Public business

Public Inquiry into Mid Staffordshire NHS Foundation Trust: Key issues for pharmacy regulation

Purpose
To set out our initial analysis of the Public Inquiry into Mid Staffordshire NHS Foundation Trust and our proposed approach to ensuring the Council takes full account of the issues raised by the inquiry and recommendations in the Report.

Recommendations

The Council is asked to provide feedback on the issues raised by the Inquiry and highlighted in this paper and to agree:

i. Support for the first overarching recommendation in the Report

ii. That the executive be tasked with ensuring detailed action planning be taken forward and embedded within our revised corporate planning process

iii. That priority be given to the key themes identified in this paper, subject to any amendments from Council

1.0 Introduction

1.1 Robert Francis’ long awaited report (The Report) into the profound failings of care that occurred at Mid Staffordshire NHS Foundation Trust between 2005 and 2009 was finally published on 6 February 2013\(^1\). The Government published its preliminary response to the Report on 27 March 2013\(^2\).

\(^1\) [http://www.midstaffspublicinquiry.com](http://www.midstaffspublicinquiry.com)
1.2 The Report forensically examines the circumstances surrounding the failings of care given at the trust and also the failure of all those who should have played a more effective role in identifying and responding to the appalling care provided. These groups included the trust’s leadership team including the Board and clinical teams, the NHS performance management structures including commissioners and strategic health authority, as well as national regulators.

1.3 The main focus of the Report is Mid Staffordshire NHS Foundation Trust and the narrative of the Report most directly relates to quality of care in the NHS managed secondary care system. There is no direct reference in the recommendations to pharmacy, pharmacy professionals or the GPhC, although improvement of medicines administration on wards is the focus of one of the recommendations.

1.4 Council has, however, already indicated its strong support for the proposition there are lessons for all those involved in providing health and care services and particularly those regulating both individual clinicians and service providers including ourselves as the pharmacy regulator.

1.5 Indeed the Report sets out at length wider issues and lessons for the health and care system as a whole, and its 290 recommendations include a number either directly or indirectly aimed at those involved in regulation, both professional and system/quality regulation, which we will need to consider.

1.6 The key criticisms aimed at the professional regulators (the GMC and NMC were specifically identified as having weaknesses, but the Report implies those criticisms need to be considered by all the professional regulators) include both a failure in approach, as well as poor operational systems. A key criticism in the Report is a perceived failure of the professional regulators to be proactive and to look at issues, rather than responding to individual complaints and concerns. This approach is something Robert Francis suggested needed to be reconsidered.

1.7 Specific operational weaknesses also referred to in the Report about the GMC and NMC, were around their systems for sharing information, particularly with the Care Quality Commission, as well as the time taken to deal with investigations.

1.8 These issues were picked up in the Government’s preliminary response, which highlighted a number of areas including specifically the following points:

The General Medical Council, the Nursing and Midwifery Council and the other professional regulators have been asked to tighten their procedures for breaches of professional standards.

In reference to a statutory duty of candour for NHS providers, the Government also added:

We will also work closely with professional regulators to examine what more can be done to encourage professionals to be candid with their patients at all times.

The Government response also raised the work of the Law Commissions:

The General Medical Council, the Nursing and Midwifery Council and the other professional regulators are hampered by an outdated legislative framework that is too slow and reactive in tackling poor care by individual professionals. As part of the implementation of the Law Commission’s review, we will seek to legislate at the earliest possible opportunity to overhaul radically 150 years of complex legislation into a single Act, which will enable faster and more proactive action on individual professional failings.

2.0 Key considerations and proposed approach

2.1 Council has already indicated its commitment to looking in detail at the implications for the GPhC of the analysis provided and recommendations of the public inquiry. Given the significance of the events and our broad support for the process, it is recommended that Council reiterates its support for the first recommendation in the Report. This recommendation proposes that all those involved in the health and care system should set out its position, in relation to the relevant findings, and ensure it reports progress towards implementation³.

2.2 Agreeing to report progress periodically is, however, only the first step. Far more difficult a challenge is to agree an approach which, on the one hand recognises the need to avoid being distracted from the significant workload identified in the corporate plan and required to bring improvements to pharmacy regulation, but also is consistent with Council’s commitment to looking at, and considering, the implications of the Inquiry for us.

³ It is recommended that all commissioning, service provision, regulatory and ancillary organisations in healthcare should consider the findings and recommendations of this report and decide how to apply them to their own work; each such organisation should announce at the earliest practicable time its decision on the extent to which it accepts the recommendations and what it intends to do to implement those accepted, and thereafter, on a regular basis but not less than once a year, publish in a report information regarding its progress in relation to its planned actions... (Public Inquiry recommendation 1, http://www.midstaffspublicinquiry.com/)
2.3 This paper has not attempted to set out exhaustively all those themes and issues within the inquiry that have relevance for the GPhC. There are many issues which we will need to take into account as we develop policy and implementation of regulatory changes across standard setting, education, inspection and enforcement.

2.4 Council has approved its corporate plan and has also asked that an updated model of reporting be developed to enable monitoring of our commitments and accountability for delivering them. We are not recommending that a separate process for reporting and monitoring our response and follow up activities to the Francis report be established. However, we do believe that the corporate planning reporting process will need to ensure, in a clear and transparent way, that the necessary activities take full account of the Report and are captured appropriately.

2.5 The approach we are proposing is as follows:

- We consider and agree the main themes of relevance to the GPhC
- The executive is tasked with reviewing the corporate plan to ensure any additional work required is properly resourced and that progress can be tracked
- The progress report would be produced in time to inform discussions on an updated strategic plan which are scheduled for June.

3.0 Key themes for the GPhC

3.1 Set out below are some of the key themes identified following discussion with Council and having considered the responses of other stakeholders including patient groups, other professional regulators and the Professional Standards Authority. We have also had an opportunity to consider the preliminary response from Government.

3.2 This paper is intended to stimulate discussion and we hope enable some agreement on whether these, or a variation on them, are the key themes for the GPhC. The Francis Report argues that for culture change to take place in the NHS there needs to be three core characteristics: Openness, transparency and candour. Although transparency and candour are referenced separately below, we agree that these, along with other themes are linked and we acknowledge could be set out jointly or separately.
3.3 We will need to continue to review feedback from others including patient groups, professionals, other regulators and the Government (and devolved administrations) as each reflect further on the implications of the Report and any additional analysis which we need to take into account. Indeed, there have already been some announcements from Government about further significant proposed changes to the role of the Care Quality Commission, Monitor and NICE in setting and enforcing standards.

3.4 The key themes we have identified for discussion and which we think are directly relevant to our work as the pharmacy regulator are highlighted below:

- Patient experience and patient voice
- Transparency (including data and information)
- Candour
- Whistleblowing
- Professionalism

3.5 Patient experience and patient voice

3.6 If there was one lesson from the events at Mid Staffordshire, it was arguably that although concerns were raised by patients and their families, no one was listening or appeared to hear and take action. All involved in the health and care system need to ensure that if patients or their representatives speak up, they can be heard and given an appropriate response.

3.7 A key challenge for the GPhC will be to ensure the progress already made to engage and listen to patients and the public is strengthened as we develop our new approach to pharmacy regulation. We will need to develop the ways in which we promote our new role and our capacity and capability to better capture and analyse feedback. This could be directly or from third parties about the professional advice and care from pharmacists and pharmacy technicians and/or about health services obtained from pharmacies.

3.8 Specific issues we will need to consider and build into our work include:

- How we capture patient feedback as part of our assessment of risk in pharmacies
- How we share and use information that either we gather through our inspections, or the NHS and other regulators gather as part of their commissioning/planning/contract monitoring and inspection processes
- How we can improve our processes so that patients are able to raise issues, as well as specific concerns about individuals and that this
information is managed appropriately
- Whether additional processes will be needed to ensure we are engaging appropriately with new patient structures in England (including HealthWatch and Local Health and Wellbeing Boards) and considering further engagement work needed across Great Britain.

3.9 **Transparency**

3.10 This principle is mentioned in at least eight of the Report’s recommendation and is a key theme running through the Report. The Report as a whole refers to the critical role of transparency and argues that it serves at least two core purposes: firstly, it enables patients to understand better the quality of care provided in different settings; and secondly, it helps to improve patient safety and quality of care, by driving up standards by shining a light on poor practice and equally those areas of good or excellent practice.

3.11 Council has already demonstrated a commitment to increased transparency in its work and recognised the benefits it can bring. This is reflected, for example, in our new inspection model and plans to publish inspection reports.

3.12 Related to transparency is the requirement to capture data better and to turn it into information that can be used intelligently. Although much of the focus in the Report is, inevitably, on the use of Hospital Standardised Mortality Ratios (HSMRs), the Report also sets out the need for all in the health and care system to consider how they can better capture and interrogate, analyse, share and publish data including on patient experiences. A particular challenge for the GPhC will be to work with those in the NHS, including other national professional and system regulatory bodies, across England, Scotland and Wales to consider how data can be shared more effectively and lessons learnt.

3.13 Specific issues we will need to consider and build into our work include:

- How we capture, code, analyse and publish data and information which can be used to support our regulatory activities (across all our regulatory functions, but particularly fitness to practise procedures and inspection) and help pharmacy learn and improve.
- Further work is needed to build on the progress to test inspection reporting from a patient perspective as well as registrant feedback.
- The need to plan and prioritise our information and knowledge management work alongside the Information Technology changes and applications software work set out in the corporate plan.

3.14 **Candour**
3.15 In relation to candour, the Report recommends that there should be a statutory obligation on both providers and on health professionals. The government has indicated its support for a statutory duty of candour for (NHS) health and care providers but stops short of agreeing to introduce a statutory duty of candour for health professionals.

3.16 The duty on providers will not, as current defined by the government, apply to (community) pharmacy. Their response does, however, say, “we will also work closely with professional regulators to examine what more can be done to encourage professionals to be candid with their patients at all times.”

3.17 The GPhC’s standards of conduct, ethics and performance clearly state that registrants must “respond honestly, openly and politely to complaints and criticism”, it also adds that “if something goes wrong or if someone reports a concern to you, make sure that you deal with it appropriately”. We agree with the Report’s analysis and the Government’s response that professional regulators need to consider whether more can be done to encourage candour.

3.18 The Government is still considering whether a statutory duty of candour will apply to individual health professionals, but we will work constructively with them as we consider what more can be done to encourage professionals to be honest at all times with patients.

3.19 Specific issues we will need to consider and build into our work include:

- Responding to the Government’s specific commitment to work with professional regulators
- Considering what we can do to ensure pharmacy professionals are open and honest with patients and understand their professional obligations
- Ensure that we specifically consider candour and its importance when we are inspecting against our new standards for registered pharmacies, specifically the requirement for there to be a “culture of openness, honest and learning”
- Considering the need for candour as part of our work to review our indicative sanctions guidance, as well as the review of our core professional standards of conduct, ethics and performance.

3.20 Whistleblowing

3.21 As with the issue of candour, our own professional regulatory standards set out the importance of raising concerns. Our guidance on raising concerns is explicit
in stating, “if you do not report any concerns you may have about a colleague or others it would be a breach of our standards of conduct, ethics and performance, and this may call into question your own fitness to practise.”

3.22 We do, however, know that much more can be done to ensure employees feel able to raise concerns (and that employers are more open to receiving them) and ensuring that we, as the regulator, are able to capture and consider any concerns raised with us.

3.23 We have previously raised with the Department of Health our view that the GPhC should be listed as a prescribed body for the purposes of the Public Interest Disclosure Act. We have been assured that this is likely to happen before the summer.

3.24 Specific issues we will need to consider and build into our work include:

- Evaluation of initiatives at regulatory bodies, including the CQC and the GMC to establish ‘hotlines’ for whistleblowers
- Consider whether further work is needed to understand what barriers exist for pharmacy professionals raising concerns, either about fellow registrants, or the registered pharmacies (or indeed other healthcare settings) they work in.

3.25 **Professionalism**

3.26 Much of the Francis Inquiry considered how it could be that the standards of professionalism had become so weak at Mid Staffordshire and what could be done to mitigate this in other settings given that it is ‘front line’ clinicians who are best placed to deliver high quality care and take action when patients may be at risk.

3.27 The GPhC has set out on a number of occasions its view that supporting and enhancing professionalisms is the strongest defence against poor care. This includes giving professionals the education and training needed before they come onto the register, but also that our standards and enforcement activities support good decision making, in the best interests of patients, and that accountability is clear and perceived to be appropriate.

3.28 Specific issues we will need to consider and build into our work include:

- What are the barriers to demonstration of professionalism within pharmacy and whether further research is needed
• How we can work better with the professional leadership bodies to support their work and the responsibilities to promote professionalism
• How this issue is reflecting in our ongoing work to review CPD and develop proposals for revalidation of pharmacists and pharmacy technicians.

3.29 Summary

3.30 The issues highlighted in the above sections do not attempt to reach a conclusion about a specific response or action plan, but instead provide an overview of themes and issues in order to facilitate feedback from Council about whether they are the key issues and our initial thinking on areas of specific work, which may need to be considered.

3.31 If these are agreed, it is proposed that each theme is considered in more detail and action planning be set out and embedded within GPhC corporate planning and Council receives ongoing feedback through associated reporting mechanisms and specifically in advance of its discussions on strategic planning in June.

4.0 Equality and diversity implications

4.1 There are no specific equality and diversity implications within this paper although any changes to our policies or regulatory work will need to be considered for impact on equality and diversity.

5.0 Communications implications

5.1 The Francis Inquiry and the Government’s response remains a high profile issue, not least because of the profound failings of care which were so starkly highlighted. Each of the themes set out in this paper require effective communications and engagement and will need to be built into resource planning.

6.0 Resource implications

6.1 We already have significant work underway to improve the regulation of pharmacy professionals and pharmacies. This work is factored into the budget for 2013/14. However, we may need to consider further any additional resources required following Council’s discussion and any resulting changes to priority activities within the Corporate Plan.
7.0 Risk implications

7.1 Council has previously highlighted the risk that by developing a specific programme of policy work focussed solely on the Francis Inquiry creates a risk that we are distracted from the significant improvement work and major changes being introduced within pharmacy regulation. Equally we need to avoid the risk that we fail to draw all necessary lessons from the Inquiry and that our overarching strategy, as well as current work, takes these into account. The recommended approach in this paper attempts to mitigate these risks.

Recommendations

The Council is asked to provide feedback on the issues raised by the inquiry and highlighted in this paper and to agree:

i. Support for the first overarching recommendation in the Report

ii. That the executive be tasked with ensuring detailed action planning be taken forward and embedded within our revised corporate planning process

iii. That priority be given to the key themes identified in this paper, subject to any amendments from Council

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