Monitor
Independent Regulator
of NHS Foundation Trusts

Update on progress following the Internal Audit report *Learnings and Implications from Mid Staffordshire NHS Foundation Trust*

5 August 2010

Contents

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Context

Mid Staffordshire NHS Foundation Trust was authorised by Monitor on 1 February 2008. The Healthcare Commission commenced an investigation into the quality of care at the trust in March 2008 and published its report on standards of care on 18 March 2009.

In response to the Healthcare Commission's report, Monitor's Board commissioned a review from Monitor's internal auditors, KPMG, to assess learnings for both the assessment process of applicant NHS foundation trusts and the ongoing compliance of NHS foundation trusts.

KPMG's report *Learnings and Implications from Mid Staffordshire NHS Foundation Trust* covered the period from 1 October 2007 to 30 April 2009, and was published by Monitor on 3 September 2009.

The report made 14 recommendations across Monitor's assessment, compliance and intervention activities. It also considered wider structural matters related to the regulation of healthcare, in particular recognising the important inter-relationships between the various regulators.

Monitor's Board accepted all the recommendations and agreed follow up actions as set out in Monitor's *Management response to the Internal Audit report on lessons learnt from Mid Staffordshire NHS Foundation Trust* which was published alongside the KPMG report on 3 September 2009. At the same time it established a Steering Committee to oversee the delivery of agreed actions to meet each of the recommendations.

Since then, in addition to Monitor's ongoing scrutiny of performance at the trust, and periodic reviews of progress undertaken by the Care Quality Commission, Robert Francis QC has also published the findings of his review of the trust which covered the period from January 2005 to March 2009. The National Quality Board also published a report in February 2010, *Review of Early Warning Systems in the NHS: Acute and Community services,* based on learnings from the events at Mid Staffordshire NHS Foundation Trust.

Purpose of this report

This report sets out the actions taken and progress against each of the recommendations in the Internal Audit report. A summary of these recommendations is set out below. This is followed by the detailed recommendations from the Internal Audit report, together with Monitor's initial management response to each recommendation as set out in the reports published in September 2009. Associated with each (and highlighted by a surrounding box) are the actions taken to date. Any remaining work to conclude is set out at the end of the report.

Going forward Monitor will review all actions and requirements in light of the recently published Department of Health White Paper *Equity and Excellence: Liberating the NHS.*

Any references or actions referred to in this report are not intended to replace the regulatory framework set by Monitor and with which NHS foundation trusts comply. Further information about Monitor and how it regulates NHS foundation trusts is available on our website and in publications including the *Compliance Framework 2010/11*, *Memorandum of Understanding with the Care Quality Commission* (and the detailed Working Practices document).

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 NHS 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

Recommendations, initial management responses and actions taken

Assessment

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

1.1 *Initial management response (Sept 2009)*: We will seek written assurances from the Care Quality Commission 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 Care Quality Commission at two points in our assessment process to ensure we have an up-to-date view from the Care Quality Commission 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 the Care Quality Commission is content that the applicant is compliant with registration standards at authorisation, and that there are no planned or ongoing investigations. As the Care Quality Commission 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 the Care Quality Commission 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 strategic health authorities, primary care trusts, the National Patient Safety Agency and the Parliamentary and Health Service Ombudsman.

Actions taken:

Care Quality Commission assurances

As part of our work to agree the quality bar for authorisation as described under our response in 2.1 below, we have agreed wording for a formal letter of assurance that we will receive from the Care Quality Commission before we take our authorisation decision.

This letter sets out the Care Quality Commission's up-to-date view on compliance with registration standards and confirmation that there are no planned or ongoing investigations as detailed below.

Care Quality Commission Assessment of Quality of Care for [name of applicant trust]

I have reviewed the Quality Risk Profile (QRP) for [name of trust] which details the Care Quality Commission's current view of the risks to registration for this organisation. I can confirm that the data and information in the QRP is the most up-to-date that we have. I have also reviewed the most recent judgement of compliance against registration requirements and can confirm:

a) *The overall judgement for the most recent review of compliance for all of the provider's locations is [compliant / minor /moderate concern of compliance] and [high] level of confidence in the provider's capability.*
b) *The Care Quality Commission has no current information, either in the QRP or via other sources, identifying risks that would trigger the need for a responsive review of compliance.*
c) *No enforcement or investigations activity is ongoing or due to begin including preliminary investigations into mortality outliers.*

Department of Health assurances

We have worked with the Department of Health to agree the wording of a formal letter that will be provided to Monitor before we take our authorisation decisions. From January 2010 onwards we have received a letter from the Department of Health which confirms the date the Secretary of State made the decision to support the application and that they are not aware of any further matters since that date that may have materially affected the Secretary of State's decision.

We have highlighted in our update to the *Guide for Applicants* that if any issues are raised in the letter from the Care Quality Commission or the Department of Health, which could affect the authorisation decision, we are likely to decide to delay any authorisation decision until the specific matters are satisfactorily resolved.

2. *Recommendation*: *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

g. Conduct additional tests on quality during the Care Quality Commission transition period

2.1 *Initial management response (Sept 2009):* 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 view on this issue.

Actions taken: We have worked with the Care Quality Commission and Department of Health to define the quality bar for authorisation which incorporates registration standards, the Secretary of State gateway threshold and Monitor's governance risk rating by reference to the *Compliance Framework*. The confirmed position is as follows:

From 1 April 2010 applicant trusts must demonstrate that:

(a) they are registered with the Care Quality Commission without compliance conditions;

(b) they continue to meet the quality threshold set by the Department of Health at the time of Secretary of State referral;

(c) the Care Quality Commission's current judgement of compliance against registration shows:

- the overall level of concern is no worse than

"*moderate"* and with "*high confidence"* in capacity;

- the Care Quality Commission is not conducting or about to conduct a responsive review into compliance;
- no enforcement/investigation activity is ongoing or planned including preliminary investigations into mortality outliers; and

(d) they have a governance risk rating, assessed by reference to the recently published *Compliance Framework* of no worse than amber-green.

This criteria for authorisation has been reflected in an update to the *Guide for Applicants* which was published in July 2010. We will continue to review the threshold or quality "bar" to ensure it remains appropriate in light of developments, in particular to the Care Quality Commission's processes to monitor compliance with registration standards (for example developments in the Quality Risk Profiles).

2.2 *Initial management response (Sept 2009):* Subject to agreement with Care Quality Commission, Monitor will place significant weight on their 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 healthcare system. We will also refer any serious concerns or risks on performance against essential standards, which we identify during assessment, to the Care Quality Commission for consideration.

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

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

As now, where necessary, we will consult and engage qualified third parties to support these reviews, e.g. the Healthcare-Acquired Infections Team at Department of Health.

Actions taken: We have agreed with the Care Quality Commission in the *Memorandum of Understanding* with them that we will place significant

weight on their assurance that essential standards of quality performance are being met by applicants and that services are safe. We have further developed the way we work with the Care Quality Commission during the assessment process through more focused meetings and in particular, regular dialogue with the Care Quality Commission's Operations Directorate. It is via these meetings that we raise any serious concerns or risks on performance against essential standards we have uncovered during the assessment process. We also provide the Care Quality Commission with a copy of any deferral or rejection letters to applicant trusts where clinical concerns have been identified.

We describe the way we work with the Care Quality Commission to inform our authorisation decision in the update to the *Guide for Applicants* published in July 2010. This reflects the position set out in the published *Working Practices* document as described in 14.2 below.

2.3. *Initial management response (Sept 2009):* We will initiate a study to build on our existing work with applicants to develop an improved approach during assessment to evaluating 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.

Actions taken: Monitor has undertaken a detailed study to identify good practice in this area to enhance our assessment process and then inform our approach to compliance. As part of this work we decided to adopt the terminology of "quality" governance, following the definition of "quality" in the Darzi Report in 2008, rather than "clinical" governance which has its own history as a topic. Quality governance is the combination of structures and processes at and below board level to lead on trust-wide quality performance

including: (a) ensuring required standards are achieved; (b) investigating and taking action on sub-standard performance; (c) planning and driving continuous improvement; (d) identifying, sharing and ensuring delivery of best-practice; and (e) identifying and managing risks to quality of care. We have developed a framework for quality governance against which we can assess applicant trusts. In summary, these proposals require applicants to provide:

- a self certification on quality governance;
- an accompanying board memorandum which explains the board's approach to quality governance, which enables the trust board to sign the self certification statement; and
- direct evidence supporting their responses.

A team of assessors will then assess and evaluate the quality governance arrangements at applicant trusts. The work will involve:

- ensuring quality governance arrangements support ongoing improvements in standards of care;
- structured interviews at and below board level to assess the arrangements for managing and reporting quality risks;
- a review of the effectiveness of key governance meetings, including the board and sub-committees;
- a review of documents and direct evidence provided by the trust; and
- third party interviews as appropriate.

Pilots of the above framework and approach have been completed with four foundation trusts, using both internal and external expertise. We have now evaluated the pilot studies and consultation responses to our enhanced approach to quality governance in assessment. We have concluded that for the majority of cases the enhanced assessment will be carried out by a Monitor led team with higher risk applications being assessed by an external audit firm experienced in quality governance assessments and access to clinical expertise (see 2.6 below for full details). The criteria, framework and approach are set out in the update to the *Guide for Applicants*, published in July 2010.

2.4 *Initial management response (Sept 2009):* We have started to develop our approach to assessing the clinical risks associated with cost improvement

plans (CIPs); for example, we now request evidence on how the board has assessed clinical risks of 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:

- their quality improvement objectives and programme as part of the 5 year plan;
- the KPIs they will use to identify if clinical quality is at risk, e.g. staffing ratios;
- principal clinical risks to the five-year plan; and
- how it has 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 the assessment of the:

- 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 risks 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 impact 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.

Actions taken: Understanding and assessing the potential implications of CIPs on clinical quality has been a key area of focus as part of our study into enhancing our approach to assessing quality governance at applicant trusts. As part of this work we have defined the standards that applicants should meet to demonstrate that they are sufficiently aware of the risks to

quality. We have also provided details of what good practice looks like against these standards together with further guidance on developing CIPs and suggested indicators to assess their potential quality impact.

As part of this enhanced approach to assessing quality governance, applicant trusts will be required to provide evidence of how the board monitors and understands current and future risks to quality and takes steps to address them. Specifically applicants will be required to demonstrate that they have evaluated financial and operational initiatives (e.g. CIPs and other business cases) for their impact on quality (for example, this could include benchmarking analysis, 'lean' analysis of current processes and analysis of historical evidence). Applicants will also be required to describe how clinicians are involved in the development of CIPs. Finally, applicants will be required to demonstrate how the impact of financial and operational initiatives on quality is monitored on an ongoing basis (post-implementation, i.e. which quality indicators will be tracked as an early warning indicator).

2.5 *Initial management response (Sept 2009):* 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.

Actions taken: Revised transitional Board-to-Board packs have been developed and adopted, for example including further detail on the impact of CIPs on headcount numbers and a description of how applicants monitor and manage CIPs for their impact on quality. We have now finalised the pro-forma Board-to-Board pack pages that will be used to capture appropriately the quality governance findings of future assessments.

2.6 *Initial management response (Sept 2009):* 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.

Actions taken: We have now evaluated the pilot studies and consultation responses to our enhanced approach to quality governance in assessment.

We have concluded that for the majority of cases the enhanced assessment will be carried out by a Monitor led team with higher risk applications being assessed by an external audit firm experienced in quality governance assessments and with access to clinical expertise. As part of the evaluation of the pilot study and feedback from the pilot sites we have concluded that we will not recruit clinical advisers to the assessment team but will continue to access clinical expertise where necessary. As detailed under 6.1 below we have continued to develop and build our network of expert advisers including access to clinical and nursing skills and the Department of Health intensive support teams which we will utilise where necessary during the assessment of quality governance at applicant trusts. We have recently made two Director level appointments into the senior compliance team with significant senior experience within hospital management who can provide support and advice to the assessment team.

In addition, we propose to enhance the challenge function to the assessment team by creating an external panel of quality governance experts comprising at least two clinical advisers and two partners from independent auditing firms (who have had significant experience in quality governance). For each assessment we will draw on the panel of experts to provide further challenge to the assessment team with a member of the panel acting as a quality governance sponsor on each assessment. The role of the sponsor is expected to cover: (i) reading Board-to-Board briefing papers; (ii) meeting with the team to probe and challenge on issues; (iii) potential for attendance and challenge at Board-to-Board meetings; (iv) identification of issues for follow up post Board-to-Board meetings; and (v) calibration advice.

2.7 *Initial management response (Sept 2009):* Significant developments to the system of quality regulation are planned over the next 18 months. In particular, the Care Quality Commission will introduce the full system of registration for hospitals from April 2010. The Care Quality Commission will also develop both periodic reviews and their 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 the Care Quality Commission and these other enhancements have been completed, we will continue to place material weight on the Care Quality Commission 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; and
- have a minimum governance risk rating on service performance as set out in the *Compliance Framework* of at least amber.

We will also review the Organisational Risk Profiles from the Care Quality Commission 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 also continue to:

- work with the Care Quality Commission 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 Care Quality Commission will develop to inform the registration requirements;

- share quality concerns identified in the assessment process with the Care Quality Commission 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 Care Quality Commission at two points in our assessment process to ensure we have an up-to-date view from the Care Quality Commission before we take our authorisation decision;

- write to the Department of Health before we take our authorisation decision to request written confirmation that it is 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 strategic health authorities, primary care trusts, the National Patient Safety Agency 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.

Actions taken: The above approach was implemented and has been in operation in the transition period between September 2009 and March 2010. The Foundation Trust Network was advised and details of these transitional arrangements formally communicated to all applicant trusts on 4 September 2009. Now the Care Quality Commission's registration process has taken effect (1 April 2010) our approach going forwards is as set out in 2 above. It should be noted that as part of the Department of Health applications process there is now a regular meeting of strategic health authority medical directors where current applications are considered. At that meeting a conclusion is reached which is considered to be the view of the strategic health authority medical director. The view of the strategic health authority medical director will carry significant weight within the decision whether to recommend Secretary of State support to the application or not.

Compliance

3. ***Recommendation*: *Redefine the quality and clinical governance thresholds in Compliance***

3.1 *Initial management response (Sept 2009):* We will continue to develop how the introduction of registration standards should be reflected in the *Compliance Framework*.

> *Actions taken*: The impact of the Care Quality Commission's registration standards (and any associated compliance conditions) has been incorporated in the amended *Compliance Framework* which was published on 31 March 2010. Our approach reflects the immediate governance risk associated with the registration of a foundation trust with either restrictive or other compliance conditions and then the enhanced risk associated with a foundation trust not satisfying requirements for their removal within the timescales set by the Care Quality Commission. When a trust is registered with a compliance condition it will immediately be rated at least amber-green for governance risk until such time as the condition is removed. For restrictive compliance conditions an immediate amber-red risk rating will apply on the same basis. Any foundation trust failing to meet the requirements of any condition within agreed timescales will be red rated for governance risk and subject to appropriate escalation procedures.

3.2. *Initial management response (Sept 2009):* We will evaluate quality metrics emerging from work led by the Department of Health and the Care Quality Commission'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 risk rating.

> *Actions taken*: Initial consultation on the potential introduction of risks identified by the Care Quality Commission in their Quality Risk Profiles was published by Monitor in December 2009, as part of its consultation on an amended *Compliance Framework* for 2010/11. These included a score being allocated for risks in the Quality Risk Profiles based on whether the concern was *"moderate"* or *"major"*. The *Compliance Framework* was published on 31 March 2010 and applies from 1 April 2010. Consideration as to further changes (to be incorporated in the *2011/12 Compliance Framework*) will be given in 2010/11 as the Care Quality Commission's approach and methodologies continue to develop.

3.3. *Initial management response (Sept 2009):* 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.

Actions taken: This is set out in the 2010/11*Compliance Framework*. Where there is evidence of potential quality governance concerns we are likely to use a similar in-depth review of quality governance processes and procedures as described in 2.3 above.

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

4.1. *Initial management response (Sept 2009):* We will hold monthly meetings with the Care Quality Commission to discuss:

- emerging clinical quality concerns with specific foundation trusts (which will be informed by the Care Quality Commission 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.

Actions taken: Monthly meetings with the Care Quality Commission have been and continue to take place, to ensure that emerging clinical concerns are identified and then acted upon as appropriate. The meetings are part of a comprehensive set of working practices agreed between Monitor and the Care Quality Commission that were published on 10 March 2010 and which can be found on the websites of both organisations.

4.2 *Initial management response (Sept 2009):* We will continue to contribute to risk summits organised by the Care Quality Commission on clinical quality issues for foundation trusts.

Actions taken: Monitor is represented on the National Collaborative Group, organised by the Care Quality Commission, which includes a number of other health partner organisations, which agree the approach and framework for all risk summits. To date these summits have been either planned (Planned

Collaborative Reviews, which are held in each strategic health authority region at least once every 12 months), or one-off meetings called due to specific concerns around a particular trust (Triggered Risk Summits). Monitor's involvement and contribution is an integral part of all the reviews and summits held relating to foundation trusts.

4.3 *Initial management response (Sept 2009):* We undertook a review in 2008, the Information Project, to understand how Monitor could better capture, analyse and share relevant clinical quality, clinical governance and other information across Assessment and Compliance. We will continue to develop 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.

Actions taken: A number of enhancements in Monitor's information management systems were introduced during 2009 and more will follow in 2010 and beyond. During 2009 Monitor commissioned a review of its information and knowledge management systems and processes and following that review established a new senior knowledge management role. In January 2010 we appointed a Director of Knowledge Management. We have approved an integrated knowledge management strategy to support the more effective capture, analysis, sharing and retention of information relevant to the performance of our role and implementation of this has commenced. The development of a more resilient knowledge management system, working closely with others in the healthcare sector (e.g. reviewing intentions with primary care trusts) where appropriate, will help support the early identification of potential problems, and their timely resolution.

5. ***Recommendation: Include an evaluation of the impact NHS 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

5.1 *Initial management response (Sept 2009):* 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.

Actions taken: Monitor's templates for the annual submission of three year plans by each foundation trust have been significantly amended for 2010/11 in part to assist in the early identification of potential risks to care quality from planned actions. In particular where significant cost reduction is planned, this will be highlighted as a potential risk and is likely to result in more in-depth analysis as part of a second stage review of plans, and a more detailed analysis of specific risks by Monitor. This additional focus on effective and integrated planning will assist boards of foundation trusts to understand the potential implications of their actions and their impact on healthcare provision. It will also allow Monitor to take action where there is evidence these risks are either not understood or not satisfactorily mitigated.

5.2 Initial management response (Sept 2009): 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.

Actions taken: We reviewed the feasibility (and cost/benefit implications) of introducing a separate rating for clinical quality and more detailed risk assessments. A set of criteria and triggers has been developed and incorporated in our revised approach to annual planning in 2010/11. These will assist in the early identification of risks. Where necessary, this will then result in further in-depth analysis and review being carried out (Stage 2 review). Whilst we do not envisage in 2010 a specific rating for clinical quality risk either on a quarterly basis or following the annual plan review, it remains a core focus of our regulatory activity and is reflected in our approach to compliance and planning risks.

6. ***Recommendation*: *Provide access to clinical management skills***

6.1 *Initial management response (Sept 2009):* Monitor will continue to access and use qualified third parties to conduct targeted studies on particular clinical risk areas, e.g. 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 healthcare system,

e.g. Care Quality Commission experts, National Clinical Directors, and strategic health authority medical directors and directors of nursing.

Actions taken: Monitor has continued to develop and build its network of expert advisers including access to clinical and nursing skills, combined with direct recruitment within the senior compliance team. In the past year we have for example:

- continued to develop our relationship with the Care Quality Commission and Department of Health intensive support teams. We continue to leverage off this knowledge and expertise when considering clinical quality and performance concerns;
- agreed with the Chief Nurse key senior nursing contacts with Department of Health. This allows us rapid access to senior nursing advice and expertise;
- agreed with the Medical Director of the NHS key contacts with senior medical advisers. This allows us access to medical knowledge and specialities in a range of situations where regulatory action may be necessary; and
- continued to build direct contacts with medical advisers, for instance to support interventions where necessary.

6.2 *Initial management response (Sept 2009):* 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.

Actions taken: Senior appointments have been made at Director-level within the compliance leadership team of individuals with significant experience of hospital management.

6.3 *Initial management response (Sept 2009):* 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.

Actions taken: As described under 2.6 above, we have now concluded on our approach to quality governance in assessment and plan to create an external panel of Quality Governance experts to provide additional challenge and support to the assessment team rather than recruit additional clinical advisers

on a permanent basis. We will continue to access external expertise in quality governance which is already in place. Where there is potential evidence of quality governance concerns in a foundation trust we are likely to use the expertise of the external quality governance panel as set out above as part of our compliance operations. We will also leverage off the knowledge and experience acquired in the assessment team.

7. *Recommendation*: *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. strengthening Internal Audit assurance;

d. conducting periodic assurance on clinical governance and data quality;

e. requiring independent assurance from foundation trusts' external auditors; and

f. re-assessing foundation trusts periodically.

7.1 *Initial management response (Sept 2009):* Relationship Managers at Monitor 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 the:

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

Actions taken: Guidance has been developed and published within Monitor that sets out our expectations and requirements regarding regular contact between our relationship teams and trust management. This covers key senior functions at a trust together with the minimum contact expected each year, either as part of the annual planning process and/or throughout the rest of the year. This will ensure:

- a consistent approach where appropriate towards Monitor's overall relationship management with trusts;
- where clinical quality or other relevant concerns arise which may result in a breach of the Authorisation, that all the key members of the trust board understand and are aware of Monitor's role and individuals within Monitor to contact;
- where clinical issues arise, that the relationship team will have already established regular contact with the senior clinical members in a trust, and its commissioners, to enable effective discussion to take place on a timely basis; and
- where regulatory escalation meetings take place, and there is potential for future intervention, that the Relationship Manager is placed to provide sound and evidence-based advice to the senior team in Monitor on the most effective regulatory action.

7.2 *Initial management response (Sept 2009):* 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.

Actions taken: An initial scoping document has been prepared, proposing a study to evaluate the feasibility of including the quality governance framework into the Statement of Internal Control, and has been agreed in principle by Monitor's Strategy Committee in April 2010. Subject to resource being available (following the conclusion of the government's review of "Arms Length Bodies" and management costs) this will be taken forward as a key workstream as part of the review and update of the *Compliance Framework* for 2011/12. The work is planned to take place in 2010 to consider the benefits and feasibility of requiring boards of foundation trusts to obtain

greater assurance on quality governance (including clinical data) through the above mechanisms. The outcome of the study will result in a set of options being presented to Monitor's Board followed by consultation and implementation as appropriate during 2011/12 as part of Monitor's wider regulatory framework.

7.3 *Initial management response (Sept 2009):* We will continue to develop with third party advisers 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.

Actions taken: This has been reflected in the amended *Compliance Framework* which applies from 1 April 2010, and also in our revised approach to the annual plan review and relevant processes set up as detailed under 5.1 and 5.2 above.

7.4 *Initial management response (Sept 2009):* 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 riskier trusts seen more frequently. Alternatively this could be considered as an escalation option where the on-going risk rating process suggested major problems.

Actions taken: The feasibility and cost/benefit implications of in-depth reviews were considered. As a result, a revised two-stage approach has been incorporated as part of the annual plan review in 2010/11. A set of specific criteria and triggers have been developed, and incorporated in the annual plan review process to assist in the identification of those plans that may be higher risk or may not reflect the quality of planning expected. For a selection of trusts which meet these high risk criteria, this will result in further second stage in-depth analysis and review (Stage 2 review) and subsequent meetings with senior management in the trust as appropriate.

Intervention

8. ***Recommendation*: *Consolidate intervention system documentation***

8.1 *Initial management response (Sept 2009):* 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.

> *Actions taken*: Monitor has now published the amended *Compliance Framework* which includes an outline of escalation and intervention processes. Based on this approach we have also now published a draft manual setting out in more detail our approach to intervention (and escalation) for internal use by all members of the compliance team and more widely within Monitor. This will be reviewed and, if necessary, amended in the coming months.

9. ***Recommendation*: *Document decisions not to intervene***

9.1 *Initial management response (Sept 2009):* 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.

> *Actions taken*: This approach has been adopted and where a trust is found in significant breach of its Terms of Authorisation but a decision is taken not to intervene, this is fully considered by the relevant committees and the Board, the minutes of which are published. These decisions also remain subject to periodic and ongoing review until a trust returns to compliance.

10. ***Recommendation*: *Enhance central documentation of events at issue trusts***

10.1 *Initial management response (Sept 2009):* 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, strategic health authority, and Care Quality Commission officials;

- communications with Parliament, including written submissions and transcripts of oral evidence; and
- press releases and public statements.

Actions taken: A new information management system has been developed and key parts have already been introduced throughout Monitor. Continued enhancements and development form part of Monitor's Information Project. The delivery of that project (described under 4.3 above) will ensure more effective capture, analysis, sharing and retention of all information relevant to the more effective performance of Monitor's role. The development within Monitor of a more accessible, searchable and resilient knowledge management system, together with a culture of knowledge sharing, will help support early identification of potential problems, and their more timely resolution.

11. *Recommendation*: *Increase the level of engagement with governors*

a. Encourage training for governors

b. Include governors in the dialogue at Issue Trusts

11.1 *Initial management response (Sept 2009):* Monitor will encourage the development of appropriate training for governors by third parties (such as the Appointments Commission) and by foundation trusts themselves. We currently have a Guide for Governors out for consultation.

Actions taken: Monitor published *Your Statutory Duties: A Reference Guide for NHS Foundation Trust Governors* in October 2009, setting out their statutory role and providing guidance on carrying out their duties. We have also worked with the Appointments Commission to assist it to launch a programme of training specifically aimed at governors (launched after the above guide with a pilot course in December 2009).

11.2 *Initial management response (Sept 2009):* 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 governors.

Actions taken: Monitor has established the requirement (after discussion with the Foundation Trust Network) for the designation by each foundation trust of a lead governor to ensure direct liaison between Monitor and the board of

governors but only in very specific circumstances. Appointments have been made and contact details received for lead governors for 119 (92%) of foundation trusts. The remaining trusts are in the process of finalising arrangements which will be in place by the end of July 2010.

11.3 *Initial management response (Sept 2009):* 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.

Actions taken: This has already been introduced and relevant processes will be documented in Monitor's internal escalation and intervention manual.

11.4 *Initial management response (Sept 2009):* We will ensure that governors are notified of our actions where we have formally intervened.

Actions taken: Our communication process with governors, as above, has now been developed and relevant changes introduced. This is documented in more detail in our escalation and intervention manual. In addition, where a trust is found to be in significant breach of its Terms of Authorisation but no intervention is considered necessary at that stage, this is published on our website and governors are also informed at that time together with the relevant background.

Structural matters

12. *Recommendation*: *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

12.1 *Initial management response (Sept 2009):* We agree we will need to access additional clinical governance skills. Once our approach to assurance and 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.

Actions taken: The approach to assurance on quality governance has been finalised as set out under 2.6 above. We have concluded that at this stage we will not recruit additional staff with clinical expertise to the assessment team but will create an external panel of quality governance advisers. We will use this panel to advise both on assessment and compliance quality governance concerns including advice on where to source appropriate clinical expertise to evaluate the concerns identified.

12.2 *Initial management response (Sept 2009):* 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. Though such experience is not identical to quality 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.

Actions taken: Two Director-level appointments have been made within the senior compliance team of individuals with significant senior experience within hospital management.

12.3 *Initial management response (Sept 2009):* We have strengthened the senior levels of the Assessment team by appointing a second Assessment Director.

Actions taken: A second Assessment Director has been appointed and commenced in role in September 2009.

12.4 *Initial management response (Sept 2009):* Monitor will continue to strengthen and formalise our relationships with external advisers who currently provide Monitor with advice on specific clinical issues. This includes the Healthcare-Acquired Infections, A&E and 18-weeks teams at Department of Health, senior clinicians and nurses and the Care Quality Commission.

Actions taken: Monitor has continued to develop and build its network of expert advisers including access to clinical and nursing skills, combined with direct recruitment within the senior compliance team (see 6.1 above).

12.5 *Initial management response (Sept 2009):* 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.

Actions taken: Having reviewed internal processes and organisational structures Monitor has created a Compliance Board Committee (CBC), which includes members of the Executive and two Non-Executive Directors and is chaired by Monitor's Deputy Chairman. The CBC provides independent challenge where Monitor is considering the significance of a breach of the Terms of Authorisation and also the potential need for the Board of Monitor to use its formal powers to intervene at a trust. It also considers all decisions as to whether or not a trust is likely to be in significant breach of its Terms of Authorisation prior to making a recommendation to Monitor's Board. The CBC's role, and the nature of this challenge, is also reflected in the escalation and intervention manual.

12.6 *Initial management response (Sept 2009):* 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 2 to 4 by the end of 2009, which will allow us to introduce increased experience in the operation of hospitals.

Actions taken: The structure of Compliance has been developed following the appointment to the new role of Compliance Director in October 2009. This appointment, together with the appointment of a Director of Restructuring and Mergers & Acquisitions, has provided Monitor with additional senior capacity in Compliance. There are also now four Portfolio Directors reporting to the Compliance Director. In addition we have created a specialist restructuring, mergers and acquisition team, to support these activities going forward. Furthermore, responsibility for developing our regulatory approach for the future is now the responsibility of the Strategy team, working closely with the Compliance team.

13. *Recommendation*: *Establish an interim recruitment process*

13.1 *Initial management response (Sept 2009):* 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.

Actions taken: Monitor has worked with a partner to build and establish a live database to include a pool of high quality and experienced leaders (Chairs and Chief Executives). This pool will continue to be developed to provide coverage and access in the event of formal intervention by Monitor focused on a need to enhance board leadership. This pool has now been established and plans are being developed to hold bi-annual networking events to continue to inform and develop best practice.

14. *Recommendation*: 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:

14.1 *Initial management response (Sept 2009):* Agreeing memorandums of understanding (MOU) with both the Care Quality Commission and the Department of Health.

Actions taken: Monitor and the Care Quality Commission have agreed and published an MOU, alongside detailed guidance on the ways in which Monitor and the Care Quality Commission work together at an operational level. These will remain under review and continue to evolve as necessary. A revised MOU has been drafted between Monitor and the Department of Health and is awaiting approval from the Department of Health and the new Chairman of Monitor.

14.2 *Initial management response (Sept 2009):* Developing working practices with the Care Quality Commission 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).

Actions taken: The working practices between Monitor and the Care Quality Commission have been revised, documented and published and should ensure aligned regulatory activity consistent with our respective roles. These remain under constant review. This ensures that where there are any clinical performance or safety issues, these are communicated in a timely manner to ensure effective action by the appropriate lead authority.

14.3 *Initial management response (Sept 2009):* Working as a member of the National Quality Board to set out the design of the quality improvement system for providers including foundation trust hospitals. In particular, we are currently working on a Mid Staffs sub-group to consider lessons learned for the healthcare 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 National Quality Board sub-group to assist their review.

Actions taken: Monitor has been working as a member of the National Quality Board sub-group and has shared the KPMG report and our management

response with this group. This work has supported/informed the National Quality Board's report to the Secretary of State *Review of Early Warning Systems in the NHS: Acute and Community Services* which was published in February 2010.

14.4 *Initial management response (Sept 2009):* 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 National Quality Board, or by working with a lead strategic health authority.

Actions taken: Monitor has further developed a better understanding of how commissioners will track provider performance on clinical quality against contracts, particularly through work with other NHS bodies. The role of commissioners in monitoring provider performance and quality issues is set out in the National Quality Board report *Review of Early Warning Systems in the NHS: Acute and Community Services* mentioned above. In addition, Monitor has issued a guide - *Briefing for Commissioners* - setting out who they should contact in relation to various governance concerns. Consideration is now being given as to how best to develop, share and embed this further to support commissioners and Monitor in our respective roles.

14.5 *Initial management response (Sept 2009):* Continue to encourage primary care trusts to raise clinical quality concerns directly with Monitor at assessment or as part of the compliance process by building on the existing primary care trust Briefing and close working with the Primary Care Trust Network.

Actions taken: Monitor has continued to build and share communication with key stakeholders, including commissioners, to ensure that all parties understand Monitor's role, approach and responsibilities. For example we have created a specific commissioner's section on Monitor's website, where information and briefings can be found. We have in addition conducted a programme of primary care trust briefings across the country, held engagement events with a number of primary care trusts and attended a Primary Care Trust Network board meeting. An ongoing communications and engagement strategy between Monitor and primary care trusts continues to be developed for the future.

14.6 *Initial management response (Sept 2009):* Consider how best to ensure that Local Involvement Networks (LINks) are aware of our role.

Actions taken: Monitor published information specifically for LINks in February 2010 which sets out the role of Monitor and NHS foundation trusts.

Remaining actions

In summary, 15 months following the publication of the Healthcare Commission's report into Mid Staffordshire NHS Foundation Trust, and nine months after publication of KPMG's report, Monitor has taken a wide range of actions to respond to key recommendations and enhance its processes, both in the assessment of trusts for NHS foundation trust status and in our ongoing compliance activities. Many of these actions focus on clinical quality and clinical governance. Others include our approach to the use of information to support effective regulatory activity. In addition, Monitor has also reflected a recognition of the need for better and more wide-reaching communication between regulators and with other key stakeholders.

Many of the actions we have taken are also highly relevant in the context of the National Quality Board's February 2010 report to the Secretary of State, *Review of Early Warning Systems in the NHS: Acute and Community Services.*

A summary of matters requiring further action, each of which are underway, is set out below:

Assessment

- 2.6. Set up the panel to provide the external aspects for the input of quality governance skills into the assessment process (for authorisation decisions made from 1 August 2010 onwards).

Compliance

- 4.3. Continued implementation of the integrated knowledge management strategy for the more effective capture, analysis, sharing and retention of information relevant to the performance of our role (ongoing throughout 2010).

- 7.2. A study will be carried out to consider the benefits and feasibility of requiring boards of foundation trusts to obtain greater assurance on quality governance (including clinical data) through various mechanisms (e.g. Statement of Internal Control). The outcome of the study will result in options being presented to Monitor's Board followed by consultation and implementation as appropriate during 2011/12 as part of Monitor's wider regulatory framework. This will be taken forward as a key workstream as part of the comprehensive review and update of the *Compliance Framework* for 2011/12.

Intervention

- 11.2. Finalisation of lead governor contact details for all remaining NHS foundation trusts (by end July 2010).

Structural matters

- 14.1. Final approval of the MOU between the Department of Health and the new Chairman of Monitor.

We will complete these remaining actions over the next few months, continue to measure the impact and effectiveness of all the actions we have taken and also to embed and evolve our approach where necessary.

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