

**Management response to
KPMG's internal audit report**
*Learning and Implications from
University Hospitals Morecambe
Bay NHS Foundation Trust*

26 June 2012

Management response to KPMG's internal audit report "Learning and Implications from University Hospitals Morecambe Bay NHS Foundation Trust"

Introduction and purpose of response

As the Independent Regulator of NHS Foundation Trusts, Monitor's statutory role includes assessing NHS trusts that apply for foundation trust status and authorising those that satisfy the required standards. Monitor authorised University Hospitals Morecambe Bay as a Foundation Trust on 1 October 2010. In October 2011, Monitor's Board found the Trust to be in significant breach of conditions 2, 5(1), 6(1) and 6(2) of its terms of authorisation, with the quality of care in maternity services and overall governance being the main causes for concern.

Given the brief span between authorisation and breach and the nature of the concerns, Monitor's board decided to review the case to see what lessons could be learned. Monitor's board commissioned KPMG, its internal auditors, to review events at Morecambe Bay between the start of the assessment process, March 2009, and 31st December 2011, and recommend any changes to Monitor's assessment process it deemed necessary. (The full text of KPMG's report is available [here](#)).

Overall, KPMG found that Monitor had conducted its assessment of Morecambe Bay correctly but there were nevertheless underlying issues concerning the quality of services at Morecambe Bay that the assessment process at that time did not uncover. Since that assessment, Monitor has been implementing a number of changes to the assessment process aimed at strengthening our capacity to test quality governance without overburdening applicant trusts.

The purpose of this response to the Morecambe Bay review is to document and accept the lessons learned and KPMG's two resulting recommendations, setting them in the context of Monitor's overall approach to assessing applicants for foundation trust status and ongoing improvements to our assessment process.

Monitor's approach to assessing applicants for foundation trust status

Our approach to assessment rests on the principle underpinning foundation trust policy, namely that the boards of foundation trusts have primary responsibility for the performance of their trust. Monitor's assessment process therefore focuses on the capability of the board to operate an autonomous organisation that can identify and manage clinical and financial risk. Specifically, our assessment process is designed to find out whether applicant trusts are (i) well governed, (ii) financially viable and (iii) legally constituted. To be authorised applicants must demonstrate that they meet these three tests and also that they are delivering services of a sufficient quality. In addition, our assessment process is designed to identify any material risk that applicants do not meet these tests without placing on them too heavy a regulatory burden.

Testing governance

The part of the process aimed at finding out whether a trust is well-governed comprises tests of the trust's organisational capacity, risk and performance management processes, quality

governance and financial governance. Taken together, the results of these tests should indicate whether a trust is ready to run as an autonomous organisation.

Testing quality of services

To understand the quality of services at an applicant, we need to know whether a trust produces good health outcomes for patients, its services are safe, and it offers a good patient experience. However, for the purposes of our assessment, the task of taking a view on the quality of services at an applicant trust falls largely to the Care Quality Commission (CQC), the quality regulator. The CQC has its own process for registering hospitals and ensuring they continue to comply with registration standards that reflect its essential standards of quality and safety.

Monitor does not want to increase the regulatory burden on trusts by duplicating the work of the CQC, so we give significant weight to the CQC's view of each applicant in our assessment. To assure Monitor that its services are of sufficient quality to merit authorisation, Monitor requires each applicant to demonstrate that:

- It is registered with the Care Quality Commission without conditions, meaning that the trust complies with the CQC's essential standards of quality and safety
- The CQC's most recent judgement shows that the CQC has no more than moderate concerns about the trust's compliance with its essential standards of quality and safety and that, overall, the CQC has high confidence in the trust's capacity
- The CQC is not conducting or about to conduct a responsive review or investigation into the trust (i.e. responding to identified concerns)

In addition, during the assessment process, Monitor communicates regularly with the CQC to understand any current quality issues and seeks the CQC's confirmation in writing that it has no major concerns about the applicant.

[Balancing the regulatory burden against risk](#)

Overall, Monitor's assessment process aims to keep the burden and cost of regulation to foundation trusts proportionate to the risks being managed. Therefore Monitor's assessment process is designed to identify material risks to the quality of governance at a trust and its financial viability. In addition, we work with the CQC to understand material risks to the quality of care a trust is providing.

Our assessment process is not designed to detect all weaknesses in a trust's operations. This risk-based approach to assessment is considerably less intensive than would be a comprehensive commercial due diligence exercise involving full-scope financial, commercial, clinical, operational and legal due diligence investigations. It reflects our aim to maintain the regulatory burden on the trust at an appropriate level.

Consequently, Monitor's approach does not involve detailed reviews of a trust's operations; rather, the assessment work focuses on governance at the Board and subcommittee level with limited probing into divisional performance. However, where our work identifies that an applicant is close to our authorisation threshold, we have to decide what deeper probing is required to conclude whether the applicant is unquestionably above or below Monitor's assessment bar.

Ongoing improvements to Monitor's assessment process

Of the 144 FTs that Monitor has authorised in the past eight years, so far only three have required intervention within 18 months of authorisation, suggesting that our risk-based approach to assessment is generally robust. That said, we are continually seeking to improve our processes. On 1 October 2010, Monitor introduced a new Quality Governance (QG) review into the assessment process in light of lessons learned from the assessment of Mid Staffordshire NHS Foundation Trust. These indicated that Monitor should increase its scrutiny of applicant boards' governance of quality performance which includes:

- Ensuring required standards are achieved
- Investigation and taking action on sub-standard performance
- Planning and driving continuous improvement
- Identifying, sharing and ensuring delivery of best practice; and
- Identifying and managing risks to the quality of care.

Monitor's QG review involves testing the applicant Board's processes, structures and capacity in quality governance against a set of good practice guidelines set out in Monitor's Quality Governance framework.

In September 2011, Monitor's Board initiated a comprehensive review of its assessment process to ensure this is as efficient and "fit for purpose" as possible for the remaining trusts to be authorised. This review incorporated a review of Monitor's new Quality Governance approach outlined above, as this had then been in use for a year.

The assessment process at Morecambe Bay

University Hospitals Morecambe Bay NHS Foundation Trust was referred to Monitor by the Secretary of State at the beginning of 2009, triggering the third and final stage of the trust's overall assessment for foundation status. During the assessment, Monitor's team identified a concentration of serious untoward incidents in the trust's maternity services (5 out of the 12 SUIs reported were in that department). These were referred to the Care Quality Commission (CQC). Monitor put Morecambe Bay's assessment on hold while awaiting the outcome of the CQC's resulting investigation.

The CQC had introduced a new system of registration against essential standards of quality and safety in 2010. On 1 April 2010, the CQC registered Morecambe Bay under this new system without conditions and set its overall risk rating for the trust at a level of minor concerns. This meant that the trust was within the quality performance threshold set by Monitor, so Monitor resumed Morecambe Bay's assessment.

In June 2010 the CQC informed Monitor that, in line with its new process and given previous concerns, it planned to conduct a responsive review into maternity services at Furness hospital. This review covered 6 outcomes against the 16 registration standards. The CQC concluded that the trust was compliant with the outcomes reviewed. In accordance with the agreed authorisation protocol, the CQC then provided Monitor with the required letter

confirming that the trust met the care quality criteria for authorisation and confirmed that the results of the responsive review were positive. The rest of our assessment work confirmed that the trust met the remaining authorisation criteria concerning quality governance (the trust just met the threshold on this standard), financial governance and viability, and the legality of its constitution. Monitor subsequently authorised the Trust on 1 October 2010.

In June 2011 the CQC conducted a second review at the trust's Royal Lancaster site which did not reveal any major concerns. However, during June 2011, following an inquest into the death of a baby who had been treated at the hospital in October 2008, the Coroner issued a rule 43 letter to the Trust informing them that he had identified issues that should be addressed to prevent other deaths occurring. The letter highlighted concerns about clinical governance and working relationships in maternity services at the Trust. As a result, the CQC conducted a further review of maternity services at all three of the Trust's sites in July 2011 during which the CQC found the Trust to be in breach of a number of quality and safety standards. In September 2011, the CQC issued an enforcement notice, triggering a review by Monitor of the Trust's governance. On 11 October 2011, Monitor found the Trust to be in significant breach of its Terms of Authorisation.

As a result of the significant breach decision, Monitor intervened at the Trust, requiring it to:

- i. accept the appointment by Monitor of expert clinical advisors to review underlying problems in maternity services and its interface with paediatrics; and
- ii. commission an independent review into overall governance, to be agreed with Monitor, including their approach to quality governance

These reviews were conducted between October 2011 and January 2012, the first by clinicians from Central Manchester and the second by PwC.

Findings from the KPMG Review of Morecambe Bay

As the significant breach occurred within one year of the decision to authorise Morecambe Bay and stemmed from issues similar to those identified during the assessment, Monitor commissioned KPMG to review the events of the case between 1 March 2009 and 31 December 2011 and identify lessons to be learned.

[Questions addressed by the KPMG review](#)

KPMG's review of Monitor's assessment at Morecambe Bay addressed the following four questions:

1. What was the scope of the assessment activity prior to authorisation and how was the work focussed and carried out?
2. Is there evidence to indicate (either way) that problems currently being faced by Morecambe Bay were present at the time it was authorised?
3. What else could have been done during assessment or subsequently to identify the issues currently being faced by Morecambe Bay?
4. What changes should Monitor make to its approach to Assessment as a result of the issues at Morecambe Bay?

Summary of findings

Overall, KPMG found that Monitor's assessment process was applied appropriately and by an experienced team. However, KPMG found it difficult not to conclude that the issues that eventually led to the Trust being in significant breach of the terms of its authorisation were present at the time of the authorisation decision. To uncover those issues—subsequently pinpointed by the Central Manchester review and the PwC governance report—Monitor would have needed to probe more deeply into operational performance at the trust and undertake further work during the assessment.

KPMG notes that the quality governance (QG) review of the Trust that Monitor carried out as part of its assessment was the first such QG review undertaken by Monitor. The Trust was, in fact, only subject to a QG review because of a further delay to its assessment due to issues arising from the Trust's current trading position. Originally the assessment had been scheduled to complete on 1 August 2010 but the delays pushed completion to beyond 1st October 2010, when Monitor introduced QG reviews as a standard part of our assessment process.

As a consequence, the QG review at Morecambe Bay was more limited in scope than those we carry out today. Specifically:

- Monitor viewed the CQC's registration and results of the CQC's responsive review at Furness hospital conducted in June 2010 as evidence that the Trust had dealt with the issues in maternity services. The assessment team did not probe more deeply into governance in this area as they sought to avoid duplicating the role of the Quality regulator.
- The QG review was the first to be conducted, following pilots during the consultation phase, so the process was still in development. Over the past year the assessment team has refined the QG review process and it now takes longer, to allow more interviews and observation of committees at work. In addition, we have now conducted 17 such reviews, so we have more data against which to benchmark applicants.

KPMG's report confirms that Monitor followed the required protocols governing its collaboration with the CQC, which gave Monitor a satisfactory view of the Trust's quality of care. However, the review of maternity services that the CQC conducted during the assessment was a responsive review linked to maternity concerns and did not therefore cover a full assessment of compliance with all the CQC's standards. The review covered 6 outcomes against the 16 essential standards of quality and safety and was conducted at only one of the trust's sites, Furness, where the death referred to in the Coroner's letter occurred. A more in-depth evaluation would have been needed to uncover the issues in maternity services that have subsequently come to light.

KPMG also found that the Trust itself provided neither CQC nor Monitor with a report into maternity services that the Trust had commissioned from Dame Pauline Fielding. Earlier sight of this report could have given a fuller picture of the situation and led to different conclusions. The report was finalised in August 2010 and was provided to the Coroner at the June 2011 inquest.

Setting KPMG's findings in the context of on-going changes to Monitor's assessment process

Monitor accepts all KPMG's findings outlined above. As noted above, several changes to our assessment process that have already been introduced as a result of the assessment review commissioned in 2011 are relevant to the lessons of Morecambe Bay. These concern our tests of quality governance, collaborating with CQC, and enhancing the approach to the assessment of board governance.

Probing quality governance

We are already probing quality governance more deeply, having refined our QG assessment processes over the last year. In addition, Monitor will bring senior experienced clinical staff into the "board to board" meetings between applicants and Monitor that form a critical part of the assessment. We are about to begin recruiting senior secondees from the NHS with extensive operational and governance experience into our assessment team. In addition, we plan to triage applicants to identify those trusts with greater potential risks. These will be subject to more complex assessments. We also now require an independent opinion on quality governance for high risk trusts.

Collaborating with the CQC

The events at Morecambe Bay highlight the importance of collaborating with the CQC in determining the scope of work required to investigate quality concerns. Accordingly, we have also agreed with CQC that, where concerns about quality arise during an assessment, we will determine with CQC exactly what work should be done to investigate those concerns before any final assessment decision. This work might be a peer review conducted by specialists from another NHS organisation, or an independent review of the trust's governance arrangements, or it could be a responsive review by the CQC. We have also agreed with the CQC to align the timing of its annual compliance reviews with our assessment timetable. This will mean that the letter confirming a trust's performance against the CQC's registration standards should always be based on a recent CQC review.

Assessing Board governance

To enhance our assessment of Board governance, Monitor has contributed to the development of the Department of Health's Board Governance Assurance Framework, which all aspiring applicants must now complete before they reach Monitor's assessment process. All applicants will be reviewed independently against this good practice framework and the results of this review and how the applicant has dealt with any issues identified will feed into Monitor's assessment process.

Stakeholder engagement

Lastly, we will keep under review the sources of stakeholders' feedback we use to understand the quality of services an applicant delivers. Under our existing approach we meet with PCTs, Clinical Commissioning Groups, the Strategic Health Authority, the CQC, patient user groups, patient representatives (e.g. Patient Advice and Liaison Services or Local Involvement Networks) and staff groups to triangulate views on the quality of services at each applicant. We also analyse other performance indicators including the NHS staff survey, patient surveys, published information on national healthcare targets (such as

waiting times and infection rates) and review information contained in the CQC's quality risk profile and information in the press. Finally we write to each applicant's local MPs asking if they have any concerns that they wish to raise in connection with the applicant trust. As part of our work to consider whether we can enhance our approach in this area we will consider whether we should meet with MPs and whether we should develop a staff survey tool to enable us to collect more up to date information from staff.

KPMG recommendations

Having considered actions relevant to the lessons learned from Morecambe Bay that Monitor is taking already, KPMG made two recommendations to improve our assessment process further. The first is that Monitor should find a more systematic way of evaluating the cumulative impact of concerns that individually may not be significant but in combination may indicate the need to probe more deeply into a trust's operations before concluding on authorisation. The second is that Monitor should obtain a letter of representation from the Boards of all applicant trusts confirming that the information they have provided to Monitor is complete and does not omit any potentially significant items.

Monitor agrees with these recommendations, and we are already requiring deeper probes into governance arrangements for some applicants that are close to Monitor's authorisation threshold. We will continue to implement both recommendations, subject to appropriate consultation with the sector, as follows:

1) Evaluation of cumulative operational impact of concerns across governance, risk and quality governance

Where Monitor identifies concerns about an applicant's governance, risk management or quality governance during assessment which individually do not indicate a decision against authorising but are concerns nevertheless, we will record them on a comprehensive organisational scorecard. Monitor's senior team, with appropriate input from individuals with senior health management skills and the CQC, will then decide, according to the evidence recorded, whether:

- a. No further work is required as the level of evidence is sufficient to conclude that the concerns can be tolerated and lie within the authorisation threshold; or
- b. No further work is required as the level of evidence is sufficient to conclude that the concerns together with the supporting action plans are sufficient to allow an authorisation with a side letter; or
- c. There is insufficient evidence to conclude that the level of concern is within the tolerance for authorisation and therefore more in depth analysis is required to determine the operational implications.

Where more in depth analysis is required, Monitor will decide with the CQC on the most appropriate way to conduct the additional analysis. This may include:

- Deeper probes into operations and management at the divisional level conducted by Monitor's internal Quality Governance team;
- Investigation by the CQC;
- Forming an external peer review team to probe more deeply into service performance; or
- Commissioning an external review into governance arrangements

In addition, in line with the recommendations of Monitor's overall assessment review, we will:

- Appoint independent members with senior NHS operational experience onto Monitor's Board to Board panel for applicant trusts;
- Enhance our internal capability on Quality Governance reviews by recruiting individuals with senior healthcare experience to support our existing assessors;
- Further develop our risk-based approach to QG reviews by:
 - Refining our internal risk indicators and enhancing the level of work carried out on more complex assessments; and
 - Reconsidering our definition of high risk trusts that will be required to obtain an external quality governance opinion, as detailed in the current Guide to Applicants

2) Completeness of sharing information

We will introduce a requirement for all applicants to certify that they have provided all relevant information to us in their assessment submissions. (This measure was also recommended by Monitor's overall assessment review.) To implement this recommendation, we are:

- a. Developing a letter of representation with input from the independent accounting firms which will require applicants to confirm, to the best of their knowledge and belief and having made the appropriate enquiries, all relevant matters have been disclosed including all other significant information that they believe is relevant to the authorisation decision.
- b. Updating the information request lists that we send to applicants to include all reports/peer review information (including drafts) commissioned either internally or externally covering governance arrangements or the quality of services at the trust within the last two years.
- c. Updating the Guide for Applicants to describe the changes above; and
- d. Updating the presentation that we deliver to all applicants at the start of their assessment to describe our requirements in terms of completeness of information.

Conclusion

Monitor needs continually to learn and to improve its assessment process so that we find the right balance between identifying all material concerns and placing too great a regulatory burden on trusts and the public purse. Monitor has had to intervene only three times within 18 months of authorising a foundation trust out of 144 authorisations so far. Nevertheless, the findings from Morecambe Bay clearly indicate that further investigation is needed at applicants where the cumulative impact of concerns puts them very close to our authorisation threshold. We will involve CQC and individuals with senior NHS operational experience in deciding whether to require trusts in these circumstances to undertake further work.

Our responses to the lessons we have learned from Morecambe Bay will reinforce the broader set of improvements we are already making to our assessment process resulting from the review commissioned by Monitor's board in 2011.

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