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Learning and Implications from University Hospitals Morecambe Bay NHS Foundation Trust

Monitor – Independent Regulator of NHS Foundation Trusts

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INTERNAL AUDIT, RISK AND COMPLIANCE SERVICES

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1. Introduction and scope

Background

Monitor commissioned KPMG to conduct a 'lessons learnt' exercise based on the events relating to University Hospitals Morecambe Bay NHS Foundation Trust (Morecambe Bay) during the period March 2009 to 31 December 2011. The purpose of the exercise was to identify where existing Assessment processes could be improved by analysing the events during that period with the benefit of hindsight, understanding why decisions were made and actions taken, and identifying learning and recommendations to improve processes.

Scope of services

This exercise was designed to address a series of questions relating to the assessment process and authorisation of Morecambe Bay. These were:

1. What was the scope of the assessment activity prior to authorisation & how was the work focused and carried out?

2. Is there any evidence to indicate (either way) that the problems currently being faced by Morecambe Bay were present at the time it was authorised? In dealing with this question we set out the events from authorisation through to the current date.

3. What else could have been done by Monitor during the assessment process 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?

In dealing with this final question we have taken into account a range of changes already being implemented in Assessment based on an independent review commissioned by Monitor's Board to ensure that it was efficient and up to date in advance of the anticipated increase in the applicant pipeline. The review started in the autumn of 2011 and resulted in the Board approving changes in January 2012.

In conducting this review we have met with the CQC in order to understand the linkages with Monitor but are not critiquing their processes. We are aware that the DH has conducted an effectiveness review at the CQC, the results of which were published recently but have not included comment here on that report. We have not sought to contact other organisations so as to maintain the focus of the evaluation and learning within Monitor.

Approach

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

- A kick off meeting to finalise the approach to the review in January 2012;
- A review of key documentation to identify issues to explore and additional questions that might need to be addressed.
- Early meetings with Assessment and Compliance staff involved with Morecambe during the period being considered plus key senior individuals at Monitor to clarify the chronology and lessons already identified so that the review does not focus on known lessons learnt but builds on existing knowledge;
- Identification of any additional information required and issues to explore in specific interviews;
- Undertaking interviews with key individuals at Monitor (and one at the CQC) to investigate specific issues and identify areas to explore further;
- Development of our preliminary findings and report based on the issues and recommendations identified to date;
- Reviewing the preliminary findings and report with the Project Sponsor;
- Scheduling of additional interviews and/or calls to gain further information to supplement lessons learnt and recommendations;
- Further analysis and finalisation of recommendations in a report;
- Refinement of findings and finalisation of high level recommendations.

A glossary of terms used is attached on page 17 as Appendix A

2. Executive Summary

The purpose of assessment is to determine, within a tolerance, whether or not a trust has cleared the bar set for authorisation. It is not designed to, nor could it, identify all weaknesses in the operation of the Trust's activities at the governance level. Accordingly, there remains a possibility that a trust might be authorised when there exist matters at the operational level that are significant and would prevent authorisation were they known. In the eight years since Monitor started there have been 144 FTs authorised from which there have been three interventions within 18 months of authorisation, at: Bradford, Mid Staffs and Morecambe Bay.

University Hospitals Morecambe Bay NHS Trust made its application to be a Foundation Trust (FT) in 2009. Relatively soon after the assessment process at Monitor had started five SUIs in maternity (one being Joshua Titcombe) were Identified which gave cause for concern. These were reported by Monitor to the CQC and the assessment process was halted while the CQC investigated the implications.

In March 2010 the CQC registered Morecambe Bay under the new registration system without conditions and subsequently wrote to Monitor in April confirming its risk grading, which was an acceptable level of minor concerns. At this time the assessment was restarted.

Before the assessment process was complete the CQC conducted a Responsive review at FGH, one of Morecambe Bay's three sites. The unit was found to be compliant against the outcomes evaluated. Prior to authorisation the CQC provided Monitor with the required letter of comfort confirming their view on quality matters. Morecambe Bay was authorised on 1 October 2010.

The CQC was made aware of the Fielding Report by Mr Titcombe in January 2011. However, they did not act upon it until March/April 2011 when the report was formally received from the trust. They subsequently received a Coronor's Rule 43 letter that cited the report and a range of issues at FGH in relation to the death of Joshua Titcombe. A subsequent review by the CQC found the FT to be in breach of a number of safety standards and an enforcement notice was issued in September 2011.

In October 2011 the trust was found to be in significant breach of three conditions of its terms of authorisation and Monitor intervened to require two independent reports to be commissioned. A further investigation was also Launched by the CQC into emergency care services. Monitor intervened again on 6 February 2012 to appoint a new interim Chairman and require further management changes.

This engagement has been requested by the COO at Monitor to establish what learning can be gained from the events relating to Morecambe Bay. In doing so it addresses four questions. For the avoidance of doubt we first provide a reminder, of the purpose of assessment and authorisation.

Q1. What was the scope of the assessment activity prior to authorisation & how was the work focused and carried out?

1.1 The assessment was performed by an experienced team that followed Monitor's procedure and covered the ground expected;
1.2 The assessment was stopped in 2009 when a concern was raised in relation to SUIs in maternity and only restarted in 2010 once the necessary assurances had been provided by the CQC;
1.3 The CQC signed off quality matters from their perspective prior to authorisation;
1.4 The Quality Governance (QG) evaluation was triggered by a delay in the process and comprised a limited review due to the timing of the assessment. It was first such review ever conducted. The score of 3.5 represented a pass;
1.5 Weaknesses identified in governance, risk, QG and other areas were explored by the team and resolved or logged in Board briefing papers as residual concerns;
1.6 Any residual concerns were also flagged and explored during the Board to Board meeting. The quality of evidence provided by management was sufficient to satisfy the Monitor Board at the time.
1.7 The decision to authorise was not complex because, while a range of issues was identified in the final Board authorisation pack, none was sufficiently significant to warrant a deferral or to prevent authorisation.

Q2. Is there any evidence to indicate (either way) that the problems currently being faced by Morecambe Bay were present at the time it was authorised?

2. Executive Summary (continued)

2.1 The focus of governance work in the FRP review is at the corporate level and so not sufficient for the full operational implications of issues identified to be evaluated. Based on a comparison of the FRP report and the recent PWC governance evaluation, which had a much broader scope, there is evidence of consistency in certain issues before and after authorisation.
2.2 The Central Manchester report highlights a lot of detailed operational weaknesses that underpin some of the evidence/examples that arose in the form of maternity SUIs;
2.3 The CQC work in 2009/10 was not investigative in nature and so not of a sufficient depth to find the problems later highlighted by the Central Manchester report. It is our understanding that the CQC's conclusions would have been based on evidence from management, stakeholders in the NHS, Risk Summits and limited time on site visits;
2.4 The CQC and Monitor were not aware of the Fielding report until 2011 when it was brought to their attention by Mr Titcombe. The Fielding report implies that the maternity concerns were all present during assessment period;
2.5 It would be hard to conclude anything other than that most of the underlying issues in maternity were present throughout the period of assessment and up to the current time.

Q3. What else could have been done during assessment or subsequently to identify the issues currently being faced by Morecambe Bay?

3.1 Given the existing practices in Assessment and the authorisation threshold, Monitor would have needed to probe the concerns identified more deeply to find the operational implications. This might have involved performing more work at a divisional service level on governance, risk management and QG with a view to obtaining a greater level of evidence and assurance before proceeding. In this context, Monitor might also have adopted a different course towards events such as the discovered SUIs and required a greater depth of investigation, over and above that undertaken by the CQC's processes, before proceeding with the assessment;
3.2 In the context of Morecambe Bay, the same might also be said of the CQC's challenge to Quality and Safety Standards. Either a more in-depth evaluation of specified areas could have been conducted or a third party review required to address issues of concern.

Q4. What changes should Monitor make to its approach to Assessment or Compliance & Monitoring as a result of Morecambe Bay?

The assessment process is designed to identify and investigate concerns at the corporate level with limited probing at the divisional level. However, if Monitor is to improve its chances of identifying significant concerns at the operational level relating to governance, risk management and QG, then it can only do so by probing, more deeply, concerns identified during assessment. In doing so the intention would not be to raise the bar for authorisation but to be more certain that the trust has cleared that bar by reducing the level of tolerance.

4.1 Governance, Risk and QG concerns: The primary change required to achieve this would be to establish a more systematic way of gathering and evaluating the cumulative operational impact of concerns on governance, risk management and QG during assessment with a view to determining, in conjunction with the Monitor Board:
a) Which can be accepted or tolerated;
b) Which will result in a side letter but will not prevent authorisation;
c) Which require more information or investigation in the area of concern;
i) Either by Monitor to enable a better understanding of the implications of concerns in governance or risk management; or
ii) By a third party, eg to conduct a full evaluation of corporate governance, QG or operational performance in response to a pattern of concerns.
The purpose of this additional work will be to reduce the risk of undiscovered weaknesses.
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4.2 Completeness of sharing information: Monitor should require more formal representations from trust management signed by the Chairman and CEO on the completeness of disclosure of relevant information during and at the end of the assessment process.

3. Findings: Q1 What was the scope of the assessment activity prior to authorisation & how was the work focused and carried out?

Introduction

The scope of Monitor's due diligence for an FT application is less intensive than that used for a standard piece of due diligence on a commercial acquisition. It follows on from two previous phases on work, as described in Appendix C:

- **SHA led Trust Development phase**: to prepare NHS trusts for the application process and Secretary of State support;
- **Secretary of State Support phase**: to determine whether applicant NHS trusts are eligible to apply to Monitor for assessment.

Monitor's assessment process starts when the relevant approvals have been obtained in the first two phases and focuses mainly on an evaluation of the trust's arrangements to answer three key questions:

- Is the trust well governed?
- Is the trust financially viable?
- Is the trust legally constituted?

These are addressed at the corporate level, ie the Board and its sub committees.

The extent of validation or testing is relatively limited and is designed to identify potential risks for further investigation. It is not designed to, nor could it, identify all weaknesses in the operation of the Trust's activities at the governance level.

The assessment performed on Morecambe Bay appears to have been consistent with Monitor's standards, practices and process, at the time, for conducting such evaluations. The work was conducted by a suitably skilled and experienced team. The process for Morecambe Bay included the first Quality Governance (QG) review to be performed by Monitor as a part of the assessment process.

Timeline

The assessment process started in March 2009.

In April 2009 Monitor received an ORP from the CQC indicating that it had only minor concerns at Morecambe Bay.

In April 2009 Monitor, as one of its standard checks, the team considered a number of SUIs relating to Morecambe Bay. Of the twelve SUIs identified, five related to maternity services.

One of these cases related to Joshua Titcombe. On further investigation it appeared that the CQC was not aware of these cases. Accordingly, Monitor wrote to the CQC expressing its concern regarding these cases given the high proportion relating to maternity services. Following an exchange of telephone calls and letters:

- The CQC risk rating was raised to 'concern' and a review was instigated by them of midwifery services at Morecambe Bay;
- Monitor wrote to Morecambe Bay indicating that the assessment of the FT application was postponed pending the outcome of the review. It was noted that the assessment process would not restart until formal clearance of maternity services had been received from the CQC;
- The Parliamentary Health Service Ombudsman reviewed the Titcombe case but decided not to investigate further.

In the following months Monitor obtained sight of a number of independent external reviews concerning maternity services including systems and processes, training, record keeping, staffing levels and multi disciplinary policy development. The reports identified a number of shortfalls around staffing levels, multi-disciplinary working and communications between midwives and consultants which the Trust incorporated into action plans.

There were exchanges of information during July, August and September 2009 between Monitor and the CQC.

In February 2010, the SHA stated they were monitoring the Trust and were satisfied with actions the Trust had taken with regard to the Titcombe SUI; this resulted in the SHA's risk rating being downgraded from amber to green.

In March 2010 the Trust was registered by the CQC under the new registration system without compliance conditions.

On 16 April 2010 the CQC wrote to Monitor to confirm that its level of concern had reduced to minor concerns. Nevertheless, the CQC had decided to carry out responsive reviews in the two specific areas where they previously had minor concerns: Maternity. At this point the assessment of Morecambe Bay was restarted.

3. Findings: Q1 What was the scope of the assessment activity prior to authorisation & how was the work focused and carried out? (continued)

Due to the delay in the assessment process the majority of the work needed to be re-performed. However, the assessment was conducted by largely the same team as had been involved in the original assessment in 2009.

On 9 August 2010 the CQC indicated to Monitor that, following their maternity review, which included an unannounced inspection at FGH on 29 June 2010, they were satisfied that the Trust was compliant with all required standards of safety and care in this area. Their review report highlighted that a robust system for multi disciplinary working was in place, a Midwifery Action Plan for 2009-12 which detailed the vision for maternity services over the next 3 years, that the Trust had undertaken a full review of staffing and addressed identified shortfalls with action plans; that processes for learning from clinical incidents were in place and that audits were undertaken to ensure care records are completed correctly.

Learning that had been gained by Monitor from a previous exercise on Mid Staffs had triggered the need for a consideration of Quality Governance (QG) by the end of the summer of 2010. Accordingly, when there was a short delay in the assessment process, the need for a QG review was triggered. The timing of the process meant that this review was limited in scope. It was also the first such review conducted by Monitor, and the assessment team, in a short time period late in the assessment process.

The Trust was given an overall rating of 3.5 for QG. This score needs to be lower than 4 to be regarded as acceptable; otherwise the application could have been deferred or rejected. The QG evaluation was subject to an independent challenge as a standard part of the process.

The FRP report completed by an independent firm of accountants identified no matters that either it or Monitor regarded as constituting a significant concern. It is important to note that the FRP is designed to focus on financial reporting at the corporate level and not quality or broader governance issues, which are only identified by exception through the evaluation of the financial reporting processes.

The Board to Board briefing pack did raise some questions on some aspects of governance, in particular:

- How the clinical governance issues flow through the committee structure;
- Evidence of the ability of the Board and management team to clearly articulate the business plan; and
- Concerns raised by both NHS Cumbria and NHS North Lancashire: Both had concerns about the management team's ability to look outward, think strategically and engage in partnership working. Both NHS Cumbria and NHS North Lancashire also stated that the Trust's demand assumptions were based on outdated PCT plans and that their demand management requirements were higher than stated in the IBP.

The Board to Board meeting was held on 8 September 2010 when the Board articulated convincing actions and evidence to address the concerns raised by Monitor. The results of the discussions were used to update the Board decision pack. The Monitor Board decision meeting was held on 29 September 2010. The application was approved reflecting the relatively low level of the residual issues flagged in the final Board approval pack and no side letter was issued.

The Trust was formally authorised on 1 October 2010.

Analysis and summary

The Monitor Team was largely constant across both assessment processes starting in 2009 and through 2010.

All the relevant and necessary steps that are required appear to have been completed and in accordance with Monitor's own procedures.

There were no major contra indicators identified through the assessment process. Those concerns that had been identified were either cleared or included in the Board to Board and Board decisions packs and were not rated as being a significant concern.

3. Findings: Q1 What was the scope of the assessment activity prior to authorisation & how was the work focused and carried out? (continued)

The existence of the 5 maternity SUIs (out of 12) identified in 2009 had been pursued and resulted in both the suspension of the assessment process and an investigation by the CQC. The CQC had subsequently licensed Morecambe Bay in April 2010 with only minor concerns; which had enabled the assessment process to restart. The CQC had conducted its review in maternity and concluded that the level of concern had reduced to low.

While the assessment team had been trained in the use of the quality governance evaluation and were experienced in assessment: the review was limited in scope and this was the first quality governance assessment performed by Monitor. We are aware that considerable experience has been developed within the assessment teams at Monitor in the use of the QG review since this time. The Assessment teams have also conducted their own learning reviews to improve the process and to share learning.

4. Findings: Q2. Is there any evidence to indicate (either way) that the problems currently being faced by Morecambe were present at the time it was authorised?

Following authorisation a series of events took place that gave rise to concerns as to the quality of services at Morecambe Bay and ultimately led to Monitor's intervention.

Fielding Report

In May 2011 the CQC indicated to Monitor that it had been made aware, by Mr Titcombe, of the Fielding report; a report conducted by Dame Pauline Fielding into the state of implementation of the actions agreed by management in maternity. The findings of the Fielding report were issued as final on 31 March 2010 and subsequently amended on 30 June 2010 before being finalised again on 6 August 2010. This was the period during which the Trust was registered with the CQC, subject to a responsive review into maternity services by the CQC and was undergoing its Monitor assessment.

Despite the apparent relevance of the Fielding report to the responsive review being carried out by the CQC in June 2010, and the issues previously responsible for the postponement of the Trust's Authorisation assessment, the Trust did not to disclose the existence or findings of this report to either the CQC or Monitor. Other reports were provided to Monitor including:

- Charles Flynn report (independent consultant);
- LSA report.

It is understood that the Trust viewed the Fielding report as an internal report and, by the time it was finalised in August 2010, the Trust considered the findings to be out of date as clinical practice had moved on since the review work was carried out in early 2010.

The CQC indicated that the scope of the responsive review performed in June 2010 on maternity services may have been extended had they been aware of the Fielding report.

Coroner's Rule 43 letter

The inquest into the death of Joshua Titcombe was held in June 2011. As part of the evidence supplied to the inquest the Fielding report was released which identified similar concerns to previous reports but also highlighted concerns around clinical governance in maternity and poor working relationships. The Rule 43 letter issued by the Coroner to the Trust following the inquest noted on-going concerns over record keeping, team working, pressure of work in the maternity unit and continuity of care.

Mr Titcombe, who, prior to the inquest, was not satisfied that sufficient action had been taken by the Trust , also continued to contact Monitor during this time highlighting his concerns that the trust had not appropriately dealt with the issues which had led to his son's death.

CQC responsive review

Following sight of the Fielding report and the Rule 43 letter issued to the Trust in June 2011, the CQC carried out a responsive review of the maternity and midwifery services at Royal Lancaster and found: Outcome 16, Minor concerns; Outcome 10, compliant; Outcome 13, moderate concerns. In July the CQC reviewed all three maternity sites and found that the Trust was not meeting six of the essential standards of quality and safety and identified major concerns with three of these standards: Outcome 10: Safety and suitability of premises; Outcome 13: Staffing and Assessing and Outcome 16: monitoring the quality of service provision. A warning notice was issued on 31 August 2011 before enforcement action on 13 September 2011 in relation to 'Regulation 10: Assessing and Monitoring the quality of service provision'.

The CQC responsive review also identified a number of issues with the maternity and midwifery services which had previously been raised by the Fielding report and had not been satisfactorily addressed.

The CQC Warning Notice noted that the maternity risk management strategy provided to Monitor by the Trust and dated November 2010 was in draft form despite being approved by the Clinical Quality & Safety Committee (CQSC) in December 2010. It also noted that risks are not always promptly addressed and there is not always a risk assessment procedure in place to understand the risks and put contingency plans in place.

4. Findings: Q2. Is there any evidence to indicate (either way) that the problems currently being faced by Morecambe were present at the time it was authorised? (continued)

CQC concerns – Royal Lancaster Infirmary (June 2011)

The Trust was rated Amber-Red at June 2011 due to the presence of outstanding compliance actions and moderate concerns arising from a planned CQC visit to the Royal Lancaster Infirmary ('RLI') at the end of April 2011. Three moderate concerns were noted. The CQC indicated that it had concerns that some of the issues raised may be Trust wide and not limited to the RLI site. As a result it planned to follow up with Trust wide responsive reviews in October 2011.

APR Stage 2

The Trust was selected for an APR stage 2 review in July 2011 due to concerns over the Trust's ability to deliver its CIP plans, quality governance, income risks and the potential financial burden arising from quality improvement initiatives.

The review, completed by McKinsey in September 2011, assessed the Trust as Medium/High risk, highlighting the deliverability of CIPs as the primary risk. McKinsey expressed a positive opinion in relation to the Trust's approach to quality governance and assessed it overall as medium/low risk. Quality governance issues were raised in two areas:

Whether there are clear roles and accountabilities in relation to quality governance; and
Whether are there well understood processes for managing quality governance; in particular highlighting potential problems around the escalation of identified risks.

The Compliance team was concerned that the same issues appeared to have been raised on a number of occasions suggesting that the Trust had not taken appropriate or timely action in response to risks identified.

Other developments

Monitor's Compliance team maintained a watch over Morecambe Bay during this period. A number of the concerns raised in the draft August 2011 responsive CQC report were the same as those raised in the Fielding report 12 months previously. The Compliance team was concerned as to whether the Trust had effective governance processes in place to enable the Board to drive comprehensive and timely delivery of the improvements needed.

Following the CQC's enforcement of its Warning Notice on 13 September, Monitor wrote to the Trust on 14 September requesting an escalation meeting with the Trust Board on 22 September. On 27 September 2011, following the escalation meeting at Monitor, a baby died during childbirth at FGH. On 28 September 2011 there was a further incident at FGH relating to the safeguarding and treatment of an 8 month old baby. Both incidents were registered as SUIs. The Trust indicated that the underlying cause in both cases related to issues raised by the CQC Warning Notice.

On 11 October 2011 Monitor's Board found the Trust to be in significant breach of three conditions: 2 (General Duty); 5 (Governance); and 6 (Healthcare Targets) of its terms of Authorisation and intervened. Monitor required two independent reports to be commissioned, over which they controlled the scope of work:
•Central Manchester University Hospitals: Diagnostic review of maternity and paediatric services; and
•PWC: An in-depth review of Governance.

Subsequent to this intervention in October 2011, further issues emerged at the Trust, including the Trust's failure to book thousands of outpatient follow-up appointments in line with clinically directed access dates. In December 2011, following a call from Monitor's compliance director highlighting the need to investigate emergency services at the Trust the CQC launched an investigation into the delivery of emergency care services at the Trust to determine whether there were issues which needed to be addressed.

Monitor's Board took the decision to formally intervene again on 6 February 2012 and use its powers under s.52 of the Health Service Act 2006 (the Act) to strengthen the available capacity and capability at the Trust to begin to make the changes required at the appropriate pace by:

- Appointing an interim Chairman;
- Requiring the appointment of a Turnaround Director;
- Requiring the appointment of a Chief Operating Officer; and
- Requiring the Trust to put in place a Programme Management Office.

During the period from October 2011 to January 2012 there were three independent reviews of different aspects of the Trust's operations. These were:
•The Central Manchester University Hospitals diagnostic review;

4. Findings: Q2. Is there any evidence to indicate (either way) that the problems currently being faced by Morecambe were present at the time it was authorised? (continued)

- H&H Bellairs Consulting: investigation into the Follow-up Outpatients backlog (commissioned by the trust); and
- PWC Governance review.

They are each discussed in turn.

Central Manchester (November 2011)

The review was conducted by experienced medical and nursing directors/consultants. The scope was to identify all current and potential risks within maternity and paediatric services across the Trust and to produce a comprehensive risk log. This included an assessment of issues identified in previous reviews and reports and those within the Trust's risk register to determine whether the Trust had implemented sustainable and safe solutions.

The review team established that whilst the Trust had developed a number of action plans in response to the various incidents, reports and reviews, there was a lack of overarching strategy and overall leadership. Both of these would be required as a minimum to provide the baseline strategy for improvement and assurance that the maternity and neonatal services at Morecambe Bay were safe. The report included relevant recommendations at a detailed level.

H&H Bellairs Consulting (9 January 2011)

This report was commissioned following a SUI report about a patient who had not been followed up in outpatients as required.

The Trust had implemented a new system, Lorenzo in June 2010 to help capture Guaranteed Access Dates (GAD); being a care plan for patients in the system. The GAD is the date by when a patient should have been seen in a follow-up clinic as a part of their treatment. Morecambe Bay was the first Trust to implement Lorenzo. The Trust had known for some time following implementation that they had a backlog of access plans.

The findings of the review indicate that the backlog problem was not recognised as being a serious clinical problem. Through 2010 the nature of the problem was consistently being described as administrative. It was not until February 2011 that the backlog started to appear as a concern in relation to service delivery..

However, it was not until late 2011 that the potential for clinical concern started to appear

The effect of this failure was complex to analyse. However, the report has concluded that the number of patients who had missed their GADs exceeded 14,000.

The reasons for the failures associated with this system were complex. However, at the heart of the analysis the report cited: poor governance, poor risk management and a lack of clear accountability.

PWC Governance review (Draft report 1 February 2012)

PWC had performed the FRP work during the assessment during 2010. Their FRP report had identified only low level issues and no significant concerns but did note a lack of challenge by non executive directors in areas that were outside their normal areas of experience.

The scope of this governance report was far more extensive than the level of work that is performed in the FRP during an FT assessment and included a review of:

- The Board's capability and effectiveness;
- The effectiveness of the Trust's governance arrangements, systems and processes, including quality governance;
- Risk management and escalation.

At a summary level the main findings indicate significant weaknesses in the overall governance and management processes including:

- 'The level of challenge, scrutiny and debate in respect of performance and risk at the Board and sub-committee meetings observed was not at a level PWC would have expected;
- The Board does not receive adequate performance information in respect of care quality and risk for it to obtain sufficient assurance that issues will be quickly identified and managed in a timely manner;
- The Clinical Quality and Safety Committee was not providing sufficient assurance to the Board ….;

4. Findings: Q2. Is there any evidence to indicate (either way) that the problems currently being faced by Morecambe were present at the time it was authorised? (continued)

- There is a need to develop and strengthen the skills and capabilities of the Board, in respect of both Executive and Non-Executive directors…'

While there is recognition in the PWC report that the Trust has started to implement a number of changes, it is broadly critical of the state of the arrangements in place and their operation.

Following exchanges of information between Monitor and the CQC on 14 December 2011, the CQC launched an investigation into emergency services at Morecambe Bay.

Summary

The focus of assessment is very much at the corporate structural (and design) level and not on the detail of operations. Accordingly while Monitor may identify weaknesses in structures such as governance, risk management and lines of accountability, these tend to be evaluated in isolation and without the context of operational practice (at the next level down); such as how well SUIs are managed and the quality of corrective actions arising.

The review of QG focuses at a similar level on the state of the arrangements in place. To date the work has been performed by experienced assessment staff but who do not have health management experience. Accordingly their ability to identify the potential for serious concern based on the governance structures alone, is limited by their experience.

While the three independent reports and the Dame Fielding report each addressed different aspects of the Trust's activities, together they provide a picture of the general state of governance and management at Morecambe Bay as being:

- **Central Manchester:** identifies serious service weaknesses impacting patient safety, many of which are rooted in structural problems;
- **PWC's report:** highlights weaknesses in the operation of governance, risk management and accountability, some rooted in the structure of the arrangements;
- **The H&H Bellairs report:** highlights the root cause of the failure to address the GAD problems promptly as resting in poor governance, risk management and accountability;
- **The Dame Fielding report:** identifies many matters still in maternity in the process of being addressed in August 2010.

Many of the issues cited in these reports are operational matters below the corporate level that would not, therefore, have been evident from the assessment process.

Given the timing of these reports, and the fact that so many aspects of their findings appear to have their root in the structure of governance, risk management and accountability, it would be hard to conclude other than that these issues existed in 2010 at the time of the assessment.

The assessment process focuses on obtaining an understanding of the governance arrangements at the corporate level and, within that, the quality of the Board. Any concerns raised need to be evaluated without the context of detailed testing of the operational performance, which might bring a different perspective to the matter identified.

It is our understanding that the CQC's processes operate at a similar level placing reliance on management self assessment and action plans for change; their risk analysis determines when a more detailed examination might be required.

The end result was that the trust was acknowledged as being ready for authorisation without serious concerns in the autumn of 2010.

While the scope of this exercise has not included evaluating the CQC's procedures, it is our understanding that these were operated as intended at the time. Accordingly it would appear to be the case that a greater degree of probing would also have been required by the CQC to identify the matters now being cited by recent reports.

5. Findings: Q3. What else could have been done during assessment or subsequently to identify the issues currently being faced by Morecambe?

While the steps completed by Monitor's assessment team conformed with their processes, the issues in maternity and the related weaknesses in governance appear to have persisted throughout this period from 2009 through till late 2011. In the previous section we have concluded that the assessment process was conducted as intended based on Monitor's procedures at the time. This included its dialogue with the CQC and reliance on their view on the need for further work. The question remains as to whether those procedures can be improved either though a redesign or changes to the way they are conducted.

Monitor's procedures are intended to be proportionate. They are designed to evaluate matters at the corporate level with a view to investigating significant concerns that arise during assessment. In this case the matters that have come to light are primarily in operational delivery at the level below corporate. They are visible now due to the more detailed probes undertaken and as described in more recent reviews including the CQC's responsive report in August 2011.

Additional probes

The primary way in which Monitor might have addressed this concern at the time of assessment would have been to adopt a more sceptical approach to concerns, seeking more evidence over and above assurances from the CQC as to their operational impact. This might result in undertaking more work that probes more deeply into divisional operations.

Reducing the risk an authorisation

By adopting such an approach Monitor might take additional steps, based on the risk assessments already performed during assessment and an evaluation of the evidence available, to probe more deeply. Such probes would typically address concerns identified in governance, risk management and QG. The purpose and effect of these changes would not be to raise the height of the bar for authorisation but to reduce the risk of a trust being authorised when it had (undiscovered) significant concerns at an operational level that might have led to a deferral or rejection.

Senior management time and health management skills

In deciding when to probe more deeply a greater use would be made of senior Monitor management time. Other changes already approved, such as the development of Monitor's QG team to include individuals with more health management skills, would also contribute to this ability to probe more deeply.

Quality concerns

In the context of quality concerns, Monitor should continue to liaise with the CQC. However, when specific concerns arise, in addition to that liaison, Monitor should consider, in conjunction with the CQC, whether it might be more effective to engage an independent party, or peer review team, to conduct an in-depth evaluation of the specific concern. This would have the advantage of providing both Monitor and the CQC with an independent view on the risk concern.

Completeness of disclosures

There is a concern that disclosure of the Fielding report may have changed the view of Monitor and the CQC during the assessment process.

There is no reference in the Guide for Applicants that makes it an explicit requirement to disclose a report commissioned by the Trust, even on issues being reviewed by Monitor. However, there are references in the Guide that would have made it a reasonable expectation on Monitor's part that the Trust should have considered that the Fielding Report needed to be provided, especially given that the issues covered by it were under direct consideration during the assessment. A more specific requirement should be considered.

6. Findings: Q4. What changes should Monitor make to its approach to Assessment or Compliance & Monitoring as a result of Morecambe?

Monitor adopts a philosophy of continuous learning. A paper on lessons learned for trusts was published in January 2011. In the autumn of 2011 a learning review was commissioned on assessment which resulted in recommendations for change being presented to the Board in January 2012. These recommendations were accepted and included:

- Enhancements to the Board to Board process, ie incorporating additional skills sets into the independent challenge;
- Use of an earlier decision on the need to defer applicants to avoid wasted effort;
- Enhancing the skills mix for quality governance reviews to include health management experience;
- Changes to CQC Inspection and related liaison;
- Board capability assessments: making use of the DH BGAF evaluation;
- Quality governance enhancements such as risk based reviews with higher risk applicants being required to undergo an independent review; and
- Efficiencies in the assessment process.

We are supportive of the changes proposed. Accordingly, in framing the changes that we are recommending in this report, we have sought not to repeat these. That said we strongly endorse the use of health management skills to enhance the effectiveness of work on Governance, risk management and QG and the other matters such as the deliverability of CIPs.

The recommendations made here are specific to the authorisation of Morecambe Bay. They are based on the assumption that the underlying premise and philosophy of the assessment process will remain unchanged. Within that process we are suggesting changes that we believe would increase the chances of identifying significant concerns within an applicant trust . We believe that this can be achieved primarily by conducting more probing checks into the operational weaknesses arising from concerns already identified at the top level of the applicant trusts during assessment.

6. Findings: Q4. What changes should Monitor make to its approach to Assessment or Compliance & Monitoring as a result of Morecambe? (continued)

Findings	Recommendations
1. **Assessment process**: The assessment process itself was operated as intended for the Morecambe Bay assessment. However, Monitor should consider implementing a number of potential refinements and with a view to improving the likelihood of identifying significant concerns within applicant trusts, and thereby reducing the risk of authorisation when these exist. This will involve increasing the focus on the nature of the concerns being identified during assessment and the quality and quantity of evidence being presented by management .	**Assessment process changes** Monitor operates its assessment process with a view to identifying concerns and conducting work to evaluate whether or not they might represent significant concerns. Within this established practice a greater degree of focus needs to be placed on the cumulative impact of concerns that are identified with a view to considering their potential impact on the trust's operational performance, This evaluation might include considering the cumulative impact of combinations of concern through a holistic view (balanced score card) that would help to identify dangerous combinations or patterns of concern. This would include using individuals with health management experience to identify and evaluate potentially risky combinations of concern. Based on such evaluations Monitor's senior management would need to consider whether the quality and quantity of evidence available was sufficient to reach a conclusion. Where this was not the case then, either Monitor should: • conduct further work to develop evidence and establish or clarify the implications ; or • engage a third party to develop establish and establish or clarify the implications. In making this recommendation we are aware of the recommendations for change to the detail of the assessment process approved by the Monitor Board in January and of the potential costs involved, which will need to be weighed up against the benefits.
2 Completeness of information and disclosures: There is a need to obtain clearer confirmation of the disclosure of all relevant information from applicant trusts.	**Completeness of information:** 2 As a part of the assessment process, Monitor should establish a simple but clear letter of representation to be obtained from the Boards of all applicant trusts that confirms that they have actively considered the information provided to Monitor and that it is complete and does not omit any potentially significant items. Applicants should be briefed on the meaning and purpose of this requirement at the start of the assessment process for the avoidance of doubt.

Appendix A. Glossary of terms and definitions

Acronym	Definition
AM/SAM	Assessment manager/Senior Assessment Manager
APR	Annual Planning Review: Performed may to July each year; financial projections for 3 years are evaluated together with governance and non financial matters to evaluate the level of risk at an FT
BGAF	DH Board Governance Assurance Framework
C & M	Compliance & Monitoring
CIP	Cost Improvement programme / plan
CQC	Care Quality Commission: accountable for the inspection of healthcare bodies for clinical quality performance from 1 April 2009
DH	Department of Health
FT	Foundation Trust
FGH	Furness General Hospital
FRP	Financial Reporting Processes: A review of these processes conducted by independent accountants during assessment
GAD	Guaranteed Appointment date
HMT	HM Treasury
IBP	Integrated Business Plan
NHS Trust	NHS Trust
PBR	Payment by Results
PCT	Primary Care Trust

Acronym	Definition
QG	Quality Governance review
QRP	Quality Risk Profile
SHA	Strategic Health Authority
SoS	Secretary of State
SUIs	Serious Untoward Incidents
Trust	Foundation Trust (as in 'the Trust')
	Terminology and definitions
Concern	A concern is any matter, identified during assessment, that implies to Monitor a risk to a trust's ability to run its organisation effectively.
Corporate	The level at which assessment work is performed: being at the Board and sub-committee level. It excludes detailed probes into operational practice other than as a walk through to validate the corporate process.
Significant concern	A significant concern is a matter that might prevent a trust from being authorised or might lead to authorisation subject to a side letter identifying matters that will be kept under scrutiny

Appendix B: Interviews performed and documents examined

Staff Interviewed

Name	Title
	Monitor
David Bennett	Chairman and acting Chief Executive
Stephen Hay	Chief Operating Officer
Miranda Carter	Assessment Director
Victoria Woodhatch	Senior assessment manager
Merav Dover	Compliance & Monitoring Director
Adam Cayley	Portfolio Operations Director
Kate Moore	Director of Legal Services
Harsha Shewaram	Legal consultant
Chris Mellor	Non executive director
Stephen Thornton	Non executive director
	CQC
Amanda Sherlock	Director of Operations Delivery

Documents Examined

Manuals: Assessment, Escalation and Intervention: guide to Applicants
Documentation for the assessments in 2009 and 2010
Correspondence relating to the assessments
Escalation and intervention documentation
Assessment documents including: FRP report from 2010, Quality Governance analysis, Board to Board pack, Board decision pack
DH Board Governance Assurance Framework
CQC documents including: Setting the Bar; The Judgement Framework; Quality and Safety Standards and September responsive review at FGH
January 2011 Assessment learning (Internal Monitor document)
January 2012 Proposals to enhance the assessment process (Monitor internal documents)
Sundry external reports including: - Fielding reports for March and August 2010 - Central Manchester report on maternity and paediatric care - PWC Governance review (Draft – January 2012) - H&H Bellairs Consulting report
Monitor web site

Appendix C: The Assessment Process: Phases one and two

Phase one - SHA-led Trust Development Phase

In the first phase of the assessment process, strategic health authorities (SHAs) work with NHS trusts to develop robust and credible NHS foundation trust applications.

As the local headquarters of the NHS, SHAs take ownership of and accountability for the readiness of applicants and the quality of NHS foundation trust applications submitted to the Secretary of State for Health.

There are three main stages to the SHA-led Development Phase:

- **Pre-consultation** – draft business plan and financial model, trust and board review;
- **Public consultation** – minimum of 12 weeks; and
- **Post consultation** – final business plan and financial model, historical due diligence, board-to-board practice.

Once all three stages are complete the SHA needs to demonstrate to the Secretary of State that the applicant NHS trust is ready to be assessed by Monitor and, if authorised, to operate as an NHS foundation trust. SHAs are required to build a body of evidence to demonstrate that applicants have met the seven domains of Secretary of State assurance.

The seven domains of Secretary of State assurance

SHA support for applications to the Secretary of State is dependent on the SHA being able to verify that the applicant trust has satisfied the seven domains of Secretary of State assurance. The domains are supported by a series of assurance indicators.

The SHA needs to compile a body of evidence to support its opinions on the state of readiness of applicants applying to the Secretary of State based on these domains, which are set out on the following page.

Once the SHA is satisfied that an applicant trust is ready, the trust formally applies to the Secretary of State, with the full support of the SHA. The applicant trust then begins phase two of the application process.

Phase two - Secretary of State Support Phase

The Secretary of State's support is a legislative requirement that applicants must obtain. It is not a guarantee that applicants will be successful in Monitor's assessment phase.

Applications for Secretary of State for Health support are first considered by the Department of Health's Applications Committee which then makes recommendations to the Secretary of State as to which trusts should be supported to proceed to Monitor for assessment . The final decision is made by the Secretary of State for Health.

1) Applications Committee

The Applications Committee is a body of senior level Department of Health officials that meets monthly. Its role is to advise the Secretary of State on the merits of each NHS foundation trust application, based upon the SHA support documentation submitted in phase one.

The SHA is invited to show that the applicant trust is:

•consistently demonstrating 'fitness for purpose' as an NHS foundation trust; and

•supported by the SHA to apply to Monitor for assessment, based on evidence of the Seven Domains of Secretary of State Support.

Typically, the SHA makes a short presentation, followed by some discussion of the key points with the Applications Committee.

In the event that the Applications Committee recommends that the Secretary of State does not support an NHS foundation trust application, the SHA explains the reasons for this to the trust. After discussion with the applicant, the SHA advises the Department of Health Foundation Trust Team of the trust's new application trajectory, which is the timescale over which the trust should work towards for reconsideration by the Committee.

2) Secretary of State support

The Secretary of State's support is dependent upon evidence of firm support from the SHA, as demonstrated by the assurance process, for the application being submitted. It is expected that, if the SHA assurance processes are sufficiently robust, then the likelihood of applicants not being recommended to the Secretary of State for support will be minimal.

The Department of Health informs Monitor of trusts which have received Secretary of State support and are ready to begin phase three. The final decision on whether a trust can be authorised as an NHS foundation trust rests with Monitor.

Appendix C: The Assessment Process: The seven Domains

Secretary of State needs confidence in:	Assurance indicators - how has the SHA assured itself that:
Legally constituted and representative Is the applicant legally constituted?	• The trust's proposed NHS foundation trust application is compliant with current legislation • The trust has carried out due consultation process • Membership is representative and sufficient to enable credible governor elections
Good business strategy Is the applicant financially viable?	• Strategic fit with SHA direction of travel • Commissioner support to strategy • Takes account of local/national issues • Good market, PEST and SWOT analyses
Financially viable Is the applicant financially viable?	• FRR of at least 3 under a downside scenario • Surplus by year three under a downside scenario and reasonable level of cash • Above underpinned by a set of reasonable assumptions e.g. CIPs, capex plans, IFRS treatment for trusts with PFIs, impact of tariff changes e.g. HRG4, etc. • Commissioner support for activity and service development assumptions
Well governed Is the applicant well governed?	• Evidence of meeting statutory targets • Declaring full compliance or robust action plans in place • Robust, comprehensive and effective risk management and performance management systems in place, which are proven to effect decision-making

Secretary of State needs confidence in:	Assurance indicators - how has the SHA assured itself that:
Capable board to deliver Is the applicant well governed?	• Evidence of reconciliation of skills and experience to requirements of the strategy • Evidence of independent analysis of board capability/capacity • Evidence of learning appetite via NHS foundation trust processes • Evidence of effective, evidence based decision making processes
Good service performance Is the applicant well governed?	• Evidence of meeting all statutory and national/local targets • Evidence of no issues, concerns, or reports from third parties, e.g. HCC and in future CQC • Evidence that delivery is meeting or exceeding plans
Local health economy issues/external relations Is the applicant well governed?	• If local health economy financial recovery plans in place, does the application adequately reflect this? • Any commissioner disinvestment or contestability not reflected • Effective and appropriate contractual relations in place • Other key stakeholders such as local authorities, SHAs, other trusts, etc.

Appendix C: The Assessment Process: Phase three - Monitor

Phase three - Monitor Phase

At the final stage of the NHS foundation trust application process, Monitor has the power to authorise trusts that meet its application criteria. This decision is made at Monitor's monthly Board decision meeting.

The Department of Health advises Monitor of applicants that have received the support of the Secretary of State for Health. These trusts must then formally apply to begin Monitor's assessment process.

Post application to Monitor, trusts are informed of the start date of their assessment. Each applicant is allocated an assessment team including a senior assessment manager. It is usual for the assessment team to spend a number of days visiting the trust during the assessment process to conduct interviews and analysis. This is in addition to careful scrutiny of information provided by the trust and third parties. We work particularly closely with the Care Quality Commission to ensure we have an up-to-date view of their position on applicant trusts.

Monitor's assessment process takes approximately three to four months from the start date, finishing in the authorisation of successful trusts. Key elements of the process are summarised below.

Monitor's Three key assessment criteria

Is the trust well governed?

Is the trust financially viable?

Is the trust legally constituted?

Information about what is required to demonstrate each of these criteria is available in the Guide for Applicants .

The Care Quality Commission

The CQC registers, and therefore licenses, providers of care services if they meet essential standards of quality and safety and then monitors them to make sure they continue to meet these standards. All applicant trusts are required to demonstrate that:

- they are registered without compliance conditions;
- the CQC's overall level of concern is no worse than 'moderate concerns' and 'high confidence' in capacity;
- the CQC is not conducting, or about to conduct, a responsive review into compliance; and
- there is no enforcement or investigation activity ongoing or due to begin, including preliminary investigations into mortality outliers.

The CQC provides the results of this assessment to Monitor.

Quality Governance reviews

The Quality Governance evaluation process was developed in response to the Mid Staffs learning report which was published in August 2009. The review is designed to evaluate the quality of the governance arrangements in place at a trust in relation to its patient services. The intention is to identify the relative strength/weakness of the arrangements and the way the information is used to highlight potential risks and then address them. The evaluation is designed to create a score such that an assessment of the overall design of the arrangements can be rated on a consistent basis.

The Board to Board presentation

As part of the assessment process, each trust is given the opportunity to present its business plan to Monitor's Board at a board-to-board meeting. This meeting is held midway through the assessment period.

The trust executive and non-executive board members are expected to attend this meeting. Monitor's Board asks questions and challenges the application, picking up issues identified through the assessment.

This meeting allows the applicant board to demonstrate that it is aware of the risks facing the trust and provide details on how these risks can or have been managed and mitigated. It also provides Monitor's Board with a key opportunity to question the non-executive directors of the trust to determine whether they have the skills required to effectively challenge the executive team.

Appendix C: The Assessment Process: Phase three – Monitor (continued)

The decision process

Towards the end of the process Monitor's assessment team finalises papers to present at a Board decision meeting, where the application are formally considered by Monitor's Board. A decision may be made at this meeting to authorise, defer or reject a trust's application.

Monitor has been granted power under section 35 of the NHS Act 2006 to authorise applicant trusts. If the decision to authorise an applicant is made at Monitor's Board decision meeting, the trust will be formally notified and issued with its terms of authorisation.

The terms of authorisation set out the conditions under which an NHS foundation trust is required to operate and cover such things as:

- the NHS foundation trust's Constitution – a legal document which describes, among other things, the purpose of the NHS foundation trust, how the board of governors and board of directors should operate and how members are recruited;
- details of the mandatory goods and services that the trust must provide to its patients and service users – these are the services which the NHS foundation trust is contracted to provide by its commissioners;
- details of the mandatory education and training that the trust must provide, as agreed with its commissioners;
- the proportion of the total patient income which NHS foundation trusts can make from private healthcare charges;
- a limit on how much the NHS foundation trust is allowed to borrow; and
- a statement of the information the NHS foundation trust must provide to Monitor and any third parties, including the Department of Health.

Once NHS foundation trusts are established, Monitor operates a compliance regime as described in its Compliance Framework to ensure that they comply with the requirements of their terms of authorisation.

Appendix D: The Fielding Report terms of reference

Professor Dame Pauline Fielding had been commissioned by Morecambe Bay in late 2009 to:

- Provide further assurance that the trust has addressed any issues highlighted by its review of maternal and infant deaths in the areas relating to patient safety, patient experience, clinical effectiveness and team working and that it has robust practices, procedures, management and leadership in place to ensure good outcomes for patients accessing its maternity services;
- Review current practice , procedures and management in respect of the key areas through to board level with a view to recommending actions which will improve the service to the best standard possible;
- Review cross bay practice in respect of the key areas with a view to ensuring that there are common standards in place;
- Consider and review any other relevant matters that may arise from the above stages;
- Provide expert advice on the Family Services Division's proposals and governance arrangements associated with the new models of care for the future.

The first draft of the report was issued in final form in March 2010, followed by an update in June 2010. A further final report was issued in August 2010. Reference was made to previous reports including the CQC report in January 2010.

The report itself identifies a sufficient number of matters of significance regarding the quality of the provision of care in maternity and the state of patient safety to suggest that it would at least have needed to be considered as a part of the assessment process by Monitor and by the CQC in its own deliberations.

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