KPMG

ADVISORY

Mid Staffs Follow Up Review

Monitor – Independent Regulator of NHS Foundation Trusts

24 June 2010

INTERNAL AUDIT, RISK AND COMPLIANCE SERVICES

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1. Executive Summary

Introduction

As part of our Internal Audit Programme in 2009 we undertook an audit within Monitor to identify learning and implications from events relating to the authorisation of Mid Staffordshire NHS Foundation Trust. The final report was issued on 5 August 2009. Monitor published the report and its formal response a few weeks later at the start of September 2009.   Since that time Monitor has been acting on the findings and recommendations in the report. This report sets out our view of the progress made by Monitor in taking action and implementing change to address the findings.

The scope of our work has included:

- Understanding and evaluating the project programme developed arising from the report and response;
- Confirming the nature of planned changes and evaluating them against the original recommendations;
- Establishing state of change; and
- Confirming the nature and status of any remaining planned actions.

Findings

Progress: Considerable progress has been made developing detailed actions and implementing change both within Monitor and in relation to its interactions with other NHS bodies to address the recommendations made. The nature of certain recommendations made it inevitable that some would require an extended period to implement. Accordingly we have taken note of, and considered, the timescales adopted within Monitor's action plan. We have also considered the nature and quality of the response developed and the implicit effectiveness and likely outcomes.

Management action: As a part of the response project, Monitor's management have taken account of other changes arising in the NHS landscape to help shape the content of its response. Therefore, in certain cases the action developed and changes made are not exactly as recommended because Monitor has adopted the spirit of the recommendation and designed and implemented a more effective change. For example, changes to the management structure in Monitor have enabled the decision making process for intervention to be changed so that there is independent challenge. We welcome and endorse the way this principle has been adopted because it has enabled further improvements to be incorporated into the changes being implemented than those envisaged when our report was drafted.

State of implementation: Of the fourteen recommendations made in our report:

- Eleven have either been fully implemented or are largely implemented and are due for clearance within a few weeks when finalised documents are formally approved and published; and
- Three will take longer to implement due to their nature. These are matters such as knowledge management and the continuing development of assurance over Quality accounts, which inherently have long term development timescales.

Where recommendations have not yet been fully implemented, this is because there are sound reasons. In each case we are satisfied with the state of progress and the quality of the solution being proposed. From our perspective, there are no recommendations that we regard as having an unsatisfactory status due to delays or a poor quality of response.

1. Executive Summary (continued)

Changes to date: The most significant changes made to date include:

- Completion of the Quality Governance ('QG') pilots and confirmation of the related decisions regarding their use within Monitor in Assessment and Compliance including updates to the Board to Board templates.

- The development of a detailed definition of QG that has been shared and agreed with the key stakeholders;

- Clarification of the mutual roles of the various NHS stakeholders in the use of the QG model in the authorisation and monitoring of FTs;

- The use of the new QG definition in the Assessment and Compliance & Monitoring functions; and

- The development of more structured working arrangements and practices between the key stakeholders for sharing of information and views on emerging issues and individual FTs.

Changes under development: The most significant changes still under development or not yet fully implemented are:

- Completion of a study into requiring Boards to increase the level of assurance obtained on clinical data and QG; and

- Confirmation of the Memorandum of Understanding with the DoH.

Actions still in process: We recognise that certain action items will continue for an extended period. The plans for these items are on course and are due to become an integral part of the management agenda at Monitor from later in 2010. Such items include:

- **Knowledge management**: required to complete the management responses to recommendations 4 and 10

- **Assurance over QG and data quality**: being further developed through the assurance over Quality accounts

The overall status of each recommendation is summarised on page 5 in this executive summary. A more detailed explanation of the status is set out in section 2 by recommendation and sub-recommendation as numbered in the original report where recommendations are not yet fully cleared.

Conclusions

1. Monitor has made significant progress in developing its response to our report and has completed and implemented all actions expected by this stage.

2. Six of our recommendations have been fully cleared and a further five are due to be completed in July 2010 following the approval of certain key documents by the Board and their publication.

3. We are satisfied with the quality of the actions taken and of the plans for completing the implementation of changes for the remaining recommendations.

4. We are satisfied that there are good reasons for the longer timescales shown for the three remaining recommendations and that it would make most sense to include these in business as usual from the summer of 2010. This includes the continuing development of knowledge management and on assurance over Quality Accounts, which is expected to continue for a period of years as a part of a wider initiative within Monitor.

5. We propose to review implementation of management's actions at a more practical level during the 2010/11 as part of the Internal Audit programme.

1. Executive Summary (continued)

Acknowledgement

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

Colour key:

We have retained the colour coding from the original report, which is:

Recommendations primarily within Monitor's control

Recommendations primarily dependent upon further third party dialogue

In addition to this analysis we have identified four different categories for the status of our findings in this report relating to the state of clearance. These are:

Actions have been designed that are sufficient and adequate for the purpose. These have been implemented.

Actions have been designed that are sufficient and adequate for the purpose. We have seen evidence of the planned implementation, which is imminent i.e. in the next 6 weeks

Actions have been designed that are sufficient and adequate for the purpose. We are aware of an implementation plan but implementation may not be for a period of over 6 weeks

Monitor is continuing to develop its actions but is on course with its implementation plans

We have only included in the detailed findings actions which are still in progress as an aid to understanding the state of management actions.

2. Executive summary (continued)

Area	Recommendations	Overall status	
Assessment	1. Obtain stronger assurances at Assessment on the state of quality	1. Assurances required on authorisation have all been clarified and agreed in principle with the relevant NHS bodies	🟩
	2. Stronger focus required on quality and clinical governance	2. A detailed definition of Qualify Governance (QG) has been piloted to support authorisation decisions and which will be used to support QG through NHS FTs	🟩
Compliance	3. Redefine the quality and clinical governance thresholds in Compliance	3. Compliance thresholds for Quality Governance have been redefined together with related metrics and included in the revised Compliance Framework	🟩
	4. Enhance stakeholder information flows to help assess compliance against revised thresholds	4. The detail of information exchanges, and related processes, with bodies such as the CQC and others has been developed and agreed in writing	🟩
	5. Include an evaluation of the impact FT plans have on clinical risk	5. The annual risk assessment process has been upgraded (now the APR) and this year's review will be completed in May 2010	🟩
	6. Provide access to clinical management skills	6. The senior management team has been strengthened and a standing list of Interims developed. External skills are also being contracted.	🟩
	7. Increase the nature and level of assurance obtained on clinical data and clinical governance	7. A study is in progress to determine the most appropriate method for requiring FT Boards to obtain greater assurance over QG through the SIC (and additional use of internal and external audit). This will complete later in 2010.	🟩
Intervention	8. Consolidate intervention system documentation	8. The system has been fully documented, including improvements and refinements. and has been published..	🟩
	9. Document decisions not to intervene	9. This approach is detailed in the Intervention manual.	🟩
	10. Enhance central documentation of events at Issue Trusts	10. The knowledge management project is being developed and implemented under the leaderships of a new knowledge management director	🟩
	11. Increase the level of engagement with Governors	11. Additional guidance has been developed and provided to Governors nationally on their role, that of Monitor and how and when to communicate	🟩
Structural matters	12. Continue to strengthen the senior management structure and skills including clinical management skills	12. Two Director level appointments have been made within Compliance with experience in hospital management. Approach to QG will be finalised now the pilot study is complete.	🟩
	13. Establish an interim recruitment process	13. An Interim recruitment process has been developed and implemented	🟩
	14. Make use of stakeholder dialogue to continue developing information flows and working practices	14. Detailed working practices have been developed and agreed with significant NHS stakeholders which includes information exchange and dialogue. The draft MOU with DH remains unsigned	🟩

2 Detailed findings – a) Assessment

Recommendations	State of change and implementation	Status
2. Stronger focus required on quality and clinical governance:		
a) Redefine quality performance.	A detailed definition of Quality Governance has been developed and agreed with the CQC and other NHS stakeholders. It has been agreed that this will form the mutual basis for any service quality related activity in regulation and how it covers quality performance and QG. Changes with the CQC came into effect on 1 April 2010. This will be detailed in an update to the Guide for Applicants which is due to be approved by the Board and published in July 2010.	
b) Define clinical governance.	QG pilot studies have been conducted and evaluated at four FTs. Following the evaluation of the pilot studies Monitor has concluded that specific clinical / operational expertise is not required within the Assessment Team. Monitor propose creating a 'Panel' of experts comprising of at least two Medical Directors and senior independent accounting firm consultants with specialism in Quality Governance. This is expected to be completed in July 2010.	
c) Identify any gaps in information available to evaluate clinical governance.	A quality bar has been defined with clear criteria for authorisation. Criteria are due to be published in an update to the Guide for Applicants which is due to be approved by the Board and published by the end of July 2010.	
d) Clinical governance reviews.	Monitor has completed a tendering exercise for preferred suppliers for support in the provision of QG skills to support its activity in this area as and when required.	
e) Forward looking assessment of clinical risks.	In the light of the pilots and their evaluation, changes have been made to the pro-forma Board packs for use at the Board to Board sessions during the Assessment process. Specific questions and in depth evaluation of Quality Governance including strategy, processes and structure, capabilities and culture and measurement are now included.	
f) Focused in-depth challenge on quality and clinical governance at the B2B	The balance between in-house and external options has been made following conclusion of pilots being conducted with four trusts as set out in 2(b) above. Monitor will draw on the panel of experts to provide further challenge to the team with a member of the panel acting as a quality governance sponsor on each assessment. This new approach is expected to commence in August 2010.	
g) Conduct additional tests on quality during CQC transition	Transitional arrangements were formally communicated to all Trusts in September 2009.	

2 Detailed findings – b) Compliance

Recommendations	State of change and implementation	Status
4. Enhance stakeholder information flows to help assess compliance against revised thresholds	• A review of Monitor's Knowledge Management Systems was completed during 2009 and a Knowledge Management Director was recruited in January 2010. The Knowledge Management Strategy was approved by the Strategy Committee in April 2010. Monitor are currently reviewing options to most effectively deliver the Strategy; two interim specialist appointments have been made (Database and CRM) and an ITT prepared to assist with delivery the first stage of the Strategy. However, due to the scope of the strategy, the implementation period is inherently going to extend beyond 2010.	
6. Provide access to clinical management skills	• An initial database has been created containing sources of clinical expertise for targeted studies. • Ownership and maintenance of the data base been assumed by the Compliance director. • Senior members of the Compliance team have been recruited with hospital operational experience. • The approach to accessing QG expertise within Compliance will be completed in the coming weeks following the completion and evaluation of the Pilot studies referred to in 2(b).	

2 Detailed findings – b) Compliance (continued)

Recommendations	State of change and implementation	Status
7. Increase the nature and level of assurance obtained on clinical data and clinical governance:		
a) Broaden interaction with individuals at the FT:	• The range of interactions with individuals at FTs has already been increased and now includes specifically the Medical director, Director of Nursing, Chair of the Clinical Governance Committee and the Head of Risk management.	
b) Self certification processes: **c) Strengthen Internal Audit assurance:**	• A study is in progress to determine the most appropriate method of requiring Boards to obtain greater assurance on QG through the Statement on Internal Control and additional use of Internal and External Audit. • A scoping document for the feasibility study is in place . Monitor has plans in place to contact a number of external consultancy firms to tender for the exercise. • It is expected that the study will be completed in the Summer of 2010 and a proposal will be submitted to the Board later in the year. Changes are due to be incorporated in the Compliance Framework and Monitor's Reporting Guidance for 2011/12.	
d) Periodic assurance on clinical governance and data quality: **e) Independent assurance provided by the FT's External Auditors:**	• Plans for the provisions of assurance over the state of QG and data quality are under development and the primary outcome will be delivered over the next year as a part of the annual audit cycle.	
f) Re-assess FTs periodically:	• A two stage approach has been developed to re-assess FTs periodically based on a risk assessment. This is due to be implemented as a part of the APR in the coming weeks and months.	

2 Detailed findings – c) Intervention

Recommendations	State of change and implementation	Status
10. Enhance central documentation of events at Issue Trusts:	• As part of the Information Project consideration is being given to the most appropriate mechanism to capture all significant communications relating to Issue Trusts and the effect this will have on the new CRM system. Progress has been made over the past few months following the appointment of an interim CRM specialist. It is envisaged that a solution will be in place before the end of the financial year (31 March 2011) although this is dependent upon the status of the current spending freeze. See also point 4.	
11. Increase the level of engagement with Governors:		
a) Encourage training for Governors	• Monitor has created guidance on the statutory guidance for Governors and has worked with the Appointments Commission to assist in developing a programme of training for Governors.	
b) Nomination of a Governor as a contact point	• All FTs have been written to and a Governor has been requested to be identified as a contact point. At the date of our report 91% of FTs have responded and the remaining Trusts are being followed up. It is expected that all FTs will have responded by the end of July 2010.	
c) Governors - write to Governors where risk of significant breach.	• The basis for writing to Governors has been included in the internal Escalation and Intervention Manual.	
d) Governors are notified when Monitor have formally intervened.	• The Escalation and Intervention Manual contains guidance on the communication process to be followed with Governors.	

2 Detailed findings – d) Structural Matters

Recommendations	State of change and implementation	Status
12. Continue to strengthen the senior management structure and skills including clinical management skills:		
a) Access to senior clinical management skills:	• Following evaluation of the Pilot Studies it is anticipated that the panel developed on assessment will also be used on compliance issues. A formal approach will be in place by the end of July 2010.	
b) Assign an independent challenge role on interventions.	• A Compliance Board Committee has been set up with two NEDs and the deputy Chairman of Monitor. Part of the remit of the Committee is to review all proposals for Trusts that may be in Significant Breach. This revised structure has been included in the Escalation and Intervention Manual.	

2 Detailed findings – d) Structural Matters

Recommendations	State of change and implementation	Status
14. Make use of stakeholder dialogue to continue developing information flows and working practices.		
14.1 I Agree MOUs - with DH	• Confirmation from the DoH of the Memorandum of Understanding is still outstanding.	
14.1 ii Agree MOUs – with CQC	• Agreed and in place in September 2009.	
14.2 Develop working practices with the CQC.	• Working practices have been developed and a regular programme of meetings are in place with the CQC.	
14.3 Design the Quality Improvement system for providers.	• Publication 'Early warning systems in the NHS' summarises the key findings on Quality Performance agreed by all key stakeholders via the National Quality Board.	
14.4 Understand how commissioners will track clinical quality performance against contracts	• There has been an ongoing campaign to engage Primary Care Trusts (PCTs). PCTs are sent quarterly reports of NHSFTs and are notified of authorisations. Monitor's website contains a bespoke area for Commissioners. • The role of Commissioners in monitoring provider performance and quality issues is also set out in the NQB report Review of early warning systems in the NHS. Acute and community services. • Monitor has issued a guide - Briefing for Commissioners - setting out who they should contact in relation to various governance concerns. Although this is an external document it has been copied to all staff for use in any discussions/briefings with PCTs.	
14.5 Encourage PCTs to raise concerns with Monitor.	• PCT briefings have been held and there is a specific Commissioners section on the website has been created.	
14.6 Consider how Local Involvement Networks (LINKS) are aware of Monitor's role.	• LINKS brochure published in February 2010 and sent to all networks and published on Monitor's website.	