is off plan, the Authority needs to understand the actions the NHS board is taking to recover, and agreements reached with commissioners. The Authority supports challenged organisations by sharing best practice and helping to identify appropriate improvement support. In determining whether intervention is required, the Authority aims to make an informed judgement based on multiple sources of intelligence. Interventions the Authority may consider include:

1. Requesting recovery plans and additional reporting
2. Increasing the frequency and seniority of engagement with the organisation
3. Commissioning an independent investigation or audit
4. Reviewing the skills and competences of executive and non-executive board members
5. Commissioning interim support to provide additional management capacity
6. In extreme situations, recommending the enacting of the unsustainable providers regime

The development and support model (26) describes how the NHS Trust Development Authority works to bring together NHS trusts from across the country to work on common issues of concern and to share best practice, or to enlist support from national organisations such as the NHS Improving Quality, the NHS Leadership Academy. The development needs, which are reviewed each year, are identified by NHS trusts themselves, as well as by the Authority staff based on the NHS trust's performance.

The approvals model (26) sets out how the NHS Trust Development Authority will support NHS trusts to develop strong foundation trust applications and approve them to move forward for assessment by Monitor. An NHS trust can only become a foundation trust when its trust board can clearly demonstrate that it is able to provide high-quality care for patients and has the right business plan in place to ensure that it can continue to deliver well into the future. The foundation trust application process, designed by the Authority, is clear and simple to follow, open and transparent, and focused on quality and sustainability: these principles both simplify and add rigour to the processes that NHS trusts follow in their journey towards foundation trust status. The same principles apply to the models the Authority has developed to support NHS trusts in organisational transactions, capital schemes and service change proposals. The guidance sets out the specific stages the Authority will go through to gain assurance about the quality, safety and sustainability of applications, as shown in Figure 3.

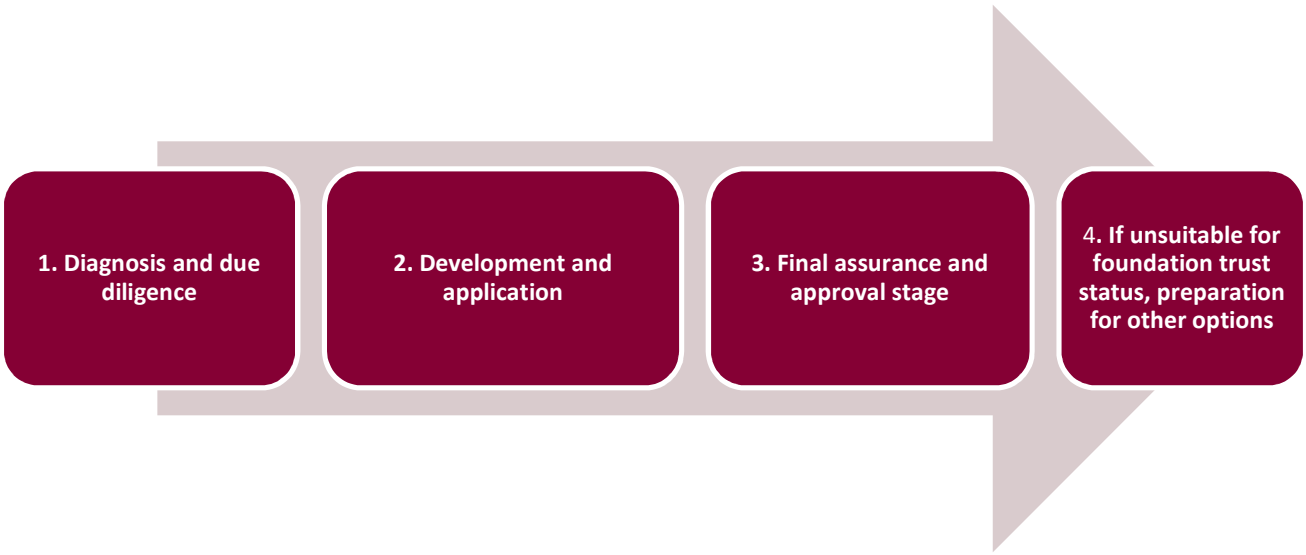


Figure 3 Specific stages the Authority will go through in order to gain assurance about the quality, safety and sustainability of application for foundation trust status

A brief description of stages 1–3 is given below:

1. An initial stage of **diagnosis and due diligence**, which involves both the NHS trust and the NHS Trust Development Authority establishing a baseline against which the trust needs to build a high-quality, safe and sustainable foundation trust application.
2. A subsequent stage of **development and application**, which involves the submission of key documents to the NHS Trust Development Authority and the testing and scrutiny of the trust's plans and personnel. It begins with the readiness review, which then leads to the identification of further development needs and additional work.
3. A final **assurance and approval** stage, which involves the full and final submission of documents to the NHS Trust Development Authority and assessment by the Authority's board that the NHS trust is ready to undergo a detailed assessment by Monitor.

The stages of preparing the foundation trust application are described in more detail in Table 15. The NHS Trust Development Authority acts in the role of examiner at each stage, in order to ensure that the information provided is accurate, the application represents the NHS trust's abilities, and the NHS board members are prepared for the robust review by Monitor. The Authority advises Monitor of applicants that it wishes to support. These NHS trusts can then formally apply to begin Monitor's assessment process.

Table 15 Stages and steps in preparing and testing the foundation trust application in England (26)

Stage	Steps or activities
Diagnosis and due diligence	1. Undertake self-assessments and begin production of key documents in line with the *Applying for NHS Foundation Trust Status: Guide to Applicants*. 2. Schedule initial external assessments comprising: I. Review of NHS trust self-assessment of Board Governance Assurance Framework by third party II. Review of NHS trust self-assessment against Monitor's Quality Governance Assessment Framework requirements by third party III. Complete financial due diligence Stage 1 by independent auditor IV. Assist the NHS Trust Development Authority in collating a range of quality information and share information in a way that reflects the duty of candour. 3. Prepare and share development plans in response to external assessments with the NHS Trust Development Authority. 4. Complete self-assessments against key foundation trust requirements and self-certifying against Compliance Framework questions and submit these to the Authority. 5. Prepare documents and supporting strategy for public consultation on the proposed foundation trust application.
Development and application	1. Make a formal submission of key foundation trust application documents to the NHS Trust Development Authority to inform foundation trust readiness review meeting. 2. Prepare for a formal foundation trust readiness review meeting with the Authority. 3. Following the readiness review, develop further iterations of key documents including their clinical and quality strategy, business plan and financial model in response to Authority feedback. 4. Update on the delivery of outstanding action plans on quality, safety, service performance and sustainability. 5. Deliver foundation trust action plans with updates to the Authority and ongoing updates of self-assessment and self-certifications.
Final assurance and approval	1. Make board-approved final submissions of key products to inform the NHS Trust Development Authority sign-off of foundation trust application and board-to-board review meeting. 2. Respond to queries from the Authority on any areas of clarification or where further assurance is sought. 3. Address any outstanding issues.

Monitor's role in establishing foundation trusts(24, 25)

Monitor (29) was established in January 2004(7) to authorise and regulate NHS foundation trusts in England. It is funded by the DoH and reports directly to Parliament. The Health and Social Care Act 2012 makes changes to the way healthcare is regulated in order to strengthen the way patients' and other users' interests are promoted and protected. Monitor's role has changed significantly since 2012 (10) as it has taken on a number of new responsibilities. Monitor is the sector regulator for healthcare, which means that it regulates all providers of NHS-funded services in England, unless exempt under secondary legislation. Monitor's main duty is to protect and promote the interests of patients. It does this by promoting the provision of healthcare services which are effective, efficient, and economic, and maintains or improves their quality.

Monitor's regulatory functions include (30): licensing healthcare facilities; regulating prices; enabling integrated care; safeguarding cooperation and competition; and ensuring continuity of services. Monitor retains its old function with respect to foundation trusts and has five new regulatory functions. Table 16 presents the functions of Monitor and the rationale for each function. The HRB authors describe the functions of Monitor that relate to NHS trusts and NHS foundation trusts in detail.

As already outlined, one of Monitor's functions is to assess the suitability of NHS trusts for foundation trust status. Its *Guide for Applicants* (25) presents detailed information about what is required to demonstrate that an NHS trust meets the three assessment criteria for foundation trust status and it covers the stages of the foundation trust application process, including Monitor's assessment process and the application outcome.

Table 16 Functions of Monitor (30)

Function	Purpose
1. Licensing providers	In carrying out its sector regulator role, Monitor licenses providers of NHS services in England. The licence is its key tool for regulating providers of NHS services. This licence replaces the authorisation contract for foundation trusts.
2. Regulating pricing for NHS-funded care	Monitor and NHS England, working in partnership, need users' and the public's help to ensure that the future NHS payment system delivers affordable, quality care and better outcomes for patients.
3. 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.
4. 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. Competition will be based on quality rather than price.
5. Supporting the continuity of services	Monitor supports commissioners by ensuring that patients can continue to access the care they need if a healthcare provider fails.

Monitor's **three key assessment criteria** are:

1. Is the trust well governed?
2. Is the trust financially viable?
3. Is the trust legally constituted?

Davies (18) highlights that these are primarily business objectives and questions in which Monitor considers the quality of care provided by foundation trusts and other healthcare providers. This issue has been raised in evaluations of Monitor's performance. Since 2013, steps have been taken to address quality issues through the governance questions and through the development of a formal relationship with the CQC.

In line with the *Guide for Applicants*, in order to be authorised as a foundation trust, each NHS applicant trust must:

- Ensure that their **constitution** complies with the 2006 Act (as amended by the 2012 Act) and is otherwise appropriate.
- Ensure the provision of **commissioner-requested services** in the business plan and that the trust can and will comply with the provider licence.
- Make governance proposals that provide a representative and complete **governance strategy**.
- Provide **board certification** that the applicant has the organisational capacity to deliver the business plan and that plans are in place to ensure on-going **compliance with the conditions of the provider licence**.
- Provide **board certification**, accompanied by a board memorandum, that **quality governance arrangements are satisfactory**.
- Have an overall quality governance score of green, with an overriding rule that none of the four categories of the **quality governance framework** is red.
- The board must demonstrate that the trust can **generate a sustainable net income surplus by Year 3** of the projected period, unless exceptional circumstances exist, and maintain a reasonable cash position.
- Have a continuity-of-service-rating of 4 on a quarterly basis unless exceptional circumstances exist.
- Provide a **board statement** that confirms **sufficient working capital** for the next 12 months, accompanied by an appropriate professional opinion on this statement.
- Provide **board certification** that **financial reporting procedures are satisfactory**, based on an appropriate professional opinion.
- Provide a **letter of representation**, prior to Monitor's authorisation decision, which confirms that all relevant information has been provided to Monitor.

Table 17 presents the **documentation** required by the three criteria for Monitor to judge whether the NHS trust is capable of being a foundation trust.

Table 17 Documentation required by Monitor to assess suitability for authorisation of an NHS trust as a foundation trust by the three criteria (24, 25)

Monitor assessment criteria	Documentation required	Main requirements
Legally constituted	Constitution including election rules Summary of statutory consultation process Membership strategy Update on implementation of membership strategy Details of electoral process and report on initial elections	Constitution compliant with Schedule 7 of the 2006 Act In addition, the constitution should: • Contain a statement of minimum age (at least 16 years but can be more) for board members • Present a dispute resolution process • Require nominations and successful board members to perform a role • Have a minimum of 50% non-executive directors • State that the chairperson has the casting vote • Have an agreed and clear name containing the following tag line 'NHS foundation trust'.
Financially viable	Final five-year integrated business plan Financial model incorporating long-term financial projections and working capital projections (i.e. five-year annual projections and two-year working capital projections) Working capital board statement and board memorandum Schedule of *commissioner-requested services* and provide a statement of commissioner support (Appendix B6a and b of the *Guide for Applicants*). Reconciliation between long-term financial projections and *commissioner-requested services*	The applicant will populate the financial model provided by Monitor starting with the existing balance sheet and cash flow and applying a number of possible scenarios which consider all possible risks. If the NHS trust has a major private finance initiative the financial model will need to be populated for 10 years. The financial model will be cross-referenced to the business implementation plan. The working capital review will provide proof that the trust has sufficient capital to meet its obligations for the first year. This model and working capital review will be evaluated independently by external accountants and Monitor. The Board will complete the proforma board statement.
Well governed	Final integrated business plan Governance arrangements and rationale Membership strategy Update on implementation of membership strategy Details of electoral process and report on initial elections Register of directors' interests Register of governors' interests Third-party inspectorate reports Self-certification statements and supporting evidence Quality governance board statement (*Guide for Applicants*) Board memorandum (*Guide for Applicants*) Quality governance external report Board governance assurance framework external report with direct evidence on: • Performance management • Risk management • Targets and standards • Quality governance Job descriptions for board members	The applicant should use the business plan template provided and have used Chapter 9 of the applicant guide during its completion. The application and board papers must comply with the board statements on corporate, financial and clinical governance, and the chair must write and sign a letter confirming that all board members agree with the contents of the application. All internal and external performance reports that cover governance over the past two years must be submitted with the application. The current risk-management strategy, its implementation process, summary of progress made against targets and any external review or evaluation of risk should be submitted with the application. Board Governance Assurance Framework and its reviews should be submitted. The board will complete a Proforma statement on quality governance in the *Guide for Applicants*.

Licensing providers

The licence contains obligations for providers of NHS services that allow Monitor to:

1. Set prices for NHS-funded care in partnership with NHS England (previously known as the NHS Commissioning Board)
2. Enable integrated care
3. Safeguard choice and prevent anti-competitive behaviour, which is against the interests of patients
4. Support commissioners to protect essential health services for patients if a provider gets into financial difficulties
5. Oversee the way that NHS foundation trusts are governed

Appendix 2 shows a copy of an NHS licence.

Monitor's standard licence conditions are grouped into sections. Some of these sections apply to all licence holders and some sections only apply to certain types of licence holder. The Health and Social Care Act (2012) requires everyone who provides an NHS healthcare service to hold a licence unless they are exempt under regulations made by the DoH, which consulted on the exemption regulations in summer 2012. Foundation trusts were licensed from 1 April 2013. All other providers (including NHS trusts) were required to apply for a licence from April 2014. Monitor has a range of powers to ensure that providers comply with their licence conditions. These powers permit Monitor to ask providers to set out how they will address areas that did not comply, and to take action when providers fail to meet their licence conditions. The licensing system inspects public, private and voluntary providers using the same criteria, and so allows commissioners to judge the abilities of licensed services on an equal footing. Davies (18) observes that the licensing system also allows Monitor to deal with market failure through the process it uses when foundation trusts fail.

Monitor steps in when there are warning signs that a provider is struggling financially, with the aim of encouraging the provider to return to financial sustainability. In exceptional circumstances where this is not achieved, and financial failure becomes likely, there is an ordered process known as the failure regime, during which Monitor may appoint a Trust Special Administrator to take control of the provider's affairs and work with commissioners to ensure that patients continue to have access to the services they need.

There are a number of metrics used to provide summary measures of the clinical and financial progress of both NHS and foundation trusts. (25) These include:

- Thrombolysis (for chest pain patients) within 60 minutes counted from first call for assistance
- Rapid access (not defined) chest (pain) clinic
- MRSA, Clostridium Difficile and other hospital-acquired infection reports
- MRSA, Clostridium Difficile and other hospital-acquired infection rates
- Four hours or more emergency department wait
- Cancer one-month (31-day) wait
- Cancer two-month (62-day) wait
- Cancer two-week wait
- Access to genito-urinary medicine clinics
- Number and proportion of cancelled operations
- Mean (average) elective inpatient waiting times
- Adjusted surplus finance margin
- Reference cost index for each procedure excluding excess bed days
- Unit costs day cases
- Unit costs non-elective inpatients (unplanned admissions or visits)

- Unit costs elective inpatients (planned admissions or visits)
- Excess mortality rates controlled for age, gender and medical condition is a more recent introduction by the CQC.

The stages in the NHS foundation trust lifecycle are (25):

- **Entering assessment**: trusts that have just begun the process of becoming a foundation trust in the last year
- **Assessment and deferral**: trusts that have been in the process of becoming a foundation trust for at least one year
- **Authorisation**: trusts that were authorised in the current year
- **Post authorisation**: trusts that have been authorised for more than one year.

In order for an NHS trust to become a foundation trust, Monitor carries out a robust and challenging process to assess NHS trusts applying for NHS foundation trust status.(24) Monitor examines the governance arrangements, financial viability, local accountability and performance against national standards and targets mentioned above. The *Guide for Applicants* provides clear guidance on how the application will be assessed. There is very detailed guidance on the assessments of both the business implementation plan and the quality governance framework.

Post application to Monitor, NHS trusts are informed of the start date of their assessment. Each applicant is allocated an assessment team that includes a senior assessment manager. During the assessment process, it is normal for the assessment team to spend a number of days visiting the NHS trust to conduct interviews and analysis. This is in addition to careful scrutiny of information provided by the trust and third parties. Monitor works particularly closely with the CQC to ensure that it has an up-to-date view of CQC's position on applicant trusts.

The CQC registers providers of care services if they meet essential standards of quality and safety and then monitors them to make sure they continue to maintain or exceed these standards. The CQC is responsible for safeguarding appropriate standards of quality and safety within adult health and social care in England.(31) All applicant trusts are required to demonstrate to Monitor that the NHS trust is:

1. Registered by the CQC and has not been subject to enforcement action
2. The CQC's current judgement of compliance against registration is as follows:
    a. The impact of non-compliance on people who use the service is no worse than moderate
    b. The CQC is not conducting, or about to conduct, a responsive review into compliance
    c. No enforcement/investigation activity is ongoing or planned, including preliminary investigations into mortality outliers.

Appendix 3 presents the CQC publications to guide healthcare providers and assist compliance with regulatory requirements.

As part of the assessment process, each NHS trust is given the opportunity to present its business plan to Monitor at a board-to-board meeting. This meeting is held midway through the assessment period. The trust executive and non-executive board members will be expected to attend this meeting. Monitor will ask questions and provide challenge on or test the application. This meeting allows the applicant board to demonstrate that it is aware of the risks facing the trust and to provide details on how these risks can, or have been, managed and mitigated. The meeting also provides Monitor with a key opportunity to question the non-executive directors of

the trust to determine whether they have the necessary skills to be able to challenge their executive team effectively.

Towards the end of the process Monitor's assessment team will finalise papers to present at a decision meeting, where the application will be formally considered by Monitor. A decision may be made at this meeting to authorise, defer or reject a trust's application. In certain circumstances, NHS trusts have the option to withdraw from the process or postpone their application until a later date. Detailed information about the implications of these outcomes is available in the *Guide for Applicants*.(25)

When an NHS trust is authorised and becomes a foundation trust it will be awarded a licence (which replaces the old authorisation contract) containing its terms of authorisation. This licence is the main tool by which Monitor regulates the trust, through the imposition of 30 licence conditions (32) split into six broad groups:

1. General
2. Pricing
3. Choice and competition
4. Integrated care
5. Continuity of services
6. Specific NHS foundation trust conditions (see Appendix 2).

As already mentioned, Monitor has a range of powers to ensure that providers comply with its licence conditions.(33)

Once licensed, each NHS foundation trust is assigned a Monitor relationship manager (details can be found in the foundation trust directory). Monitor (through the relationship manager) assesses for breaches or potential breaches of the governance and continuity-of-service licence conditions through a risk-based system of regulation, which determines the intensity of the monitoring Monitor undertakes at each foundation trust. Monitor identifies actual and potential financial and governance problems, and deals with them.

Monitor's current Risk Assessment Framework (34) describes in detail how it assesses each NHS foundation trust's compliance with:

1. The continuity-of-service risk condition (staying solvent and maintaining the continuity of services provided by the trust)
2. The NHS foundation trust governance condition (being well governed from a financial, operational and quality perspective).

The Risk Assessment Framework (34) also references Monitor's Quality Governance Framework, which measures the structures and processes in place to ensure effective, trust-wide oversight and management of quality performance. Where the Framework indicates that the foundation trusts are breaching or potentially breaching their continuity-of-service or governance conditions, Monitor considers whether formal investigation is required in order to assess the scale and scope of the breach and what, if any, regulatory action is appropriate.

Monitor requires each NHS foundation trust board to submit an annual plan and quarterly ad hoc reports.(35) These are used to assess risk on a forward-looking basis and to hold boards of foundation trusts to account. Monitor publishes sector summaries based on these submissions, on a quarterly and annual basis, and assigns each NHS foundation trust an annual and quarterly risk rating. These risk ratings are designed to indicate the risk of a failure to comply with the continuity-of-services and governance licence conditions. Monitor can adjust risk ratings to reflect the escalation process set out in the Risk Assessment Framework.

Monitor publishes two risk ratings for each NHS foundation trust on:

1. Governance (rated red or green)
2. Finance (rated 1-5, where 1 represents the highest risk and 5 the lowest).

Based on these risk ratings, the intensity of monitoring and the potential need for regulatory action is considered on a case-by-case basis. This also applies where a foundation trust is performing well, for example, moving from the usual quarterly monitoring to six-monthly monitoring.

The Risk Assessment Framework is intended to act as a trigger for considering formal investigation into financial and governance matters. Monitor takes a proportionate view of any issues of compliance and the need for formal investigation and enforcement action.

When Monitor identifies a risk of an NHS foundation trust breaching its licence, it may seek further information and/or open a formal investigation. The issues Monitor finds are likely to drive the regulatory response; for example, Monitor may seek an agreed recovery plan to return the trust to compliance. However, if the need for action is time critical, Monitor's board will consider using its formal powers to intervene. More specifically, according to Monitor's Enforcement Guidance,(33) where Monitor has reasonable grounds to suspect that there have been breaches of a licence condition or where there is failure to give information, Monitor can oblige the provider to: take steps to bring the breach to an end, take actions to restore the situation or request payment of a financial penalty or revoke the licence. The governance of an NHS foundation trust is such that where the trust fails to comply with its licence conditions, Monitor may impose additional conditions relating to governance. If those conditions are breached, then they may remove, suspend, or disqualify one or more directors or members of the council. Where there is a breach of competition law, Monitor may give directions to bring infringement to an end, and/or impose a fine.

Monitor reports that a foundation trust can be said to deliver services in a sustainable manner if those services meet the needs of the present and there is an assurance that these services can be maintained into the future. One critical factor is ensuring that the local population can access services of a standard that is equivalent to, or better than, those currently provided in other parts of the same country, and are assessed as being sustainable into the future. Sustainability in foundation trusts is measured by Monitor from three perspectives – operational, clinical and financial. (36)

Operational sustainability considers the extent to which the foundation trust has the necessary organisational structure, operating model, governance, risk-management procedures and operational processes in place to deliver its immediate corporate objectives and longer term strategy. The key tests considered when assessing operational sustainability are:

- What is the trust's current performance?
- Are the trust's governance and operations aligned with its strategy?
- Does it have the people, processes and systems in place to deliver its strategy?
- What is the impact of the operating model on clinical performance?

Clinical sustainability refers to whether the foundation trust is currently delivering acceptable levels of clinical performance, and whether this level of performance is likely to be maintained into the longer term (3–5 years). The key tests considered when assessing clinical sustainability are:

- Is current clinical performance of an acceptable standard when compared with standard performance metrics?

- Is the trust serving a catchment population that is in line with national guidelines for a hospital that delivers the full range of acute services? The Royal College Standards recommended that population size is 450,000–500,000 for an acute general hospital providing the full range of facilities, including specialist staff and expertise for both elective and emergency medical and surgical care.
- Does the trust have sufficient consultant levels established across all services to maintain a 24-hour seven day per week service?
- Is the trust able to recruit and retain appropriate clinical staff to meet the NHS England established consultant levels?

Financial sustainability or viability is the ability of a foundation trust to generate income and accrue an excess in income over expenditure for successive years (usually five) while providing a clinically sustainable service. If a foundation trust is not able to generate income and pay its debts when they fall due, and is forecast to deliver a deficit for the current financial year then, from a technical accounting perspective, it is insolvent. If a commercial entity were judged insolvent, it would have to cease its operations. The test of financial sustainability for a foundation trust is:

- Is it forecast to deliver a surplus for the current financial year and for each of the following five years?
- Is it able to generate income?
- Is it able to pay its debts as they fall due without financial support?

A summary of Monitor's approach to assessing, authorising and monitoring foundation trusts is presented in Figure 4.

Figure 4 Monitor's approach to assessing and monitoring the governance of foundation trust applicants and authorised foundation trusts

Appendices 4 and 5 present a summary of Monitor's publications to date that assist NHS trusts and foundation trusts.

Effects of regulation and governance on NHS and foundation trusts

NHS trusts

Status with respect to progress to foundation trusts

At the end of January 2014 there were 99 NHS trusts that had not either been established as foundation trusts or merged with existing foundation trusts. Of the 99 trusts, 62 provided acute hospital services. Since April 2013, the newly established NHS Trust Development Authority has undertaken a more rigorous baseline assessment process comparing a range of indicators against a baseline standard to assess the readiness or not of an NHS trust for foundation trust status. These indicators are monitored through its oversight and escalation process. The process has five numeric measures where 1 indicates that there were no identified concerns and 5 indicates that formal action is required. In March 2014 there were six NHS (hospital) trusts where formal action was required (escalation score 5) and which were undergoing a series of interventions to improve their governance and their ability to provide high-quality care.(37) In the same period, there were 27 NHS trusts assessed as having material issues (escalation score 4). In the same period, 14 hospital trusts had no identified concerns (escalation score 1), which indicates that they would be eligible to commence the process of applying for foundation trust status. More recent information indicated that one of the 14 has become a foundation trust and six have applied for foundation trust status. Between 2012 and 2015 six NHS trusts have achieved foundation status, 12 NHS trusts have applied to Monitor for foundation status, two NHS trusts have merged, two NHS trusts were sold and one trust was dissolved.

Private finance initiatives

Jones and Charlesworth (38) at the Nuffield Trust assessed the overall financial position of the NHS in England and identified financial pressures, one of which is private finance initiatives (PFIs). These show that the total bill for PFI repayments has increased by nearly £200 million in just two years, from £459 million in 2009/10 to £628.7 million in 2011/12 (these amounts only apply to NHS trusts in England). PFI deals have become problematic for three major reasons: they usually have very high interest rates, they impose much higher debts upon the taxpayer than the actual value of the infrastructure they originally helped to build (in 2011 the taxpayer owed £121.4 billion to pay for infrastructure which was only valued at £52.9 billion) and they often include expensive maintenance and service contracts which charge the public purse vastly inflated fees for performing simple tasks (one PFI hospital was apparently charged £333 to have a new light bulb installed under the terms of its maintenance contract, for example). The report from the Nuffield Trust makes it clear that the burden of PFI schemes is not distributed evenly across the NHS. Variations in the number of new schemes that used PFI financing in different geographical areas have created a strong regional imbalance. NHS trusts in London have by far the biggest burden from PFI repayments, followed by the West Midlands. In the last financial year, NHS trusts in London spent £143.9 million on PFI repayments (nearly a quarter of the total in England), which was nearly five times higher than the amount spent by NHS trusts in the region with the smallest burden from PFI debts, the South West, where the figure was a comparatively modest £26.9 million.

The report also highlights specific NHS trusts which have to spend a particularly large proportion of their overall budgets on servicing PFI schemes. In England, there are now seven trusts where PFI repayments account for more than 5% of total revenue: The report also emphasizes that interest repayments on PFI debts are mostly up-rated using the retail price index measure of inflation (RPI), which tends to be higher than other measures, such as the consumer price index (CPI). It also means that government policies which have an impact on RPI can indirectly cost the NHS money in higher PFI repayments.

In 2012, Baillie(39) reported that 22 NHS trusts were ‘landed with private financing initiatives deals they could not afford’. Critics claim that the two key factors that have put NHS trusts ‘at risk’ are the ‘inflexibility’ of some PFI contracts, which makes varying the terms mid-contract difficult, and the fact that many of the earlier deals

were inexpertly negotiated by the 'public sector side'. Torjesen (40) reported that South London Healthcare NHS Trust, which is £150 million (€187 million; US$233 million) in debt, has been placed in administration. It is just one of 22 NHS trusts in England running around 60 hospitals that are facing serious financial difficulties because of longstanding revenue problems related to underlying debt from PFI schemes.

NHS foundation trusts

Monitoring governance and continuity

Monitor publishes quarterly reports covering the performance and risk ratings for NHS foundation trusts.(41) NHS foundation trusts are part of the NHS and provide over half of all NHS hospital, mental health and ambulance services. These reports provide a summary of the performance of the foundation trust sector, and also give individual NHS foundation trusts the opportunity to understand their own performance in relation to other foundation trusts. Up to the end of March 2013, two ratings (governance and financial) were calculated from the governance, quality and financial indicators each quarter, in order to determine the well-being of the foundation trust. Effective governance (which appears to include corporate and clinical quality indicators) of a foundation trust was ranked from 'green' (no material concerns) to 'red' (significant breach of authorisation), with four ranking options. The results for 2012/2013 were:

- 46% of 145 foundation trusts were classified as 'green – no material concerns'
- 19% were classified as 'amber-green – limited concerns surrounding terms of authorisation'
- 17% were classified as 'amber-red – material concern surrounding terms of authorisation'
- 18% were classified as 'red – likely or actual significant breach of terms of authorisation'.

In summary, just over one-third of trusts were experiencing real governance concerns and had difficulty in complying with the terms of authorisation in their licence in March 2013.

The financial well-being of a foundation trust was ranked from 1 (highest risk) to 5 (lowest risk) and the results for Q4 2012/2013 were:

- 9% of 145 foundation trusts were rated as 'highest risk – high probability of significant breach of authorisation in short-term (<12 months) unless remedial action is taken'.
- 37% were rated as 'risk of significant breach in medium term (12 to 18 months) in the absence of remedial action'.
- 44% were rated as exhibiting 'regulatory concerns in one or more component'.
- 10% were deemed to have no regulatory concerns (aggregate of rating 4 and 5).

In summary, 46% of trusts were experiencing real financial concerns and having difficulty in complying with the terms of authorisation in their licence at the end of March 2013.

The proportion of foundation trusts classified as having some or many serious governance concerns increased from 27% in 2010/11 to 35% in 2012/13, and the proportion classified as high risk with respect to their financial status remained similar, 45% in Q4 2011/12 and 46% in Q4 2012/13 (Table 18).

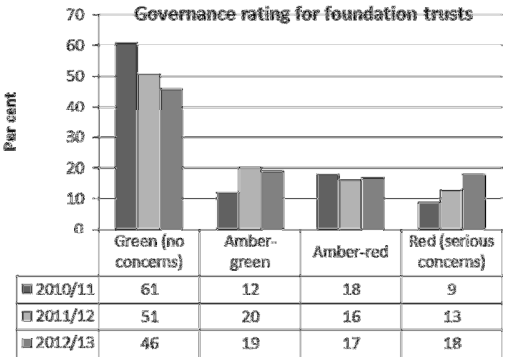
In 2012/2013, 19 foundation trusts were in significant breach of their authorisation and had remedial action taken such as contingency planning teams or new chairs appointed, and turnaround plans developed.

The competency framework was replaced by a risk-based system of regulation in late 2013. The risk-based assessment measures (42) include: the foundation trust's ability to sustain itself into the future (continuity) and the degree of concern about how the trust is run (governance); the governance measure takes account of

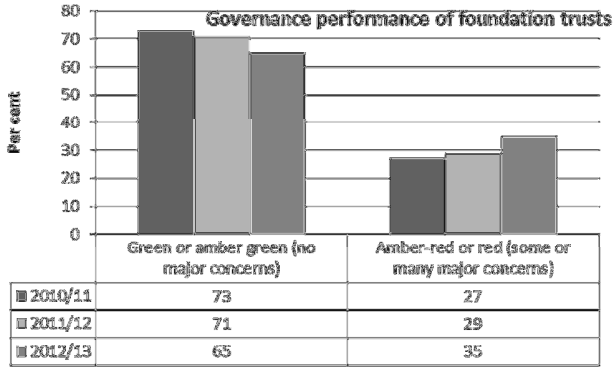
quality using assessments from the CQC. There are four continuity-of-service-ratings, where '1' is very serious risk of failure to continue its service up to '4' where there is no risk of failure. There are two governance ratings – green, which indicates no evident concerns or red, which indicates concerns. In March 2015, 23.7% of NHS foundation trusts were assessed a have a serious risk of continuity failure. In the same month, 34.3% of NHS foundation trusts had governance concerns or were under review to deal with past governance concerns. In March 2015, 33 (21.7%) of 152 foundation trusts were subject to special enforcement actions by Monitor and a further 9 (5.9%) were the subject of an investigation by Monitor. This monitoring system indicates that the governance, quality of care, financial situation and sustainability of foundation trusts are monitored closely and that immediate action is taken to deal with concerns.

Table 18 Well-being of foundation trusts 2010 to 2013 in England (41)

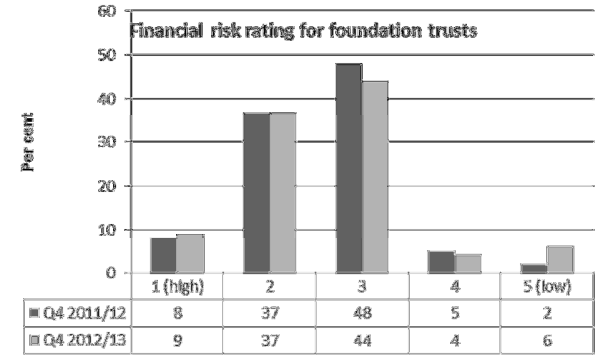
Well-being of a foundation trust



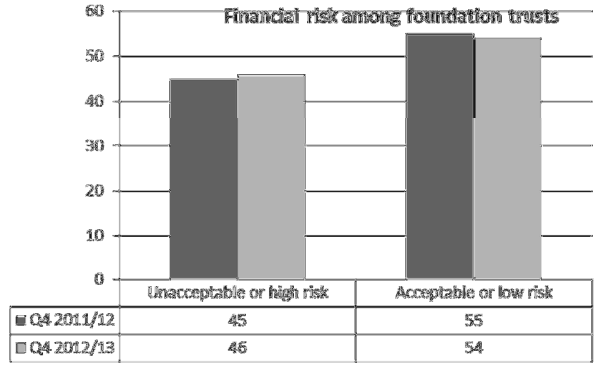
	Green (no concerns)	Amber-green	Amber-red	Red (serious concerns)
2010/11	61	12	18	9
2011/12	51	20	16	13
2012/13	46	19	17	18



	Green or amber green (no major concerns)	Amber-red or red (some or many major concerns)
2010/11	73	27
2011/12	71	29
2012/13	65	35



	1 (high)	2	3	4	5 (low)
Q4 2011/12	8	37	48	5	2
Q4 2012/13	9	37	44	4	6



	Unacceptable or high risk	Acceptable or low risk
Q4 2011/12	45	55
Q4 2012/13	46	54

Evaluating NHS foundation trusts and Monitor

In 2009, Monitor, in partnership with Frontier Economics, measured its impact on the development and governance of foundation trusts (43) using a mix of case study evidence and econometric analysis. At the time of the evaluation, Monitor had been operating for five years and 50% of the authorised foundation trusts were less than two years old. The case studies examined NHS foundation trusts where Monitor had a significant interaction with the trust either at the assessment stage (through deferring an NHS trust's application to maintain the 'assessment bar') or under the compliance regime (through formal use of its statutory powers or, informally, through increased intensity of regulatory activity). The econometrics, using a wide range of metrics over time, sought to understand whether NHS foundation trusts outperform NHS trusts, and whether higher levels of performance for NHS foundation trusts are a result of Monitor's regulatory regime. The value created by Monitor was based on the counterfactual: what would have happened if Monitor did not exist? In some cases, counterfactuals were based on evidence from the case study interviews, past performance or

performance of NHS trusts. In other cases, the counterfactuals were based on the econometric analysis of the data. The case studies examined were those where Monitor had actively intervened and, therefore, may have had a larger impact. Therefore, the case study findings cannot be extrapolated across the whole of the NHS foundation trust population. Additionally, the time periods, methodology and approach used in different parts of this study do not allow for aggregation of the findings.

The study found a range of evidence to suggest that Monitor's assessment and compliance regimes delivered value by requiring NHS foundation trusts to improve their efficiency and financial sustainability. The authors reported that:

- Maintaining the assessment bar would lead to cumulative savings of £271–£389 million by 2012–2013 across the nine case studies. Analysis across relevant case studies suggests that Monitor's decision to defer some NHS trusts from achieving foundation trust status resulted in these organisations revisiting cost improvement plans and/or re-evaluating capital investment programmes. Although data availability on quality outcomes was limited, these savings have not had a measurable negative impact on selected indicators: MRSA rates, cancelled operations or elective waiting times.
- The compliance regime resulted in financially challenged NHS foundation trusts turning around performance rapidly and delivering savings as a result: analysis across the relevant case studies suggests that NHS foundation trusts in deficit experienced considerably quicker turnarounds than equivalent NHS trusts.
- The econometric analysis found that the assessment process has delivered savings of £130 million to date. It led to an increase in surplus margin of 0.8% and a 7% increase in efficiency in day cases.
- The econometric analysis identified no statistical evidence to suggest that the financial performance of NHS foundation trusts improved at a faster rate than that of NHS trusts as a consequence of Monitor's regulatory regime. This is not inconsistent with the NHS foundation trust sector having better performance than NHS trusts, but rather any gap that does exist following authorisation is not increasing once authorised.

The study also considered the extent to which the assessment and compliance regimes are associated with improvements in the governance of the foundation trusts. The authors found that:

- Monitor has intervened in a number of NHS foundation trusts where concerns over governance arrangements arose. Case study analysis suggests that Monitor has had a direct impact in improving governance arrangements of a number of NHS foundation trusts, which has helped them to improve their performance.
- The NHS foundation trusts interviewed as part of the review have reported that Monitor's regulatory regime has introduced new financial discipline and improved financial governance. The interviewees also reported that boards have become more commercially aware.
- The econometric analysis showed that Monitor's assessment regime has led to improvements in the reduction of MRSA rates and access to elective services; MRSA rates have reduced by 11% relative to NHS trusts, and elective waiting times have reduced by 6.5% relative to NHS trusts.
- The econometric analysis identified no statistical evidence to suggest that, overall, the non-financial performance of NHS foundation trusts improved at a faster rate than that of NHS trusts as a consequence of Monitor's regulatory regime.

The key recommendations from this study were as follows:

1. Maintain the assessment bar
2. Maintain the compliance regime
3. Improve assessment of efficiency/quality relationship as the range of quality metrics currently available is limited
4. Review Monitor's role in building the capacity and capability of NHS foundation trust boards through its regulatory work and use other levers in the system such as payment by results; registration by the CQC; and involve governors and local members at NHS foundation trusts

Subsequently, the relationship between Monitor and the CQC was formalised through a 'memorandum of understanding' and the introduction of an information procedure. In addition, Monitor now sets the price of healthcare and encourages competition based on quality rather than price. It also encourages cooperation in order to ensure integrated user-centred healthcare. Future evaluations of its regulatory effectiveness will be based on cooperation, integration, quality, overall cost and competition based on quality.

In 2010 Monitor analysed regulatory breaches and foundation trusts' subsequent actions to address such breaches.(44) In its three-page document, it recorded three actions that each foundation trust had to take in order to address an existing breach or prevent a potential breach; these are as follows:

- Each foundation trust must develop a long-term corporate and financial strategy on a periodic basis.
- Business planning must be completed in consultation with potential commissioners.
- Boards of governors must review their own performance on a regular basis using a third party assessor.

These three actions were introduced in 2010 as part of the assessment and monitoring process.

Exworthy *et al*. (2011)(45) examined the implementation of foundation trusts, focusing on the nature and exercise of autonomy by foundation trusts. The authors argue that the ability of foundation trusts to exercise autonomy is in place, but the relatively limited extent of implementation may be explained by trusts' lack of willingness to exercise such autonomy. They speculate that the unwillingness may be because of continued centralisation, unclear policy and financial regimes, fear of negative impacts on relations with other local organisations, and awareness of greater risk to the foundation trusts, among others. Other authors (46) contest the view that foundation trusts do not use their autonomy.

Allen *et al*. (2012) (17) studied the external and internal governance of foundation trusts, which unlike NHS, trusts have increased autonomy, and a local representation structure. The authors completed in-depth, three-year case studies of four foundation trusts and analysed the national quantitative data on all foundation trust hospitals and NHS trust hospitals to place the case histories in a national context. Data included 111 interviews with managers, clinicians, governors and members, and local purchasers; observation of meetings; and analysis of foundation trusts' documents. The four case study foundation trusts were similar to other foundation trusts. In contrast to Exworthy's findings above (45), the foundation trusts had used their increased autonomy to develop more business-like practices. The foundation trusts in the study had developed a self-reliant ethos in which they were aware of themselves as autonomous agents within the larger structure of the NHS. The self-reliant ethos found expression largely at board level, but efforts were being made to devolve this attitude to clinical directorates as well. This exercise of greater freedom to make decisions was tempered by varied dealings with Monitor, particularly when Monitor identified problems in the foundation trust's performance. The NHS foundation trusts reported that the process to address problems with performance was intrusive. It should be noted that it is Monitor's statutory role to intervene when foundation trusts fail to comply with their authorisation. Elevation to foundation trust status had brought a cultural change in the study sites. The foundation trusts had become more business focused. They recognised a more acute need to cut the cost of

services, to grow their surplus and to re-invest in order to expand and develop services and produce more income. At the same time, the autonomy of the foundation trusts in the study should not be overstated. A wide range of national policies applies to the NHS as a whole, and not specifically to foundation trusts. These policies had a very large effect on the foundation trusts in the study. In the case of the national targets, such as the 18-week patient pathway and infection control targets, it is clear that the centralised command and control aspects of the NHS were very powerful influences on the foundation trusts in the study. Elevation to foundation trust status did affect the foundation trusts' relationships with other healthcare agencies in the local health economy. The fact that foundation trusts had developed a stronger sense of their own identity and a need to protect their services and future income streams against other trusts, and to expand services to increase income, meant that they were competing more strongly with other local hospitals. Foundation trusts' greater sense of themselves as separate entities did not always lead to deterioration in relationships with other local organisations. The foundation trusts continued to see themselves as part of the local health economy.

Turning to the changes in internal governance, Allen *et al*. (2012) (17) found that the representative structures of the foundation trusts in the study involved significant costs. These structures provided the foundation trusts with alternative sources of knowledge that could be useful in organising their services to the satisfaction of the community, and thus conveyed a sense of local legitimacy to the foundation trust. In joining the foundation trusts' representative structures, governors felt a sense of duty to the hospital. The relationships between the governors and the foundation trusts' executives were still developing, and not all of the governors felt they were able to carry out their role of holding the foundation trust to account.

The study design entailed four foundation trusts being studied in depth, in order to obtain detailed information about their governance. The comparative quantitative data demonstrate that the four case study foundation trusts were generally similar to other foundation trusts in the country in respect of issues such as financial performance, use of resources and quality of care. The quantitative data also demonstrate that, on the whole, foundation trusts are performing better than other NHS hospitals. This is mainly due to the fact that only better performing hospitals have been allowed to become foundation trusts. Finally, the quantitative data show that in their local areas, the case study foundation trusts were performing a little better than their competitors in some respects, but not all. There was clearly real competition between the foundation trusts and other healthcare providers in each case study area in terms of performance. The authors conclude that it is easier to increase autonomy for public hospitals than to increase local accountability. Hospital managers are likely to be interested in making decisions with less central government control, while mechanisms for local accountability are notoriously difficult, but necessary, to design and operate. Monitor provides specific supports to develop foundation trusts' managers, board members and governors. Examples of their development programmes include:

1. Service-line management, which identifies specialist clinical areas and manages them as distinct operational units
2. Non-Executive Director Development Programme, which builds leadership at board level through a three-day course at a business management school
3. Strategic Financial Leadership Programme, which is a business school-based development programme for finance directors to support new ways of working in a fast-changing NHS
4. NHS Foundation Trust Chairs' Academy is a programme specifically tailored to support chairs of NHS foundation trusts and aspirant foundation trusts in all aspects of leading their trusts through both current and future challenges.

Allen *et al*. (2012) (47) examined New Labour's wish to promote the involvement of users and the public in decision-making in ways other than as individual consumers; this included involving the public in the governance of organisations. This was to be done by transferring public health services to mutual ownership or by increasing

public involvement in the governance of public bodies. NHS foundation trusts were presented as mutuals. However, Allen *et al*. (2012) found that foundation trusts are not mutuals, as they cannot distribute surpluses, continue to be owned by the State and, in the event of failure, their capital infrastructure would be redistributed by the State. In the same paper, Allen *et al*. in the same study also examined the membership of four foundation trusts and reported that although membership had increased during the study it comprised about 4% of the population in 2009 served by the foundation trust. The members themselves were predominantly people with chronic diseases over 50 years, or parents who had used maternity services; the public members were generally people who had either very positive or very negative treatment experiences. In general, ethnic groups living in the geographical area were under-represented. In addition, a number of foundation trust staff became members and comprised about 20% of the membership, although interest in membership was not high among professional staff. The membership interacted with the foundation trust board through elected governors. The governors reported different interactions with their foundation trust board, which ranged from being a sounding board for ideas and decisions, supporting decisions that were already made or providing information to the membership. However, community-based governors reported an unequal relationship with the executive, in that they did not have the same knowledge as the executive, and staff governors often felt limited in what opinions they could express as they were also employees managed by the directors. Some innovative foundation trusts increased patient participation (in particular the involvement of non-members) through market research and consumer feedback, so as to boost overall community involvement. In addition, there were some local patient advisory or advocacy groups which dealt directly with the hospital directors. The main positive effect of local membership and the governors' structure was that it increased responsiveness and gave legitimacy to the services provided by the foundation trust. However, there was no evidence that the governors' structure influenced strategic planning.

In late 2013, the Comptroller and Auditor General (48) examined whether Monitor's regulation of NHS foundation trusts has been effective and found that:

- Monitor's interventions have helped trusts in difficulty to improve. Assessing the impact that Monitor has is difficult because of the range of influences on a trust and the difficulty of demonstrating what would have happened if Monitor had not taken action. However, people the auditor general interviewed in their case study trusts considered that they took faster or more effective action, or both, because of Monitor than they would have done otherwise. Monitor's interventions have worked well where the underlying issues are internal to the trust, such as poor leadership or financial management. NHS foundation trusts have regularly taken radical action, such as changing their chair or chief executive, in response. Monitor has often also required trusts to commission external consultancy support or employ turnaround directors.

- Monitor's influence has been less effective where the cause of the trust's difficulties relates to underlying issues in the local health economy. For an increasing number of trusts in difficulty, the underlying causes are rooted in the local health economy, for example where commissioners are in financial difficulty. In recent months, Monitor has changed its approach to intervening in these trusts. In some cases it has started working with commissioners, the local authority and the NHS Trust Development Authority to find solutions to address these wider issues. Monitor needs to rely on informal influence in these situations, as well as its formal powers of intervention.

- Monitor has started to increase its work to strengthen governance and financial management in NHS foundation trusts to try to reduce the risk of trusts getting into difficulty. Monitor seeks to support and develop the foundation trust sector. For example, it provides training to strengthen the capability of

boards and publishes good practice guidance. To date, Monitor has devoted only a small proportion of its resources to this type of work, and it has not assessed the overall impact or reach of this activity.

- Overall, the Comptroller and Auditor General reported that Monitor has achieved value for money in regulating NHS foundation trusts. Its processes for assessing and monitoring trusts are robust, its judgements have mostly been sound, and it has refined its approach in the light of experience. The balance of evidence suggests that Monitor has generally been effective in helping trusts in difficulty to improve. Its impact is particularly clear where the issues arise from weaknesses in trusts' internal management.

- The Comptroller and Auditor General stated that Monitor recognises that it needs to adapt how it regulates in order to address underlying weaknesses in local health economies that increase the risk of financial or clinical failure in individual trusts. It has started to take a more holistic and proactive approach in a number of cases. The Auditor General advised that Monitor will need to continue to develop its approach and work closely with other agencies within the NHS, as well as the DoH, if it is to continue to be an effective regulator and provide value for money.

Monitoring and evaluating of independent sector treatment centres

Pollock (2008)(19) reviewed the achievements of independent sector treatment centres with respect to their mandate. In addition to cost data, evaluations of productivity in the NHS rely on two key sources – bed data and admissions data.

Data on the number of available and occupied beds are collected annually from NHS trusts, but no such data are collected from independent sector treatment centres, although government policy is that they should be submitted as part of hospital episode statistics. Without these data, it is not possible to assess the contribution that these centres make to capacity, productivity, or efficiency, as extra beds, throughput, and bed occupancy cannot be measured. The NHS in England requires all providers to make a data return on each patient. These returns are used to derive hospital episode statistics. They contain information such as diagnosis and procedure, age, sex, and residence, dates of admission and discharge, and where treatment took place. Although independent sector treatment centres are required to submit hospital episode statistics returns, data from these centres are not of comparable quality to those from the NHS, and the returns provide no comprehensive account of admissions and procedures undertaken.

The Healthcare Commission found that, of those independent centres submitting data for the period April to December 2006, 59% of episodes had no diagnosis, 18% had no procedure code, 60% had no pricing information (healthcare resource group), and 83% had not been assigned an ethnicity category. It also found that outpatient data from independent centres were under-reported compared with outpatient data from the NHS. Incomplete and poor quality hospital episode statistics data limited the Commission's ability to assess quality of care in independent centres. Measures of quality and performance, including re-admission rates within 28 days, revision rates, perioperative mortality, and length of stay, all rely on hospital episode statistics data. Independent centres, however, have not been routinely providing good quality and complete data.

As part of the commercial contracting process the DoH Commercial Directorate established a separate reporting system for independent centres based on 26 unpublished key performance indicators, around eight of which are clinical, but even these indicators are of variable quality. The first research on the quality of work undertaken by independent centres was carried out by the National Centre for Health Outcomes Development on four schemes (five providers) on the basis of the key performance indicator returns. Its report, published in October 2005,

stated that data were so variable in quality and so incomplete as to render 'any attempt at commenting on trends and comparisons between schemes and with any external benchmarks, futile.'

In an assessment of wave 1, the DoH refused to provide the Health Committee with financial information on private sector contracts, or the methodology underpinning value for money, on the grounds of commercial confidentiality. In a supplementary written submission to the Health Committee, the DoH stated that value for money for private centres is calculated in relation to an 'NHS equivalent cost'. But the cash components of this equivalent cost have not been made public. The then Secretary of State for Health stated that the average premium for private treatment centres is 11% above the NHS tariff. Centres also receive a subsidy to cover costs incurred as private providers, such as bidding costs, but the actual amount is unclear.

Clinical negligence claims were assumed by private centres in wave 1 contracts, but were transferred back to the public sector in July 2004. It was reported that insurance premiums for clinical negligence formed a large part of procedure prices for private centres and that the change involved 'significant' savings, but the scale of the savings and who benefited have not been made public. The DoH failed to collect and provide data to allow evaluation of its policy of using for-profit commercial companies to deliver clinical services from NHS funds. One member of the Commons Health Committee remarked that the whole area seemed to be an evidence-free policy zone. The failure to require independent sector treatment centres, which treat NHS patients, to provide data on the same basis as the NHS raises serious accountability issues. So too does government failure to collect and publish relevant data on the productivity, performance, and quality of these centres. Its refusal to provide data on the value for money of independent centres is worrying, given that recent evaluations of Europe-wide attempts to improve health system efficiency by introducing consumer choice through market competition found no concrete evidence that the introduction or extension of choice 'works.'

Lessons learned

- It takes time, legal intervention and rigorous assessment and monitoring to establish independent hospital entities from state hospitals: 24 years in the case of the NHS in England, and the process is still not complete.
- A regulator is required to assess and monitor NHS foundation trust applications and foundation trusts themselves, once established.
- A detailed application and assessment process is required for applicant NHS trusts that wish to become NHS foundation trusts.
- A detailed legal contract, or a licence and a continuous monitoring process are required, so that the regulator can hold the NHS foundation trust to account.
- On the one hand, successful NHS foundation trusts demonstrated improved financial governance and discipline, saved money, had more commercially aware boards and improved quality. In addition, the public had a say in local healthcare services.
- On the other hand, approximately one-third of the established foundation trusts had/continue to have serious governance and/or financial problems despite rigorous oversight, and these require serious intervention by the regulator.
- Some foundation trusts compromised quality of care in order to meet financial targets.
- Quality-of-care measurements were only introduced as part of the assessment and monitoring criteria in 2009, following some serious incidents.
- PFIs have become a serious drain on hospital resources and remain a barrier to some NHS hospital trusts becoming NHS foundation trusts.

Conclusion: England

1. It is clear that preparing public hospitals to be independent entities, and maintaining them as such, requires a rigorous process including an annual licensing process, continuous monitoring and an independent organisation to provide oversight.

2. It should also be noted that, despite the rigorous procedures, 34.3% of NHS foundation trusts had governance concerns and 23% had serious continuity (financial) risks in March 2015.

3. Evaluations of the oversight procedure indicated that quality-of-care measurements were necessary alongside governance and financial measures, and these were only included after some serious incidents in 2009.

4. The introduction of competition based on quality with set prices rather than competition based on price in 2012 is an interesting measure.

Case history: New Zealand

Background: Government and politics

New Zealand is a small island nation situated in the southwestern Pacific Ocean. Originally populated by the indigenous Māori, it became a British colony in 1840 following the signing of the Treaty of Waitangi by the British Crown (Queen Victoria) and Māori tribal leaders. New Zealand became a Dominion in 1907, and its Parliament gained full legislative powers in 1947.

The Census 2013 results show that New Zealand has an estimated population of 4,242,048.(49) The population is predominantly of European ethnicity (74%), but the country also has significant Māori (15%), Pacific Island (7%) and Asian (12%) populations.(49) Approximately 20% of the population is aged 0–14 years,(49) and the proportion of the population aged over 65 years is expected to grow from its current 14%(49) to between 20% and 22% by 2031.(50)

New Zealand has a unicameral system of central government, with separation of the executive, parliament and judiciary. Prior to 1996, New Zealand ran a 'first past the post' electoral system whereby the central government was formed by the political party gaining the most seats in parliamentary elections. Since 1996, New Zealand has run a 'mixed member proportional (MMP)' system, with 120 Parliamentary seats, 60 filled through winning individual electoral seats and 60 as a result of winning a proportion of the total 'party vote'. Traditionally, there have been two main political parties: the (conservative) National Party and the (left) Labour Party. Additional parties include the Green Party (on the left), New Zealand First and United Future (centrist), and ACT (on the right). More recent additions are the Internet Party and Mana Movement (on the left) and the Conservative Party (on the right). General elections are run every three years (with the most recent held in September 2014). All governments since 1996 have been coalition governments, i.e., involving coalition agreements, led by either the National Party (1996, 2008, 2011, 2014) or the Labour Party (1999, 2002, 2005).

Local government in New Zealand currently comprises 78 regional, local territorial and unitary councils,[1] elected every three years. In terms of health, local government is responsible for core 'public health' functions relating to water and sewerage, and food services, but not for other health services.

[1] Regional councils are responsible for environmental resource management, flood control, air and water quality, pest control, public transport, regional parks and bulk water supply. Territorial authorities are responsible for local services such as local roads, water reticulation, sewerage, refuse collection, libraries, parks, recreation services, local regulations, community and economic development, and town planning. Unitary councils combine both roles. See http://www.lgnz.co.nz/home/nxs-local-government/

Background: Health system to 1990

The history and background of the New Zealand health system is well described and analysed in Cumming *et al.* (51) and Gauld (52).

Traditionally, health care in New Zealand has been substantially financed by central government through general taxation. In 1980, government funding accounted for 88.1% of total health expenditure; by 1990/1991 it had fallen to 82.2% (53). This public financing supports a comprehensive range of health services, such as public health; preventive screening services; primary health care through general practitioners (GPs) and nurses, pharmaceuticals and pharmacist services, and diagnostic tests; out-patient hospital care; in-patient medical and surgical care; hospital-related community-based district nursing services; rehabilitation services; and palliative care. It excludes optometry services, non-urgent dental care for adults, and counselling services (although those on low incomes may get social welfare funding to support use of these services). Most hospital and hospital-related community services are free, but service users have generally always paid a user charge for primary health care services provided by GPs and, since the mid-1980s, for prescription items.

Since the 1960s, New Zealanders have been able to purchase private health insurance, which covers primary health care user charges and provides faster access to (non-urgent) elective services and better facilities in privately owned hospitals. Since 1974, New Zealand has had a parallel social insurance system called ACC (Accident Compensation Corporation), which funds accident-related health care. This is a no-fault scheme, which reduces the need for those who have been injured to sue in order to cover the costs of care.

A central government Minister of Health oversees health policy, supported by a Department of Health (DoH)/Ministry of Health (MoH) – DoH up to July 1993; MoH after that date. The DoH was responsible for policy, regulation, the funding of services, the funding of training, and monitoring the performance of the then existing area health boards (established during the 1980s). DoH responsibilities included psychiatric and age-related disabilities, while a separate department, the Department of Social Welfare, was responsible for overseeing services for people with intellectual and physical disabilities (54).

Hospital services have been predominantly provided by geographically based publicly owned hospitals. The trend prior to the 1980s had been to amalgamate these hospitals into larger groupings. By 1980, there were 27 hospital boards, with governing boards elected locally. Hospital boards were funded on a cost-plus basis i.e., with annual budgets.

Traditionally, primary health care services have been provided by a large number of independent practitioners. Most New Zealanders had a general practice which they were enrolled with, providing general practitioner (GP) and practice nurse first-contact services. Most practices were small, with one or two GPs. Traditionally, practices were paid largely on a fee-for-service basis, although a few were paid on a capitation basis. In addition, fee-for-service payment arrangements have traditionally existed for pharmacy services, pharmaceutical prescriptions, laboratory, and X-ray services.

A number of national and local community-based providers, usually established as not-for-profit organisations (NGOs), have also traditionally provided some services e.g., health promotion services, well-child services, sexual health services. Usually, these organisations received grants to deliver services.

Prior to the 1980s, a number of attempts had been made to reorganise the health system, to more actively prioritise and plan services, and to provide a more integrated approach to service delivery (see details in (51)). It was not until the 1980s, however, that the system began to be reformed, with the establishment of 14 geographically based area health boards (AHBs), responsible for public health and for the delivery of hospital and hospital-related community services. AHBs were established throughout New Zealand during the second

half of the 1980s, with locally elected governing boards. By the end of the decade, there was increased accountability to central government through some central government appointments to AHB boards and the introduction of new accountability arrangements through which central government began to hold AHBs to account (e.g., a set of goals and targets for AHBs to achieve, and annual contracts between central government and AHBs) (55). It is interesting to note that during this time, real funding to AHBs fell almost 8% between 1989/1990 and 1992/1993; employee numbers and bed numbers fell significantly, average length of stay (ALOS) reduced, and hospital discharges rose. These gains were achieved through consolidating services, reducing beds as ALOS decreased, and closing smaller hospitals (56). However, AHBs also ended up with significant deferred maintenance and a 1992/1993 aggregate operating deficit of more than NZ$60 million (56).

Reviews of the health system in the 1980s

During the mid-1980s, the fourth Labour government introduced major reforms of the New Zealand economy, designed to significantly improve its performance. Key reforms included floating the exchange rate, removing government subsidies, and establishing government trading departments as more commercially-oriented state-owned enterprises (57).

Two significant reviews of the health sector were undertaken during this time:

The first, the 1986 *Health Benefits Review* (58), raised a number of concerns around the performance of the New Zealand health system. For example, in relation to primary health care, it noted that the New Zealand health system was not providing equitable access to services, with the more affluent receiving a greater share of services than those with higher needs; it pointed to an unresponsive, medicalised service not meeting the needs of local communities, benefitting providers more than users of services, and underemphasising health promotion and wellness. In addition, it suggested that there was a significant lack of accountability for tax funding. In relation to secondary (hospital) care, the 1986 Review noted the rapid growth in expenditure in previous years, but that the automatic growth in secondary care funding was now increasingly seen to be at odds with growing evidence that primary health care investment might be a better use of resources; in addition, it noted that long waiting times for elective services in main centres were leading to significant inequities in access to elective services, with those able to pay for themselves or through health insurance having much better access to care. The Review also noted that the health status of New Zealanders was deteriorating over time compared with people in other Organisation for Economic Co-operation and Development (OECD) countries; it also noted the poorer health status of Māori. The Review provided five options for reform, recommending that the state retain its dominant position as funder, but with a move to a mix of state provision and a greater use of contracts with providers, and a need to also consider the role of user charges and the respective levels of subsidies paid for different services.

The second review of the health sector was an independent review, established in 1987. The Hospital and Related Services Taskforce report (59) entitled *Unshackling the Hospitals*, but also known as the *Gibbs Report* after its Chairman, noted major inequities in the system, in terms of waiting times around the country and by specialty; with medical practitioners favoured over other providers; and with access to benefits and services dependent on where a person resided. It pointed to the existence of few community-based services, and suggested that hospital services lacked responsiveness to different needs – in particular, the needs of women and Māori. The 1987 review suggested that significant efficiency gains could be made throughout the hospital sector, indicating that between NZ$450 million and NZ$600 million per year, i.e., between 24% and 32% of then operating expenditure, might be saved by reducing length of stay; reducing hospital facilities; creating more

efficient units; and introducing better incentives (59).[2] Key management deficiencies were also the focus of attention in this report: such deficiencies were seen to arise from consensus triumvirate management arrangements by a senior clinician, senior nurse and senior administrator, thus leading to lack of responsibility being taken in the system; the centralisation of salary negotiations; and lack of management information and cost consciousness. The report also argued that many of the incentives faced by New Zealand hospitals were inappropriate – in particular, the fact that AHBs were incentivised to support their own services, as opposed to ensuring that the most cost-effective provider delivered care. This review recommended the introduction of a purchaser-provider split, with the establishment of six locally elected regional health authorities acting as purchasers representing consumers, buying services from both publicly and privately owned providers. It was expected that providers would be paid for the value of the services they provided and thus would make 'massive efficiency gains' if the purchaser-provider split were to be introduced (59).

Neither of these two reviews resulted in any significant changes in the health system at the time; however, both influenced the thinking of the review that followed in 1991.

New Zealand's health reforms in the 1990s

1990s health reforms – proposals

In October 1990, a National Party-led government was elected. It continued with major reforms in the New Zealand economy, extending them to the labour market and social policy (60). In health care, the new government undertook two major reviews – one relating to the role of user charges within the system (61, 62), and a second relating to the structure of the health system (63). These reviews had not been signalled during the October 1990 election campaign.

The health system review, undertaken by a specifically established taskforce, drew on findings from the earlier 1986 Health Benefits and 1987 Gibbs reports. On Budget night (July 1991) the Taskforce's report was released.(64) It recommended major reforms of the New Zealand health system, in order to improve the overall value for money provided by the system, as well as improve efficiency and responsiveness to service users.

The stated goals of the reforms were to:

- Improve access for all New Zealanders to a health care system that is effective, fair and affordable.
- Encourage efficiency, flexibility and innovation in the delivery of health care to the community.
- Reduce waiting times for hospital operations.
- Widen the choice of hospitals and health care services for consumers.
- Enhance the working environment for health professionals.
- Recognise the importance of the public health effort in preventing illness and injury, and in promoting health.
- Increase the sensitivity of the health care system to the changing needs of people in our society.(64)

The following reforms were recommended:

- The model would encompass a 'purchaser-provider split' with a 'quasi' market, based on the principles of i) key organisations having particular and focused roles within the system; ii) competition and contracting to encourage efficiency and service responsiveness; and iii) service user choice.

[2] Quite how these estimates were reached has remained unclear, especially given the well-recognised lack of cost data available in the system (52. Gauld R. Revolving Doors: New Zealand's Health Reforms - The Continuing Saga. Second edition ed. Wellington: Institute of Policy Studies and the Health Services Research Centre; 2009.

- A central Ministry of Health (MoH) would oversee the system as a whole, focusing on policy, financing and funding, and regulation. Funding for primary health care, hospital and community, and disability services was amalgamated into a single pool. Population-based public health funding was separated out into its own funding pool.
- Four geographically based regional health authorities (RHAs) would become the purchasing authorities, setting priorities and purchasing/contracting for services. RHA Board members were to be appointed by central government.
- A single, national Public Health Commission (PHC) would be established to set priorities and purchase/contract for public health services.
- AHB hospital and community services were to be established as stand-alone, state-owned enterprises (SOEs) (later given the name Crown Health Enterprises (CHEs)). Board members would be appointed by central government. Publicly owned hospitals were to compete against each other (and against private hospitals and other private providers) to win contracts to deliver services. They were expected to make a surplus, with the surplus returned to the Health Vote. Some publicly owned hospitals had regional public health services as part of their organisation, to be contracted by the PHC.
- Privately owned hospitals could also compete for contracts with the RHAs.
- Primary health care providers would move from fee-for-service regulations to formal contracts and also compete for contracts with the RHAs.
- Local communities could purchase smaller, publicly owned facilities, and run them as independent, privately owned, not-for-profit community trusts, also competing for contracts with the RHAs. This would ensure the availability of services and would allow communities to manage services themselves; generally, these would be facilities in rural areas.
- Other community-based providers previously with grants would also move to formal contracts and could compete for contracts with the RHAs.
- A national Core Services Committee would be established, in order to determine the 'core' services which should be publicly financed – and which would form the basis of contractual requirements for RHAs – and would thus ensure that they delivered a consistent mix of services.

The purchaser-provider reform proposals drew on 'quasi' market reforms proposed for the United Kingdom.(65) These reforms were originally envisaged as a starting point only, however. The longer-term aim was to establish a 'managed competition' model, i.e., to encourage the establishment of privately owned Health Care Plans (HCPs), which would compete with RHAs as purchasers of health care services. This idea drew in particular on work being undertaken at the time on managed competition in the United States of America(66) and the Netherlands (67). New Zealanders would be allocated an amount of funding that they could take to the purchaser of their choice, an RHA or HCP, which in turn would then purchase services on their behalf. Longer term still, it was hoped that RHAs and HCPs would form integrated purchaser-provider agencies, competing with each other to deliver a more integrated set of services.

Implementing the 1990s reforms

The government established an intricate set of arrangements to implement the reforms (63). Rather than relying on its advisor (the then Department of Health) to implement the reforms, it set up a new, separate group of agencies to undertake all arrangements. The original functions envisaged for each agency were set out in Upton's report (63). The agencies were to report independently through relevant Ministers to a specifically established Cabinet Committee. Key players included the following:

Commissioners of AHBs: AHB Boards were disestablished on Budget night July 1991 and Commissioners were immediately appointed to manage AHBs in the interim period, i.e., until new agencies were established and new legislation was in place.

The Health Reform Directorate (HRD): Shortly after the July 1991 Budget, the HRD was established as part of the Department of Prime Minister and Cabinet to oversee the reforms process – in particular to coordinate the various work required to establish the new model.

The HRD included (68):

- The National Interim Provider Board (NIPB), which was to determine the arrangements for CHEs, as well as finalise all arrangements relating to their finances, including balance sheets (i.e., assets and liabilities). (The NIPB's terms of references were included in *Providing Better Health Care for New Zealanders: Report to the Government and the New Zealand Public*.(69) In May 1992 the NIPB created 23 CHEs. All but one (Healthlink South in Christchurch) has a trauma hospital providing 24-hour acute care (69). CHE establishment boards were appointed in November 1992.(70)
- The Policy, Implementation and Regulation Directorate (PIRD), which was responsible for policy and regulation, communications, as well as funding and contracting arrangements (for details on the work of the PIRD, see.(68)

A grace period of two years was allowed to complete the establishment of the new agencies, with the new model expected to be fully established by July 1993 (63).

It became clear early on that reforms, such as those proposed, would take a considerable length of time and work to bed in. The Department of Health needed to restructure and establish new roles and processes as a Ministry of Health[3] to oversee the new RHAs and the PHC. The Core Services Committee began work on determining the set of services that should be publicly funded. RHAs and the PHC needed to appoint staff; establish new decision-making processes to support priority setting; develop contracting and negotiating skills, in addition to developing new tendering and contracting processes and documentation. Providers, including CHEs, also needed to develop contracting and negotiating skills, and set up new data collections to determine the range and number of services being delivered as well as to determine their costs. Furthermore, they needed to begin to understand their likely competitive advantage. The Crown Company Monitoring Advisory Unit (CCMAU) had to begin to monitor the performance of CHEs (for further detail, see below). The reforms involved a significant amount of work to unbundle the AHB funding, in order to allocate budgets to the appropriate new agencies; develop and pass the legislation required for the new reforms; legally establish the new agencies; finalise the values of AHB hospital assets and liabilities, in order to establish clean balance sheets and financial positions for the new CHEs.

Early issues

The reforms were critiqued from early on, and from the outset, were highly unpopular with the general public.

In terms of critiques of the reforms, key concerns were raised in relation to:

- lack of consultation about the reforms, the pace of change, and the lack of evidence to back up the reform proposals (see various authors in *Health Reforms: A Second Opinion* (71))

[3] In New Zealand, Departments typically have both policy and operational functions; Ministries have policy functions only.

- the likely cost of the reforms – not only the costs of restructuring but also the ongoing costs associated with the appointment of new Boards of Directors for RHAs and CHEs – as well as the contract processes themselves (71-73)
- the competitive model and how successful it would be, given a likely tendency for purchasers to work largely with existing providers and the likely lack of competition between providers in New Zealand (73)
- likely difficulties in being able to describe some services adequately for contracting purposes (e.g., mental health) and in assessing care quality (72, 74-76)
- how a more competitive environment might affect the sector's traditional cooperative approaches in the delivery of services, and whether a profit-driven sector would sacrifice quality of care to ensure profitability (71)
- whether any gains to be made from the reforms would be sufficient to outweigh the considerable implementation and ongoing costs associated with contracting (74).

At an early stage, concerns began to be expressed about the costs of implementing the new model, including the costs of low morale in the health workforce (71, 72). (Later estimates put the costs of the reforms at between NZ$85 million and NZ$348 million, and in some cases up to NZ$800 million (52).)

The public's views on the reforms were also coloured by service user charges, which were introduced at the same time as the above reforms, but through a separate review process.(62) Prior to 1991, a universal subsidy, albeit a very low subsidy, was available for primary health care services. The 1991 proposals introduced a targeted regime from February 1992 onwards, with lower-income and higher service-using New Zealanders holding a community services card that would entitle them to higher subsidies, whereas other New Zealanders would pay in full for primary health care services out of their own resources. In addition, the government introduced a user charge for hospital in-patient and out-patient services. The public viewed these reforms of the user charge regime alongside the organisational reforms as a single package. As Gauld (68) noted:

'User charges were both a policy and a public relations disaster for the government. … The introduction of user charges created an ill-feeling among the public about the government's intentions for the health sector, and further promoted a belief that 'privatisation' of the health system was imminent. Moreover, the vast administrative requirements and costs of introducing and facilitating the charges were seen as indicative of increasing expenditure on management. In turn, the health reforms came to be viewed in a similar light: that they would only result in downsizing of the public health system and increasing transaction costs.'

Throughout 1992, key parts of the reforms were changed, either as a result of the difficulties associated with their implementation or as a result of the public's concerns, the media attention and the government scrambling to not lose support that might cost it the 1993 General Election. The hospital charges were dropped only a year after their introduction; it is estimated to have cost around NZ$8.012 million to establish billing systems. In addition, hospitals found it difficult to collect the fees, thus resulting in lower than expected revenue as well as high costs from referrals of debts to debt collectors.(68)

The Core Services Committee quickly moved away from defining explicit core services, on the basis that it would be too simplistic to set out an explicit list of services at a general level, given that some services could, in particular circumstances, provide substantial benefit to patients (Cumming J, personal communication 2014). Instead, the Committee focused on identifying key principles for priority setting (77), and (later) on developing more nuanced guidelines to ensure that services were delivered to those mostly likely to benefit. In addition, the Committee focused on the development of a clearer and fairer process for deciding which patients should

receive publicly funded elective services. The MoH continued the core work to some extent, developing a service coverage document and annual service priority documents to hold RHAs to account (78).[4]

HCPs were also an early casualty of the reforms. In 1992, it was announced that this aspect of the reforms would not proceed, due to perceived difficulties in designing the funding arrangements i.e., the risk-adjusted entitlements that individuals would need in order to fund their care (74, 79)).[5]

With the reforms so unpopular, the government needed to reassure the public about 'continuity of services during the transition' (56) (Appendix 2.2) i.e., in the early stages of CHE development. Thus, 'low- impact' arrangements required RHAs to fund CHEs at 98% of the previous year's budgets, and to fund the same type and range of services as had been provided the previous year (78). In addition, in 1993/1994, CHEs were 'asked not to significantly reduce or stop any services, close any hospitals or wards, or carry out any measures involving significant reductions in clinical staffing'. Later, arrangements were put in place to ensure that six months' notice was given in relation to any key decisions to exit services. Additional funding was also provided by the Minister of Health to increase the monies paid to CHEs, given the early deficits they were running (74). Ashton suggests that this meant the efficiency gains sought by the reforms were not being achieved.

In December 1994, it was announced that the PHC was to be abolished; it formally ceased operations on 30 June 1995, and funding for public health services returned to the MoH. Advice and monitoring of public health was also returned to the MoH; purchasing of public health services was allocated to the four RHAs.(68)

Arrangements for Crown Health Enterprises

CHEs were established as companies (first incorporated under the Companies Act 1955 and then re-registered under the Companies Act 1993). (56) They were wholly owned by the central Government, with shares held in equal numbers by the Minister of Crown Health Enterprises and the Minister of Finance. CHEs were also subject to the Health and Disability Services Act 1993. In 1996/1997, of the NZ$5 billion in Vote Health, NZ$2.8 billion was allocated to CHEs.

CHEs were to operate as businesses, and they would be governed by government-appointed boards (as opposed to the locally elected boards of AHBs) (for further details, see Appendix 1.13 of (70) attached as Appendix 2 to this report). It has been noted that the type of company chosen to establish the CHEs 'as one being most likely to ensure they managed their resources in a sustainable and efficient way using commercial disciplines' (56). It

[4] Some experts have argued that the lack of an explicit core set of services held up the development of purchasing, as RHAs were unclear about what services they would need to purchase (Crown Company Monitoring Advisory Unit 1996). It is difficult to imagine that the Core Services Committee could have established an explicit core set of services in time for the reforms to commence on 1 July 1993, however, especially as this was one element of the reform package that the government sought consultation on, and also because the timelines included in the reform document did not include a timeline for finalising a core set of services prior to the full introduction of the reforms on 1 July 1993. Indeed, the reform document suggested that a staged approach might be taken when finalising the core set of services, with RHAs starting to purchase the range of services currently delivered. In the view of one of the authors of this report (JC), the lack of a core set of services was only seen later to have been an issue in relation to the reforms.

[5] Again, some experts have perceived health care plans as a major impediment to the reforms, as health care plans would provide significant incentives for RHAs to perform. However, in the view of one of the authors of this report (JC), the purchaser-provider split arrangements were conceived in their own right as a reform model, and it is this model that is the focus of the Ashton report.

was expected that CHEs would respond to clear price signals from the RHAs,[6] and that they would compete by reducing costs and improving quality of care (i.e., those promoting the model assumed that costs could be lowered and quality of care improved). It was also expected that the better performing CHEs would grow, while poorer performers would contract. Overall, it was expected that 'more efficient, high quality innovative providers would emerge because of competitive pressure to maintain performance' (56).

In the New Zealand case, contracts between purchasers and providers had full legal status, and purchasers and providers were covered by the Commerce Act 1986 (80). This meant that contracts which might have the effect of substantially reducing competition were not enforceable.

Effectiveness and impacts of the reforms

The new arrangements formally came into force on 1 July 1993. No formal evaluations of these reforms took place. The evidence base surrounding the effectiveness and impacts of the reforms is generally limited and is not based on rigorous research designs or data. A number of key reports and academic papers set out how the reforms developed, and they provided some analyses and commentary on their effectiveness and impacts, usually using analyses of trend data to compare key measures before and after the reforms. Key analyses are summarised below.

The reforms were highly unpopular and were expensive to implement (see Section 4.3 above). There is also evidence to suggest that the CHE reforms generally failed to live up to expectations[7] (79). The major savings envisaged did not materialise (79), and therefore such savings were not available to reinvest in new services. The promised reductions in waiting times did not happen; in fact, waiting lists and waiting times rose significantly (81). The reforms may also have been detrimental to health outcomes (82, 83).

Ashton (74) set out some key data to suggest that, from an early stage, the reforms were not achieving their key objectives. She noted that in the first year of the new model (1993/1994) the number of surgical operations increased, but that this was in line with earlier trends. Waiting lists also increased, but, again, this was in line with earlier trends. CHE expenditure in the first year exceeded revenue by 11%, thus suggesting that CHEs were not being adequately reimbursed for the services they provided. Additional funds were later provided by the then Minister of Health, who argued that the real cost of service provision was becoming known for the first time. Ashton understood this statement to suggest that the efficiency gains sought from CHEs were not being achieved at this early stage of the reforms. Ashton also suggested that there were some gains in quality of care in rest homes, and that quality in CHEs (measured through a composite index including infection rates, patient falls, and unplanned readmissions and returns to theatre) showed no obvious changes during the first six months of the reforms. She also reported on improvements in accountability for the use of public funds as a result of the reforms.

[6] It was not clear how this would occur, other than presumably through a tendering process and improved understanding of what fees RHAs would accept through negotiations, and a final contract agreed set of fees.

[7] Beyond CHEs, some gains were made through the reformed model. New Zealand GPs quickly established representative organisations to undertake contract negotiations on their behalf, and to develop more peer processes to support expanded and better quality general practice services. Independent practitioner associations (IPAs) allowed the development of new ways of contracting for primary health care services, including moving to more capitation contracts, contracts to better manage pharmaceutical prescribing and laboratory test ordering, and in one case, a global budget to manage primary health care services and reduce acute admissions to hospital. Some studies show that considerable savings were made as a result of a number of these arrangements (see summaries in Cumming, McDonald *et al.* (2014); Gauld (2009)).

Ashton (84) similarly noted that the desired efficiency gains did not seem to materialise during the reforms, with previous trends in the increase in outputs continuing, whereas costs, especially labour costs, actually rose. Payments from RHAs did not cover the costs of service delivery, with CHE deficits increasing over time. Ashton also noted the difficulties in contracting for some services, e.g., mental health services, which continued to be contracted for on an input basis (e.g., number of cases and mix of staff).

The most comprehensive detail about the performance of CHEs was provided in a 1996 briefing paper prepared by the CCMAU(70) for the incoming Minister of Health and also for CHEs.[8,9] It is worth noting, however, that the briefing paper did not consistently provide data or rigorous evidence to support its findings. The 1996 paper noted the significant anxiety being generated about public hospitals arising from concerns about long waiting times for elective surgery; concerns about quality of care; adequacy of government health funding; public confusion over the roles of purchaser and provider, with little appreciation of the roles of RHAs in making decisions; the public airing of conflicts between CHEs and RHAs over contract negotiations; apparently irrational decisions; a perceived increase in bureaucracy, and the well-publicised resignations of CHE chairs and chief executives.[10]

The 1996 briefing paper noted public opposition to the new structure. Clinicians, it was argued, are 'influenced by ethical duties to their patients, their loyalty to their profession and colleagues and their financial rewards'. They can therefore have difficulty reconciling these factors with the increased emphasis on their status as CHE employees and carrying out their responsibility for managing substantial, but finite, publicly-owned resources'. The paper noted the 'rejection of the "profit-driven" model for health and the jargon of management and economics rather than health', and the ongoing issues relating to attempts to ensure the allocation of resources to the best location/provider, rather than to hospitals. It also noted difficulties in defining 'core' services, thereby 'frustrating attempts to institute equitable, consistent and agreed rationing' as well as leading to 'heightened awareness that services are actually being rationed'.

An immature contracting environment was noted within the sector. The CCMAU noted that not all RHAs were giving clear signals about their purchasing, thus making it difficult for CHEs to plan. The contracting process broke down early on, in part due to poor information and because of 'differing understandings of the basis for negotiations between RHAs and CHEs' (56) (Appendix 2.1) – but the CCMAU did not specify what the different understandings were between RHAs and CHEs. Instead, a centrally driven mediation/arbitration process was used. But even this was not fully accepted by CHE Boards, with Boards requiring letters of comfort from their shareholding Ministers for CHEs and Finance, in order to provide evidence to creditors that CHEs would have sufficient revenue to pay their bills. Where efficiency gains were made, they tended to lead to price reductions, with the RHAs keen to capture any savings made.

The CCMAU also pointed to the lack of competition on both sides (i.e., purchasing and provision) compromising the reforms. On the provision side, the 'low-impact', uncertain contracting environment, short length of contracts (often, only one year), and potentially low (uneconomic) prices being offered by RHAs were seen to be contributing to providers not developing new services or infrastructure (56). Economies of scale and scope,

[8] These 'Briefings to the Incoming Minister' are provided by government agencies after each general election,, as summaries of key issues for incoming Ministers.

[9] This briefing paper includes a significant amount of information about CHEs, their origins, their legislative frameworks, and the key organisations they work with.

[10] Flood 80. Flood CM. International Health Reform: A Legal, Economic and Political Analysis. London: Routledge; 2000.reported that by late 1996, 12 of the 23 CHEs had seen their CEOs resign. Gauld (2009) reported that by 1996, only 3 of the 23 new CHE CEOs remained in their posts.

access requirements giving CHEs a 'geographic franchise' (i.e., the right to provide monopoly services in an area), and the need for cooperation and collaboration among health professionals to provide high-quality care, were also issues restricting competition. In addition, high transactions costs on both sides of the market were noted by the CCMAU, meaning that contracting was not generating large price reductions.

In the 1996 CCMAU report,(70) it was noted that 21 of the 23 CHEs remained in deficit. The CCMAU also noted that it was difficult to determine the extent to which this was due to inefficiency, underpricing or other contributing factors. Indeed, the report argued that there was potential for further efficiency gains through further reductions in length of stay, new service delivery models and 'substantial' reductions in capacity, but that this would not be sufficient to meet the gap between expected and actual price levels at the quality of service required. RHA fees were perceived to be too low, and the government was picking up the difference through deficit support of CHEs. Where deficits were the result of poor performance, this was being rewarded through deficit support.[11] Although CHE deficits were reducing, this was a slow process. The CCMAU did not seem to believe that CHEs would achieve what was expected of them in the following three years; even by 1998/1999, it was expected that an overall deficit would remain. In 1994/1995, 11 CHEs had not developed an agreed business plan indicating that a viable business would be achievable by 1996/1997.

The 1996 CCMAU report did, however, note some significant progress in the area of improving value for money. The 1993 reforms, it was argued, focused on better decision-making, based on improved information and explicit contracting, more rigorous performance monitoring, clearer accountabilities and better incentives to perform – all leading to 'greater efficiency as well as more health services'. A number of examples of CHE initiatives were set out in an appendix to the main report. These initiatives mainly focused on new relationships with, for example, iwi (Maori tribes), the development of services (including new services), workforce developments, quality improvements, and information systems development. In addition, the appendix set out information on the number of services being delivered by CHEs, as well as the savings made as a result of contracting out non-core support services (such as laboratory, cleaning, property management, gardening, food, ambulance, laundry and other services).

The 1996 report noted that the reforms themselves contained valuable lessons, including 'distraction of key management, lowered workforce morale and reduced public confidence in the sector's ability to deliver'. It also noted that 'reform fatigue' meant that many good people had already left the health system as a result of 'burn-out', and other people would not be able to withstand further structural reform.

In a 2004 book and paper, Ashton, Cumming and McLean (86, 87) discussed the contracting approaches undertaken by the RHAs, and the implications of these approaches for the reforms. They pointed to the early commercial approaches taken to contracting, resulting in long contracting processes (sometimes as long as two years); vigorous bargaining and adversarial relationships; very formal, legalistic terminology and therefore lengthy contract documentation. By the third year of contracting, however, contracts were shorter and were written in plain English. In the early days, many contracts were for one year only, because that is how the RHAs

[11] The Ministry of Health 85. Ministry of Health. Health Expenditure Trends in New Zealand 1990-200. Wellington: Ministry of Health; 2002. noted deficit funding of NZ$195.6 million in 1993/94, NZ$216.7 million in 1994/95, NZ$178.9 million in 1995/1996, NZ$226.4 million in 1996/1997, NZ$193.5 million in 1997/1998, NZ$39.6 million in 1998/1999, and NZ$6.4 million in 1999/2000, i.e., a total of NZ$1,057.1 million over seven years. Total health funding in 1999/2000 reached NZ$8,952 million. It should be noted that the reductions in deficit support over time in part came about as a result of new funding being provided to RHAs to provide higher fees for CHE services. Public expenditure rose on average by 4.7% per annum from 1993/1994 to 1999/2000, compared with 2.33% between 1979/1980 and 1990/1991.

themselves were funded. The duration of contracts gradually extended over time, with contracts of between two and three years (and up to five years) becoming increasingly common.

In general, most contracts were allocated to incumbent providers, but some contestable processes were used where there were many providers and some surplus capacity (e.g., rest home services); where the purchaser was seeking additional volumes 'on a spot contract basis' (e.g., elective surgery); for new services (e.g., community-based mental health services); and where there were concerns over quality of service.

Only in a few cases did private providers win contracts for elective services; private providers argued that they did not have sufficient information about the risk profile of patients and therefore needed to build a risk premium into their prices, potentially making them more expensive than the publicly owned providers. But private providers also felt there was a bias against them, given that RHAs were seen to be under political pressure to maintain the financial viability of publicly owned hospitals.

Ashton, Cumming and McLean (86, 87) also note that the HFA learnt from the earlier RHA processes, and established a more 'relational' style of contracting, including working more closely with key providers to plan and develop services. They also sought to develop a more nationally consistent approach to contracting, developing a National Service Framework, with a common set of contract terms and conditions, service specifications, and a national pricing schedule based on the estimated cost of "efficient" service provision.

However, concerns were also raised over issues relating to quality of care. In one hospital, a series of patient deaths and complaints between 1993 and 1996 led to an investigation being undertaken by the Health and Disability Commissioner. The findings were complex, but included the fact that, under pressure from the governing board, the chief executive had prepared a business plan to which he was fundamentally opposed (83). This in turn led to a change in management style, a breakdown in communications, poor staff morale, and disruption of services. All of these were found to be factors contributing to the poor quality of patient care and to adverse health outcomes. In a second hospital, significant financial pressure leading to reorganisation, coupled with strained management-staff relationships, were also seen to play a key role in patient safety breaches in 1999/2000 (88).

A key desired outcome from the reforms was improved efficiency – and to achieve this through a variety of means, including potentially delivering more outputs with the same amount of resources; delivering higher quality of care with the same resources; providing a better mix of services to deliver improved outcomes with the same resources, including potentially through lower cost service providers and in lower cost settings. Despite these stated objectives, no formal assessments of trends in efficiency were undertaken in conjunction with the 1990s reforms. However, a number of later pieces of research can be used to explore the impact of the 1990s models, as well as to examine trends in efficiency, and compare and contrast trends with the later DHB model. Against this background, we first discuss the key findings, and then discuss their implications for determining the impact of different models of health sector organisation on efficiency.

The New Zealand Treasury (2005) explored efficiency changes between 1995–6 and 2000–1, and 2000–1 and 2003–4. The Treasury cautioned against drawing strong conclusions from its analyses, due to major gaps in data availability (e.g., only 35%–45% of hospital outputs, by expenditure, were centrally recorded at the time, and there was a lack of reliable input data on staffing levels). The Treasury also noted that it was unable to assess quality of care; neither was it able to assess whether or not improvements in health outcomes achieved from care increased over time. It found that real expenditure per cost-weighted discharge rose between 1995–6 and 1997–8, then fell between 1997–8 and 2000–1, before rising again between 2000–1 and 2003–4. This suggests that value for money, i.e., how much output was purchased during these time frames, increased by 1.1% per

annum between 1997–8 and 2000–1, but fell by 2.6% per annum between 2000–1 and 2003–4. Note, however, that the Treasury used the Consumer Price Index (CPI) to deflate increases in overall expenditure; use of a specific health sector index may well have improved the value for money delivered by the health sector. The Treasury also found that cost-weighted discharges per full-time equivalent, which was a measure of labour productivity i.e., outputs delivered by inputs, fell by 2.7% per annum for doctors and 1.8% per annum for nurses between 2000–1 and 2003–4. The Treasury cautioned, however, against drawing strong conclusions from these results, as staff time may have shifted towards outputs not counted in the analyses, quality of care may have improved, or the health outcomes achieved from care may also have improved over the periods (2000–1 and 2003–4).

A Ministry of Health report published in 2007, which we have not been able to source, used two approaches to assess efficiency over the 2000–1 to 2005–6 period. The authors of the Ministry of Health report found that hospital outputs grew between 2000–1 and 2005–6; that cost per output grew faster than the CPI and a forecast funding track; that output per full-time equivalent decreased from 2000–1 to 2003–4, but increased in 2004–5 and 2005–6. Maniparathy (89) focused in particular on the DHB years (2000–1), but included some data on the last years of the 1990s model (1998–99, 1999–2000). He suggested cost per unit of output, i.e., value for money, reduced between 1998–99 and 2000–01, but then increased, with cost per unit of output rising by between 11% and 18% (depending on the measures used) between 2000–1 and 2005–6. Again, the CPI was used to adjust for inflation. In terms of outputs per staff member (labour productivity), he found a small reduction between 1998–99 and 1999–2000, an improvement between 1999–2000 and 2000–1, followed by a further reduction of 8% between 2000–1 and 2005–6. Medical personnel productivity fell by 15% and nursing productivity fell by 11% over the 2000–1 to 2005–6 time period.

Walker(90) criticised both the Ministry of Health 2007 report and the report by Maniparathy(89). She noted that the former was a more rigorous report, but that both suffered from data deficiencies and from being unable to report on quality of care and health outcomes, and she criticised the use of the CPI rather than a specific health sector index to deflate expenditure over time. She also noted that change can be disruptive and that it reduced efficiency in the short term – something which may also apply to each of the different reforms that took place during the 1990s and early 2000s. In addition, she noted that reductions in staff hours, rather than being seen as a poor outcome, may have been necessary in order to retain skilled staff and ensure patient safety.

More sophisticated research, which also included a wider range of outputs than the earlier studies, suggests that technical efficiency may have improved in DHBs between 2007 and 2009 by between 1.3% and 3.1% (Desai J, personal communication). This research also showed that the results were highly dependent on the methodology used.

Drawing conclusions from these studies about the impact of the 1990s reforms on efficiency is extremely difficult. With incomplete data, any conclusions on the above studies are tentative. In addition, it is difficult to clearly separate the time periods during which different models of health system organisation applied. Transitional arrangements between the RHAs and the HFA occurred during 1997–8. However, a new government was elected in late 1999 and began the process of changing legislation and establishing DHBs during 1999–2000 and 2000–1. Even so, there is some evidence to suggest that in the early years of the DHB model, value for money and labour efficiency may have reduced – when results for these years are compared with some of the years when the 1990s models were in operation. On the other hand, technical efficiency may have improved during later years – when the DHB model was in operation. This suggests that it may not be the model of health system organisation that influences trends in efficiency; rather, the pressure that is brought to bear on hospital expenditure by central government may be an important influence. In any case, none of the studies is able to adequately adjust for any improvements in quality of care and health outcomes that may also have

occurred over time, thus making it impossible to draw final conclusions about the impact of the various models on efficiency.

Two research studies have also examined the impact of the reforms with respect to health outcomes. Unfortunately, both studies had some methodological shortcomings: in particular, both assessed the association of the health reforms with key outcomes rather than with causation, as neither study had a counterfactual or control group, thus making it difficult to be certain that it was the health reforms *per se* that had led to the outcomes found in each study.

- A paper by McCloskey and Diers (91) examined the impact of the 1990s reforms on the nursing workforce and outcomes. The authors found that, between 1993 and 2000, there was a 36% reduction in nursing full-time equivalents (FTEs), coupled with a reduction in nursing hours per 1,000 discharges. FTEs and hours worked per 1,000 patient days fell by 9%. There was, however, an offsetting increase of 18% in skill mix, with a shift towards employing fewer less qualified nurses. Average length of stay fell by 25% for medical patients and by 18% for surgical patients. The authors also found that some nurse-sensitive outcome indicators deteriorated over time, i.e., there were statistically significant increases in the rates for central nervous system (CNS) complications, decubitus ulcers, sepsis, urinary tract infections, physiological and metabolic derangement, pulmonary failure, and wound infections. Some rates – for example, for deep vein thrombosis/pulmonary emboli, upper gastrointestinal bleeds, pneumonia, and shock – either remained stable or initially increased, but later returned to rates close to pre-reform levels. Mortality for medical discharges decreased by 37% in 2000 when compared to the 1992 baseline rate; in contrast, surgical mortality rates remained stable. The authors also found that nursing workforce change variables explained approximately 50% to 80% of the variance in CNS complications, decubitus ulcers, and sepsis rates among medical discharges, and 50% to 96% of the variance in CNS complications, decubitus ulcers, deep vein thrombosis or pulmonary embolism, sepsis, urinary tract infection, physiological and metabolic derangement, pulmonary failure, and wound infections rates among surgical discharges. Although they point to some data issues which may mean that negative outcomes were present at the time of the patients' admission, their conclusion is that the changes in the health system in New Zealand, including the introduction of a diagnostic-related group funding model and the wider focus on efficiency, led to significant changes in the nursing workforce and unintended negative consequences for key health outcome measures.

- A study by Davis *et al.* (92) examined the effects of health system reform and reductions in bed numbers available between 1998 and 2001. The authors found that the number of in-patient beds in use decreased by one-third over this period, whereas the national population grew by almost one-fifth. In contrast, discharge volumes increased significantly; this was achieved by reducing length of stay and increasing the proportion of day surgery. On the downside, rates of emergency admissions increased, as did rates of unplanned readmissions. Rates of in-patient admissions were generally maintained, as were access levels for vulnerable groups – although the authors did note a fall in admissions for those living in significantly deprived areas. At the same time, age-adjusted, post-admission patient mortality rates decreased by a quarter over the period of study. Multi-level analysis suggested that a change in patient attributes (age, gender, ethnicity, diagnosis grouping, number of diagnoses) accounted for over half the reduction in mortality, while the hospital workload adjuster (length of stay and unplanned readmissions) showed a slight negative impact on outcomes. Reform phase, i.e., the health system structure in place at the time of data collection, showed a small positive effect during the market-oriented reforms. However, the study had limited overall information on supply issues (such as staff mix and overall financial resources) which the authors acknowledged may have influenced the results. The authors concluded that 'the long-term improvement in patient outcomes was slowed slightly by aspects of

hospital workload adjustment but not by reform phase' and that 'these findings suggest that, other things being equal, national public hospital systems can maintain high levels of performance and patient responsiveness while undergoing drastic organizational change'.

Changes to the reform model

In 1996, the country's first MMP election saw a National Party-led government being formed with the support of New Zealand First. The Coalition agreement resulted in a 1997 review of the health system (93). Gauld(68) has noted how the coalition and a more consultative approach to the review may have influenced its recommendations. This suggested a softening of aspects of the purchaser-provider model, but that key aspects of the original model – in particular the purchaser-provider split and those involved in purchasing roles – continued through a focus on 'competition, efficiency and financial accountability'.

A number of changes were made to the structure of the health sector as a result of the 1997 review. Changes were formalised through the Health and Disability Services Amendment Act 30 June 1998. As follows:

- CHEs became Hospital and Health Services (HHSs), with the requirement to make a revenue surplus removed.
- A decision was taken to amalgamate the four RHAs into a single purchaser; reduce duplication across the RHAs; improve consistency in terms of services and contracts, and reduce overall transaction costs. (Note: A Transitional Health Authority was established on 1 July 1997 before a new national Health Funding Authority (HFA) commenced operations on 1 January 1998 – prior, it seems, to the formal establishment of the HFA).(68)
- It was expected that in future a more transparent, collaborative and less competitive approach would be undertaken in relation to the planning, funding and delivery of health services.

At the end of 1999, a Labour-led Coalition government was elected. This government overturned key aspects of the purchaser-provider model – in particular, re-integrating the purchasing and provision of hospital and hospital-related community services in the form of 21 (now 20) DHBs. DHBs are governed by majority-elected Boards, with central government appointing four members of each Board. DHBs are explicitly accountable to the Minister of Health, who appoints the Chair of each Board. Hospitals are no longer independent entities: they are part of DHBs, which have overall responsibility for planning for and delivering health services to their geographically based communities.

Elements of the purchaser-provider/contracting model remained, however, with a central MoH undertaking some national purchasing and contracting (e.g., for services from national non-governmental organisations), and with DHBs taking over the responsibility for purchasing local primary health care, public health and community services through contracts with a range of private for-profit and not-for-profit providers.

Findings from research undertaken on this model in the early 2000s suggested significant support for the 'local' focus of this model. Furthermore, concerns were raised on an ongoing basis about purchasing and provision residing within a single organisation, thus potentially leading to DHBs providing preferential treatment by their own services, and failing to ensure overall cost-effective service delivery e.g., through primary health care and community services (94); however, no high-quality research evidence on this issue has been found.

The DHB model remains in place today (2015), with a current emphasis on increasing shared decision-making between DHBs and primary health care providers in particular, and a focus on strengthening primary health care services and delivering services closer to home (51).

New Zealand: specific questions for this review

This section of the report answers the specific questions sought in this review by the Health Research Board (Ireland). The answers draw on material presented in previous sections of the review, in addition to noting key legislative arrangements.

Rationale and degree of independence

Describe the rationale for independent hospital entities.
As noted above, New Zealand hospitals had independent status as Crown Health Enterprises (CHEs) from 1993 to 1997, and as Hospital and Health Services (HHSs) from 1997 to end 2000.

CHEs were established following major reforms of New Zealand's health system, which drew on market-oriented principles. CHE providers were to compete against each other and against privately owned providers to deliver services on contract to stand-alone purchasers of health services (Regional Health Authorities or RHAs) (and also, until 1995, the Public Health Commission (PHC)).

The reforms were designed to significantly enhance:

- **cost-effectiveness**, through the ability of RHAs to allocate resources to obtain the best value for money from health spending. Prior to this, resources were directly allocated to hospitals, with little assessment of whether or not the hospital was the best place to deliver services.
- **technical efficiency and quality of care**, through competitive processes and pressure from the RHAs to improve performance. As part of this, the reforms would also improve the availability of information on the costs of services.
- **responsiveness to service users**, again from competitive processes and pressure from the RHAs to improve performance.
- **improved overall financial performance as a result of the reforms**, significant debts held by the previous AHBs were written off, thus placing CHEs on a stronger financial footing. New financial oversight arrangements were put in place, with CHEs reporting to the Minister of Finance through the Crown Company Monitoring Advisory Unit (CCMAU).

List the chief national or provincial laws (with dates and links) that were implemented in each jurisdiction to establish state-owned hospitals as independent hospital entities (Table 19).

Table 19 Chief national or provincial laws, New Zealand

Act	Link
Health and Disability Services Act 1993: Establishing the reformed model	http://www.nzlii.org/nz/legis/hist_act/hadsa19931993n22304
Companies Act 1993 (as enacted): CHEs were established as companies under this Act.	http://www.nzlii.org/nz/legis/hist_act/ca19931993n105134/
Commerce Act 1996: Competition legislation governing health purchasers and providers	http://www.legislation.govt.nz/act/public/1986/0005/latest/DLM87623.html?search=ts_act%40bill%40regulation%40deemedreg_commerce+act_resel_25_a&p=1
Health and Disability Services Amendment Act 1995: Abolishing the Public Health Commission	http://www.nzlii.org/nz/legis/hist_act/hadsaa19951995n84384
Health and Disability Services Amendment Act 1998: Replacing the RHAs with the HFA; CHEs become HHSs	http://www.nzlii.org/nz/legis/hist_act/hadsaa19981998n74384/

Define the term 'independent hospital entities', including legal status and powers.
'"Crown health enterprise" and "enterprise" mean a company formed and registered by the shareholding Ministers in accordance with section 37 of this Act' (the Health and Disability Services Act 1993).

The objectives of crown health enterprises are:

- The principal objective of every crown health enterprise shall be to-
    - Provide health services or disability services, or both; and
    - Assist in meeting the crown's objectives under section 8 of this Act by providing such services in accordance with its statement of intent and any purchase agreement entered into it, while operating as a successful and efficient business.
- Without limiting subsection (1) of this section, every crown health enterprise shall have the following objectives:
    - To exhibit a sense of social responsibility by having regard to the interests of the community in which it operates:
    - To uphold the ethical standards generally expected of providers of health services or disability services, or both, as the case may be:
    - To be a good employer:
    - To be as successful and efficient as comparable businesses which are not owned by the crown.

Describe the independent hospital entities' official relationship with the Department of Health, quality and economic health regulator bodies, health care funding organisations and health governance bodies.
A central Ministry of Health focused on policy, financing and funding (of purchasing authorities), as well as on regulation. It also monitored the performance of the RHAs and the PHC against their funding agreements with the Crown.

Four RHAs and the PHC (until 1995) acted as purchasing authorities, planning and purchasing/contracting for services. Each RHA and the PHC had its own government-appointed governing Board. The Ministry of Health set out purchasing requirements each year for these organisations. The RHAs and the PHC reported to the Ministry of Health. Purchasing guidelines were produced by the Ministry of Health to guide purchasing each year (Performance Monitoring Unit 1995; Contract Monitoring Group 1996; Ministry of Health 1997; Performance Management Unit 1998).

Twenty-three CHEs delivered hospital and hospital-related community services. Each had its own government-appointed governing Board. CHEs sought contracts with the RHAs (for personal health services) and the PHC (for population-based public health services). CHEs reported to the RHA or the PHC on contractual issues, and to the Crown Company Monitoring Advisory Unit (CCMAU) in terms of financial performance, via shareholder government ministers.

Legal establishment and governance

Describe the legal establishment and governance (corporate, financial, and clinical) processes envisaged for independent hospital entities at the beginning of the process.
The government announced health reforms in July 1991. It allowed two years for the new arrangements to be put in place, with an expected start date of 1 July 1993 for the new model.

CHEs were established along the lines of the state-owned enterprise (SOE) model and were able to contract with staff, raise capital and operate independently (i.e., with limited government involvement in day-to-day business decisions) under the Companies Act 1993 as limited liability companies, and were subject to commercial legislation.

Assessment requirements, process and outcomes

Describe the process to assess the legal and governance (corporate, financial, and clinical) capability of state-owned hospitals, in order to establish them as independent entities, and its changes over time and the drivers for change.

Describe the period of time required to assess one entity and to complete assessment of all entities.

Describe the findings of the assessment process, and also describe the procedures in the case of success and in the case of failure.

There is very little information available on these issues.

CHEs were automatically established from the existing AHBs, as there was no process in place for formally approving that these entities were 'fit' to contract with RHAs. No information is available on how RHAs determined the suitability of private providers to deliver services. However, such services were delivered

following a tender process, which is likely to have included some type of review process by the RHAs around, for example, business sustainability and quality of care.

A two-year grace period was allowed between the announcement of the reforms and their implementation in full. In practice, however, it is clear that the development of purchasing strategies (by the RHAs) – coupled with the collection and analysis of volume, cost and quality information needed in order to implement the contracting model – took longer to put in place, thus making the early years of contracting difficult. Very little information is available about the planning for purchasing processes and purchasing decisions that might have occurred during the two-year implementation period.

Monitoring and intervention

Describe the monitoring system put in place to oversee the corporate, clinical and financial governance in independent hospital entities on a periodic basis.

Describe the monitoring system findings over time.

Describe actions taken when the monitoring systems flagged concern(s).

CHE financial performance was monitored by the CCMAU. An example of a CHE report is contained in Appendix 2 in this HRB review.

No detailed information about individual CHE performance over time is available; general findings are set out in Section 4 above. In particular, see the CCMAU 1996 report (Appendix 2 in this HRB review) (79).

Where concerns over CHE financial performance were raised, the government would appoint a Crown monitor to the Board. Ultimately, the government could sack the Board if it chose to do so. The authors of this review are unable to obtain information on these processes

CHE performance in terms of delivering health services was monitored by the four RHAs. However, it was not possible to source information on such performance for this HRB review.

Evaluation and lessons learned

Describe any (self, joint or independent) evaluations or reviews of the application and assessment process and their outcomes.

As noted above, CHEs were established from earlier AHBs, and no formal process of review took place in New Zealand to determine appropriateness for being established as a CHE.

No information is available on the evaluations or reviews of application and assessment processes, or around the contract processes that RHAs undertook to assess contract tenders or quality of care of services delivered on contract for the RHAs.

Describe actions taken following reviews and evaluations.

Key material on CHEs is discussed in Section 4 – in particular, the review undertaken in 1996 by the CCMAU (79) (see Appendix 2 in this HRB review).

No formal evaluation of the reforms as a whole took place, but in terms of the hospital reforms, it is generally felt that they did not meet expectations. Previous trends in outputs continued; costs rose – perhaps even faster than in previous years; waiting lists and waiting times rose; the expected efficiency gains were generally not achieved (see data in Section 4 above).

Views on key positive and negative factors supporting the delivery of services through CHEs depend in part on analysts' and commentators' views on whether or not the reforms were a success, and views on whether or not the reforms were seen to have been given a chance to work. In this assessment, the HRB reviewers' position is that the parts of the reforms aimed at making significant efficiency gains from CHEs generally failed: the government was unable to fully implement the reforms as originally anticipated, and there is little evidence to suggest that CHE overall performance improved relative to earlier trends. This is not to say that there were no improvements in performance by CHEs over the period. There were – principally around reducing average length of stay and increasing outputs, including day surgery. Some of these gains may have come about because of changes introduced during the reforms, including, for example, the introduction of activity-based funding. But, such changes could have occurred without the introduction of the purchaser-provider split, and the significant sums spent on the reforms could well have been used to better effect.

Key positive factors included:

- When they were established, CHEs were placed on a sounder financial footing (including through the writing off of debt).
- Over time, the reforms generated improved information on costs and volumes of services delivered.

Key negative factors included:

- The lack of consultation on and lack of support for the reforms as a whole, coupled with the high cost of the reform processes themselves, made it difficult for the government to fully implement the reforms as envisaged.
- Major reforms took a considerable period of time to implement and to bed in, and were very costly to implement.
- There were highly unrealistic expectations of efficiency gains and how the proposed model would work in practice in the New Zealand setting. In particular, a lack of competition and a focus on ensuring access to services in a country with a widely dispersed population – and where many small population centres have no private hospital service provision – meant that many CHEs had a monopoly over the delivery of

a wide range of services; consideration should have been given at an early stage as to how the model would work in practice in such circumstances.

- The poor financial position of CHEs when they were established – resulting from lack of funding in the previous decade, coupled with strong public support for CHEs – led to ongoing concerns about the financial position of CHEs and, consequently, a lack of public confidence that services would continue to be available.
- A lack of clear analysis and information on the likely impact of the reforms on publicly owned hospitals was also evident in the reforms. Public concern over potential privatisation was also a factor, leading to a lack of support for the model.
- The lack of information available to support purchasing in the early days made negotiations and pricing difficult.
- A highly legalistic approach to contracting led to adversarial relationships and high ongoing transaction costs, thereby further undermining the model.
- With a lack of general support for the reforms, the government hampered the ability of the model to deliver gains by introducing a 'low-impact' environment that prevented significant change, and suggested to purchasers and providers that there was a lack of commitment to seeing reforms through, which would mean significant change in service delivery patterns.

Key lessons learned included:

- In New Zealand, health sector reforms that emphasise the business and efficiency aspects of health care provision are deeply unpopular with the public.
- The introduction of additional copayments is also politically fraught.
- Health sector contracting relationships appear to take some time to mature; high transaction costs and pressure to deliver services also hamper the development of strong contracting processes.
- Acute hospitals in sparsely populated countries such as New Zealand are generally natural monopolies, implying that market strategies based on competition are unlikely to succeed.
- The failure to properly monitor quality of care, and build quality into contracts, also hampers reforms.
- The failure to adequately monitor efficiency limits New Zealand's ability to assess a key aspect of the performance of the New Zealand health sector.

Time frame

From the findings, provide an overall timeline for the process, from legislation to independent entity.
As noted above, all AHBs were converted into CHEs and there was no process for assessing if CHEs were ready to become an independent entity.

The overall time frame for the establishment of the new model, i.e., from announcements made in July 1991 to full implementation in July 1993, was two years. However, in practice it took many more years for organisations to settle and for contracting processes to mature.

Key organisations, their relationships and timelines

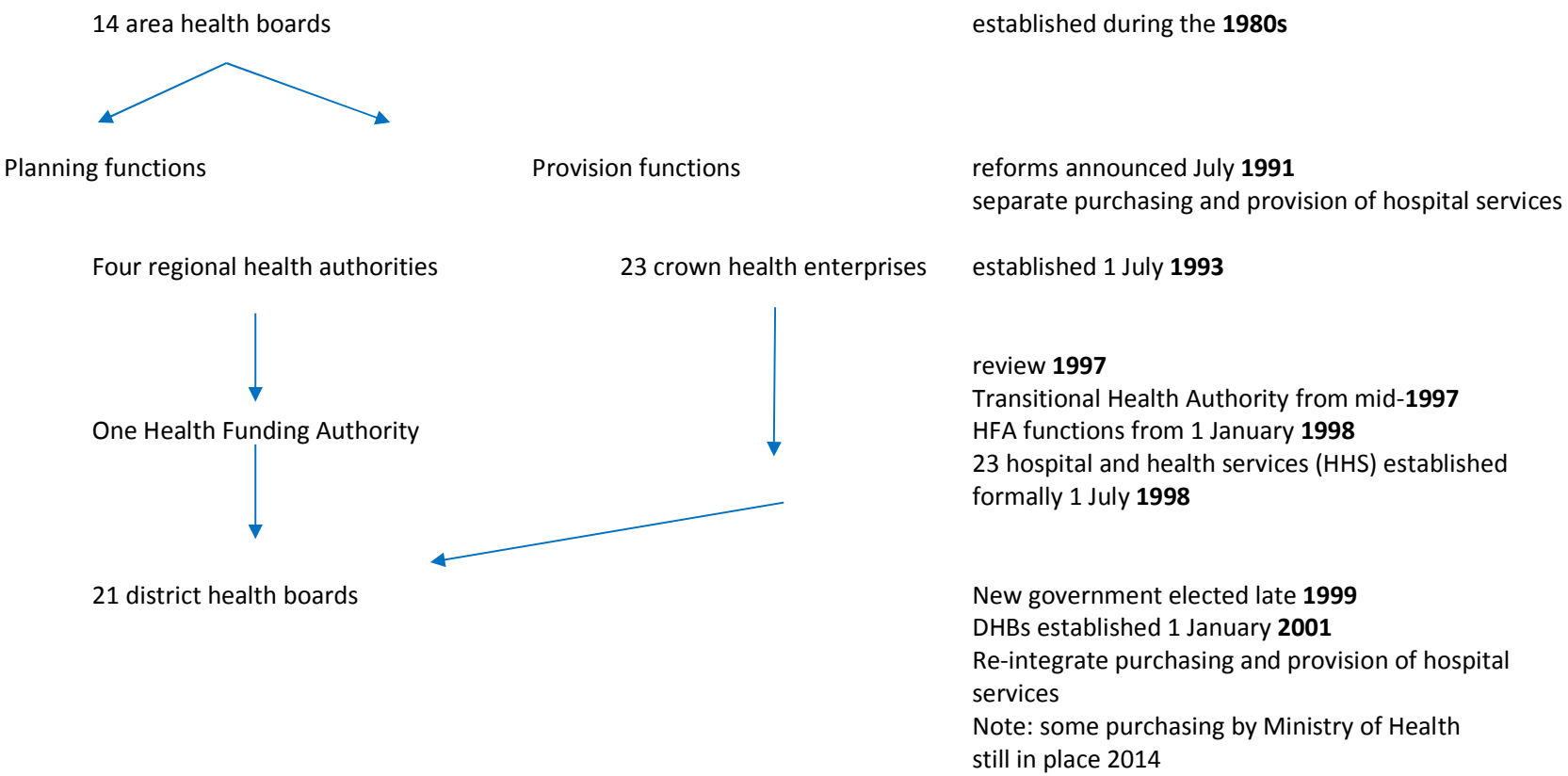
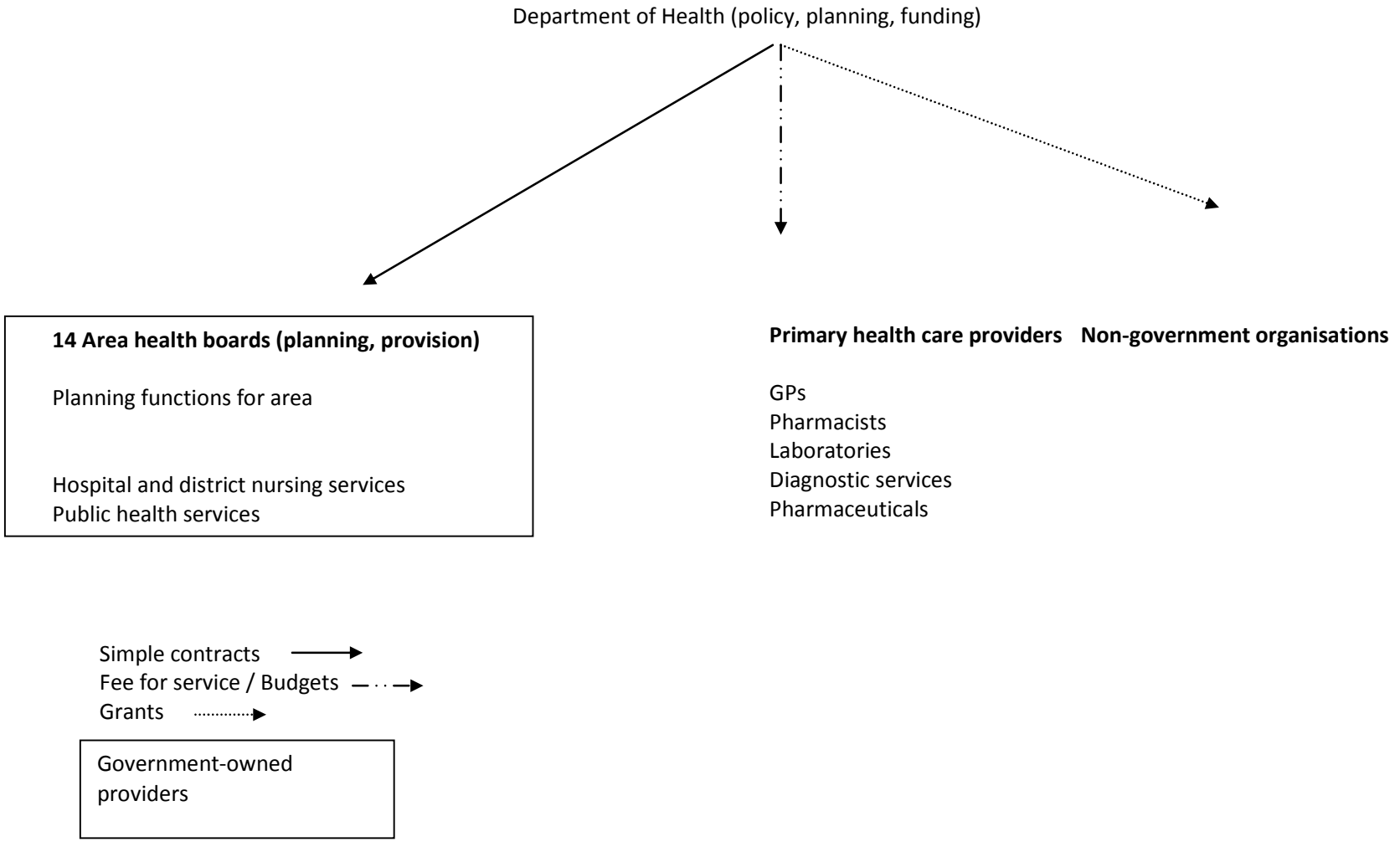
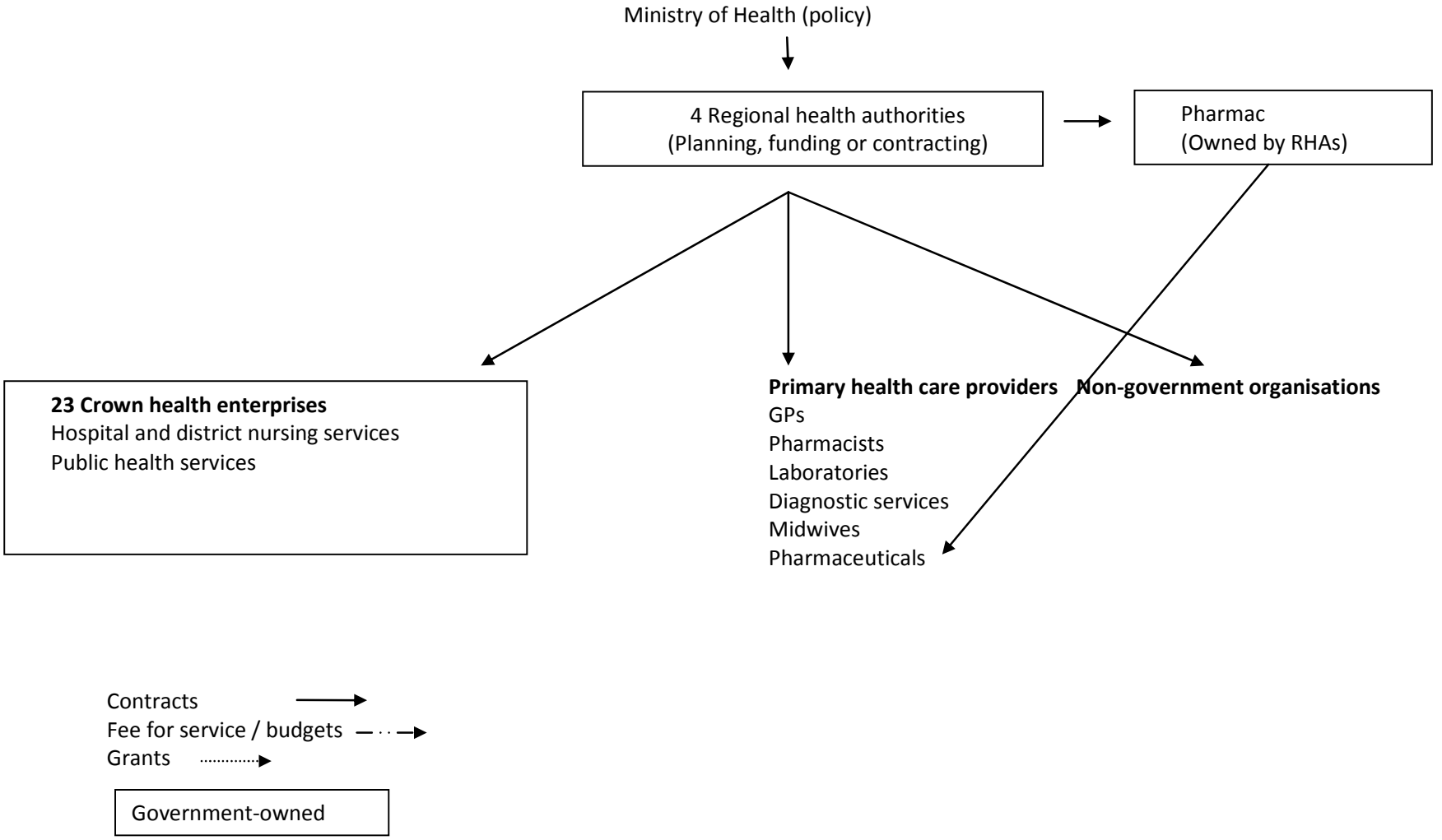


Figure 5 Publicly owned hospital arrangements 1980s–2001, presenting key organisations and their relationships to each other

Area health boards 1980s



Purchaser-provider split 1990s



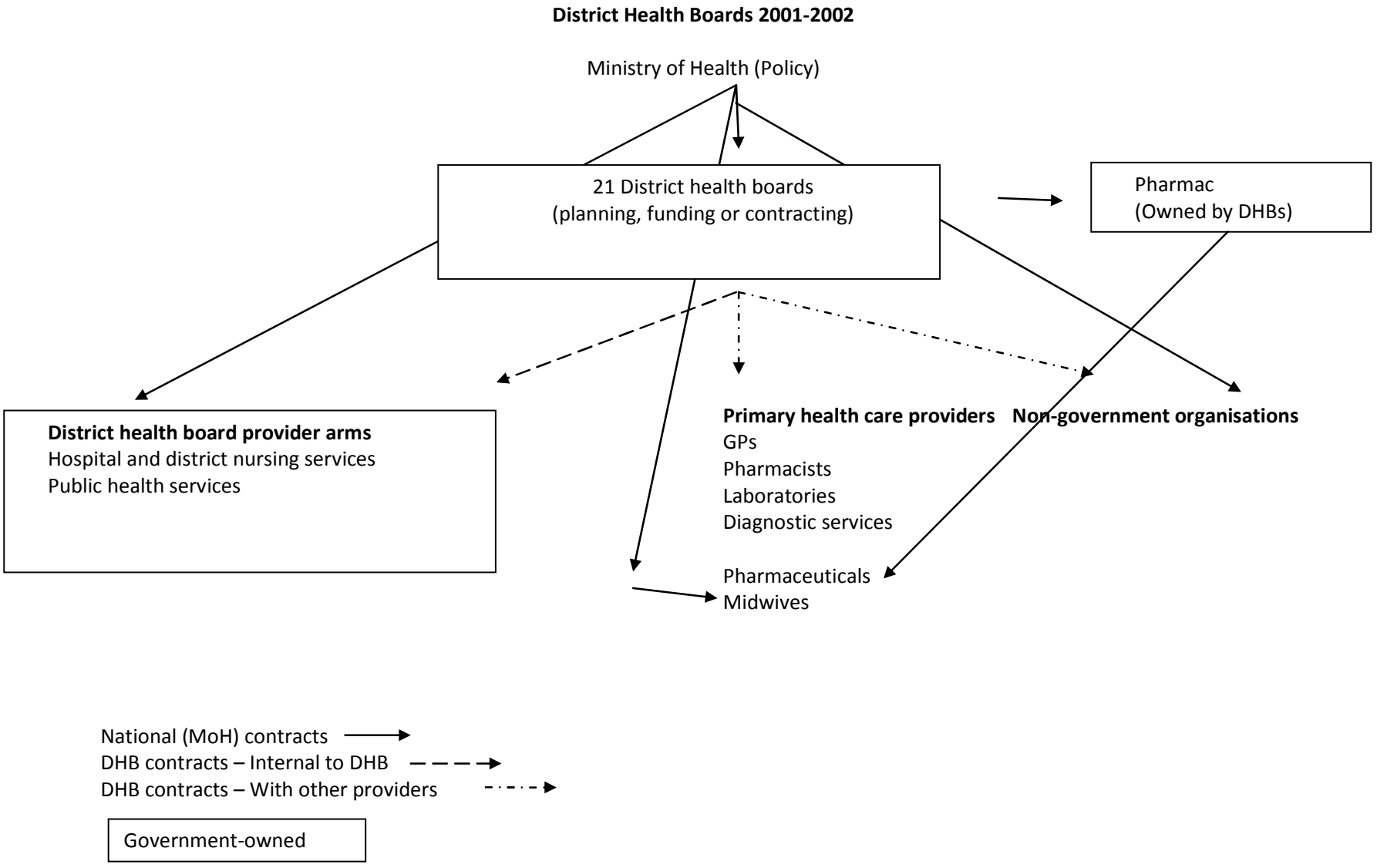


Figure 6 Models of health sector organisation in New Zealand, 1980s–2002

New Zealand conclusion

Although it is widely acknowledged in the literature that the 1990s purchaser-provider reforms failed to meet their objectives with respect to hospital services, there are diverging views on whether this was due to the reforms not being implemented fully or appropriately, or whether the model itself was unsuitable for New Zealand.

1. In conversations about the reforms, some experts argue that once the single national HFA was established, relational contracting developed, and a less legalistic approach was adopted with regard to contracting. The purchaser-provider reforms had the potential to deliver gains in the longer term – in particular, by putting pressure on CHEs to perform (even if they held monopoly positions) and by enabling RHAs to allocate increasing resources to primary health care settings, thus potentially generating improved overall value for money. However, by the time the HFA was fully established and was up and running (in January 1998, i.e., six and a half years after the announcement of the reforms), the financial and political costs of the reforms had been significant, and the gains had been insufficient for the public and the health services.

2. An alternative view is that that the model was totally unsuitable for New Zealand. Here, the arguments are that political factors are impossible to remove from decision-making in a system where the largest proportion of spending comes from the government, and where New Zealanders hold government ministers to account for the performance of the health system. This means that a single national purchaser is never truly independent; transaction costs remain high with any contracting system; there is only ever likely to be very limited competition between publicly owned and privately owned hospitals, given the dispersed nature and small size of the New Zealand population. In addition, the separation of purchasing and provision creates too much uncertainty for hospital providers in terms of longer-term planning, and too little flexibility to respond to short-term issues.

3. Some experts continue to argue for a return to a purchaser-provider split model, suggesting a re-establishment of a HFA in New Zealand. The main reasons for this seem to be to enable a purchasing authority to use a formal contracting process to make efficiency gains within hospitals, and also to allocate resources to primary health care providers, with an increased focus on wellness rather than sickness. As yet, however, there does not seem to be any real appetite for reform, given the potentially high financial costs and the likelihood that significant reform would divert attention and focus on reform issues for a period of at least several years – as opposed to focusing attention on the key issues currently facing the health sector.

Appendix 1: The authorisation contract

The authorisation contract is the summary document which details the financial, legal and clinical standards to be complied with in the effective regulation and management of foundation trusts. It conforms to the requirements of a number of Acts. The principle Act is the Health and Social Care (Community Health and Standards) Act 2003; however the National Health Service Act, 1977 and the Interpretation Act 1978 also underpin the document contents. This document contains details all the known supports and obstacles to achieving the effective provision of acute health care in an independent hospital trust.

Main features of the authorisation contract

Section One	
1 Authorisation	Recognises the, non-assignable, right of the foundation trust to exist as a legal entity, Records the date of enforcement and Monitor's rights to contractual variations
2 Interpretation and Construction	States the legal statutes under which words and expressions in the document are to be understood or interpreted are detailed.
3 Conditions	Outlines: • the purpose, duties, constitutional restrictions, issues of compliance and enforcement and governance responsibilities • health care standards, mandatory services and authorised services to be delivered • matters of property protection, limits and caps to private health care and borrowing are demarcated • issues of finance, e.g. viability and dividend payment on public dividend capital • transparency and accountability requirements • fees and representative membership of the foundation trust and the various boards • obligations regarding co-operation with other bodies, planning and IT development • the foundation trust's audit committee and auditing practices, public interest reporting, notification to Monitor and information for Parliament and Members of Parliament

Appendix 2: NHS provider licence standard conditions

The contents of the NHS licence are:

Section 1 – General Conditions
G1: Provision of information
G2: Publication of information
G3: Payment of fees to Monitor
G4: Fit and proper persons
G5: Monitor guidance
G6: Systems for compliance with licence conditions and related obligations
G7: Registration with the Care Quality Commission
G8: Patient eligibility and selection criteria
G9: Application of Section 5 (Continuity of Services)

Section 2 – Pricing
P1: Recording of information
P2: Provision of information
P3: Assurance report on submissions to Monitor
P4: Compliance with the National Tariff
P5: Constructive engagement concerning local tariff modifications

Section 3 – Choice and competition
C1: The right of patients to make choices
C2: Competition oversight

Section 4 – Integrated care
IC1: Provision of integrated care

Section 5 – Continuity of Services
CoS1: Continuing provision of Commissioner Requested Services
CoS2: Restriction on the disposal of assets
CoS3: Standards of corporate governance and financial management
CoS4: Undertaking from the ultimate controller
CoS5: Risk pool levy
CoS6: Cooperation in the event of financial stress
CoS7: Availability of resources

Section 6 – NHS foundation trust conditions
FT1: Information to update the register of NHS foundation trusts
FT2: Payment to Monitor in respect of registration and related costs
FT3: Provision of information to advisory panel
FT4: NHS foundation trust governance arrangements

Section 7 – Interpretation and Definitions
D1: Interpretation and Definitions Section 1 – General Conditions

Section 1 – General Conditions

Condition G1 – Provision of information

1. Subject to paragraph 3, and in addition to obligations under other Conditions of this Licence, the Licencee shall furnish to Monitor such information and documents, and shall prepare or procure and furnish to Monitor such reports, as Monitor may require for any of the purposes set out in section 96(2) of the 2012 Act.
2. Information, documents and reports required to be furnished under this Condition shall be furnished in such manner, in such form, at such place and at such times as Monitor may require.
3. In furnishing information documents and reports pursuant to paragraphs 1 and 2 the Licencee shall take all reasonable steps to ensure that:
(a) in the case of information or a report, it is accurate, complete and not misleading;
(b) in the case of a document, it is a true copy of the document requested; and
4. This Condition shall not require the Licencee to furnish any information, documents or reports which it could not be compelled to produce or give in evidence in civil proceedings before a court because of legal professional privilege.

Condition G2 – Publication of information

1. The Licencee shall comply with any direction from Monitor for any of the purposes set out in section 96(2) of the 2012 Act to publish information about health care services provided for the purposes of the NHS and as to the manner in which such information should be published.
2. For the purposes of this condition "publish" includes making available to the public, to any section of the public or to individuals.

Condition G3 – Payment of fees to Monitor

1. The Licencee shall pay fees to Monitor in each financial year of such amount as Monitor may determine for each such year or part thereof in respect of the exercise by Monitor of its functions for the purposes set out in section 96(2) of the 2012 Act.
2. The Licencee shall pay the fees required to be paid by a determination by Monitor for the purpose of paragraph 1 no later than the 28th day after they become payable in accordance with that determination.

Condition G4 – Fit and proper persons as Governors and Directors (also applicable to those performing equivalent or similar functions)

1. The Licencee shall ensure that no person who is an unfit person may become or continue as a Governor, except with the approval in writing of Monitor.
2. The Licencee shall not appoint as a Director any person who is an unfit person, except with the approval in writing of Monitor.
3. The Licencee shall ensure that its contracts of service with its Directors contain a provision permitting summary termination in the event of a Director being or becoming an unfit person. The Licencee shall ensure that it enforces that provision promptly upon discovering any Director to be an unfit person, except with the approval in writing of Monitor.
4. If Monitor has given approval in relation to any person in accordance with paragraph 1, 2, or 3 of this condition the Licencee shall notify Monitor promptly in writing of any material change in the role required of or performed by that person.
5. In this Condition an unfit person is:
(a) an individual;
(i) who has been adjudged bankrupt or whose estate has been sequestrated and (in either case) has not been discharged; or
(ii) who has made a composition or arrangement with, or granted a trust deed for, his creditors and has not been discharged in respect of it; or

(iii) who within the preceding five years has been convicted in the British Islands of any offence and a sentence of imprisonment (whether suspended or not) for a period of not less than three months (without the option of a fine) was imposed on him; or
(iv) who is subject to an unexpired disqualification order made under the Company Directors' Disqualification Act 1986; or
(b) a body corporate, or a body corporate with a parent body corporate: Section 1 – General Conditions
(i) where one or more of the Directors of the body corporate or of its parent body corporate is an unfit person under the provisions of sub-paragraph (a) of this paragraph, or
(ii) in relation to which a voluntary arrangement is proposed under section 1 of the Insolvency Act 1986, or
(iii) which has a receiver (including an administrative receiver within the meaning of section 29(2) of the 1986 Act) appointed for the whole or any material part of its assets or undertaking, or
(iv) which has an administrator appointed to manage its affairs, business and property in accordance with Schedule B1 to the 1986 Act, or
(v) which passes any resolution for winding up, or
(vi) which becomes subject to an order of a Court for winding up. Section 1 – General Conditions

Condition G5 – Monitor guidance

1 Without prejudice to any obligations in other Conditions of this Licence, the Licencee shall at all times have regard to guidance issued by Monitor for any of the purposes set out in section 96(2) of the 2012 Act.
2 In any case where the Licencee decides not to follow the guidance referred to in paragraph 1 or guidance issued under any other Conditions of this licence, it shall inform Monitor of the reasons for that decision.

Condition G6 – Systems for compliance with licence conditions and related obligations

1. The Licencee shall take all reasonable precautions against the risk of failure to comply with:
(a) the Conditions of this Licence,
(b) any requirements imposed on it under the NHS Acts, and
(c) the requirement to have regard to the NHS Constitution in providing health care services for the purposes of the NHS.
2. Without prejudice to the generality of paragraph 1, the steps that the Licencee must take pursuant to that paragraph shall include:
(a) the establishment and implementation of processes and systems to identify risks and guard against their occurrence; and
(b) regular review of whether those processes and systems have been implemented and of their effectiveness.
3. Not later than two months from the end of each Financial Year, the Licencee shall prepare and submit to Monitor a certificate to the effect that, following a review for the purpose of paragraph 2(b) the Directors of the Licencee are or are not satisfied, as the case may be that, in the Financial Year most recently ended, the Licencee took all such precautions as were necessary in order to comply with this Condition.
4. The Licencee shall publish each certificate submitted for the purpose of this Condition within one month of its submission to Monitor in such manner as is likely to bring it to the attention of such persons who reasonably can be expected to have an interest in it.

Condition G7 – Registration with the Care Quality Commission

1. The Licencee shall at all times be registered with the Care Quality Commission in so far as is necessary in order to be able lawfully to provide the services authorised to be provided by this Licence.
2. The Licencee shall notify Monitor promptly of:
(a) any application it may make to the Care Quality Commission for the cancellation of its registration by that Commission, or
(b) the cancellation by the Care Quality Commission for any reason of its registration by that Commission.
3. A notification given by the Licencee for the purposes of paragraph 2 shall:
(a) be made within 7 days of:
(i) the making of an application in the case of paragraph (a), or
(ii) becoming aware of the cancellation in the case of paragraph (b), and
(b) contain an explanation of the reasons (in so far as they are known to the Licencee) for:
(i) the making of an application in the case of paragraph (a), or
(ii) the cancellation in the case of paragraph (b). Section 1 – General Conditions

Condition G8 – Patient eligibility and selection criteria

1. The Licencee shall:
(a) set transparent eligibility and selection criteria,
(b) apply those criteria in a transparent way to persons who, having a choice of persons from whom to receive health care services for the purposes of the NHS, choose to receive them from the Licencee, and
(c) publish those criteria in such a manner as will make them readily accessible by any persons who could reasonably be regarded as likely to have an interest in them.
2. "Eligibility and selection criteria" means criteria for determining:
(a) whether a person is eligible, or is to be selected, to receive health care services provided by the Licencee for the purposes of the NHS, and
(b) if the person is selected, the manner in which the services are provided to the person.

Condition G9 – Application of Section 5 (Continuity of Services)

1. The Conditions in Section 5 shall apply:
(a) whenever the Licencee is subject to a contractual or other legally enforceable obligation to provide a service which is a Commissioner Requested Service, and
(b) from the commencement of this Licence until the Licencee becomes subject to an obligation of the type described in sub-paragraph (a), if the Licencee is an NHS foundation trust which:
(i) was not subject to such an obligation on commencement of this Licence, and
(ii) was required to provide services, or was party to an NHS contract to provide services, as described in paragraph 2(a) or 2(b);
for the avoidance of doubt, where Section 5 applies by virtue of this subparagraph, the words "Commissioner Requested Service" shall be read to include any service of a description falling within paragraph 2(a) or 2(b).
2. A service is a Commissioner Requested Service if, and to the extent that, it is:
(a) any service of a description which the Licencee, being an NHS foundation trust with an authorisation date on or before 31 March 2013, was required to provide in accordance with condition 7(1) and Schedule 2 in the terms of its authorisation by Monitor immediately prior to the commencement of this Licence, or
(b) any service of a description which the Licencee, being an NHS foundation trust with an authorisation date on or after 1 April 2013, was required to provide pursuant to an NHS contract immediately before its authorisation date, or

(c) any other service which the Licencee has contracted with a Commissioner to provide as a Commissioner Requested Service.
3. A service is also a Commissioner Requested Service if, and to the extent that, not being a service within paragraph 2:
(a) it is a service which the Licencee may be required to provide to a Commissioner under the terms of a contract which has been entered into between them, and
(b) the Commissioner has made a written request to the Licencee to provide that service as a Commissioner Requested Service, and either
(c) the Licencee has failed to respond in writing to that request by the expiry of the 28th day after it was made to the Licencee by the Commissioner, or
(d) the Commissioner, not earlier than the expiry of the [28th] day after making that request to the Licencee, has given to Monitor and to the Licencee a notice in accordance with paragraph 4, and Monitor, after giving the Licencee the opportunity to make representations, has issued a direction in writing in accordance with paragraph 5.
4. A notice in accordance with this paragraph is a notice:
(a) in writing,
(b) stating that the Licencee has refused to agree to a request to provide a service as a Commissioner Requested Service, and
(c) setting out the Commissioner's reasons for concluding that the Licencee is acting unreasonably in refusing to agree to that request to provide a service as a Commissioner Requested Service
5. A direction in accordance with this paragraph is a direction that the Licencee's refusal to provide a service as a Commissioner Requested Service in response to a request made under paragraph 3(b) is unreasonable.
6. The Licencee shall give Monitor not less than [28] days' notice of the expiry of any contractual obligation pursuant to which it is required to provide a Commissioner Requested Service to a Commissioner for which no extension or renewal has been agreed.
7. If any contractual obligation of a Licencee to provide a Commissioner Requested Service expires without extension or renewal having been agreed between the Licencee and the Commissioner who is a party to the contract, the Licencee shall continue to provide that service on the terms of the contract (save as agreed with that Commissioner), and the service shall continue to be a Commissioner Requested
Service, for the period from the expiry of the contractual obligation until Monitor issues either:
(a) a direction of the sort referred to in paragraph 8, or
(b) a notice in writing to the Licencee stating that it has decided not to issue such a direction.
8. If, during the period of a contractual or other legally enforceable obligation to provide a Commissioner Requested Service, Monitor issues to the Licencee a direction in writing to continue providing that service for a period specified in the direction, then for that period the service shall continue to be a Commissioner Requested Service.
9. No service which the Licencee is subject to a contractual or other legally enforceable obligation to provide shall be regarded as a Commissioner Requested Service and, as a consequence, no Condition in Section 5 shall be of any application, during any period for which there is in force a direction in writing by Monitor given for the purposes of this condition and of any equivalent condition in any other current licence issued under the 2012 Act stating that no health care service provided for the purposes of the NHS is to be regarded as a Commissioner Requested Service.
10. A service shall cease to be a Commissioner Requested Service if:
(a) all current Commissioners of that service as a Commissioner Requested Service agree in writing that there is no longer any need for the service to be a Commissioner Requested Service, and Monitor has issued a determination in writing that the service is no longer a Commissioner Requested Service, or
(b) Monitor has issued a determination in writing that the service is no longer a Commissioner Requested Service; or

(c) it is a Commissioner Requested Service by virtue only of paragraph 2(a) above and 3 years have elapsed since the commencement of this Licence; or
(d) it is a Commissioner Requested Service by virtue only of paragraph 2(b) above and either 3 years have elapsed since 1 April 2013 or 1 year has elapsed since the commencement of this Licence, whichever is the later; or
(e) the contractual obligation pursuant to which the service is provided has expired and Monitor has issued a notice pursuant to paragraph 7(b) in relation to the service;
(f) the period specified in a direction by Monitor of the sort referred to in paragraph 8 in relation to the service has expired.
11. The Licencee shall make available free of charge to any person who requests it a statement in writing setting out the description and quantity of services which it is under a contractual or other legally enforceable obligation to provide as Commissioner Requested Services.
12. Within [28] days of every occasion on which there is a change in the description or quantity of the services which the Licencee is under a contractual or other legally enforceable obligation to provide as Commissioner Requested Services, the Licencee shall provide to Monitor in writing a notice setting out the description and quantity of all the services it is obliged to provide as Commissioner Requested Services.
13. Unless it is proposes to cease providing the service, the Licencee shall not make any application to Monitor for a determination in accordance with paragraph 10(b):
(a) in the case of a service which is a Commissioner Requested Service by virtue only of paragraph 2(a) above, in the period of 3 years since the commencement of this Licence or
(b) in the case of a service which is a Commissioner Requested Service by virtue only of paragraph 2(b), in the period until the later of 1 April 2016 or 1 year from the commencement of this Licence.
14. In this Condition "NHS contract" has the meaning given to that term in Section 9 of the 2006 Act.

Section 2 – Pricing

Condition P1 – Recording of information
1. If required in writing by Monitor, and only in relation to periods from the date of that requirement, the Licencee shall:
(a) obtain, record and maintain sufficient information about the costs which it expends in the course of providing services for the purposes of the NHS and other relevant information, and
(b) establish, maintain and apply such systems and methods for the obtaining, recording and maintaining of such information about those costs and other relevant information,
as are necessary to enable it to comply with the following paragraphs of this Condition.
2. From the time of publication by Monitor of Approved Reporting Currencies the Licencee shall maintain records of its costs and of other relevant information broken down in accordance with those Currencies by allocating to a record for each such Currency all costs expended by the Licencee in providing health care services for the purposes of the NHS within that Currency and by similarly treating other relevant information.
3. In the allocation of costs and other relevant information to Approved Reporting Currencies in accordance with paragraph 2 the Licencee shall use the cost allocation methodology and procedures relating to other relevant information set out in the Approved Guidance.
4. If the Licencee uses sub-contractors in the provision of health care services for the purposes of the NHS, to the extent that it is required to do so in writing by Monitor the Licencee shall procure that each of those sub-contractors:
(a) obtains, records and maintains information about the costs which it expends in the course of providing services as sub-contractor to the Licencee, and establishes, maintains and applies systems and methods for the obtaining, recording and maintaining of that information, in a manner that complies with paragraphs 2 and 3 of this Condition, and

(b) provides that information to Monitor in a timely manner.
5. Records required to be maintained by this Condition shall be kept for not less than six years.

6. In this Condition: "the Approved Guidance"	means such guidance on the obtaining, recording and maintaining of information about costs and on the breaking down and allocation of costs by reference to Approved Reporting Currencies as may be published by Monitor;
"Approved Reporting Currencies"	means such categories of cost and other relevant information as may be published by Monitor;
"other relevant information"	means such information, which may include quality and outcomes data, as may be required by Monitor for the purpose of its functions under Chapter 4 (Pricing) in Part 3 of the 2012 Act.

Condition P2 – Provision of information

1. Subject to paragraph 3, and without prejudice to the generality of Condition G1, the Licencee shall furnish to Monitor such information and documents, and shall prepare or procure and furnish to Monitor such reports, as Monitor may require for the purpose of performing its functions under Chapter 4 in Part 3 of the 2012 Act.
2. Information, documents and reports required to be furnished under this Condition shall be furnished in such manner, in such form, at such place and at such times as Monitor may require.
3. In furnishing information documents and reports pursuant to paragraphs 1 and 2 the Licencee shall take all reasonable steps to ensure that:
(a) in the case of information or a report, it is accurate, complete and not misleading;
(b) in the case of a document, it is a true copy of the document requested; and
4. This Condition shall not require the Licencee to furnish any information, documents or reports which it could not be compelled to produce or give in evidence in civil proceedings before a court because of legal professional privilege.

Condition P3 – Assurance report on submissions to Monitor

1. If required in writing by Monitor the Licencee shall, as soon as reasonably practicable, obtain and submit to Monitor an assurance report in relation to a submission of the sort described in paragraph 2 which complies with the requirements of paragraph 3.
2. The descriptions of submissions in relation to which a report may be required under paragraph 1 are:
(a) submissions of information furnished to Monitor pursuant to Condition P2, and
(b) submissions of information to third parties designated by Monitor as persons from or through whom cost information may be obtained for the purposes of setting or verifying the National Tariff or of developing non-tariff pricing guidance.
3. An assurance report shall meet the requirements of this paragraph if all of the following conditions are met:
(a) it is prepared by a person approved in writing by Monitor or qualified to act as auditor of an NHS foundation trust in accordance with paragraph 23(4) in Schedule 7 to the 2006 Act;
(b) it expresses a view on whether the submission to which it relates:
(i) is based on cost records which have been maintained in a manner which complies with paragraph 2 in Condition P1;
(ii) is based on costs which have been analysed in a manner which complies with paragraph 3 in Condition P1, and

(iii) provides a true and fair assessment of the information it contains.

Condition P4 – Compliance with the National Tariff

1. Except as approved in writing by Monitor, the Licencee shall only provide health care services for the purpose of the NHS at prices which comply with, or are determined in accordance with, the national tariff published by Monitor, in accordance with section 116 of the 2012 Act.
2. Without prejudice to the generality of paragraph 1, except as approved in writing by Monitor, the Licencee shall comply with the rules, and apply the methods, concerning charging for the provision of health care services for the purposes of the NHS contained in the national tariff published by Monitor in accordance with, section 116 of the 2012 Act, wherever applicable.

Condition P5 – Constructive engagement concerning local tariff modifications

1. The Licencee shall engage constructively with Commissioners, with a view to reaching agreement as provided in section 124 of the 2012 Act, in any case in which it is of the view that the price payable for the provision of a service for the purposes of the NHS in certain circumstances or areas should be the price determined in accordance with the national tariff for that service subject to modifications.

Section 3 – Choice and Competition

Condition C1- The right of patients to make choices

1. Subsequent to a person becoming a patient of the Licencee and for as long as he or she remains such a patient, the Licencee shall ensure that at every point where that person has a choice of provider under the NHS Constitution or a choice of provider conferred locally by Commissioners, he or she is notified of that choice and told where information about that choice can be found.
2. Information and advice about patient choice of provider made available by the Licencee shall not be misleading.
3. Without prejudice to paragraph 2, information and advice about patient choice of provider made available by the Licencee shall not unfairly favour one provider over another and shall be presented in a manner that, as far as reasonably practicable, assists patients in making well informed choices between providers of treatments or other health care services.
4. In the conduct of any activities, and in the provision of any material, for the purpose of promoting itself as a provider of health care services for the purposes of the NHS the Licencee shall not offer or give gifts, benefits in kind, or pecuniary or other advantages to clinicians, other health professionals, Commissioners or their administrative or other staff as inducements to refer patients or commission services.

Condition C2 – Competition oversight

1. The Licencee shall not:
(a) enter into or maintain any agreement or other arrangement which has the object or which has (or would be likely to have) the effect of preventing, restricting or distorting competition in the provision of health care services for the purposes of the NHS, or
(b) engage in any other conduct which has (or would be likely to have) the effect of preventing, restricting or distorting competition in the provision of health care services for the purposes of the NHS,
to the extent that it is against the interests of people who use health care services.

Section 4 – Integrated care

Condition IC1 – Provision of integrated care

1. The Licencee shall not do anything that reasonably would be regarded as against the interests of people who use health care services by being detrimental to enabling its provision of health care services for the purposes of

the NHS to be integrated with the provision of such services by others with a view to achieving one or more of the objectives referred to in paragraph 4.
2. The Licencee shall not do anything that reasonably would be regarded as against the interests of people who use health care services by being detrimental to enabling its provision of health care services for the purposes of the NHS to be integrated with the provision of health-related services or social care services by others with a view to achieving one or more of the objectives referred to in paragraph 4.
3. The Licencee shall not do anything that reasonably would be regarded as against the interests of people who use health care services by being detrimental to enabling it to co-operate with other providers of health care services for the purposes of the NHS with a view to achieving one or more of the objectives referred to in paragraph 4.
4. The objectives referred to in paragraphs 1, 2 and 3 are:
(a) improving the quality of health care services provided for the purposes of the NHS (including the outcomes that are achieved from their provision) or the efficiency of their provision,
(b) reducing inequalities between persons with respect to their ability to access those services, and
(c) reducing inequalities between persons with respect to the outcomes achieved for them by the provision of those services.
5. The Licencee shall have regard to such guidance as may have been issued by Monitor from time to time concerning actions or behaviours that might reasonably be regarded as against the interests of people who use health care services for the purposes of paragraphs 1, 2 or 3 of this Condition.

Section 5 – Continuity of Services

Condition CoS1 – Continuing provision of Commissioner Requested Services
1. The Licencee shall not cease to provide, or materially alter the specification or means of provision of, any Commissioner Requested Service otherwise than in accordance with the following paragraphs of this Condition.
2. If, during the period of a contractual or other legally enforceable obligation to provide a Commissioner Requested Service, or during any period when this condition applies by virtue of Condition G9(1)(b), Monitor issues to the Licencee a direction in writing to continue providing that service for a period specified in the direction, then the Licencee shall provide the service for that period in accordance with the direction.
3. The Licencee shall not materially alter the specification or means of provision of any Commissioner Requested Service except:
(a) with the agreement in writing of all Commissioners to which the Licencee is required by a contractual or other legally enforceable obligation to provide the service as a Commissioner Requested Service; or
(b) at any time when this condition applies by virtue of Condition G9(1)(b), with the agreement in writing of all Commissioners to which the Licencee provides, or may be requested to provide, the service as a Commissioner Requested Service; or
(c) if required to do so by, or in accordance with the terms of its authorisation by, anybody having responsibility pursuant to statute for regulating one or more aspects of the provision of health care services in England and which has been designated by Monitor for the purposes of this condition and of equivalent conditions in other licences granted under the 2012 Act.
4. If the specification or means of provision of a Commissioner Requested Service is altered as provided in paragraph 3 the Licencee, within [28] days of the alteration, shall give to Monitor notice in writing of the occurrence of the alteration with a summary of its nature.
5. For the purposes of this Condition an alteration to the specification or means of provision of any Commissioner Requested Service is material if it involves the delivery

Condition CoS2 – Restriction on the disposal of assets
1. The Licencee shall establish, maintain and keep up to date, an asset register which complies with paragraphs 2 and 3 of this Condition ("the Asset Register")

2. The Asset Register shall list every relevant asset used by the Licencee for the provision of Commissioner Requested Services.
3. The Asset Register shall be established, maintained and kept up to date in a manner that reasonably would be regarded as both adequate and professional.
4. The obligations in paragraphs 5 to 8 shall apply to the Licencee if Monitor has given notice in writing to the Licencee that it is concerned about the ability of the Licencee to carry on as a going concern.
5. The Licencee shall not dispose of, or relinquish control over, any relevant asset except:
(a) with the consent in writing of Monitor, and
(b) in accordance with the paragraphs 6 to 8 of this Condition.
6. The Licencee shall furnish Monitor with such information as Monitor may request relating to any proposal by the Licencee to dispose of, or relinquish control over, any relevant asset.
7. Where consent by Monitor for the purpose of paragraph 5(a) is subject to conditions, the Licencee shall comply with those conditions.
8. Paragraph 5(a) of this Condition shall not prevent the Licencee from disposing of, or relinquishing control over, any relevant asset where:
(a) Monitor has issued a general consent for the purposes of this Condition (whether or not subject to conditions) in relation to:
(i) transactions of a specified description; or
(ii) the disposal of or relinquishment of control over relevant assets of a specified description, and
the transaction or the relevant assets are of a description to which the consent applies and the disposal, or relinquishment of control, is in accordance with any conditions to which the consent is subject; or
(b) the Licencee is required by the Care Quality Commission to dispose of a relevant asset.
9. In this Condition:
"disposal"
means any of the following:
(a) a transfer, whether legal or equitable, of the whole or any part of an asset (whether or not for value) to a person other than the Licencee; or
(b) a grant, whether legal or equitable, of a lease, licence, or loan of (or the grant of any other right of possession in relation to) that asset; or
(c) the grant, whether legal or equitable, of any mortgage, charge, or other form of security over that asset; or
(d) if the asset is an interest in land, any transaction or event that is capable under any enactment or rule of law of affecting the title to a registered interest in that land, on the assumption that the title is registered,
and references to "dispose" are to be read accordingly;
"relevant asset"
means any item of property, including buildings, interests in land, equipment (including rights, licences and consents relating to its use), without which the Licencee's ability to meet its obligations to provide Commissioner Requested Services would reasonably be regarded as materially prejudiced;
"relinquishment of control"
includes entering into any agreement or arrangement under which control of the asset is not, or ceases to be, under the sole management of the Licencee, and "relinquish" and related expressions are to be read accordingly.
10. The Licencee shall have regard to such guidance as may be issued from time to time by Monitor regarding:
(a) the manner in which asset registers should be established, maintained and updated, and
(b) property, including buildings, interests in land, intellectual property rights and equipment, without which a licence holder's ability to provide Commissioner Requested Services should be regarded as materially prejudiced.

Condition CoS3 – Standards of corporate governance and financial management

1. The Licencee shall at all times adopt and apply systems and standards of corporate governance and of financial management which reasonably would be regarded as:
(a) suitable for a provider of the Commissioner Requested Services provided by the Licencee, and
(b) providing reasonable safeguards against the risk of the Licencee being unable to carry on as a going concern.
2. In its determination of the systems and standards to adopt for the purpose of paragraph 1, and in the application of those systems and standards, the Licencee shall have regard to:
(a) such guidance as Monitor may issue from time to time concerning systems and standards of corporate governance and financial management;
(b) the Licencee's rating using the risk rating methodology published by Monitor from time to time, and
(c) the desirability of that rating being not less than the level regarded by Monitor as acceptable under the provisions of that methodology.

Condition CoS4 – Undertaking from the ultimate controller

1. The Licencee shall procure from each company or other person which the Licencee knows or reasonably ought to know is at any time its ultimate controller, a legally enforceable undertaking in favour of the Licencee, in the form specified by Monitor, that the ultimate controller ("the Covenantor"):
(a) will refrain for any action, and will procure that any person which is a subsidiary of, or which is controlled by, the Covenantor (other than the Licencee and its subsidiaries) will refrain from any action, which would be likely to cause the Licencee to be in contravention of any of its obligations under the 2012 Act or this Licence, and
(b) will give to the Licencee, and will procure that any person which is a subsidiary of, or which is controlled by, the Covenantor (other than the Licencee and its subsidiaries) will give to the Licencee, all such information in its possession or control as may be necessary to enable the Licencee to comply fully with its obligations under this Licence to provide information to Monitor.
2. The Licencee shall obtain any undertaking required to be procured for the purpose of paragraph 1 within 7 days of a company or other person becoming an ultimate controller of the Licencee and shall ensure that any such undertaking remains in force for as long as the Covenantor remains the ultimate controller of the Licencee.
3. The Licencee shall:
(a) deliver to Monitor a copy of each such undertaking within seven days of obtaining it;
(b) inform Monitor immediately in writing if any Director, secretary or other officer of the Licencee becomes aware that any such undertaking has ceased to be legally enforceable or that its terms have been breached, and
(c) comply with any request which may be made by Monitor to enforce any such undertaking.
4. For the purpose of this Condition, subject to paragraph 5, a person (whether an individual or a body corporate) is an ultimate controller of the Licencee if:
(a) directly, or indirectly, the Licencee can be required to act in accordance with the instructions of that person acting alone or in concert with others, and
(b) that person cannot be required to act in accordance with the instructions of another person acting alone or in concert with others.
5. A person is not an ultimate controller if they are:
(a) a health service body, within the meaning of section 9 of the 2006 Act;
(b) a Governor or Director of the Licencee and the Licencee is an NHS foundation trust;
(c) any Director of the Licencee who does not, alone or in association with others, have a controlling interest in the ownership of the Licencee and the Licencee is a body corporate; or
(d) a trustee of the Licencee and the Licencee is a charity

Condition CoS5 – Risk pool levy

1. The Licencee shall pay to Monitor any sums required to be paid in consequence of any requirement imposed on providers under section 135(2) of the 2012 Act, including sums payable by way of levy imposed under section 139(1) and any interest payable under section 143(10), by the dates by which they are required to be paid.
2. In the event that no date has been clearly determined by which a sum referred to in paragraph 1 is required to be paid, that sum shall be paid within 28 days of being demanded in writing by Monitor.

Condition CoS6 – Co-operation in the event of financial stress

1. The obligations in paragraph 2 shall apply if Monitor has given notice in writing to the Licencee that it is concerned about the ability of the Licencee to carry on as a going concern.
2. When this paragraph applies the Licencee shall:
(a) provide such information as Monitor may direct to Commissioners and to such other persons as Monitor may direct;
(b) allow such persons as Monitor may appoint to enter premises owned or controlled by the Licencee and to inspect the premises and anything on them, and
(c) co-operate with such persons as Monitor may appoint to assist in the management of the Licencee's affairs, business and property.

Condition CoS7 – Availability of resources

1. The Licencee shall at all times act in a manner calculated to secure that it has, or has access to, the Required Resources.
2. The Licencee shall not enter into any agreement or undertake any activity which creates a material risk that the Required Resources will not be available to the Licencee.
3. The Licencee, not later than two months from the end of each Financial Year, shall submit to Monitor a certificate as to the availability of the Required Resources for the period of 12 months commencing on the date of the certificate, in one of the following forms:
(a) "After making enquiries the Directors of the Licencee have a reasonable expectation that the Licencee will have the Required Resources available to it after taking account distributions which might reasonably be expected to be declared or paid for the period of 12 months referred to in this certificate."
(b) "After making enquiries the Directors of the Licencee have a reasonable expectation, subject to what is explained below, that the Licencee will have the Required Resources available to it after taking into account in particular (but without limitation) any distribution which might reasonably be expected to be declared or paid for the period of 12 months referred to in this certificate. However, they would like to draw attention to the following factors which may cast doubt on the ability of the Licencee to provide Commissioner Requested Services".
(c) "In the opinion of the Directors of the Licencee, the Licencee will not have the Required Resources available to it for the period of 12 months referred to in this certificate".
4. The Licencee shall submit to Monitor with that certificate a statement of the main factors which the Directors of the Licencee have taken into account in issuing that certificate.
5. The statement submitted to Monitor in accordance with paragraph 4 shall be approved by a resolution of the board of Directors of the Licencee and signed by a Director of the Licencee pursuant to that resolution.
6. The Licencee shall inform Monitor immediately if the Directors of the Licencee become aware of any circumstance that causes them to no longer have the reasonable expectation referred to in the most recent certificate given under paragraph 3.
7. The Licencee shall publish each certificate provided for in paragraph 3 in such a manner as will enable any person having an interest in it to have ready access to it.
8. In this Condition: "distribution" includes the payment of dividends or similar payments on share capital and the

	payment of interest or similar payments on public dividend capital and the repayment of capital;
"Financial Year"	means the period of twelve months over which the Licencee normally prepares its accounts;
"Required Resources"	means such: (a) management resources, (b) financial resources and financial facilities, (c) personnel, (d) physical and other assets including rights, licences and consents relating to their use, and (e) working capital as reasonably would be regarded as sufficient to enable the Licencee at all times to provide the Commissioner Requested Services.

Section 6 – NHS Foundation Trust Conditions

Condition FT1 – Information to update the register of NHS foundation trusts

1. The obligations in the following paragraphs of this Condition apply if the Licencee is an NHS foundation trust, without prejudice to the generality of the other conditions in this Licence.
2. The Licencee shall ensure that Monitor has available to it written and electronic copies of the following documents:
(a) the current version of Licencee's constitution;
(b) the Licencee's most recently published annual accounts and any report of the auditor on them, and
(c) the Licencee's most recently published annual report,
and for that purpose shall provide to Monitor written and electronic copies of any document establishing or amending its constitution within 28 days of being adopted and of the documents referred to in sub-paragraphs (b) and (c) within 28 days of being published.
3. Subject to paragraph 4, the Licencee shall provide to Monitor written and electronic copies of any document that is required by Monitor for the purpose of Section 39 of the 2006 Act within 28 days of the receipt of the original document by the Licencee.
4. The obligation in paragraph 3 shall not apply to:
(a) any document provided pursuant to paragraph 2;
(b) any document originating from Monitor; or
(c) any document required by law to be provided to Monitor by another person.
5. The Licencee shall comply with any direction issued by Monitor concerning the format in which electronic copies of documents are to be made available or provided.
6. When submitting a document to Monitor for the purposes of this Condition, the Licencee shall provide to Monitor a short written statement describing the document and specifying its electronic format and advising Monitor that the document is being sent for the purpose of updating the register of NHS foundation trusts maintained in accordance with section 39 of the 2006 Act**.**

Condition FT2 – Payment to Monitor in respect of registration and related costs

1. The obligations in the following paragraph of this Condition apply if the Licencee is an NHS foundation trust, without prejudice to the generality of the other conditions in this Licence.
2. Whenever Monitor determines in accordance with section 50 of the 2006 Act that the Licencee must pay to Monitor a fee in respect of Monitor's exercise of its functions under sections 39 and 39A of that Act the Licencee shall pay that fee to Monitor within 28 days of the fee being notified to the Licencee by Monitor in writing.

Condition FT3 – Provision of information to advisory panel

1. The obligation in the following paragraph of this Condition applies if the Licencee is an NHS foundation trust, without prejudice to the generality of the other conditions in this Licence.
2. The Licencee shall comply with any request for information or advice made of it under Section 39A(5) of the 2006 Act.

Condition FT4 – NHS foundation trust governance arrangements

1. This condition shall apply if the Licencee is an NHS foundation trust, without prejudice to the generality of the other conditions in this Licence.
2. The Licencee shall apply those principles, systems and standards of good corporate governance which reasonably would be regarded as appropriate for a supplier of health care services to the NHS.
3. Without prejudice to the generality of paragraph 2 and to the generality of General Condition 5, the Licencee shall:
(a) have regard to such guidance on good corporate governance as may be issued by Monitor from time to time; and
(b) comply with the following paragraphs of this Condition.
4. The Licencee shall establish and implement:
(a) effective board and committee structures;
(b) clear responsibilities for its Board, for committees reporting to the Board and for staff reporting to the Board and those committees; and
(c) clear reporting lines and accountabilities throughout its organisation.
5. The Licencee shall establish and effectively implement systems and/or processes:
(a) to ensure compliance with the Licencee's duty to operate efficiently, economically and effectively;
(b) for timely and effective scrutiny and oversight by the Board of the Licencee's operations;
(c) to ensure compliance with health care standards binding on the Licencee including but not restricted to standards specified by the Secretary of State, the Care Quality Commission, the NHS Commissioning Board and statutory regulators of health care professions;
(d) for effective financial decision-making, management and control (including but not restricted to appropriate systems and/or processes to ensure the Licencee's ability to continue as a going concern);
(e) to obtain and disseminate accurate, comprehensive, timely and up to date information for Board and Committee decision-making;
(f) to identify and manage (including but not restricted to manage through forward plans) material risks to compliance with the Conditions of its Licence;
(g) to generate and monitor delivery of business plans (including any changes to such plans) and to receive internal and where appropriate external assurance on such plans and their delivery; and
(h) to ensure compliance with all applicable legal requirements.
6. The systems and/or processes referred to in paragraph 5 should include but not be restricted to systems and/or processes to ensure:
(a) that there is sufficient capability at Board level to provide effective organisational leadership on the quality of care provided;

(b) that the Board's planning and decision-making processes take timely and appropriate account of quality of care considerations;
(c) the collection of accurate, comprehensive, timely and up to date information on quality of care;
(d) that the Board receives and takes into account accurate, comprehensive, timely and up to date information on quality of care;
(e) that the Licencee including its Board actively engages on quality of care with patients, staff and other relevant stakeholders and takes into account as appropriate views and information from these sources; and
(f) that there is clear accountability for quality of care throughout the Licencee's organisation including but not restricted to systems and/or processes for escalating and resolving quality issues including escalating them to the Board where appropriate.

Appendix 3: Care Quality Commission publications to guide healthcare providers and assist compliance with regulatory requirements

Publications	Summary
Care Quality Commission Essential standards of quality and safety 2010(95) http://www.cqc.org.uk/sites/default/files/media/documents/gac_-_dec_2011_update.pdf	This document lists and describes the essential standards of quality and safety required by the Care Quality Commission. This document described the essential standards of quality and safety required by a providers under the following headings: **involvement and information;** respecting and involving people who use services; consent to care; and treatment; fees; personalised care, treatment and support; **care and welfare of people who use services**; meeting nutritional needs; cooperating with other providers; **safeguarding and safety**; safeguarding people who use services from abuse; cleanliness and infection control; management of medicines; safety and suitability of premises; safety, availability and suitability of equipment; **suitability of staffing**; requirements relating to workers; staffing; supporting workers; **quality and management**; statement of purpose; assessing and monitoring the quality of service provision; complaints; notification of death of a person who uses services; notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983; notification of other incidents; records; **suitability of management**; requirements where the service provider is an individual or partnership; requirement where the service provider is a body other than a partnership; requirements relating to registered managers; registered person: training; financial position; **notifications** – notice of absence; notifications – notice of changes; standard of quality and safety escalator table.
Care Quality Commission Enforcement policy 2012 (96) http://www.cqc.org.uk/organisations-we-regulate/registered-services/how-we-enforce	This document details the enforcement policy which describes the Care Quality Commission powers in detail and the general approach to using them. This document described the principles of enforcement; the Care Quality Commission's enforcement powers and how they will use them; publication and notification of enforcement action; working with other organisations; investigations; principles of enforcement under the Ionising 28 radiation (Medical Exposure) Regulations 2000; and offences and fines
Care Quality Commission Judgment framework 2012 (96) http://www.cqc.org.uk/organisations-we-regulate/registered-services/how-we-enforce	This document described Care Quality Commission's regulatory model and judgement framework covering: manner of determining whether they have enough evidence to make a judgement; making a judgement about whether the evidence demonstrates non-compliance with one or more of the regulations; determining the impact on people who use services; determining our regulatory response; regulations covered by the framework, and the regulatory response escalator table.
Care Quality Commission The scope of registration 2012(97) http://www.cqc.org.uk/organisations-we-regulate/registering-first-time/regulated-activities/changes-our-scope-registration	This documents list the requirement of registration for organisations who provide, or are intending to provide, healthcare or adult social care. This document described: who has to register; information on types of service providers and general exemptions from registration; what activities that are covered by registration and how do regulated activities relate to each other. The regulated activities identified include: accommodation for persons who require nursing or personal care and those who require treatment for substance misuse; accommodation and nursing or personal care in the further education sector; treatment of disease, disorder or injury; assessment or medical treatment for persons detained under the Mental 35 Health Act 1983; surgical procedures; diagnostic and screening procedures; management of supply of blood and blood-derived products; transport services, triage and medical advice provided remotely; maternity and midwifery services; termination of pregnancy; services in slimming clinics; nursing care, and family planning service

Appendix 4: Monitor's publication by its five regulatory functions

Monitor function	Publications	Summary
1. Licensing providers	The New NHS **provider licence** 14 February 2013(98) http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishLicenceDoc14February.pdf	Monitor's response to the statutory consultation on the new NHS provider licence. This document includes the final standard licence conditions. There are only two licensing criteria: the requirements to hold a CQC registration and to confirm that relevant people are fit and proper ('fit and proper' persons are defined as those without recent criminal convictions and director disqualifications, and those not bankrupt (undischarged). The licence applies to different providers and not all sections of the licence are applicable to all providers of NHS. • General Conditions: applies to all licence holders. • Pricing Conditions: only affect licence holders who provide services covered by the National Tariff document. • Choice and Competition Conditions: applies to all licence holders. • Integrated Care Condition: applies to all licence holders. • Continuity of Services Conditions: applies to licence holders who supply Commissioner Requested Services. • NHS Foundation Trust Conditions applies to NHS foundation trusts. Regarding licence provision Monitor does not normally carry out any checks in advance of issuing a licence to a healthcare provider unless something prompts them to do so. However, in advance of issuing licences, Monitor will contact all NHS foundation trusts to confirm the accuracy of certain information required, such as names, titles and addresses.
1. Licensing providers	**Impact assessment** the new NHS **provider licence** 5 September 2012(99) http://www.monitor-nhsft.gov.uk/sites/default/files/Final%20report%20IA.pdf	Monitor has developed 30 proposed licence conditions split into six broad groups: • General • Pricing • Choice and Competition • Integrated Care • Continuity of Services, and • NHS foundation trust. Monitor will have a range of powers enabling it to enforce these licence conditions. PwC's report analyses the costs and benefits of each of the proposed licence conditions. The licence conditions and impact assessment were developed in parallel so that impacts could be taken into account as Monitor completed its licence proposals. The impact assessment was then finalised to reflect the proposed licence conditions as published. The impact assessment finds that the benefits of the proposed licence conditions are expected to outweigh the costs. This conclusion is based on a number of assumptions about the way in which Monitor will implement each of the conditions in practice. Monitor will use these assumptions as a starting point as it continues to develop the detail of our regulatory framework.
2. Regulating pricing for NHS funded care 4. Cooperation and competition 5. Supporting continuity of services	Economies of scale and scope in healthcare markets 16 August 2012(100) http://www.monitor-nhsft.gov.uk/economiesofscaleandscope	The independent study, commissioned by Monitor, investigates the extent to which there are economies of scale and scope in healthcare markets and how these can be measured by Monitor. The issue of economies of scale and scope will sit at the heart of many of Monitor's decisions as sector regulator. The development of cost curves to measure economics of scale and economic of scope in the areas of: 1. Obstetrics; 2. Accidence and Emergency departments; 3. Orthopaedics, and in addition, 4. a better understanding of the costs of support services. The extent of economies of scale and scope will be important for the continuity of service, pricing, and competition regimes.

Monitor function	Publications	Summary
2. Regulating pricing for NHS funded care	**Evaluation** of the **reimbursement** system for **NHS-funded care** 23 February 2012(101) http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-15	Pwc evaluation of the reimbursement system for NHS-funded care is an in-depth, independent and extensive evaluation of the reimbursement system in the NHS in England. It is the most comprehensive analysis of pricing in the NHS that's ever been done. The report highlights the vital importance of good quality information which accurately identifies the true costs of providing care. Pwc's key finding is that the information underpinning the reimbursement system needs significant improvement. The investigators found unexplained variations in the unit costs for the same services between providers. Existing evidence has also highlighted areas where data quality is poor. This finding applies across acute, community and mental health services. Payment by results has delivered benefits – for instance enabling choice, improving information availability, and driving some quality and efficiency improvements. However, unless the information is accurate and reliable, reimbursement may not be set at a level that is sufficient to deliver high quality care. Poor information can also affect the stability of prices. Pwc found that over 40% of prices set under payment by results change by 10% or more each year. This undermines the confidence of providers and commissioners, they do not understand why prices fluctuate widely, and find it difficult to respond to price signals. There is little evidence of increased delivery of care closer to the home. In the last year growth in expenditure on community services was 6%, only moderately outstripping the 5% rate of growth in expenditure on acute care. It is not surprising that providers and commissioners are increasingly deciding to negotiate reimbursement locally, given incentive and information problems Pwc highlight. Pwc found that non-tariff income has been increasing, and its survey evidence shows that 50% or more providers engage in local negotiations with commissioners, outside the rules of payment by results.
2. Regulating pricing for NHS funded care	A **methodology** for approving local modifications to the national **tariff** commissioned by Monitor from Frontier Economics 3 April 2012(102) http://www.monitor-nhsft.gov.uk/node/1170	A methodology for approving local modifications to the national tariff was commissioned by Monitor from Frontier Economics. The national tariff sets a price which is paid to providers for delivering health services to NHS patients. Where a particular provider believes it can no longer provide certain services, because they are uneconomic, it may be appropriate for Monitor to approve a local modification to the national tariff for that provider. Local modifications are one small part of a system of reimbursement for NHS services, and are intended to complement (rather than replace) existing reimbursement mechanisms. Frontier Economics say that local modifications should be the exception rather than the rule. They are not intended to subsidise poor quality or inefficiency. It should be up to providers and commissioners to agree whether a local modification is required for a service to remain sustainable, and what services should be provided in the best interests of local NHS patients. Monitor should decide whether to allow modifications on the basis of the evidence provided. Monitor should provide support and guidance to assist providers and commissioners in developing their capabilities in this respect. This report provides a recommended methodology for assessing whether or not to allow a local modification.
2. Regulating pricing for NHS funded care	**Strategic** options for **costing** 19 June(103) 2012 http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-13	This independent report recommends that Monitor should collect patient-level cost data from providers that can meet a mandated cost allocation methodology and assurance requirements. The move to Patient-Level Information and Costing Systems requires: 1. The development of mandatory and more detailed standards for cost allocation, building on the Health Finance Management Association clinical costing standards; 2. The continued collection of patient-level cost data; 3. The use of costs from a representative sample of providers to develop mechanisms of price setting, which could improve data quality, and 4. Systems to assure the accuracy of cost submissions using a combination of self-assessment, peer review and targeted external assurance. Monitor and HFMA held a joint webinar on 24 July 2012 to update stakeholders on the key recommendations in the Strategic Options for Costing report. The whole session can be viewed again here. On 3 September 2012 Monitor published a summary of stakeholder responses to the report

Monitor function	Publications	Summary
2. Regulating pricing for NHS funded care	**Costing Patient Care**: Monitor's approach to costing and cost collection for price setting 20 November 2012(104) http://www.monitor-nhsft.gov.uk/node/1170	A methodology for approving local modifications to the national tariff was commissioned by Monitor from Frontier Economics and is another part of the growing evidence base that Monitor will use to determine its approach as sector regulator. This independent report will inform the development of Monitor's policy on approving local modifications to the national tariff. *The procedures in seeking local modification to the national tariff consist of:* 1. An agreement between a commissioner and provider, in which both jointly propose a modification to the national price; but if they fail to reach agreement then 2. An application from a provider proposing a modification to the national price to Monitor can be submitted. On 16 July 2012 Monitor published a summary of stakeholder responses to the report.
2. Regulating pricing for NHS funded care	Approved **Costing Guidance**: A draft for stakeholder feedback 20 November 2012 *Reissued 12 July 2013*(105) http://www.monitor-nhsft.gov.uk/costingguidance	This guide sets out costing principles, costing standards, and guidance for both reference costs and patient-level Information and Costing Systems collections for 2012/13. The guide also gives details of the requirements that providers of NHS-funded services will need to comply with to meet the pricing conditions of the NHS provider licence. Monitor's guidance consolidates and streamlines existing guidance into a coherent framework, and should help to facilitate providers' compliance with the relevant aspects of the provider licence. The guidance comprises four chapters: Chapter 1 - Monitor's costing principles contains the costing principles that apply to NHS providers; Chapter 2 - Healthcare Financial Management Association's Acute Health Clinical Costing Standards Chapter 3 - Department of Health's Reference Costs Guidance for 2012/13 Chapter 4 – Monitor's sets out the guidance for the collection of 2012/13 patient-level costs, what data will be collected, and the fields and other features of the data collection template.

Monitor function	Publications	Summary
2. Regulating pricing for NHS funded care	Summary of stakeholder responses to Costing Patient Care and draft Approved Costing Guidance 21 February 2013(106) http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishSummaryOfResponsesCosting.pdf	Summary of stakeholder responses to Costing Patient Care and draft Approved Costing Guidance Costing Patient Care, a policy document describing Monitor's proposed approach to improving the quality of the cost data on which prices are based, and which reflected the results of research and stakeholder responses to Strategic Options for Costing, was published in November 2012. Between 20 November 2012 and 11 December 2012, Monitor sought the views of stakeholders on it and on drafts of chapters 1 and 4 of the draft Approved Costing Guidance. Monitor received 56 written responses which, in general were very supportive of our approach and to the draft chapters of the Approved Costing Guidance. Monitor asked stakeholders eleven questions in relation to the policies set out in Costing Patient Care, and the guidance in chapter 1 and chapter 4 of the draft Approved Costing Guidance. The findings were: 1. More than four-fifths of the respondents agreed on the approach to costing patient care; 2. Almost all respondents agreed with costing principles and steps; 3. Only 60% of respondents had information and financial systems that could comply with the costing requirements; 4. Four-fifths were willing to participate in the pilot.
3. Enabling integrated care	Enablers and barriers to integrated care and implications for Monitor 11 June 2012(107) http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-23	A consortium, led by Frontier Economics, and including The King's Fund, The Nuffield Trust and Ernst & Young, was appointed by Monitor to consider issues relating to the delivery of integrated care. This report sets out the evidence, analysis and findings. The authors found that the impact of fragmentation is that quality of care for patients and service users does not reach its potential and that possible efficiencies are not made. Individuals can get lost in the system, access to services can be blocked or get delayed or duplicated, and the quality of care can decline. The authors identified three dimensions of what integrated care means : 1. Integrated care seeks to improve the quality and cost-effectiveness of care for people and populations by ensuring that services are well co-ordinated around their needs, it is by definition both 'patient-centred' and 'population-oriented'; 2. Integrated care is necessary for anyone for whom a lack of care co-ordination leads to an adverse impact on their care experiences and outcomes; 3. The patient or users perspective is the organising principle of service delivery. The research report suggests some early steps Monitor might take to enable improvements in the integration of care. Monitor's integrated care role will be supported by the new provider licence, which will enable Monitor to step in where integrated care is not being delivered, in spite of decisions and efforts made by commissioners. The Integrated Care Condition states that all licence holders shall not do anything that could reasonably be regarded as detrimental to enabling integrated care. It also includes a patient interest test which means that the obligations only apply to the extent that they are in the interests of people who use healthcare services.
4. Cooperation and competition	Briefing sheet: Mergers involving NHS trusts and NHS foundation trusts 22 March 2013(108) http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-20	The respective roles of Monitor, the Office of Fair Trading and the Competition Commission in relation to mergers involving NHS trusts and NHS foundation trusts. Section 79 of the Health and Social Care Act 2012 imposes an obligation on the Office of Fair Trading to notify Monitor as soon as reasonably practicable where the Office of Fair Trading decides to carry out an investigation under Part 3 of the Enterprise Act 2002 of a matter involving an NHS foundation trust. The Office of Fair Trading's view that an NHS trust may fall within the definition of an 'enterprise' as per the Enterprise Act is distinct from its application of the Competition Act 1998. Proposed mergers involving NHS foundation trusts are subject to review by the Office of Fair Trading. The Office of Fair Trading assesses the impact of the merger on competition. Monitor, the sector regulator, will advise the Office of Fair Trading about the patient benefits of the proposed transaction. This approach will apply to mergers between NHS foundation trusts, mergers between an NHS foundation trust and an NHS trust, and mergers between an NHS foundation trust and another organisation.

Monitor function	Publications	Summary
4. Cooperation and competition	**Consultation** on guidance on Monitor's **approach to market investigation** references (market investigation) 27 March 2003(109) http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishCCPMarketIvestigationReferences27March13.pdf	Monitor has concurrent powers with the Office of Fair Trading to make market investigation references to the Competition Commission under the Enterprise Act where it has reasonable grounds for suspecting that any feature, or combination of features, of a market is preventing, restricting, or distorting competition. This guidance explains the approach Monitor will take when using these powers. Monitor describes the three stages: 1. To make a reference to the Competition Commission (CC) under Part 4 of the Enterprise Act if Monitor have reasonable grounds for suspecting that any feature, or combination of features, of a market in the UK prevents, restricts, or distorts competition in connection with the supply or acquisition of any goods or services in the UK or part of the UK (a market investigation reference). 2. Upon a market investigation reference, the CC must decide whether competition is prevented, restricted or distorted, and, if so, whether any action should be taken to remedy the adverse effect on competition or any detrimental effect on customers resulting from it. 3. To consult with those people whose interests Monitor consider are likely to be substantially affected by its decision.
4. Cooperation and competition 1. Licensing providers	**Licence conditions** - **choice and competition**: consultation on **draft guidance** for providers of NHS-funded services. Issued on: 27 March 2013 Deadline for responses: 25 June 2013. (110) http://www.monitor-nhsft.gov.uk/sites/default/files/publications/Guidance%20on%20choice%20and%20competition%20licence%20conditions.doc.pdf	This draft guidance sets out Monitor's interpretation of the choice and competition conditions of the NHS provider licence and explains how Monitor will assess whether a licensee's behaviour is consistent with these conditions. **Identifying possible breaches** Monitor expect to become aware of potential breaches of the choice and competition licence conditions in a number of ways, including: • Complaints from third parties; • Intelligence from another regulator or authority; • Facts that emerge from Monitor's current or completed cases and reviews; or • Monitor's own monitoring of the sector. Accordingly, Monitor may start investigations both in reaction to complaints and on their own initiative if they have reasonable grounds for suspecting a breach. Monitor will accept complaints from anyone regarding suspected breaches of the choice and competition licence conditions, including a provider, a commissioner, a representative body, a patient group, or an individual user of healthcare services. **Process for conducting cases** Monitor set out the general procedures that it intends to follow when conducting a case that may result in us taking formal enforcement action in separate guidance (see Monitor's Enforcement Guidance). This 'Licence conditions - choice and competition: consultation on draft guidance for providers of NHS-funded services' sets out Monitor's interpretation of the choice and competition conditions of the NHS provider licence and explains how Monitor will assess whether a licensee's behaviour is consistent with these conditions. This guidance concerns sections of the licence relating to choice and competition. The 'Licence conditions - choice and competition: consultation on draft guidance for providers of NHS-funded services' also include draft guidance about how the CCP propose to enforce the Procurement, Patient Choice and Competition Regulations (№2) 2013 currently before Parliament

Monitor function	Publications	Summary
5. Supporting continuity of services	Draft: Risk Assessment Framework, consultation document Issued on 10 January 2013 Deadline for responses: 4 April 2013(34) http://www.monitor-nhsft.gov.uk/sites/default/files/ToPublishDraftRAFConsultationDocandDraftRAF10Jan13.pdf	Monitor's consultation on the draft Risk Assessment Framework. The framework sets out Monitor's approach to assessing the risk of NHS providers failing financially. It also describes how it will continue to oversee the governance of foundation trusts. Monitor's new powers now cover a wider range of providers of NHS services, and consequently the Compliance Framework is being replaced with a new regulatory tool, the Risk Assessment Framework. The principles behind the Risk Assessment Framework are the same as those Monitor has used so far to regulate NHS foundation trusts, so do not represent any significant change to its current approach. This new framework will enable Monitor to protect the continuity of key NHS services provided by both NHS foundation trusts as well as commercial or third-sector providers. In developing proposals, Monitor has simplified its approach to focus on risk of financial failure, rather than overall financial position of organisations. It has also made this risk assessment more explicitly forward-looking. Monitor intends for all NHS foundation trusts to have a governance licence condition. It proposes using a wider range of information, such as staff and patient satisfaction surveys, to reinforce their Boards' responsibilities across the areas of governance. The Risk Assessment Framework is intended to act as a trigger for considering formal investigation into financial and governance matters; Monitor will, as now, take a proportionate view of any issues of compliance and the need for formal investigation and enforcement action.
1-5. All regulatory functions	Draft Enforcement Guidance: consultation document Issued on: 18 December 2012 Deadline for response:11 February 2013(111) http://www.monitor-nhsft.gov.uk/home/news-events-publications/consultations/closed-consultations/2012/draft-enforcement-guidance-con	Monitor's consultation on draft guidance which sets out its general approach to exercising its enforcement powers in relation to potential and actual breaches of the licence and other regulatory obligations. Monitor's enforcement guidance explains the action it can take to require compliance with the provider licence and other regulatory obligations on providers, and the process it will follow to take action. It sets out the proposed process for prioritising issues, deciding on the action to take and seeking input from stakeholders on its proposed actions. Monitor's enforcement guidance explains the action they can take to enforce compliance with the provider licence and other regulatory obligations on providers and others required to provide Monitor with information needed to perform its functions. It sets out the proposed process for prioritising issues, deciding on the action to take and seeking input from stakeholders on its proposed actions. The document is their consultation on draft guidance which sets out Monitor's general approach to exercising their enforcement powers in relation to potential and actual breaches of the licence and other regulatory obligations. The discretionary requirements that Monitor may impose are: • Compliance requirements which require a provider to take such steps as Monitor may specify to ensure that the breach in question does not continue or recur; • Restoration requirements which require a provider to take such actions as Monitor may specify to restore the situation to what it would have been, were the breach not occurring or had not occurred; and • Variable monetary penalties which require a provider to pay a penalty. More specifically where Monitor has reasonable grounds to suspect that there have been breaches of a licence condition or where there is failure to give information Monitor may action enforcement undertakings, and the provider may give an undertaking to: take steps to bring the breach to an end, take actions to restore the situation and any other actions. Where a breach of a licence condition or failure to give Monitor information, Monitor can oblige the provider to: take steps to bring the breach to an end, take actions to restore the situation or request payment of a financial penalty or revoke the licence. The governance of an NHS foundation trust is such that where the trust fails to comply with its licence conditions monitor may impose additional conditions relating to governance and if those conditions are breached then remove, suspend, disqualify one or more directors or members of the council. Where there is breach of competition law Monitor may give directions to bring infringement to an end, and/or impose a fine. The Draft Enforcement Guidance: consultation document is in its early states. Monitor has licensed foundation trusts from April 2013, and will licence other eligible NHS providers from April 2014.

Appendix 5: Monitor's governance publications to guide foundation trusts and assist compliance with regulatory requirements

Monitor's publications to guide foundation trusts	Summary
Schedule 6 of the terms of authorisation 2012 (archived by monitor)	Schedule 6 of an NHS foundation trust's terms of authorisation lists the information they have a legal or statutory obligation to supply This documents lists the mandatory information which Monitor requests from FTs it includes: the National Cancer Dataset Waiting Times Subset; Mandatory Surveillance of Healthcare Associated Infection; Estates Return Information Collection (ERIC) [FT Version Only] KC62; Adult Screening Programme: Breast Screening (Screening Unit) KC65; Colposcopy clinics, referrals, treatments and outcomes; Hospital and Community Health Services (HCHS); Complaints (K041A); Quarterly Monitoring Accident and Emergency (QMAE); Annual HCHS medical and dental workforce census; Annual HCHS non-medical workforce census; Central Alerting System (Safety Alert Broadcast Register); Defects and Failure reporting system; Annual Plan - Financial Projections; Annual Accounts (unaudited); Audited annual accounts/report; Reconciliation between annual plan and audited accounts; Quarterly Financials; Exception Reports NHS Pension Scheme Contributions (ALB); Critical Care Minimum Data Set; Neonatal Critical Care Minimum Dataset (NCCMDS); Radiotherapy Contract Data Set (RT CDS); Integrated Drug Treatment; System for prisons Clinical Activity; Equity ownership of special purpose vehicles (SPV) in PFI schemes; National Cancer Registration Dataset; Quarterly Monitoring Cancelled Operations (QMCO); Venous Thromboembolism (VTE) Prevention; Accident & Emergency Clinical Quality Indicators; Child and Adolescent Mental Health Services (CAMHS); Dataset; Community Information Dataset; KA34 Performance and Clinical Quality Indicators for ambulance services; Abortion statistics; Surplus Land for Housing; National Drug Treatment Monitoring; KH03 Bed availability and occupancy; Public Procurement Contracts; Sexual and Reproductive Health Activity Dataset; Monthly Activity Flow Diagnostic Imaging Dataset; Reference Costs Database; Information Sharing between A&Es and CSPs to tackle violence; Cancer Outcomes and Services Dataset (COSD); Diagnostic waiting times and activity (including quarterly diagnostic census); Referral to treatment monthly returns
Compliance Framework 2012 (112) http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-59	The Compliance Framework sets out the approach taken to assess the compliance of foundation trusts with their terms of Authorisation and to intervene where necessary. This approach is supported by law and will be replaced by a risk assessment framework.
NHS Foundation Trust Annual Reporting Manual 2012(113) http://www.monitor-nhsft.gov.uk/our-publications/browse-category/guidance-foundation-trusts/mandatory-guidance/nhs-foundation-trust-	The NHS Foundation Trust Annual Reporting Manual provides guidance to foundation trusts on producing their annual reports and accounts.
Detailed guidance for external assurance on quality reports 2012(114) http://www.monitor-nhsft.gov.uk/our-publications/browse-category/guidance-foundation-trusts/mandatory-guidance/detailed-guidance-ext	This document sets out detailed guidance for NHS foundation trusts and their auditors to enable to obtain external assurance on the 2011/12 Quality Report is specified in paragraph 7.76 of the Foundation Trust Annual Reporting Manual 2011/12. This document reports on the assurance engagements that will be undertaken on Quality Reports which NHS foundation trusts return. They include: the key controls in place to prepare a quality report; issues about the directors' responsibilities; issues around the auditors, and issues around the auditor' report.
Audit Code for NHS Foundation Trusts 2011(115) http://www.monitor-nhsft.gov.uk/home/our-publications/browse-category/guidance-foundation-trusts/mandatory-	This manual sets out the code, which applies to audits and auditors of NHS foundation trusts. This document reports on the general principles underpinning the audit, the procedure for appointing auditors, describes the audit processes and reporting. The procedure for completing quality reporting, the statutory responsibilities of the NHS foundation trusts and auditors in relation to accounting and auditing. The criteria for selection of auditors and the rotation of auditors. Finally, it provides the memorandum of understanding between the Comptroller and Auditor General and the auditors of the NHS foundation trusts..

guidance/audit-code-nhs-f	
Restructuring costs / revenue recognition 2011(116) http://www.monitor-nhsft.gov.uk/home/our-publications/browse-category/guidance-foundation-trusts/mandatory-guidance/restructuring-co	This document provides guidance for foundation trusts on issues regarding recognition of revenue and restructuring costs.
Contract dispute resolution: advice for NHS foundation trusts 2011(117) http://www.monitor-nhsft.gov.uk/home/our-publications/browse-category/guidance-foundation-trusts/mandatory-guidance/contract-dispute	This document summarises the contract dispute resolution procedure for NHS foundation trusts. This document identifies and discusses the three stages of formal contract dispute resolution process: negotiation, mediation and adjudication.

Appendix 6: Applicability of competition law to health care in New Zealand

Competition law in New Zealand is governed by the Commerce Act 1986. The purpose of the Act is "to promote competition in markets for the long-term benefit of consumers within New Zealand" (Section 1A).

The Act prohibits anti-competitive behaviour in New Zealand markets, e.g., behaviour such as price fixing and anti-competitive mergers. It also prohibits businesses that have substantial market power in a market from taking advantage of that power (such as by restricting entry by new competitors into the market). The Act is enforced by the Commerce Commission, a government agency that can issue decisions, impose penalties and take court action.

Health providers need to clearly understand need the implications of the legislation if they are contemplating:

- discussing prices with competitors
- starting, running or ending a roster among competing practitioners
- setting fees
- entering agreements that could restrict competition
- promoting services
- offering deferred payment options to patients
- collaborating with competitors
- merging a practice with another practice

(See http://www.comcom.govt.nz/business-competition/fact-sheets-3/health/how-competition-and-consumer-laws-apply-to-the-health-sector/)

Under the Commerce Act, there are some exemptions – for example, where other legislation overrides the Act, and where inter-connected agencies work together. One exemption, for instance, allowed the four RHAs to jointly establish PHARMAC to purchase prescription medicines in New Zealand.

A voluntary pre-merger clearance system exists. If a business believes its merger with a competitor may be viewed as anti-competitive, it can seek clearance from the Commerce Commission for the merger to proceed. The Commission will grant clearance if it is satisfied that the merger will not substantially lessen competition in a market.

Businesses are not obliged to seek clearance from the Commission. However, if a business merges with a competitor without obtaining Commission clearance, and if the Commission deems that the merger could result in a substantial reduction in competition, the Commission can take legal action, resulting in the imposition of penalties on the business. The court may order that the merger be reversed.

In making its determinations, the Commission must take into account any public benefits (including efficiencies) that may accrue from the activities under scrutiny. The Commission may permit anti-competitive behaviour if it is satisfied that public benefits will, or are likely to, outweigh any lessening of competition.

Commerce Commission decisions can be appealed through the courts. Generally speaking, the Commerce Act applies to the commercial activities of organisations operating in the New Zealand health sector (Commerce Commission, 2014). Thus, for example, in 1995 the Commerce Commission refused to authorise a ten-year

contract between a Regional Health Authority and a mental health facility on the grounds that the market for mental health services could become competitive within five years (Flood, 2000).

To visit the Commerce Commission's website, go to www.comcom.govt.nz

The Commerce Act can be viewed here:
http://www.legislation.govt.nz/act/public/1986/0005/latest/DLM87623.html?search=ts_act%40bill%40regulation%40deemedreg_commerce+act_resel_25_a&p=1

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Appendix 7: Crown Company Monitoring Advisory Unit 'Crown health enterprises briefing to the incoming minister' (1996)

Source: (79)

(See separate attachment)

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