KPMG

ADVISORY

Learning and Implications from Mid Staffordshire NHS Foundation Trust

Monitor – Independent Regulator of NHS Foundation Trusts

Final Report dated 5 August 2009

INTERNAL AUDIT, RISK AND COMPLIANCE SERVICES

AUDIT ▪ TAX ▪ ADVISORY

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Report Status	
Preliminary findings presented to Board	27 May 2009
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Dr William Moyes, Executive Chairman	Jan Quirke, Secretary to the Board
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1. Introduction and scope

Background

Monitor commissioned KPMG to conduct a 4 to 6 week 'lessons learnt' exercise based on the events relating to Mid Staffordshire NHS Foundation Trust (Mid Staffs) during the period 1 October 2007 to 30 April 2009. The purpose of the exercise was to identify where existing processes across Assessment and Compliance could be improved, identifying learning and recommendations to improve processes. This included consideration of compliance actions identified following the notification of a review by the Healthcare Commission's (HCC's) investigation at Mid Staffs in 2008.

Scope of services

This exercise covered the domains of quality and clinical governance, but not legal constitution or financial viability, except where issues in these areas were material to the questions of quality and clinical governance (defined in Appendix A). During the exercise, we reviewed a small sample of similar Assessment and Compliance cases to provide useful comparison and validation of learning.

Approach

At a high level, the key steps in this review included:

- A kick off meeting to finalise the proposed approach, agree documentation to review, participants and project communication (Appendix B);
- Early meetings with Monitor's Assessment and Compliance staff who worked directly on Mid Staffs and key senior individuals at Monitor to sketch out the high level chronology and lessons learnt to date so that the review did not just focus on known learning but also built on existing knowledge;
- A review of certain documentation to identify the issues to explore;
- Building the timeline showing the chronology of events over the specified time period and identifying the interdependencies between the streams of activity in Assessment and Compliance (outlined in Appendix C);
- Development of a 'stakeholder map' highlighting information flows between Mid Staffs, Monitor and the key stakeholders including the HCC, National Patient Safety Agency (NPSA), Strategic Health Authority (SHA), Primary Care Trust (PCT) and Department of Health (DH) (provided in Appendix D);
- Identification of any additional information required and issues to explore in specific interviews;
- Drawing on a range of KPMG specialists on our advisory panel, with knowledge of the sector, to analyse the chronology, challenge the issues identified, confirm areas to explore further in interviews. We also used our KPMG advisory panel to help identify recommendations for change at an early stage;
- Undertaking interviews with key individuals to investigate specific issues and identify areas to explore further and develop recommendations;
- Development of our preliminary report presentation based on the issues and recommendations identified to date;
- Using our advisory panel of KPMG specialists to challenge the initial findings and recommendations and content of the preliminary report presentation issued prior to the Monitor Board meeting in May 2009;
- Reviewing the preliminary report presentation with the Project Sponsor and other senior management stakeholders, prior to issue for first Board meeting on 27 May 2009;
- Presentation of the preliminary findings to the Monitor Board in May;
- Scheduling additional interviews to gain further information to supplement lessons learnt and recommendations;
- Holding a workshop with Monitor's Senior Management following the May 2009 Board meeting to challenge and refine recommendations;
- Conducting further analysis in order to finalise recommendations;
- Close out meetings with senior management to discuss and confirm Monitor's management response to the findings;
- Presentation to the Monitor Board in July 2009; and
- Finalisation and issue of the report.

2. Executive summary

In summarising our findings and recommendations we think it is important to understand the context within which Monitor operates.

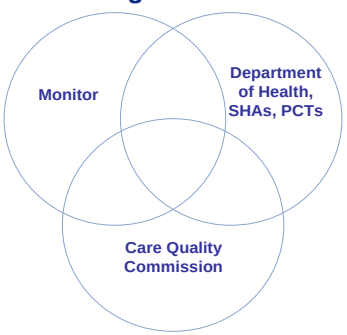
Stakeholder responsibilities for quality and clinical governance

During the period under review the primary stakeholder relationships that Monitor maintained were with the DH, the HCC (now the Care Quality Commission (CQC)) and the SHAs and PCTs associated with Foundation Trusts (FTs) and Foundation Trust applicants.

The working relationships in place are crucial in handling the complexity of the responsibilities across the NHS system for evaluating and monitoring quality of performance at a detailed level and then evaluating and monitoring management performance in clinical governance as a result.

The precise nature of responsibilities, particularly where individual bodies' responsibilities intersect or overlap has evolved and is not entirely clear, which can give rise to confusion and uncertainty. In the case of Monitor's role in authorising and monitoring compliance for FTs the structure is broadly as shown below in Figure 1.

Figure 1 – NHS high level inter-relationships



Responsibilities for quality and clinical governance

The DH is responsible for strategy, policy and funding. This is delivered through the SHAs at regional level and the PCTs for commissioning services. Monitor is responsible for authorising NHS Trusts to become FTs and then monitoring their compliance with their terms of authorisation. It is also responsible for interventions based on significant breaches of the authorisation conditions. The CQC is responsible for overseeing the quality of service delivery within the NHS.

Whereas at the highest level these roles and responsibilities are relatively simple, we believe that they are more complex at a detailed operational level. It is not until they are addressed at a level of detail and stress tested, in the event of marginal performance by an FT applicant or FT, that one can be sure that the system itself has no significant gaps, cracks or uncertainties. It may equally be that more than one stakeholder takes responsibility for certain activity, which can be just as confusing in such a complex environment.

Recent history

When Monitor was established in 2004 the quality threshold for FTs was clear; only Trusts with a 3 star rating from CHI (superseded by HCC annual review) were supported by the Secretary of State for referral to Monitor. This provided a clear benchmark. Subsequently, this basis changed. From 1 April 2006 star ratings were replaced by the HCC's Annual Health Check ratings (Weak, Fair, Good, Excellent) which include the DH's Targets and National Core Standards.

While targets and standards are important indicators, they do not provide a full picture of quality, and other factors need to be considered to develop a holistic picture of quality performance. Although the HCC Annual Health Check includes a review of clinical governance within the Standards for Better Health, ratings are self certified by the Trust Board annually and supported by periodic risk based spot checks by the HCC. Additionally the Health Overview and Scrutiny Committee, SHA and Local Involvement Networks (LINks) are asked to comment on the Annual Health Check.

From 2008/09, FTs are required to publish Quality Accounts, summarising their quality aspirations and supporting clinical quality indicators. In 2009/10, all NHS organisations will be required to publish Quality Accounts, with supporting clinical quality data. However, there is recognition from the Audit Commission's 2009 publication 'Taking it on Trust' that the quality of clinical data is not as reliable as would be expected, therefore raising questions on the level of assurance needed over data quality.

2. Executive summary (continued)

Following publication by Dr Foster, SMRs also appear to have become recognised within the NHS as an important indicator of clinical quality performance, although we have not sought to obtain the DH's view of their status. Nevertheless, whereas it was clear in 2004 what constituted the threshold for quality, it is now less clear what set of factors is regarded as the key data set for evaluating quality performance at an aspiring FT.

We are not clear how the mutual responsibilities of the various stakeholders involved in the evaluation of quality and clinical governance relate inter-se. This is applicable at Assessment, within Compliance and in the event of escalation of an Issue Trust to Intervention. Furthermore, we are not clear what constitutes the threshold for an acceptable level of quality performance and clinical governance for an NHS Trust to be accepted as an FT. Accordingly, we are unclear what level of work ought or needs to be performed by Monitor, in conjunction with its stakeholders, to ensure that the aspiring Trust has achieved an acceptable level of quality performance and is capable of continuing to do so.

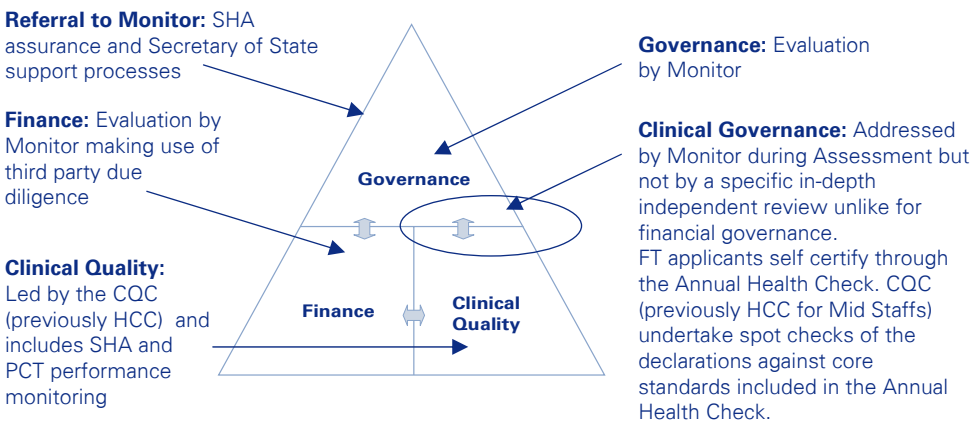
The types of question we have asked include:

- What is Monitor's regulatory role in relation to clinical governance?
- What is the CQC's role in relation to clinical governance?
- How much of Monitor's role is addressed by what the CQC does on clinical governance?
- Is there a gap between Monitor's role and what the CQC can assure?
- How, when and where does the gap arise?
- How might the gap be covered off?
- Who would discharge the work required to fill the gap?

At a high level the analysis of responsibilities at Assessment appears to be broadly as set out in Figure 2 on this page which also summarises the stakeholders involved for Mid Staffs. There are considerable differences in the depth and breadth of activity amongst the stakeholders with regard to assurance over quality and clinical governance versus that for financial governance.

Monitor will not receive a high degree of assurance over quality performance (the quality of underlying data) and clinical governance effectiveness at Assessment and subsequently in Compliance until the potential gaps, overlaps and uncertainties in roles, responsibilities and ways of working across the stakeholders have been resolved.

Figure 2 – Trust level external oversight activities at Assessment



Clinical Governance/Clinical Quality

By clinical governance we mean the way a Trust organises itself to manage and monitor clinical performance, plan and manage continuous improvement, identify performance that is below standard and then investigating and taking appropriate management action (See Appendix A). Clinical governance is not the same as clinical quality. For example, it is possible for a Trust to achieve the DH's Targets and National core Standards but to have poor clinical governance. If a Trust has a good level of clinical governance, that does not, in itself, guarantee that the DH's targets and National core Standards will be achieved; they are complementary. Greater clarity is required about the relationship between the two topics, stakeholders' mutual responsibilities and how Monitor can make best use of its resources to focus on the most relevant aspects in discharging its role.

2. Executive summary (continued)

Analysis and summary

While the quality threshold on Assessment may have been clear at one time, it is now much less clear:

- What constitutes the threshold for clinical governance on Assessment and subsequently through Compliance; and
- What scope of review should be used by Monitor in the context of quality and clinical governance.

In order to identify the main learning and implications from this audit we have gone back to first principles and asked a series of questions about Monitor's role in relation to quality and clinical governance. The end result of the line of thought that we have followed has been a broader question: Should Monitor focus more time and attention on clinical governance at Assessment and then subsequently during Compliance?

We believe that there are some areas where Monitor should place more focus; for example, on clinical governance as a part of the Assessment process and then subsequently through Compliance.

In making this statement, we are also cognisant of the:

- Hampton Principles for regulation and the need for Monitor to operate in a proportionate and risk based manner; and
- Need for Monitor to operate within the existing NHS stakeholder framework. That is, certain changes might only be feasible if made by mutual consent amongst the stakeholders.

More specifically, we recognise that there are recommendations where further analysis will be required to assess the feasibility, practicality and cost benefit of further work. Certain of our recommendations can only be implemented successfully with the co-operation of the other key stakeholders in the NHS regulatory system. Accordingly, the actions arising from those recommendations require a broader dialogue amongst the stakeholders to ensure that they are based on a mutual understanding/agreement and aligned to cover their respective roles and responsibilities. We have indicated in our recommendations where such collaboration is required to achieve the desired objective.

The structure of the body of this report is based round the findings and recommendations under three primary headings: Assessment, Compliance and Intervention. Following these headings we have included a further section dealing with structural matters that are largely a matter for implementation i.e. how the primary findings might be addressed. This section is broken into internal matters, relating to Monitor's management; and external matters, how it interacts with the stakeholder community.

While the primary focus of this report has been to identify learning arising directly from Mid Staffs, other matters that have come to our attention are addressed. For example, there are no findings, arising from Mid Staffs that related to the Compliance process, per se. This is because the Trust moved almost directly from Assessment to being an Issue Trust, which places it in Monitor's Intervention process. In our recommendations we have suggested that the principles identified in Assessment should be taken and the implications considered for Compliance as well to ensure consistency in approach and to give Monitor a sound basis for identifying the risk of non compliance in an FT at the earliest opportunity.

We have not just taken a backward look at events. We have also considered the potential implications for Monitor looking forward based on the understanding that we have gained from the detailed work. Accordingly, we have also made some recommendations that we believe would help Monitor to continue to develop. In doing so we have noted certain objectives already included in the Corporate Plan 2009-2012.

We have also considered a wide range of potential developments and activity for Monitor in response to its role and the findings. Certain of these have been discounted as being outside Monitor's span of responsibility. For example, we believe that the development by Monitor of a detailed analysis of clinical indicators to help identify potentially poor performance in clinical areas would be outside the scope of its role and also conflict with the roles of the CQC and of PCTs.

2. Executive summary (continued)

Summary findings

In the following paragraphs we provide a high level picture of the findings and recommendations in each section of the report.

Assessment

It is now less clear than it was what is regarded as the acceptable standard or threshold for Trusts aspiring to Foundation Trust (FT) status for quality and clinical governance. This impacts the potential nature and level of work required of Monitor on Assessment.

We believe that Monitor should work with its partners to redefine the standards for quality and clinical governance for use on Assessment and subsequently. Monitor should then perform more specific and focused work as a part of Assessment on clinical governance at aspiring FTs to address those areas requiring additional assurance not covered by the other stakeholders.

Compliance

While the internal audit findings do not impact Monitor's Compliance systems directly, there will be a need to consider whatever standards may be defined for quality and clinical governance as a part of future Compliance activity in order to maintain the same standard after authorisation. Following the work on Assessment, Monitor will also need to agree with its stakeholders what the new threshold for quality and clinical governance means under Compliance, how their mutual roles fit together and contribute to effective monitoring of FTs' performance and what information needs to flow between them.

Changes that we recommend include a range of measures designed to increase the level of evidence and assurance that Monitor should seek regarding the performance of individual FTs. The matters we raise represent a menu from which Monitor will need to adopt a number depending upon the circumstances, their feasibility and the relative cost benefit. The intention behind these recommendations is to reduce the risk of failing to detect non compliance at an early stage.

Intervention

When Monitor detects significant non compliance in performance at an FT it becomes an Issue Trust; such FTs are escalated and the intensity of regulatory activity increased through the intervention system.

Through the audit we have identified some administrative matters that we believe should be addressed, relatively simply. We are also aware of changes to intervention processes that have continued as a part of Monitor's natural development during the last 18 months. There are also objectives cited in the Corporate Plan 2009-2012 relating to Governors which we believe need to be progressed as they are consistent with our findings.

Structural matters

In addressing the specific recommendations made in relation to Assessment, Compliance and Intervention there are a number of related matters that will need to be considered.

Management Capacity

Monitor has continued to develop and strengthen its senior management team since its creation. The activities required of Monitor in relation to Mid Staffs were handled within its regular management capacity.

We believe that Monitor should engage clinical management skills to assist the existing management team in addressing the actions envisaged by this report. As a part of the actions being developed, we expect Monitor to define what skills and competencies might be required to best address its continuing needs. Depending upon the outcome we would expect a decision to be made regarding the need for clinical management skills as an integral part of the management structures, whether in Assessment, Compliance or elsewhere. Such skills would be expected to help Monitor discharge its role and not to take over roles encompassed by the CQC and the PCTs.

2. Executive summary (continued)

Stakeholder relationships

In developing its view of clinical governance Monitor will need to use its key stakeholder relationships to ensure that there is a mutual understanding and agreement of any position reached. This should include confirming the basis of Monitor's role in relation to clinical governance, the threshold determined for Assessment and the nature of the assurances available from stakeholders in support of the elements of the overall structure for which they may be responsible.

While a positive set of assurances is obtained during Assessment, Compliance is based on negative assurances and it is, accordingly, more difficult to identify non compliance. Agreement amongst the stakeholders of their mutual roles within the overall framework will be vital if the effectiveness of the broader regulatory system is to be maintained. This should include mutually agreeing the practicalities of maintaining prompt information flows amongst the stakeholders.

In practice this is an opportunity for the key stakeholders to revisit the detail in the architecture of the regulatory system so as to make sure that there is:

- Sound mutual understanding of the respective roles and responsibilities;
- Clarity of purpose and terminology amongst stakeholders; and
- Mutual agreement on detailed roles, activity and information flows.

Management action

We are aware that Monitor has already identified and addressed some of the matters referred to in this report. The Corporate Plan 2009-2012 also includes activities related to our recommendations. Therefore, we have sought to position matters raised and the related recommendations in that context.

We are also aware that certain of our recommendations are of necessity subject to agreement with other stakeholders or are subject to Monitor's need to analyse the feasibility and cost/benefit.

Acknowledgement

We would like to thank the many members of Monitor's management and staff for their assistance during this review.

Recommendations

The main recommendations that we make in the body of this report are:

Area	Recommendations
Assessment	1. Obtain stronger assurances at Assessment on the state of quality 2. Stronger focus required on quality and clinical governance
Compliance	3. Redefine the quality and clinical governance thresholds in Compliance 4. Enhance stakeholder information flows to help assess compliance against revised thresholds 5. Include an evaluation of the impact FT plans have on clinical risk 6. Provide access to clinical management skills 7. Increase the nature and level of assurance obtained on clinical data and clinical governance
Intervention	8. Consolidate intervention system documentation 9. Document decisions not to intervene 10. Enhance central documentation of events at Issue Trusts 11. Increase the level of engagement with Governors
Structural matters	12. Continue to strengthen the senior management structure and skills including clinical management skills 13. Establish an interim recruitment process 14. Make use of stakeholder dialogue to continue developing information flows and working practices

3. Key findings and recommendations

In this section we set out our findings and recommendations. This section starts with a narrative that explains the findings established by the audit. It is followed by summarised findings and recommendations structured as:

In the detailed findings and recommendations we have differentiated between those where Monitor is in a position to implement the recommendation itself from those that are dependent on further discussion, development and agreement with stakeholders, for example, the CQC, the DH, SHAs and PCTs.

Key

- Findings
- Recommendations primarily within Monitor's control
- Recommendations primarily dependent on further third party dialogue

3.1 Key findings – Assessment

Background

The Assessment process at Monitor is designed to establish whether or not a Trust is ready for Foundation status. Prior to receiving an application at Monitor other stages of approval will have already been reached. These are:

- The SHA-led Trust Development Phase: the SHA works with the Trust to prepare it for FT applicant status. The SHA is required to support the Trust in its application to the Secretary of State for referral to Monitor; and
- Secretary of State-led Support Phase: prior to referring the Trust to Monitor, the DH undertakes its own review of the potential FT applicant and refers that Trust to Monitor for Assessment and subsequent authorisation, should it be satisfied the Trust is ready for Foundation status. This referral provides Monitor a level of assurance from the DH that it considers the applicant Trust to be of a sufficient standard to become an FT.

Monitor undertakes a high level review of referrals from the Secretary of State through its batching process and at times has delayed FT applicants if there are high level outstanding issues.

Once in the Assessment process, prior to the authorisation of Mid Staffs, Monitor's work in Assessment to review quality and clinical governance included:

- A detailed review of board processes to identify and manage clinical risks including interviews with board members and clinical governance sub committees, interviews at directorate level and a review of action plans;
- Evidence of compliance with the NHS Litigation Authority's risk management standard of level 1 and above;
- A review of external information from other regulators e.g. external reviews by the HCC, including the Annual Health Check;
- Interviews with external parties, specifically the PCT and SHA;
- A review of performance data including target performance and standardised mortality; and
- A review of data from surveys and other benchmarking data, staff/bed ratios, day case rates, average length of stay and bed occupancy.

Assessment teams also were beginning to seek views from the HCC's local representative, although this was not a formalised and consistently applied component of Monitor's Assessment process.

Through these consultations and the analysis performed by the Assessment team, Monitor seeks to establish whether there are any negative indicators of quality or clinical governance effectiveness.

In the autumn of 2007 and up to March 2008 the primary basis of the evaluation of quality performance was on the DH Targets and National Core Standards as well as Monitor's own assessment of the effectiveness of broader governance processes at the FT applicant as described above.

The purpose of Monitor's process has not been to re-evaluate the quality performance data provided by the SHA, PCTs and HCC (now the CQC). It has been to understand what that information indicates and whether there are any indications of management strength or weakness in the context of clinical governance processes i.e. the effectiveness of oversight of quality performance within the Trust.

Monitor defers decisions on FT applicants pending receipt of independent reviews on topics of concern related to clinical governance or where broader governance concerns exist. Decisions are also deferred if an FT applicant is subject to an independent clinical inquiry.

Finally, there is no clear definition of what constitutes good / best practice in clinical governance that has been agreed by the current key stakeholders, including the CQC and PCTs. Accordingly there is no agreement amongst stakeholders of the key indicators of potential weaknesses in quality performance and clinical governance.

Findings

The evaluation of quality and clinical governance relies heavily upon information from other stakeholders as well as self certifications from and dialogue with the FT applicant. The focus of the activity at SHAs, PCTs and the HCC is on historical quality performance. Other than the SHA-led Trust development phase prior to referral to the DH, and Mid Staff's own preparatory work to prepare for FT status, no specific pieces of work were undertaken by stakeholders outside of their normal cycle of activity to provide further assurance to Monitor of the status of quality and clinical governance at Mid Staffs prior to authorisation.

3.1 Key findings – Assessment (continued)

Findings (continued)

The historical financial information provided by FT applicants is audited by their external auditors. In addition, a firm of independent accountants is commissioned to conduct a historical due diligence review and provide an independent opinion on the two year working capital forecasts and on the financial reporting procedures. This is not the case on quality performance measures. There is no standard evaluation during Assessment of the potential quality implications of cost improvement plans (CIPs).

The quality indicators used by Monitor, at the time Mid Staffs was approved, were primarily the DH Targets and National Core Standards. However, the Assessment team did also review risk information and quality performance data provided by Mid Staffs. This included standardised mortality (SMR) data and a supporting CHKS report in 2007 commissioned by Mid Staffs to review clinical coding, as the Trust primarily attributed the high SMR to data concerns around coding. Mid Staffs had action plans in place to address the coding issues identified in the CHKS report.

Monitor consulted with stakeholders (SHA, PCT) during the Assessment process for Mid Staffs with the exception of the HCC. Neither the PCT nor the SHA expressed concerns about quality performance or A&E during these meetings with Monitor. However, at that time, Monitor did not, as a discipline, require written confirmation from all stakeholders that there were no outstanding concerns, contra indicators or other matters that Monitor needed to know at the point of authorising a Trust for Foundation status. The actual level of formal assurance provided from each stakeholder had not been specifically defined at that time.

The Board to Board (B2B) meeting did include, as a matter of course, challenge on quality performance. However, this was not necessarily as structured as the challenge of financial performance and did not consider in any depth the risks of reducing quality of service that might be associated with delivering a cost improvement programme (CIP) at the Trust.

The Assessment team at Monitor has developed a significant depth of experience since its inception. However, the Assessment team at Monitor does not include any long-standing experience of clinical management and clinical governance in health delivery. Monitor does have two non executives with clinical managerial experience (mental health and acute) and one of these attends an FT applicant's Board to Board meeting to provide more in depth challenge on clinical matters.

At the time of the Mid Staffs' Assessment, Monitor did not include as a part of its Assessment process a formal independent review of clinical governance at FT applicants prior to authorisation.

Changes made since March 2008

Following the authorisation of Mid Staffs, Monitor gained formal agreement from the HCC that they would confirm in writing for each FT applicant if any concerns existed or that no outstanding concerns existed, i.e. provision of negative assurance. Since July 2008, this has included a number of emails from the HCC to Monitor providing details of any outstanding concerns it was aware of at the FT applicant. From January 2009 the HCC (now CQC) provides Monitor with Organisational Risk Profile (ORP) reports summarising all outstanding concerns of which it is aware, including details of planned or ongoing investigations.

These FT applicant ORP Reports are updated before the B2B and prior to authorisation by Monitor to highlight any current outstanding concerns from the CQC. The Assessment Director at Monitor is working with the CQC to further evolve these reports.

Since the authorisation of Mid Staffs, Monitor has continued to evolve its Assessment processes. In particular, processes have been extended to cover a more systematic review of performance data including:

- Board reporting and analysis of standardised mortality rates;
- More detailed analysis of results from patient and staff surveys; and
- A review of themes arising from complaints and Serious Untoward Incidents (SUIs).

Monitor is also in dialogue with the NPSA to understand the level of additional information they can provide on each applicant FT over and above published data.

Meetings are now held with the DH Infection Control team to gain intelligence on applicant FTs' performance on HCAI (including review of action plans) and also with the DH Intensive Support team to obtain intelligence on 18 weeks performance.

3.2 Key findings – Compliance

Background

Monitor's Compliance system relies on the evaluation of quarterly and annual performance information and comparisons against budgets and targets provided directly by FTs, together with other third party information and intelligence, to identify matters of concern.

Mid Staffs had not been authorised long enough for the relevant issues cited by the HCC to be identified as a part of the Compliance system at Monitor. Therefore, there are no direct findings arising from Mid Staffs that impact specifically on Compliance. However, there are matters that we believe should be reconsidered by Monitor based on the findings within Assessment. These relate mainly to the lack of clarity regarding the threshold for quality and clinical governance being applied on Assessment as the basis for authorisation.

The matters that read across to Compliance are, broadly:

- **Threshold**: the quality standard being applied by Compliance to quality and clinical governance;
- **Stakeholder information**: What information is or ought to be used during Compliance to inform Monitor in discharging its responsibilities;
- **Forward look at Quality**: Whether and how the quality impact of business plans and CIPs should be considered as a part of the Compliance regime;
- **Clinical management expertise**: Whether access to additional expertise in clinical management within the Compliance team would provide Monitor with additional value in evaluating and monitoring FTs' performance; and
- **Assurances**: What assurances might be required from the stakeholders including the FT itself on a continuing basis regarding the effectiveness of clinical governance and quality of underlying data.

Changes made since March 2008

Since March 2008 a range of further information has been used by Compliance to evaluate the state of FTs. This now includes:

- More formal reviews of SUIs, complaints and surveys (staff and patients);
- The capture of relevant information in Monitor's holistic risk indicator one page report showing a heatmap of potential governance and clinical issues in the context of authorisation;
- More formal and greater interaction with PCTs and SHAs. For example, Monitor's Compliance teams more often combine their annual visits to the FT with SHA and PCT visits;
- Compliance managers leading on specific topics regularly liaise with a wider range of specialists at the DH for a number of the higher risk DH targets and standards contained within Monitor's Compliance Framework; and
- Since autumn 2008, Monitor's relationship managers in its Compliance team have attended the annual risk summits hosted by the HCC (now the CQC) to share knowledge with other regulators and stakeholders on issues identified at FTs.

3.3 Key findings – Intervention

Background

Any FT rated Amber within Monitor's Compliance Framework is regarded as an Issue Trust which places it within Monitor's escalation and intervention processes. Quality and clinical governance issues are reflected in Monitor's Governance Risk Rating within the Compliance Framework. For Amber rated Issue Trusts, Monitor requests additional information on the causes of the risk and the actions proposed and confirms its expectations and timeframe for action. Monitor may hold a formal regulatory meeting subject to the Trust meeting defined escalation criteria.

FTs are rated Red for their Governance Risk Rating when their service performance score (based on the DH Targets and National Core Standards) exceeds 3.0 and / or one or more aspects of governance gives rise to a concern that the FT could be in significant breach of its terms of authorisation. Additionally, FTs achieve a Red Risk Rating for Governance if they are Amber for 3 consecutive quarters for failing to achieve the same national requirement. For Red rated FTs, Monitor further increases the intensity of its monitoring activity. This includes a formal assessment as to whether an FT may be in significant breach of its authorisation.

A decision by Monitor to use its powers to intervene may result in changes to the Board or require an action plan, potentially with the use of external support and review. Monitor has to date formally intervened 7 times (in a total of 3 FTs) since its inception; twice for financial issues and five times for more general governance issues, of which two occasions were at Mid Staffs.

Findings

There are a number of documents within Monitor that refer to Interventions and their basis. However, there is no single document or manual that describes all aspects of regulatory escalation including the internal and external communications.

While records of events are maintained within Compliance on the Portfolio Update System, the system does not currently capture all meetings held by senior management. Therefore, the record lacks certain key information, events, external communications and decisions.

A series of decisions was made in relation to Mid Staffs between March 2008 and April 2009. While the final decision to intervene was clearly recorded, we were unable to find a clear record of support for earlier decisions such as the decision not to intervene during this period. Accordingly, it has not always been possible to check how decisions were made and their basis.

In 2009 after the publication of the Mid Staffs HCC report, Monitor met all the Governors of Mid Staffs. We understand that the Governors at that time were not clear as to Monitor's role and their powers and accountabilities. To date, there has been no training provided for Governors by Monitor or a predefined structure for such meetings, or mechanism for ongoing dialogue.

Changes made since March 2008

Since March 2008 a range of further measures has been introduced to the Intervention process to improve the information available to Monitor on the state of FTs' action and to provide a further stimulus to ensure timely and effective action. The measures adopted by Monitor now include:

- Increased use of third parties to undertake specialist reviews to determine whether there are deeper or specific governance concerns;
- Asking for evidence of changes made to address concerns over the previous 12 months as well as forward looking actions where Monitor is not convinced on the quality of clinical governance but all DH standards are being met;
- Engaging with Governors at Issue Trusts, when appropriate, to explain the seriousness of the breach and to provide a reminder of their accountabilities and responsibilities in driving mitigating action locally; and
- Clarification and publication of accelerated escalation processes for C.Difficile, MRSA, 18 weeks and Accident and Emergency waiting times; to reflect ongoing or potentially significant issues at a number of FTs, unrelated to Mid Staffs.

3.4 Key findings – Structural matters

Management Capacity

Since its creation in 2004 Monitor has operated with an annual budget of under £18M supporting a staff that has only recently grown to around 100 and a small senior management team. At 1 August 2009, Monitor has now authorised 122 FTs and as such is continuing to review resources required to respond to the increasing needs.

The most time consuming matters for the senior management after Authorisation, following a formal handover from Assessment to Compliance teams, arise from Issue Trusts and on Intervention. While Monitor has only formally intervened on seven occasions using its legal powers, over the years there has been a larger number of Issue Trusts close to Intervention when extensive senior management time and attention has been required.

Findings

At the time of publication of the Mid Staffs report and intervention in early March 2008, Monitor had another intervention in process.

Monitor's top management structure comprises a small number of individuals with limited capacity to manage multiple concurrent interventions. While there was sufficient management capacity, the volume of work limited Monitor's ability to address other matters in its Corporate Plan.

The Executive Chairman was heavily involved in discussions regarding Mid Staffs from March 2008 through to intervention. Due to this executive role, it was not easy for him to stand back to take a broader view of the needs of the stakeholders and any associated communications during this period.

While the senior management team has been drawn from a range of professional disciplines this does not include practical experience of clinical management.

The Executive Chairman has an extensive network of contacts across the NHS and throughout its stakeholder network. This is less well developed amongst other members of the senior management team.

Stakeholder relationships

Monitor has continuously evolved its processes since its inception in 2004 and has many established stakeholder relationships which are used to develop the effective flow of information in support of improved regulation.

We have observed the following changes in stakeholder relationship management, communication and interaction, since March 2008:

- Relationships with the newly formed CQC are under development at the time of drafting. The senior management teams of both organisations are now meeting on a monthly basis to agree a high level Memorandum of Understanding (MoU), with a view to determining detailed practical arrangements for ongoing liaison; and
- From 1 April 2009 PCTs have been charged with responsibility for holding FTs to account for quality performance where it is agreed within their contract. It is not yet clear what impact this will have on the level or quality of information on quality and clinical governance available to Monitor on Assessment and subsequently.

In order to address certain of the recommendations we believe that Monitor will inevitably need to enter into a more extensive dialogue with the key stakeholders in order to exchange information and ideas on topics such as defining:

- Clinical governance;
- What constitutes the minimum requirements at Assessment for clinical governance;
- What constitutes appropriate proxy indicators for clinical governance within the Compliance regime; and
- What might comprise a formal review of clinical governance.

3.5 Detailed findings and recommendations – Assessment

Findings	Recommendations
Monitor could improve its ability to manage the risks associated with authorisation by ensuring the completeness of assurances received from stakeholders.	1. **Obtain stronger assurances at Assessment on the state of quality:** Monitor should continue with its revised practice of ensuring that formal communication takes place with key stakeholders during the Assessment process and that written confirmation of any issues or concerns is obtained (where agreed) from each stakeholder at the point of authorisation to ensure clearance. Stakeholders Monitor should seek written assurance from include: the CQC, DH (and PCTs, SHAs where not covered by the DH process). Additionally, Monitor may wish to continue to consult with: the Parliamentary and Health Service Ombudsman, the Health Overview and Scrutiny Committee, NPSA, NHSLA, and Internal and External auditors of the Trust.
For Mid Staffs, some concerns were identified through the Assessment process regarding the impact of planned CIPs. At that time Monitor did not have a mechanism in place to evaluate the service quality impact of CIPs on Trusts, i.e. there was no forward looking analysis of the potential clinical impacts. Monitor's Assessment procedures at the time did not include a formal evaluation by an independent third party of clinical governance of FT applicants. Therefore, clinical governance was not supported by an independent opinion or as in depth analysis as received for financial governance.	2. **Stronger focus required on quality and clinical governance:** Monitor should continue to undertake its own analysis of quality performance and clinical governance but seek to rely on the information and assurances provided by its stakeholders on quality and clinical governance as much as possible. In order to reduce the level of risk Monitor will need to: a) **Redefine quality performance**: Where gaps are identified in quality performance, these should be explored as part of Monitor's review with the FT applicant and actions should be agreed to mitigate issues to an acceptable level. If Monitor's concerns on quality matters are not cleared, it should consider engaging an independent qualified third party to undertake a review of the relevant topic prior to authorisation. This might be a specific area such as MRSA performance. b) **Define clinical governance:** Monitor should develop a definition of clinical governance that addresses its Assessment (and Compliance) needs and validate this with its stakeholders to ensure consistency of understanding. c) **Identify any gaps in information available to evaluate clinical governance and address them:** Evaluate the information already received and its quality and work with the key stakeholders to identify and address gaps in information and evidence. d) **Clinical governance reviews**: Monitor should include in its Assessment programme a formal evaluation of clinical governance at FT applicants based on the framework defined and making use of the information available from its key stakeholders. While such review can be performed by Monitor's Assessment staff we believe that greater insights will be gained by using staff with extensive clinical management experience and / or requesting an independent third party to provide an opinion. e) **Forward looking assessment of clinical risks:** Monitor should define a formal scope of work to evaluate the forward looking impacts of the business plan on clinical quality in more depth. This should include a focus on the quality impact of CIPs. Formalised activities to enhance existing Assessment processes could include: requiring FT applicants to set quality objectives and measures on application; seeking comment in applications regarding the quality impact of business plans and considering using third parties to undertake focused exercise. f) **Focused in-depth challenge on quality and clinical governance at the B2B:** Monitor should use the information gained from the above work to develop a specific agenda for each B2B to provide a focused in-depth challenge on quality and clinical governance based on the findings from Assessment work performed. Consideration should be given to using clinical management specialists to enable more experienced challenge. g) **CQC Transition period:** It is not yet clear to what extent the work of the HCC and the resulting information flows, such as the ORP Reports, will be incorporated into an overall conclusion or rating of the quality performance of a Trust as part of its registration. Accordingly Monitor needs to establish a contingency plan that will address any shortfall in information during this transition period. This may include developing its own tests for quality and clinical governance effectiveness.

3.5 Detailed findings and recommendations – Compliance

Monitor should apply the learning gained from Assessment to ensure that the principles flow through into Compliance to maintain that same standard of performance.

Findings	Recommendations
The Compliance Framework makes use of the DH Targets and National Core Standards to underpin the service performance element in the Governance Risk Rating. Other information used includes SUIs, local press and patient and staff surveys, in line with Assessment practices.	3. **Redefine the quality and clinical governance thresholds in Compliance:** Monitor should re-evaluate the thresholds implicit in the Compliance Framework in the light of any changes being made to the Assessment process. In doing this Monitor will need to be clear as to the rationale for and basis of any differences between the two. As a part of this re-evaluation, Monitor should also consider whether it wishes to place more focus on quality and clinical governance matters by including a specific clinical governance element in the Compliance Framework, and the specific indicators it would use to measure compliance.
The range of quality indicators used in Compliance is not the same as that used during Assessment. This reflects the differences between the underlying bases used by Monitor for Assessment and Compliance. One document not used in Compliance is the CQC's ORPs. Other differences include less face to face time and greater reliance in Compliance on self certification by Trusts.	4. **Enhance stakeholder information flows to help assess compliance against revised thresholds:** Depending upon the decision regarding the threshold to be applied, Monitor may need to increase or change the quality and quantity of data and information it receives from stakeholders on quality and clinical governance in order to meet its objectives. For example, Monitor may consider whether its Compliance teams liaise with the CQC to receive the CQC's Trust specific ORP Reports outlining outstanding concern levels as they are updated. Any changes will need to be negotiated with the relevant stakeholders.
Forward looking clinical quality risks are not explicitly analysed in depth during the Annual Risk Assessment (ARA) process. From our review of a sample of Issue Trusts, it was not clear whether the current Compliance regime includes indicators to demonstrate how Trusts drive innovation and continuous improvement in the quality agenda.	5. **Include an evaluation of the impact FT plans have on clinical risk:** Monitor should consider how best to challenge an FT's forward evaluation of clinical risks. a) **Evaluate the impact of the business plan on clinical governance:** Monitor could research how to apply the forward looking process used at Assessment as part of the challenge of the quality impact of the business plans during the ARA process. This could include a review of the principal clinical risks and uncertainties and associated mitigation and a specific focus on evaluating the impact of CIPs on quality, where CIPs are of a material value. b) **Continuous improvement in quality:** Monitor could adapt the ARA process to request explicit inclusion of the clinical risks in the business plan as a trigger to help its challenge of an FT's focus on innovation and continuous improvement in their quality agenda.
Within the Compliance team, there is no practical experience of clinical risk management. The team have developed knowledge of clinical risks through their work since 2004.	6. **Provide access to clinical management skills:** As a part of its re-evaluation of the Compliance Framework, Monitor should consider the benefit to be derived from greater access to clinical management skills. We believe that this might enable a more effective challenge to quality and clinical governance matters.

3.5 Detailed findings and recommendations – Compliance (continued)

Findings	Recommendations
The Chief Accounting Officer is the Chief Executive at the FT and Monitor's Senior Relationship Managers liaise primarily with them, although practice varies across Compliance teams and often includes a wider set of individuals. Monitor relies primarily on Board self certification on matters such as quality standards and performance, but underpins this with other published information, soft intelligence and the analysis of the DH Intensive Support Teams. Where Monitor has concerns as to the basis of self-certification made by FTs, it has required independent reviews in the past. The level of assurance over clinical governance through the Compliance process is less rigorous than that required over financial governance. There are currently no formal requirements placed on Trust Boards or external auditors to positively validate quality data; although it is expected that Trust Boards will want and need to validate data in support of their own objectives. The Audit Commission's recent 2009 publication 'Taking it on Trust', highlighted concerns as to the level of reliance that should be placed on self certification processes and the strength of assurance provided.	**7. Increase the nature and level of assurance obtained on clinical data and clinical governance:** In order to reduce the risk of failing to identify emerging issues at FTs, Monitor should consider ways of strengthening the level of assurance it obtains over the actual performance level in FTs. There is a range of ways in which this might be achieved and we have provided examples below for Monitor's consideration, depending on the Compliance philosophy adopted in point 3 above: **a) Broaden interaction with individuals at the FT:** Monitor could broaden its Senior Relationship Manager interactions to include representatives from the FTs involved in clinical governance. Monitor could define minimum interaction, for example, formal discussion with FTs by the relationship team as part of the periodic or annual assessment of risk. Other key individuals might include the Medical Director, Chair of the Clinical Governance Committee (or equivalent), Head of Governance and Head of Risk Management. Monitor could include them in their face to face visits to the FTs in addition to the Chief Executive. **b) Self certification processes:** Monitor could investigate the feasibility and cost benefit associated with requiring FTs to establish assurance processes or a more formal challenge to their assessment of the quality of clinical data as an additional mechanism to support the Statement of Internal Control (SIC) in an FT's annual report and accounts. **c) Strengthen Internal Audit assurance:** Monitor could investigate the feasibility and cost benefit of requiring an FT's Internal Auditors to undertake an annual or periodic review of clinical governance and data quality as part of their Internal Audit plan to support the SIC. This might be a review focused on a particular topic or issue. **d) Periodic assurance on clinical governance and data quality:** Monitor could consider using an appropriately qualified third party to undertake periodic clinical governance effectiveness and data quality assurance reviews at FTs. This might be required at all FTs on a rolling basis. **e) Independent assurance provided by the FT's External Auditors:** Monitor could investigate the feasibility and cost benefit of changing the FT Audit Code to require FTs' External Auditors to provide more formal assurance regarding the effectiveness of clinical governance structures, activities, processes and underlying data quality. **f) Re-assess FTs periodically:** Depending on their risk appetite, Monitor could consider undertaking a more in depth review of FTs. This would involve a similar challenge process as on authorisation but could not impact authorisation itself. Such a review could be either following the ARA process if indicators of unacceptable residual risk are identified or on a rolling basis, for example every 3 to 5 years, to provide in-depth challenge to FTs' business plans, quality accounts and governance structures.

3.5 Detailed findings and recommendations – Intervention

Findings	Recommendations
There are a number of documents that describe the various elements of the Compliance and Intervention processes. These do not include a description of the role expected of Communications.	**8. Consolidate the intervention system documentation:** Monitor should consolidate the escalation and intervention processes and system in an Intervention Manual. This should include not only external actions with Issue Trusts but also internal roles and actions for each part of Monitor and cross working processes between senior management, Compliance, Communications, Legal and other teams.
For Mid Staffs, a number of internal meetings were held at which the potential need to intervene was discussed. There is no evidence to support the decisions not to intervene.	**9. Document decisions not to intervene:** When decisions are made not to intervene, Monitor should find a way to capture the basis of the decision in order to build up a case history of judgements for later reference and aid corporate knowledge and learning.
Since the inception of the Portfolio Update System in 2008, key events have been logged for each FT in the portfolio by the Compliance team. However, the entries for Mid Staffs over the period under review do not reflect all the meetings undertaken by senior management. External communications with Parliament, the public and broader stakeholders are not recorded in the system.	**10. Enhance central documentation of events at Issue Trusts:** Monitor should establish a mechanism to ensure that it can record in the Portfolio Update System all key events and communication associated with an Issue Trust. This revised process should include not just direct communications but also those with stakeholders. We are aware of the Information Project that is currently underway and it may make sense to include this recommendation in the scope.
At the time of authorisation the Governors have only just been elected. Monitor does not have the statutory remit to evaluate the adequacy of Governors' skills, competencies and performance. Some of the Governors at Mid Staffs were not aware of Monitor's role and the powers of the Governors and their accountability to Monitor during the period under review.	**11. Increase the level of engagement with Governors:** Monitor should engage with Governors as part of their stakeholder relationship management to maintain awareness of its role and Governors' accountabilities to Monitor. New draft advice for Governors has already been issued during 2009 for consultation. **a) Training for Governors:** Monitor should continue to encourage the development and provision of training for Governors as cited in the Monitor Corporate Plan for 2009-12. **b) Include Governors in the dialogue at Issue Trusts:** Should an FT become an Issue Trust at risk of Intervention, Monitor should consider formally briefing Governors, or their representative, to refresh their understanding of their role in challenging the Board's plans and to ensure they are aware of the level of concern at Monitor and the nature and seriousness of the breach. This may require Monitor and the Governors establishing a primary point of contact within the Governor group for each FT.

3.5 Detailed findings and recommendations – Structural Matters

Findings	Recommendations
At the time of publication of the Mid Staffs report and Intervention in early March 2008, Monitor had another Intervention running. Monitor's top management structure comprises a small number of individuals – with limited capacity to manage multiple concurrent interventions. While there was sufficient management capacity, the volume of work limited Monitor's ability to address other matters in its Corporate Plan. The Executive Chairman was heavily involved in discussions regarding Mid Staffs from March 2008 through to Intervention. It was not possible for him to stand back to take a broader view of the needs of the stakeholders and any associated communications as well as taking an active part in the operational aspects. Monitor's NHS clinical managerial experience and expertise is limited to two Non Executive Directors. The Assessment and Compliance teams do not include individuals with skills in clinical management.	**12. Continue to strengthen the senior management structure and skills including clinical management skills:** Monitor is in the process of recruiting a new Compliance Director (splitting the role of the Regulatory Operations Director) and a further Portfolio Operations Director and should continue to enhance its top level management structure in order to: – Enable focus on operational matters, while ensuring that the regulatory strategy continues to develop; – Provide more contingency and back-up cover; – Enhance flexibility when dealing with multiple interventions and assist with greater delegation; – Enable greater delegation; – Provide more capacity for change. **a) Access to senior clinical management skills:** We believe that Monitor should access skills in clinical management to support its actions in responding to the recommendations in this report. This would not require a permanent position, but would help Monitor to ensure that any developments made best use of knowledge on clinical management and clinical governance. Once the ongoing requirements are clear a decision could be made regarding the need to recruit and the appropriate skills. **b) Independent challenge role on Interventions:** As a part of the structure for Issue Trusts with a Red Risk Rating for Governance, Monitor should consider assigning an individual from the senior management team to take on an independent challenge role. The Executive Chairman could fulfil this role while the other officers address the operational aspects of the Intervention.
The Executive Chairman was able to identify interim managers for Mid Staffs using his personal contacts and networks. There is no formal process in place within Monitor to identify interim managers.	**13. Establish an interim recruitment process:** In order to be sustainable for the future, Monitor should plan how to identify interims in the event of future Intervention. We believe that this is likely to involve the increased use of personal networks amongst the senior management team.
The CQC and PCTs are still clarifying their roles and developing action plans for addressing their responsibilities. Given the extent of the CQC and PCTs' roles, the working relationships Monitor has with them will be fundamental in enabling it to discharge its duties to best effect in the future.	**14. Make use of the stakeholder dialogue to continue developing information flows and working practices:** Monitor already has an extensive dialogue with the various stakeholders and should continue to strengthen and formalise these relationships. This should include developing working protocols and encourage continuous improvement in: – Information flows; – Understanding leading practice approaches to clinical governance; – Strength of assurance provided; – Sharing and resolution of mutual concerns at Issue Trusts and problems using scenarios and stress testing; – Identifying and agreeing the most appropriate responses to emerging issues.

Appendix A. Glossary of terms

Acronym	Definition
B2B	Board to Board: Monitor's Board challenge the FT applicant Board's strategy and any risks and concerns identified prior to authorisation
CHI	Commission for Health Improvement (Healthcare Commission's predecessor)
CIP	Cost Improvement programme / plan
CQC	Care Quality Commission: primarily accountable for the inspection of healthcare bodies for clinical quality performance from 1 April 2009
DH	Department of Health
FT / FT applicant	Foundation Trust / Trust applying for Foundation Trust status
HCAI	Health care acquired infections e.g. MRSA
HCC	Healthcare Commission (Care Quality Commission's predecessor)
MoU	Memorandum of Understanding or principles of working between two organisations
ORP	Organisational Risk Profile report produced by the CQC on each FT or FT applicant summarising concerns
PCT	Primary Care Trust
SfBH	Standards for Better Health
SHA	Strategic Health Authority
SIC	Statement of Internal Control
SMR / HSMR	Standardised Mortality Rate / Hospital Standardised Mortality Rate
SUI	Serious Untoward Incident

Definition
Clinical Quality or Quality
Lord Darzi in 'High Quality Care for All' defined quality in the NHS as safe and effective care of which the patient's whole experience is positive. The components of clinical quality include patient safety, patient experience and clinical effectiveness, with performance measured by clinical indicators.
Definition:
We use quality or clinical quality in this report to refer to the components referred to above.
Clinical Governance
From 1999, Trust Boards assumed a legal responsibility for quality of care that is equal in measure to their other statutory duties (proper financial management of the organisation and an acceptable level of patient safety). Clinical governance is the mechanism by which that responsibility is discharged.
Clinical governance is the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish.
Clinical governance will be delivered via the Quality Framework, as described by Lord Darzi in 'High Quality Care for All'. There are seven steps in the Quality Framework: quality standards; measure quality; publish quality performance; recognise and reward quality; clinical leadership; safeguard quality; stay ahead.
Components to consider within the quality framework include risk management, clinical audit, research and development, patient involvement, information management, staff involvement, education / training and development.
Definition:
Within this report we use the term Clinical Governance to mean the combination of the structures and arrangements in place at, and immediately below, the Board level to manage and monitor clinical performance, plan and manage continuous improvement, identify performance that may be below standard or out of line, investigate it and take management action.

Appendix B. Staff interviewed and documents examined

Staff Interviewed

Name	Title
Bill Moyes	Chairman and Chief Executive
Adrian Masters	Director of Strategy
Stephen Hay	Chief Operating Officer
Kate Moore	Director of Legal Services
Rebecca Gray	Director of Public Affairs and Communications
Edward Lavelle	Regulatory Operations Director
Miranda Carter	Assessment Director
Yvonne Mowlds	Portfolio Operations Director
Patrick Fraher	Portfolio Operations Director
Stephanie Coffey	Senior Relationship Manager / Senior Compliance Manager
Paul Streat	Senior Relationship Manager / Senior Compliance Manager
Katie Cox	Compliance Manager
Carla Wilson	Senior Legal Advisor
David Hill	Senior Assessment Manager
Craig Watson	Assessment Manager
Claire Lucas	Assessment Manager
Anna Jefferson	Communications Manager
Jonathon Marron	Policy Director
Sonia Brown	Chief Economist
William Bessell	Q&T Compliance Manager

Documents Examined

Mid Staffs FT application documentation including the integrated business plan, historical due diligence, self certification, governance structures, risk management and performance data
Mid Staffs Board to Board papers and minutes
Mid Staffs Compliance Files from 1 February 2008 to date
Monitor Compliance Committee agendas, papers and minutes over the period under review
Monitor Board papers and minutes over the period under review related to Mid Staffs
Monitor communications sent and received regarding Mid Staffs over the period under review with a variety of stakeholders
Holistic risk indicators for a sample of Issue Trusts and supporting Compliance Committee papers
Example Organisational Risk Profile from the CQC
Example FT applicant Monitor Board Decision pack from 2009
Compliance Framework over the period and Monitor Compliance Escalation Procedures for Issue Trusts
HCC Investigation into Mid Staffs final report and drafts
Monitor's Guide for FT Applicants
Monitor Compliance Team and Assessment Team job descriptions

Appendix C. Summary chronology

Date	Event and High level Summary
Pre 1 October 2007	Mid Staffs Performance: 2006/7 HCC ratings = Fair (Quality), Good (Resources), 2005/6 HCC ratings = Fair (Quality), Fair (Resources), 2004/5 HCC star rating = 1*
1 October 2007 – 8 October 2007	Mid Staffs Assessment process begins following Secretary of State referral in June 2007.
8 October 2007 – 14 November 2007	Monitor holds meetings with Mid Staffs' Board, management and staff.
15 October 2007	Monitor meets Mid Staffs' SHA.
14 November 2007	Monitor meets Mid Staffs' PCT.
5 December 2007	Mid Staffs' Board to Board.
6 December 2007 – 25 January 2008	Communication between Mid Staffs and Monitor to clarify outstanding issues.
7 January 2008	Mid Staffs submits self certification.
30 January 2008	Monitor Board Decision on Mid Staffs.
1 February 2008	Mid Staffs is authorised by Monitor.
13 March 2008	HCC notifies Monitor of the investigation at Staffordshire Ambulance Service NHS Trust and the impact on Mid Staffs.
16 March 2008	HCC announces investigation at Mid Staffs.
March 2008	The Mid Staffs' Board decides to fund the shortfall in nurses.
March 2008	The Monitor Compliance team contacts the HCC's Investigations team and agrees ways of working and dialogue during the Mid Staffs' investigation.

Date	Event and High level Summary
March 2008	Monitor reviews the Mid Staffs' Assessment pack.
March to August 2008	Monitor maintains dialogue with HCC and Mid Staffs' Board.
26 March 2008	HCC meets Mid Staffs' Chair, CEO and Executive Team regarding the investigation.
8 May 2008	Monitor holds an early meeting with Mid Staffs' Board.
20-22 May 2008	The HCC Investigation team visit Mid Staffs' A&E ward.
23 May 2008	HCC letter to Mid Staffs summarising a formal notification of concerns and their provisional findings from the A&E visit.
May 2008	Discussion amongst the Monitor Executive Team regarding the potential need to intervene at Mid Staffs.
29 May 2008	Monitor holds a call with Mid Staffs' CEO to encourage early corrective action in response to feedback from the HCC.
May 2008	Mid Staffs engages PWC to provide support.
3 June 2008	Mid Staffs writes to the HCC summarising the actions being taken to address the concerns raised by the HCC's first letter.
6 June 2008	Monitor's Executive management meet to discuss whether to intervene at Mid Staffs.
June 2008	Mid Staffs starts its Emergency Care action plan in response to issues identified in the first HCC letter.
7 July 2008	Second HCC letter to Mid Staffs highlighting the themes of concerns raised by patients and relatives.
24 July 2008	Mid Staffs responds to the HCC second letter summarising their Confidence in Caring action plan.

Appendix C. Summary chronology (continued)

Date	Event and High level Summary
August 2008	Chairman of Mid Staffs' is re-elected by the Governors.
September 2008	PWC presents its initial report to Mid Staffs'.
October 2008	South Staffs PCT issues a Performance Notice on A&E.
October 2008	HCC Annual Health Check is published, showing Mid Staffs rated as: Good for quality and Good for resources.
October 2008	Mid Staffs is declared compliant with the Hygiene Code following an inspection by the HCC.
7-9 October 2008	HCC visits Mid Staffs focusing on governance.
15 October 2008	Third HCC letter to Mid Staffs summarising key areas for action arising from the investigation.
29 October 2008	PWC reports the findings of their governance review.
Late October 2008	HCC issues the first draft of its report to Mid Staffs and Monitor for comment.
November 2008	South Staffs PCT issues second Performance Notice on A&E.
27 November 2008	Monitor writes to Mid Staffs requiring Mid Staffs to redress and sustain performance in A&E by the end of 2008.
November 2008	Mid Staffs meet the A&E target throughout November
December 2008 and January 2009	Mid Staffs receives 3 further mortality alerts from Dr Foster and the HCC re December 2008 and January 2009.
22 December 2008	HCC issues the second draft of its report to Mid Staffs and Monitor for comment.
30 January 2009	HCC issues the third draft of its report to Mid Staffs and Monitor for comment.
20 February 2009	Monitor's Executive Chairman emails the Chairman of Mid Staffs summarising the areas that will be taken into account in determining whether an Intervention would be needed and what the likely course of action could be.
23 February 2009	Monitor Compliance team meets with Head of the HCC Investigations to discuss whether special measures may need to be applied.
3 March 2009 8.45am	Special Monitor Board meeting is held to discuss Mid Staffs, approve an Intervention and propose as an interim Chairman, and an interim Chief Executive.
3 March 2009 am	Monitor sends a letter by email to the Council of Governors at Mid Staffs explaining why Intervention was necessary.
3 March 2009 pm	Chairman of Mid Staffs resigns at the Governors' meeting.
3 March 2009 pm	The Monitor Executive Chairman formally requests David Stone to step in as interim Chairman at Mid Staffs.
3 March 2009 pm	Monitor issues a press release announcing the appointment of interim chair and the Mid Staffs Intervention Monitor issues Section 52 notices to the Trust.
5 March 2009	Monitor issues a press release announcing the appointment of an interim Chief Executive at Mid Staffs.
16 March 2009	Secretary of State for Health holds a meeting with Monitor, the HCC and advisors to discuss the HCC report.
By 17 March 2009	David Stone and Eric Morton were appointed as interim Chairman and Chief Executive respectively at Mid Staffs.
17 March 2009	HCC sends a letter to the Minister for Health highlighting that during the HCC's unannounced visit to the Mid Staffs A&E ward at the end of February 2009, significant improvement had been made when compared to the May 2008 visit.
18 March 2009	The HCC report on Mid Staffs is published. Covering letter to Monitor advises that no 'special measures' were required.
2 April 2009	Monitor visit Mid Staffs to gain an update. The Monitor team also meets the Governors of Mid Staffs.

Appendix D. Mid Staffs stakeholder information flows at Assessment