

Memorandum of understanding (“Memorandum”) between the Care Quality Commission (“CQC”) and the Independent Regulator of NHS Foundation Trusts (“Monitor”)

Introduction

1. This Memorandum sets out the framework for the working relationship between the CQC and Monitor.
2. The CQC and Monitor recognise that there is a distinct and unique relationship between the two regulators. Accordingly the framework set out in this Memorandum takes account of that relationship and details ways in which they will work together and alongside one another in delivering their respective statutory functions. The framework is intended to communicate clearly and unambiguously that CQC and Monitor will work together where relevant to do so and will adopt the Better Regulation principles and behaviours.
3. Monitor and the CQC recognise their respective statutory responsibilities and independence, but will always seek to collaborate and cooperate when relevant and appropriate to do so in delivering our core functions.
4. In agreeing this Memorandum Monitor and CQC recognise that, as the new regulator for health and social care, the CQC is in the process of reviewing, and where relevant revising, the tools and methods needed to deliver the statutory functions of registration and reviews. The Memorandum will therefore need to be reviewed in January 2010 as any potential changes to tools and methods come on stream with any revisions to the Memorandum agreed before March 2010.
5. This Memorandum cannot override the statutory duties and powers of the CQC and Monitor, and is not enforceable in law. However the CQC and Monitor agree to adhere to the principles set out and will show proper regard for each others’ activities.
6. The Memorandum sets out principles that Monitor and the CQC will agree to follow in the course of day-to-day working relationships. The Memorandum may need to be supported by protocols and other documents not included here which set out in more detail operational considerations of how Monitor and the CQC will work together.

7. This Memorandum sets out:

- the statutory responsibilities of CQC and Monitor
- the general principles for collaboration and cooperation
- the working arrangements to underpin effective collaboration as set out in Annexes A-E.

Statutory Responsibilities of the CQC and Monitor

8. The responsibilities of the CQC and Monitor are contained in legislation. Monitor's responsibilities are set out primarily in the National Health Service Act 2006 (the "2006 Act") and those of the CQC in the Health and Social Care Act 2008 (the "2008 Act").
9. Monitor is an independent, corporate body established under the 2006 Act and is responsible for authorising, monitoring and regulating NHS foundation trusts. In particular, Monitor:
- i. receives and considers applications from NHS trusts seeking foundation status. Monitor sets the criteria for authorisation and if satisfied that its criteria in relation to governance, finance, legality of constitution and mandatory services are met, Monitor authorises them to operate as NHS foundation trusts; sets the terms of a NHS foundation trust's Authorisation under which it is required to operate;
 - ii. sets the reporting framework for NHS foundation trusts;
 - iii. monitors NHS foundation trusts' compliance with their Authorisation; and
 - iv. takes action where an NHS foundation trust is not compliant with its Authorisation, and has the discretion to exercise its legal powers in respect of an NHS foundation trust which is (or may again be so in the future) in significant breach of its Authorisation.
10. The CQC is an independent, corporate body established under the 2008 Act. It is responsible for the regulation of the quality of health and social care services. In relation to NHS foundation trusts the CQC:
- i. registers NHS foundation trusts where they meet the quality requirements for registration set out in the regulations;
 - ii. monitors compliance with registration requirements;

- iii. takes action where an NHS foundation trust is in breach of its registration requirements;
 - iv. undertakes and publishes the results of a periodic review of NHS foundation trust performance on the quality of services; and
 - v. undertakes special reviews of particular quality issues or services.
11. The legislation recognises the need for, and therefore requires, the CQC and Monitor to work together to effectively discharge their functions. Section 70 of the 2008 Act states that:

(1) The Commission and Independent Regulator of the NHS Foundation Trusts must co-operate with each another in the exercise of their respective functions.

(2) In particular –

- a. The Commission must keep the Independent Regulator informed of the provision of healthcare by NHS Foundation Trusts, and*
- b. The Independent Regulator must give the Commission any information the Independent Regulator has about the provision of healthcare by an NHS Foundation Trust which the Independent Regulator or the Commission considers would assist the Commission in the exercise of the Commission's functions.*

(3) Without prejudice to subsection (2)(a) the Commission must, on request, provide the Independent Regulator with any material relevant to –

- a. A review under section 46 [periodic review] or 49 [power to extend periodic review]*
- b. A review or investigation under section 48 [special reviews and investigations], or*
- c. A study promoted, or undertaken, by the Commission under section 54 [studies as to economy, efficiency etc.], so far as the material relates to the provision of health care by an NHS Foundation Trust.*

General principles of our collaborative working

12. Monitor and the CQC acknowledge the statutory responsibilities of each other and will take account of these when working together.
13. CQC will normally be the main provider of information and advice for Monitor about the quality of care in the NHS including in Foundation Trusts.

14. The CQC and Monitor recognise the need to collaborate and cooperate to ensure the effective discharge of their statutory functions and to ensure an efficient and effective regulatory framework for NHS foundation trusts. In particular, the CQC and Monitor will collaborate and cooperate where this:

- contributes most to improvements in quality of healthcare services;
- ensures NHS foundation trusts are clear on the requirements placed on them, and the mechanisms for holding them to account;
- ensures NHS foundation trusts are effectively held to account;
- ensures the regulation of NHS foundation trusts is proportionate, effective and efficient in line with Better Regulation principles; and
- ensures that any potential concerns regarding the provision of healthcare services by NHS trusts which are being assessed for NHS foundation trust status are shared through a joint systematic framework that is consistently applied to all applicants for NHS foundation trust status.

15. CQC and Monitor will be open and transparent in their dealings with each other.

16. In carrying out their regulatory functions, CQC and Monitor will inform the other as soon as reasonably possible of any matters that may require action or a response from one or the other. Monitor or the CQC will engage with each other through a joint working group on significant matters which include:

- material changes to proposed guidance or codes of practice which may impact on the operations of either of them;
- information held by one of the regulators that may give rise to potential concerns in relation to an NHS foundation trust; and
- information about any action taken in relation to an NHS foundation trust by one of the regulators that may be relevant to the functions of the other. This will include notification in advance when appropriate to do so.

17. Monitor and the CQC will keep each other fully informed about developments in their approach and methodologies in which the other may have an interest. This will include, but is not limited to:

- development of Monitor's Compliance Framework, regulatory documentation and risk ratings;

- development of the Assessment methodology;
- development of criteria for registration requirements; and
- development of Reviews including any ratings.

18. There are a number of specific areas where the CQC and Monitor agree to collaborate in line with Better Regulation principles and in the context of their distinctive relationship. Arrangements are set out in Annexes A – D of this Memorandum.

Arrangements to underpin collaboration and cooperation

Regular contact

19. Monitor and CQC need to understand the frameworks of regulation, monitoring, compliance and intervention operated by each of them in respect of NHS foundation trusts. This will be managed through a joint working group which will meet on a regular basis.

20. The Chair and Chief Executive of the CQC will meet with the Executive Chair of Monitor on a regular basis.

21. Day to day business will be managed outside the regular Chair, Chief Executive and Executive Chair meetings through the following contacts:

- strategic and policy issues will be managed through the CQC's Head of Strategy and Innovation and Monitor's Policy Director;
- issues related to applicant trusts will be managed through the CQC's Deputy Director of Operations and Monitor's Director of Assessment; and
- operational issues in relation to NHS foundation trusts are expected to be managed by the CQC Regional Teams and Monitor's Relationship Teams. Where the issues require escalation, or where there may be a significant risk of breach of registration requirements or terms of Authorisation, the escalation should be to the CQC's (Director of Operations) and Monitor's Regulatory Operations Director.

22. A list of operational contacts is attached to the Memorandum (at Annex E).

Press and publications

23. Monitor and the CQC will seek to ensure that they give each other adequate warning of and sufficient information about any planned announcements to the public that the other may need to know of.
24. Monitor and the CQC will seek to involve each other in the development of planned announcements, including sharing drafts of their proposals and publications, as early as possible where they will have a direct impact for both regulators.
25. In any event, Monitor and the CQC will strive to ensure that each receives:
- drafts of any planned publications with specific implications for NHS foundation trusts approximately 48 hours before they are released to the media wherever this is possible; and
 - drafts of any press releases with specific implications for NHS foundation trusts approximately 24 hours before they are released to the media wherever this is possible.
26. Monitor and the CQC will respect the confidentiality of any documents shared in advance of publication and will not act in any way that would cause the content of those documents to be made public ahead of the planned publication date.

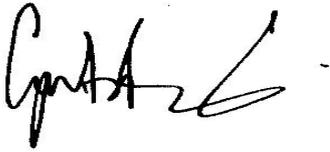
Evidence to Parliamentary Committees

27. Monitor and the CQC will share with each other details of any evidence provided to any Parliamentary Committees in relation to the operation of the regulatory regime or the exercise of their functions.

Operation and review of the memorandum

28. This Memorandum may be amended at any time by agreement between the CQC and Monitor. The Memorandum will be updated to take account of any changes to statutory responsibilities.
29. The first review of the Memorandum will take place in January 2010.

Signatures



Cynthia Bower
Chief Executive
CQC

Date: 1 September 2009



William Moyes
Executive Chairman
Monitor

Date: 1 September 2009

Registration of NHS providers including NHS foundation trusts

1. The CQC is responsible for registering NHS foundation trusts. In 2009/10 NHS foundation trusts were registered against the required standards for Healthcare Associated Infections. In 2010/11 registration will be extended to cover a wider range of quality standards as set out in regulations. The CQC is responsible for determining whether an NHS foundation trust meets the registration requirements, and for registering each NHS foundation trust with or without conditions.
2. Failure to meet or maintain the registration requirements is also a breach of the terms of Authorisation of an NHS foundation trust.
3. Monitor will ensure that the terms of Authorisation and Compliance Framework continue to reflect the requirement to be registered.
4. In registering NHS foundation trusts the CQC will:
 - inform Monitor at the earliest opportunity of any concerns they have in relation to registering any NHS foundation trust; and
 - inform Monitor of any conditions attached to the registration.
5. Where an NHS foundation trust is registered with conditions:
 - CQC will determine the conditions, and any timescale for the correction of any identified concerns;
 - Monitor will determine whether the failure leading to the imposition of conditions represents a significant breach of the terms of Authorisation and whether the use of its formal powers by Monitor is necessary;
 - CQC will share with Monitor the approach to be taken to securing compliance with any conditions or to address the identified concerns;
 - any decision to remove or vary the conditions will be for the CQC; and
 - CQC will inform Monitor when it is satisfied that the conditions have been met.

Authorisation of NHS foundation trusts

Requirement to be registered

1. Applicant NHS trusts must be registered with the CQC before they can be authorised as an NHS foundation trust.
2. Where an applicant trust has been registered with conditions requiring it to improve performance to fully comply with the registration requirements, Monitor, if requested by the DH to consider the application, will usually defer Authorisation until the CQC is satisfied the conditions have been met.

Assessment of the quality of care provided by applicant trusts

3. In the first instance Monitor will approach CQC about the quality of care in the applicant Trust and place significant weight on the CQC's assessment of the quality of care provided by the applicant trust in reaching its decision on whether to authorise the applicant as an NHS foundation trust.
4. Monitor will usually defer an Authorisation if:
 - the CQC's view of the overall level of concern associated with the applicant is greater than "Minor Concerns";
 - the CQC is "Not Confident" of the applicant's ability to meet regulatory requirements; or
 - the CQC is investigating the applicant, or an investigation is planned, including preliminary enquiries into mortality data outliers.
5. This approach will be revised as the CQC introduces its Quality Risk Profiles.

Assessment process and information to be shared

6. Monitor (Assessment Director) will write to the CQC (Deputy Director of Operations) of applicant trusts passed to Monitor for assessment and request the views of the CQC in relation to the quality of care provided by the applicants. Monitor will provide a timetable for the receipt of information from the CQC. The process for receiving CQC's views is set out in paragraphs 7-9 of this annex.
7. At the start of Monitor's assessment process, the CQC will provide Monitor with a copy of the Organisational Risk Profile (ORP) for the applicant trust which was submitted to the DH Applications Committee. Around two weeks before Monitor's Board to Board meeting, the Monitor assessment team will arrange a case review meeting with the CQC Regional Director and the SHA to discuss the ORP, any

concerns raised and share any additional information in relation to the quality of care provided by the applicant trust.

8. The CQC will provide Monitor with an updated ORP for the applicant trust one week prior to Monitor's Board to Board meeting. The update will include the latest information from the regional and central investigations and intelligence teams. The ORP will provide details of any ongoing or planned investigation by the CQC, including details of any preliminary enquires into mortality outlier information, or confirmation that none exists. Where the CQC has significant concerns these should be identified at this stage.
9. One week before the Monitor board meeting to decide on Authorisation of the applicant, the CQC will provide a final updated ORP and a letter signed by the Deputy Director of Operations confirming its view of the applicant to include:
 - CQC's view of the overall level of concern in relation to the applicant (business as usual/minor concerns/concerns/significant concerns);
 - CQC's confidence in the applicant's ability to meet regulatory requirements (very confident/confident/not confident); and
 - confirmation that the applicant is not under investigation, that no investigations are planned and there are no preliminary enquiries into mortality outliers.
10. Where Monitor identifies significant issues in relation to clinical care during the assessment process, the Assessment Director will write to the CQC (Deputy Director of Operations) to inform the CQC of these concerns. This is to ensure CQC is aware of any such issues prior to providing Monitor with its view of the applicant as set out in 9 above.

Monitor's authorisation decision and notification of CQC

11. Monitor will place significant weight on the CQC's views of the quality of care provided by the applicant as set out in para 3 of this annex.
12. Monitor will inform the CQC of the outcome of Monitor's Board decision meetings. If applicants are rejected or deferred, Monitor will provide the CQC with copies of the rejection and deferral letters where they relate to quality of care or clinical governance concerns.

Development of the Assessment process

13. The process set out in this annex is a transitional measure and will be revised as CQC introduces Quality Risk Profiles (which will replace the ORPs) to inform the CQC's judgement on the quality of care offered by registered providers.

14. This Memorandum will be revised to include the new process, based on Quality Risk Profiles, in January 2010.
15. Monitor will notify the CQC of any significant modification to assessment process and provide opportunity for the CQC to express it's views on any significant modifications.

Risk of failure to meet or maintain registration requirements leading to enforcement or intervention

Requirement to be registered

1. NHS foundation trusts are required by law and under their Authorisation to maintain compliance with the registration requirements.
2. For 2009/10, registration requirements are limited to issues relating to compliance with the Hygiene Code and Healthcare Associated Infections. For 2009/10, NHS foundation trust must continue to comply with the Department of Health Core Standards. The full registration regime will be introduced by the CQC from 2010/11.
3. Failure to maintain compliance with registration requirements could lead to intervention by CQC and, as such a failure, or risk of failure, could be a significant breach of the terms of Authorisation, and could also lead to intervention by Monitor.

Identification of failing performance

4. If the CQC or Monitor becomes aware of material information that may suggest a breach, or risk of a breach of registration requirements or the terms of Authorisation by an NHS foundation trust, they will inform the other as soon as practicable.
5. Where there is concern over a potential breach of registration requirements it will be for the CQC in the first instance to determine whether and how to investigate the concern and establish whether the NHS foundation trust is compliant with the registration requirements.
6. The CQC will share the findings of any such investigation with Monitor.
7. Where concerns are raised about aspects of the quality of care which are not covered by registration requirements, Monitor will discuss these with the CQC and may ask the CQC to investigate.

Intervention

8. The CQC will determine whether the NHS foundation trust is compliant with the registration requirements.
9. The CQC findings will inform Monitor in determining whether there is a significant breach of the terms of Authorisation.

10. Where the CQC finds that the NHS foundation trust is not compliant with the registration requirements, but Monitor determines the NHS foundation trust not to be in significant breach of its terms of Authorisation, then:

- the CQC will decide on the appropriate intervention;
- where necessary the CQC will require and monitor progress against an action plan to restore compliance with the registration requirements;
- the CQC will keep Monitor informed of progress at all stages and of any change in circumstance or performance that could lead Monitor to reappraise whether the NHS foundation trust may be in significant breach of its terms of Authorisation; and
- the CQC will determine when the NHS foundation trust has met the registration requirements and then inform Monitor.

11. Where the CQC finds that the NHS foundation trust is not compliant with the registration requirements and Monitor determines a significant breach of the terms of Authorisation has occurred then:

- Monitor and the CQC will share their conclusions on the failings in the NHS foundation trust and discuss the most appropriate interventions to rectify the failings efficiently and effectively;
- the CQC will decide whether to use its powers of intervention;
- Monitor will decide whether to use its powers of intervention;
- any use of intervention powers by Monitor does not preclude the CQC from taking enforcement action related to breaches of registration requirements or any other regulatory activity if relevant to do so. Similarly any enforcement activity by CQC does not preclude Monitor from exercising its intervention powers in relation to breaches of the terms of Authorisation if relevant to do so;
- interventions by either or both parties will be announced in a coordinated and coherent fashion, clearly specifying the failings, the rationale for the interventions and the expectations and requirements placed on the NHS foundation trust;
- an action plan will be required to address the identified failings within a timescale specified by the regulators. Where relevant progress against the action plan will be reported to both Monitor and the CQC;
- the CQC will determine when the NHS foundation trust has taken the actions to rectify the failure to meet the registration requirements; and

- Monitor will determine if and when the NHS foundation trust has rectified the breach of its terms of Authorisation.

Reviews and Risk Ratings

Periodic review and risk ratings

1. The CQC is required to produce a periodic review of health care providers including NHS foundation trusts.
2. Monitor produces quarterly risk ratings for finance, governance and mandatory services in NHS foundation trusts.
3. In operating these regimes Monitor and the CQC will:
 - provide adequate opportunity to seek the other's views, and understand the implications of developments proposed by one party on the operations of the other;
 - reduce any unnecessary variation in the measures and standards adopted, whilst recognising that some differences will be required to reflect the different roles and objectives of the two regulators;
 - rely on data collected by the other where possible in order to reduce the burdens of data collection on NHS foundation trusts

Special reviews

4. The CQC has the function of carrying out special reviews of health and social care including that provided by NHS foundation trusts. Special reviews may focus on a particular aspect of care, a particular service, or provider.
5. Where such reviews include NHS foundation trusts, the CQC will inform Monitor.
6. Any findings relevant to NHS foundation trusts (specifically or in general) will be shared with Monitor at the earliest practical opportunity and at least 48 hours before publication.

Operational contacts

There will be specific points of contact between the operational teams for Monitor and CQC as set out in paragraph 21 of the Memorandum. Where needed in cases of annual leave etc a named deputy should be contacted if required.

Strategic and policy issues

The specific contacts on all strategic and policy issues will be:

CQC: Alan Rosenbach, Head of Strategy and Innovation

Monitor: Adrian Masters, Director of Strategy

Issues related to applicant trusts

The specific contacts on issues relating to applicants for foundation trust status will be:

CQC: Amanda Sherlock, Deputy Director of Operations

Monitor: Miranda Carter, Director of Assessment

Operational issues

Operational issues in relation to NHS foundation trusts are expected to be managed by the CQC Regional Teams and Monitor's Relationship Teams across the Regions. The key contacts are set out in the table below.

CQC Regional Director	Region	Monitor Senior Compliance Manager
Norwyn Cole	Eastern	Alex Coull
Frances Carey	East Midlands	Alex Coull
Colin Hough	London	Tim Halford
Joanna Dent	North East	Rupinder Singh
Alan Jefferson	North West	David Hoppe
Roxy Boyce-Bown	South East	Russell Harris
Ian Biggs	South West	Rupinder Singh
Andrea Gordon	West Midlands	Will Ritchie
Susan McMillan	Yorks & Humber	Tim Halford

Where the issues require escalation, or where there may be a significant risk of breach of registration requirements or terms of Authorisation, the escalation should be to:

CQC: David Johnstone, Director of Operations

Monitor: Edward Lavelle, Regulatory Operations Director.