Monitor

Independent Regulator
of NHS Foundation Trusts

Management response to the Internal Audit Report on lessons learnt from Mid Staffordshire NHS Foundation Trust

3 September 2009

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Introduction and purpose of response

1. As the Independent Regulator of NHS Foundation Trusts our two core statutory roles are to:

    - Assess and authorise applicants for foundation trust status; and
    - Regulate foundation trusts to ensure they remain compliant with the terms of their authorisation.

2. Our approach, and the principle behind the foundation trust policy, is that the boards of foundation trusts have primary responsibility for the performance of their trust. Therefore, the focus of our assessment process is on the capability of the board to operate an autonomous organisation capable of providing the best possible care for its patients and service users and value for money to the taxpayer. The focus of our compliance activity is on ensuring that the board continues to manage the trust effectively. This includes the identification and management of financial risk and clinical risk (and indeed any other major risk to the foundation trust's performance and organisational health). Where boards fail to meet their obligations we consider intervening using the substantial powers granted to us in statute.

3. Following the significant failings in the quality of care at Mid Staffordshire NHS Foundation Trust (Mid Staffs) identified by the Healthcare Commission investigation (which started in March 2008 and completed in March 2009), Monitor used its powers to intervene appointing interim replacements for the Chair and Chief Executive. We again used our formal powers in July 2009 to appoint a full time chief executive for a period of two years starting in August 2009. We are now working with the trust, the Care Quality Commission (CQC) and other partners to ensure that the trust is progressing with its plans to return the hospital to a position where it is fully compliant with its authorisation and can provide a consistently good quality of care to its patients.

4. A number of reviews have been carried out concerning the events and current state of care at Mid Staffs, which have reported over the last few months. First, the Healthcare Commission's own report was published in March 2009. Subsequently reports by Professor Sir George Alberti on progress in A&E and related wards, and by David Colin-Thomé on the commissioners' role, have also been published.

5. Monitor's Board judged it would be helpful to consider how Monitor's own methods and processes could be improved to help reduce the risk of such failings in the quality of care in future. The Board therefore commissioned KPMG, who are Monitor's Internal Auditors, to conduct a review of lessons learned from the events at Mid Staffs between October 2007 (the start of the assessment process) and April 2009. The scope of the

review was focused on the areas of governance and clinical quality, where the Healthcare Commission report identified major issues at the trust.

6. Internal Audit reported to the Monitor Board in July 2009, making recommendations for improvements in Assessment, Compliance, Intervention and Structural Matters. The Board accepted all the recommendations.

7. Senior management prepared this response setting out actions to be taken to put these recommendations into effect. This document was also approved by the Board at the July 2009 Board meeting.

Overview of response

8. Monitor, as the Independent Regulator of Foundation Trusts, contributes to a system of quality regulation and improvement in the health sector. Efforts to develop and improve this quality system continue each year. Recent enhancements include the introduction of registration by the CQC (in full for healthcare providers from April 2010) and the work programme arising from the Darzi Report in 2008 covering areas such as Quality Accounts. The failings identified at Mid Staffs by the Healthcare Commission, and in subsequent reviews by David Colin-Thomé and Professor Sir George Alberti, have demonstrated the need to make the system of quality regulation more effective. The KPMG Internal Audit report describes the gaps in the overall system and identifies specific improvements to make Monitor's regulatory systems more effective. Addressing the recommendations of the report requires Monitor to consider how we can improve our own procedures - as we have done in this review - but also suggests we encourage our partners to consider changes in their own processes to improve the system as a whole. The key players in the system of quality regulation of providers are the Department of Health, strategic health authorities, CQC and Monitor. We will need to work closely together to ensure our various contributions are properly coordinated. The National Quality Board (NQB) provides an appropriate forum for this coordination.

9. Monitor's senior management team believes the various reviews over the last six months into the events at Mid Staffs point to the following main conclusions on our contribution to the system of quality regulation:

    - The essential need for risk-based regulation of hospitals has been reinforced, supported by **a development programme which helps foundation trust boards** in carrying out their role as the 'first line of regulation';
    - Given Monitor's statutory composition and framework, it cannot lawfully delegate any of its functions. However, in our consideration of the risks of failure **in matters of quality performance and safety, Monitor will seek to place significant weight on the advice and judgements of the Care Quality Commission** in order to avoid duplicating regulatory roles, expertise, and the monitoring systems and processes that they are best able to develop and operate. Consequently, improvements to the systems of assurance on quality will need to be agreed, developed and operated through close working with our partners in CQC and the Department of Health. In

particular, the authorisation threshold for foundation trusts with regard to quality performance will need to be periodically revised and restated as registration and periodic review is introduced, and as the wider approach to quality in the NHS evolves following the Darzi Report; and

- Monitor will need to continue to **enhance its approach to assurance on whether a foundation trust's board is adequately carrying out its role in ensuring good clinical governance** in the trust. By clinical governance we mean the combination of structures and arrangements in place at, and immediately below, the board level to manage and monitor clinical performance, plan and manage continuous improvement in patient care, identify performance that may be below standard or out of line, investigate it and take management action.

10. Monitor continually seeks to improve its processes. Many of the areas addressed in the KPMG Internal Audit recommendations are already scheduled for review in 2009-10 as part of our 2009-12 Corporate Plan. For example, changes have been planned to the Compliance Framework for 2010-11, to the Annual Risk Assessment round, and to our approach towards knowledge capture and management. There have already been significant enhancements to the Assessment process following the start of the Healthcare Commission investigation on Mid Staffs in early 2008 which the KPMG Internal Audit review supports. However, the KPMG Internal Audit has identified a number of areas where we judge that significant additions to our work programme are necessary. In particular a series of actions intended to strengthen our approach to gaining appropriate assurance that the trust board is ensuring good clinical governance.

11. As is the case with all regulators, Monitor has finite funding which it needs to allocate on the basis that best mitigates risk in the system. Many of our responses to the Internal Audit report will be subject to considerations of proportionality, consultation with the sector and, where appropriate, negotiation with our partners in managing the system, before the best detailed approach can be agreed on. However, we can set out proposals we intend to develop and test with our partners over the next few months.

12. The 14 main recommendations made by Internal Audit in their report are shown in the table below.

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 foundation trust plans have on clinical risks 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 capacity of 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

Responses to recommendations

Assessment

We agree with all recommendations in this section. While we have made significant improvements in the level of information and assurance gathered as part of our assessment process since March 2008 and focus increasingly on matters of clinical governance, we recognise the need to enhance our approach, in particular to clinical governance, and the need to work closely with partners to gain assurance around the quality of care provided by applicant trusts.

1. Obtain stronger assurances at Assessment on the state of quality

1. We will seek written assurances from the CQC and the Department of Health that they have no significant clinical quality concerns with the applicant before we take our authorisation decision:

- We currently ask for confirmation of any quality concerns from the CQC at two points in our assessment process to ensure we have an up to date view from the CQC before we take our authorisation decision. This confirmation includes details of any planned or ongoing investigations. As registration is fully introduced we will seek to change the basis of this written assurance to confirmation that CQC is content that the applicant is compliant with registration standards at authorisation, and that there are no planned or ongoing investigations. As the CQC develops its approach to Quality Risk Profiles we will also discuss with them whether the assessment summarised in those documents could provide us with an additional, useful source of assurance.
- We will write to the Department of Health before we take our authorisation decision to request written confirmation that they are not aware of any significant concerns which have arisen since the Secretary of State referral which should be considered as part of the assessment process. Where appropriate we would notify CQC of any such concerns.
- We will also continue to engage with other relevant stakeholders as part of our due diligence process on each application to understand any concerns they may have. This will include SHA, PCTs, the NPSA and the Parliamentary and Health Service Ombudsman.

2. Stronger focus required on quality and clinical governance

a. Identify any gaps in information available to evaluate clinical governance and address them;
b. Redefine quality performance;
c. Define clinical governance;
d. Conduct clinical governance reviews;
e. Conduct a forward-looking assessment of clinical risks;
f. Conduct a focused in depth challenge on clinical governance at the Board to Board; and
g. Conduct additional tests on quality during the CQC transition period.

1. We will determine whether or not there should be an additional quality 'bar' for foundation trusts, above the registration standard, to replace the current requirement in the Compliance Framework to comply with targets and national core standards. We will write to the Secretary of State to establish the Department of Health's view on this issue.

2. Subject to agreement with CQC, Monitor will place significant weight on CQC assurance that essential standards of quality performance are being met by the applicant and that services are safe. This will avoid Monitor duplicating the role of our partners in the system. We will also refer any serious concerns or risks on performance against essential standards which we identify during assessment to CQC for consideration.

   We will continue to conduct reviews during assessment of historic performance in specified areas related to our Compliance Framework:

   - on any national targets included in the Compliance Framework; and
   - on any key clinical metrics included in the Compliance Framework.

   As now, where necessary, we will consult and engage qualified third parties to support these reviews, for example the Healthcare Acquired Infections team at the Department of Health.

3. We will initiate a study to build on our existing work with applicants to develop an improved approach to evaluating during assessment the board's role in assuring clinical governance in the trust. This is likely to include:

   - research on good practice in clinical governance;
   - identifying existing sources of assurance on clinical governance;
   - working with our partners to determine how the level of assurance can be improved; and
   - considering how the judgement of the assessment team on clinical governance might best be supplemented through access to specialist advice and/or independent opinions.

   Once developed, we would introduce this new approach on assuring clinical governance into the assessment process for future applicants.

4. We have started to develop our approach to assessing the clinical risks associated with cost improvement plans; for example, we now request evidence on how the board has assessed clinical risks of cost improvement plans (CIPs) and undertake benchmarking analysis on future staffing ratios. But we recognise that our approach needs further development.

   We will conduct a review on how we could more effectively require applicants to consider the quality impact of their forward plans. For example, we could expect boards to set out:

   - quality improvement objectives and programme as part of the five year plan;
   - key performance indicators the board will use to identify if clinical quality is at risk, for example staffing ratios;
   - principal clinical risks to the five year plan; and
   - how they have assessed the clinical quality risks of CIPs.

   Once an improved approach to integrated business planning has been developed, we will enhance our approach to assessment, using third party expertise as necessary. A possible review of CIPs might include analysis and challenge during assessment of:

   - Evidence of the board setting the strategic direction for the CIPs;
   - Evidence of engagement with clinicians in the CIP programme and their sign off and ongoing involvement in its implementation;
   - Evidence of risk assessment of the CIPs and thorough evaluation of the clinical risks that could impact the organisation as a result of the CIP;
   - Evidence of how these are going to be managed and monitored during implementation of the CIP, i.e. clinicians have set clinical quality indicators they will monitor to ensure no adverse impacts on the business as usual activities as a result of the CIP; and
   - Evidence of how the board plans to keep appraised on the CIPs performance/progress against implementation and what oversight and performance monitoring (financial and clinical) is planned, i.e. oversight/governance of the CIP.

5. We will further develop Board-to-Board packs and meetings to encourage greater focus and challenge on clinical governance and on clinical risks to the business plan. Recent Board-to-Board agendas have already begun to develop in this direction resulting in some recent decisions to defer applications based on issues of clinical governance.

6. We agree we will need access to additional clinical governance skills. Once our approach to assurance on clinical governance is clearer we will determine the best balance for accessing those skills between in-house options (such as additions to the management team) and external expertise.
7. Significant developments to the system of quality regulation are planned over the next 18 months. In particular, CQC will introduce the full system of registration for

hospitals from April 2010. It will also develop both periodic reviews and the system of ongoing quality data monitoring, and we understand that the NHS Medical Director is planning to introduce additional quality tests for foundation trust applicants. In the transition period, before registration by CQC and these other enhancements have been completed, we will continue to place material weight on the CQC Organisational Risk Profiles and to conduct additional tests ourselves to conclude on the clinical quality performance of an applicant. We will require applicants to demonstrate that:

- they continue to meet the quality bar set by the Department of Health at the time of Secretary of State referral;
- They have a minimum governance rating on service performance as set out in the Compliance Framework of at least amber; and

We will also review the Organisational Risk Profiles from the CQC to ensure that:

- the risk rating attributed to overall level of concern is no worse than *minor concerns;*
- the risk rating attributed to the confidence of the trust's ability to meet regulatory requirements is at least *confident;* and
- the trust is not under investigation, no investigations are planned and there are no preliminary inquiries into mortality outlier data.

We will continue to:

- work with the CQC to develop further the assurance we can obtain from the Organisational Risk Profiles that we currently receive, in advance of the full introduction of the Quality Risk Profiles that the CQC will develop to inform the registration requirements;
- share quality concerns identified in the assessment process with the CQC and will request them to consider the impact of these concerns on their overall view of clinical quality of the organisation before concluding on the authorisation decision;
- require confirmation of any quality concerns from the CQC at two points in our assessment process to ensure we have an up to date view from the CQC before we take our authorisation decision;
- write to the Department of Health before we take our authorisation decision to request written confirmation that they are not aware of any clinical concerns which have arisen since the Secretary of State referral which should be considered by Monitor as part of the assessment process; and
- engage with other relevant stakeholders as part of our due diligence process on each application to understand any clinical concerns they may have. This will include SHAs, PCTs, NPSA and the Parliamentary and Health Service Ombudsman.

We will also continue to carry out our current work programme on clinical governance during the transition period.

Compliance

We agree with all recommendations in this section. Our compliance regime has been developed to ensure that we are able to identify current and emerging risks and ensure that they are dealt with effectively by the boards of foundation trusts. This system has worked well. We have increasingly worked with partner organisations to help us identify and then successfully address problems. The proposed actions below will help us to continue to evolve this approach, including refinement of indicators reflecting quality of governance.

3. Redefine the quality and clinical governance thresholds in Compliance

1. We will continue to develop how the introduction of registration standards should be reflected in the Compliance Framework.
2. We will evaluate quality metrics emerging from work led by the Department of Health and CQC's periodic review methodology to determine whether a selection of these could supplement, and possibly over time replace, the national targets currently used as indicators in the governance rating.
3. We will conduct a study to determine whether regular targeted evaluation of clinical governance, reflecting key elements of the framework developed for assessment, could be integrated into the compliance monitoring regime at an acceptable cost/benefit.

4. Enhance stakeholder information flows to help assess compliance against revised thresholds

1. CQC will be our primary source of information on clinical quality. We will hold monthly meetings with them to discuss:

    - emerging clinical quality concerns with specific foundation trusts (which will be informed by the CQC Quality Risk Profiles, as these develop);
    - handling of issue foundation trusts, where there are clinical quality concerns; and
    - potential interventions related to clinical quality issues.

2. We will continue to contribute to risk summits organised by CQC on clinical quality issues for foundation trusts.
3. We undertook a review in 2008, the "Information Project", to understand how Monitor could better capture, analyse and share relevant information on clinical quality and clinical governance and other information across Assessment and Compliance. We will continue to progress the work programme arising from that study, including recruitment of a Director of Knowledge Management in 2009 to lead future work on the design and implementation of our strategy on information management.

5. Include an evaluation of the impact foundation trust plans have on clinical risks

a. Evaluate the impact of the business plan on clinical governance
b. Include clinical risks in the business plan to promote continuous improvement

1. We will review and as appropriate revise the guidance to foundation trusts on consideration of clinical quality risks during the annual planning round. For example, requiring evaluation by the foundation trusts of the clinical risk implications of major CIPs.
2. We will conduct a study to determine the feasibility and cost/benefit implications of:
   - rating the clinical quality and clinical governance risk of future plans of all foundation trusts as part of the annual planning round; and
   - requiring more detailed risk assessment and mitigation exercises to be carried out for higher risk forward plans.

6. Provide access to clinical management skills

1. Monitor will continue to access and use qualified third parties to conduct targeted studies on particular clinical risk areas, for example A&E and MRSA. We will look to establish and develop relationships with additional sources of clinical expertise for such studies, helping to minimise duplication of such capabilities in the system e.g. CQC experts, National Clinical Directors, SHA Medical Directors and SHA Directors of Nursing.
2. As part of the recruitment and development of the senior team within Compliance, we will look to target and attract personnel with relevant hospital operational experience.
3. Once our approach to assurance on clinical governance is clearer we will continue to review the need to secure additional access to expertise in clinical governance.

7. Increase the nature and level of assurance obtained on clinical data and clinical governance

a. Broaden interaction with individuals at the foundation trust

Investigate feasibility of:

b. Additional self certification processes (to support the Statement of Internal Control)
c. Strengthen Internal Audit assurance
d. Conduct periodic assurance on clinical governance and data quality
e. Require independent assurance from foundation trust's external auditors
f. Reassess foundation trusts periodically.

1. Relationship Managers already have contact with a range of staff at foundation trusts, however greater consistency in our approach and interaction is possible. We will draw up a list of key officials at foundation trusts that Relationship Managers are expected to interact with each year, for example during the annual planning round or in-year relationship visits, or when specific clinical quality issues arise. This will ensure these foundation trust executives have regular access to Monitor to raise

quality concerns directly with us. These officials will include:

- a Medical Director;
- a Director of Nursing;
- a Chair of the Clinical Governance Committee or equivalent; and
- a Head of Risk Management or equivalent.

2. We will conduct a study to determine the feasibility and cost/benefit implications of requiring foundation trust boards to obtain greater assurance on clinical governance (including clinical data) through:

    - reporting in the Statement of Internal Control;
    - additional use of Internal Audit; and
    - additional assurance work by External Audit.

3. We will continue to develop with third party advisors a clinical governance review as an option for use with foundation trusts whose clinical quality performance or future plans indicate increased risk in this area.

4. We will conduct a study to determine the feasibility and cost/benefit implications of conducting in depth reviews of foundation trusts similar to an assessment. This could be either on a periodic basis or as part of the annual plan process with all foundation trusts being seen every few years, but trusts with greater risks seen more frequently. Alternatively this could be considered as an escalation option where the ongoing risk rating process suggested major problems.

Intervention

We agree with all recommendations in this section. We have used our formal intervention powers seven times but have in general been able to deal with emerging problems effectively working with trust boards without recourse to our statutory powers. The proposed actions below will help to formalise all elements of the process of intervention ensuring that we can be as consistent as possible in our approach and ensure knowledge is captured in the most appropriate way. These commitments also reflect the importance of governors in the accountability and good governance of NHS foundation trusts and enhance our direct relationship with boards of governors.

8. Consolidate intervention system documentation

1. We will develop and publish an escalation and Intervention Manual for use by all Monitor staff. This will consolidate the existing guidance and include further guidance to the extent gaps currently exist.

9. Document decisions not to intervene

1. Monitor already fully documents all decisions to use our statutory intervention powers. We will in addition minute meetings and other discussions at key decision points where, for instance, decisions are made ***not*** to intervene.

10. Enhance central documentation of events at Issue Trusts

1. We will establish, as part of the Information Project, mechanisms to ensure all significant communications relating to Issue Trusts are captured in a single central system, building on our Portfolio Update System, including:

    - senior management meetings and conversations with key Department of Health, SHA and CQC officials;
    - press releases and public statements; and
    - communications with Parliament, including written submissions and transcripts of oral evidence.

11. Increase the level of engagement with governors

a. Encourage training for governors
b. Include governors in the dialogue at Issue Trusts

1. Monitor will encourage the development of appropriate training for governors by third parties (such as the Appointments Commission) and by foundation trusts themselves. We have recently consulted on a guide for governors.

2. We will ask each board of governors to nominate a governor (other than the Chair) as our contact point for correspondence to be shared with the trust's governors.

3. We will, where appropriate, write to the board of governors of foundation trusts at risk of significant breach of their terms of authorisation:

- setting out the nature of the risk of breach, and possible consequences; and
- reminding governors of their role and of Monitor's role.

4. We will ensure that governors are notified of our actions where we have formally intervened.

Structural matters

We agree with all recommendations in this section. Monitor has intentionally remained a small organisation committed to employing high calibre staff and delivering maximum impact with the resources available to us. The findings in this section and our responses reflect the need for Monitor to develop both its internal resources and external sources of relevant information and support in order to effectively identify risks and manage the increasingly complex issues within the foundation trust sector.

12. Continue to strengthen the capacity of the senior management structure and skills including clinical management skills

a. Strengthen access to senior clinical management skills
b. Assign an independent challenge role on interventions

1. We agree we will need access to additional clinical governance skills. Once our approach to assurance on clinical governance is clearer, we will determine the best balance for accessing those skills between in-house options (such as additions to the management team) and external expertise.

2. As part of the recruitment and development of the senior team within Compliance, we will also look to target and attract personnel with relevant hospital operational experience. Though such experience is not identical to clinical governance experience, we believe there will be some gain in terms of better understanding of the operational processes and systems of hospital reporting on which clinical governance relies.

3. We have strengthened the senior levels of the Assessment team by appointing a second Assessment Director.

4. Monitor will continue to strengthen and formalise our relationships with external advisors who currently provide Monitor with advice on specific clinical issues. This includes the HCAI, A&E and 18 weeks teams at the Department of Health, senior clinicians and nurses and the CQC.

5. A senior individual within Monitor, who is not directly involved with the specific case, will be assigned to an independent challenge style role on trusts where we are proposing to intervene formally using our statutory powers. The scope of the challenge role will be set out in the Intervention Manual.

6. In addition, reflecting the growth in the number of NHS foundation trusts, and the number of potential issues in the future, we have already initiated actions to build further capacity within the senior part of our Compliance team:

    - the current role of the Regulatory Operations Director will be split into two roles – Director of Regulation and Compliance Director. This will provide additional senior resource to oversee the operation of compliance activities, whilst continuing to develop our regulatory approach; and

- we plan to increase the number of Portfolio Operations Directors from two to four by the end of 2009, which will allow us to also introduce increased experience in the operation of hospitals.

13. Establish an Interim recruitment process

1. We will extend our contact at a senior level with chairs and chief executives through a more systematic programme to ensure we establish and maintain a broader network of personal contacts when the need for the appointment by Monitor of interim chairs and chief executives and other senior executives arises.

14. **Make use of stakeholder dialogue to continue developing information flows and working practices**

We will continue to develop our working relationships with our partners, by:

1. Agreeing memorandums of understanding with both CQC and the Department of Health.

2. Developing working practices with CQC to support ongoing:

    - policy development;
    - authorisation;
    - monitoring, e.g. using risk profiles to identify issue foundation trusts
    - handling issue foundation trusts; and
    - formal intervention (both on registration standards and on breaches of the terms of authorisation).

3. Working as a member of the National Quality Board (NQB) to set out the design of the quality improvement system for providers including foundation trusts. In particular, we are currently working on a Mid Staffs sub-group to consider lessons learned for the system as a whole on how significant quality issues can best be identified and addressed in future. We will share the KPMG Internal Audit report and this management response with the NQB sub-group to assist their review.

4. Understanding how commissioners will track provider performance on clinical quality against contracts and how this can best be integrated with quality regulation. We will consider how best to develop this understanding – whether working through the NQB, or by working with a lead SHA.

5. Continuing to encourage PCTs to raise clinical quality concerns directly with Monitor at assessment or as part of the compliance process by building on the existing information we provide for PCTs and close working with the PCT Network.

6. Considering how best to ensure that Local Involvement Networks are aware of our role.

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