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COUNCIL

Francis Inquiry update

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Status: for discussion

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Purpose

1. The purpose of this paper is threefold. We wish to update Council on:
   1.1. the Government's full response to the Francis Inquiry;
   1.2. recent related reports that are relevant to our work; and
   1.3. progress in implementing our action plan to address the Francis Inquiry's findings.

Background

2. Following serious failings at Mid-Staffordshire NHS Foundation Trust (Mid-Staffs), the Government asked Robert Francis QC to chair a public inquiry. The report of the Francis Inquiry was published on 6 February 2013 and the Government published its initial response on 28 March 2013.

3. Council discussed the Inquiry at its meeting on 16 May 2013. The paper presented 14 issues for us to consider in light of the Inquiry, 12 of which Council agreed for us to take forward. Council placed particular emphasis on the importance of openness and candour, and on ensuring our standards place sufficient emphasis on care and compassion.

4. The paper is available here: http://www.optical.org/en/get-involved/Council_meetings_and_papers/council-papers-may-2013.cfm

5. The Government issued its full response to the Inquiry on 19 November 2013, addressing each of Francis' recommendations in turn.

6. The full Government response identified five key themes from the report:
   - compassion and care;
   - values and standards;
   - openness and transparency;
   - leadership; and
   - information.

7. The Government also responded in full to each of Francis' 290 recommendations. Annex 1 focuses on those of the most relevance to our work, and in particular those aimed at other professional regulators.

8. The Government's response followed the publication of a number of other reports looking in more detail at some of the issues Francis raised:
   - The Berwick Review into patient safety;
   - The Cavendish Review into unregistered staff in the NHS
   - The Keogh Review into 14 NHS trusts; and
   - The Clwyd/Hart Review into NHS complaints

9. The action plan in annex 2 updates Council as to progress in relation to the 12 priorities agreed in May 2013. The Executive will consider whether to make further recommendations to Council following the Government's full response.

Strategic Objective

10. The Professional Standards Authority (PSA) and the Department of Health (DH) have made clear their expectation that regulators learn from the Francis Inquiry. At its meeting in May 2013 Council committed to considering and applying the recommendations from the report and to do so in a way that was tailored and proportionate to the risks to the public in the optical sector.

Analysis

11. This paper sets out the five main themes of the Government's full response to the Francis Inquiry.

12. It then looks at the specific recommendations for the General Medical Council (GMC) and Nursing and Midwifery Council (NMC). The report is clear that these recommendations should be considered by all professional regulators, even though not all professions were directly implicated in the Mid-Staffs scandal.

13. The paper looks at the Government's response to other recommendations with relevance to our work.

14. It also considers lessons we can learn from other reports published since Council last discussed the issue in May 2013, as listed in paragraph seven.

15. It considers work done so far by the Professional Standards Authority on how professional regulators can encourage healthcare professionals to be more candid with patients, and how they can work more closely together to share information.

16. The annex updates Council on our work in addressing the priorities agreed in May 2013.

Devolved Nations

17. Any legislative change following the Inquiry is likely to affect only England. However, many of the recommendations are not reliant on legislative change, and to the extent that they are relevant to the optical sector, we would be likely to implement them on a UK-wide basis, albeit in a tailored and proportionate way.

18. However, some recommendations involve working with key stakeholder bodies. When implementing such changes we must be mindful that these bodies do not necessarily operate in the four countries of the UK and ensure we take appropriate account of differences between England, Scotland, Wales and Northern Ireland.

19. The diverging nature of the professions in the four countries of the UK must also be considered in the context of Francis. We must consider the recommendations in light of the changes in the delivery of optical care in different nations and tailor our response accordingly.

Impact

20. The Francis Inquiry has the following implications:
    - 20.1. **GOC's reserves –** no known implications
    - 20.2. **GOC's budget –** a number of the Inquiry's recommendations have budgetary implications. In particular, the onus on professional regulators to speed up their fitness to practise processes could require significant resources. The Francis Inquiry has also widened the scope of our standards review project, with budgetary implications.
    - 20.3. **Legislative change –** the Government has previously (in its initial response) stated its intention to overhaul professional regulators' legislation through the Law Commissions review to enable 'faster and more proactive action on individual changes'. We have engaged with the UK Law Commissions throughout this process.
    - 20.4. **Resources –** implementing all of the recommendations set out in annex 1 could potentially have wide resource implications. It is therefore important that we ensure our response is proportionate to the risk profile of our registrants.
    - 20.5. **Equality and diversity –** we will consider the equality and diversity implications of any regulatory changes we make.
    - 20.6. **Human rights –** none.

Communications

21. Because of the wide remit of the Inquiry and the recommendations, there could be significant communications challenges. These include consulting stakeholders on possible changes to policies, publishing new guidance and information accessibly and raising our overall profile.

22. We must also consider how we communicate the findings of the Inquiry, and our response, to registrants. As this paper notes, although the Inquiry relates largely to hospitals, it will still have significant effects for optics which our registrants and stakeholders have to be aware of.

Risks

23. Stakeholders such as the Professional Standards Authority (PSA) and the Department of Health (DH) have made clear their expectation that regulators learn from the Francis Inquiry. Failure to take account of the relevant lessons could see us falling behind other regulators and exposing ourselves to regulatory risk. In particular, we could be criticised as failing to protect the public should harm come from us failing to account for key recommendations.

Recommendations

24. Council are recommended to:
    - 24.1. note the progress made against the priorities agreed in May 2013;
    - 24.2. note the information in annex 1 about developments in relation to the Francis Inquiry and related reports since Council's last discussion; and
    - 24.3. highlight any issues they wish us to take into account as we review our action plan in the light of the Government's response to Francis and the related reports discussed in this paper.

Timeline for future work

25. This is set out in annex 2.

Annex

26. A full analysis of the Inquiry's implications for the GOC is attached at annex 1.

27. An action plan of our responses to the Inquiry is attached at annex 2.

Themes of the Government's response

1. The Government identified five major themes in its response:
    - compassion and care
    - values and standards
    - openness and transparency
    - leadership
    - information

Theme 1: Compassion and care

2. The response notes that, "s*afe, high quality, compassionate care must be at the heart of everything staff do, continually striving to improve, and speaking out if they witness suboptimal standards*."

3. There is a significant emphasis on effective staff management being an important driver for this. However, this is a challenge in sectors such as optics where staff often work in small or isolated practice settings, without the sort of large management structures that exist in hospitals.

4. The response notes the importance of supporting staff and ensuring their wellbeing to help achieve a culture of care and compassion. Important actions in this area include:
    - trusts will be liable if they have not been open with a patient – the NHS Litigations Authority will continue to make full payments on successful claims, but will have discretion to make the trust partly liable;
    - the Care Quality Commission (CQC) and NHS England will develop a dedicated hospital safety website for the public which will draw together up to date information on all the factors, for which robust data is available, that impact on the safety of care;
    - there will be a new care certificate to ensure that healthcare assistants and social care support workers have the right fundamental training and skills in order to give personal care to patients and service users;
    - NHS England has published guidance for commissioners, Transforming Participation in Health and Care, on involving patients and the public in decisions about their care and their services; and
    - by the end of the year, 96% of senior leaders and all ministers at the Department of Health will have gained frontline experience in health and care settings.

Theme 2: Values and standards

5. The NHS Constitution, updated in March 2013, now includes a common set of values for the whole health service. These are:
    - working together for patients

- respect and dignity
- commitment to quality of care
- compassion
- improving lives
- everyone counts

6. Full details of what these mean in practice are available on page 5 of https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf

7. The Government believes that sharing these common values throughout the NHS will help to provide consistently good care to everyone throughout their life. The response also notes that, "Where standards are not met, the health and care system must be quick to detect problems, take robust action and hold those who are responsible, to account."

8. Important actions include:
   - the Government intends to legislate 'at the earliest available opportunity' on wilful neglect of patients; and
   - The Care Quality Commission has appointed three chief inspectors for hospitals, adult social care and primary care.

Theme 3: Openness and transparency

9. The response has a major emphasis on openness and transparency in the NHS. It notes that, "One of the overriding lessons from the inquiry is the need for a consistent culture of openness and candour in the NHS. The health and care system must move away from previous closed and defensive responses to mistakes. It must recognise the importance of being transparent about mistakes so that errors can be addressed and lessons learnt."

10. Actions in this area include:
    - a statutory duty of candour on CQC-registered providers (note this does not include optical practices) and a professional duty of candour on individuals, through regulators' codes of conducts
    - all hospitals will have to clearly set out how patients and their families can raise concerns or complain, with independent support available from NHS complaints advocacy services, Healthwatch or alternative organisations; and
    - quarterly reporting of complaints data and lessons learned by trusts, with the Ombudsman to significantly increase the number of cases considered.

Theme 4: Leadership

11. Encouraging leadership in staff is also a key theme of the Government response. It notes the importance of leadership being embedded throughout organisations with accountable boards; however, with the majority of our registrants operating in the private sector, we can't directly influence this in the way that might be possible for a hospital.

12. Important actions include:
    - a new fit and proper person test, which will act as a barring scheme for senior managers;
    - a new fast-track leadership programme has been launched to recruit clinicians and external talent to the top jobs in the NHS in England, including time spent in a world-leading business school; and

Theme 5: Information

13. Sharing information is another key theme of the report. It notes that, "Too often the healthcare system has seen information as something to be hoarded, with poor communication between organisations." It encourages organisations to use data to get the whole picture to make healthcare more proactive and targeted.

14. The PSA has already been leading on ways to encourage regulators to share information more proactively.

Specific recommendations for professional regulators

15. The Government response has a number of recommendations specifically aimed at the GMC and/or NMC. It is not necessarily proportionate for us to implement all of these recommendations ourselves, however we must at least consider whether they are suitable for us.

> *222 The General Medical Council should have a clear policy about the circumstances in which a generic complaint or report ought to be made to it, enabling a more proactive approach to monitoring fitness to practise.*

16. The Government accepted this proposal, noting that the GMC has already made progress to become more proactive and collaborative. It stresses the importance of regulators collaborating as appropriate to share information and to looking at generic concerns.

17. It also makes specific mention of the need for regulators to investigate concerns arising from the media. As noted in paragraph 38, this is work we are already undertaking.

> *224 Steps must be taken to systematise the exchange of information between the Royal Colleges and the General Medical Council, and to issue guidance for use by employers of doctors to the same effect.*

18. The Government accepted this recommendation. To aid with sharing appropriate information ourselves, we may need to consider whether we need to more formally systemise the exchange of particular information with our own professional bodies.

> *226 To act as an effective regulator of nurse managers and leaders, as well as more front-line nurses, the Nursing and Midwifery Council needs to be equipped to look at systemic concerns as well as individual ones. It must be enabled to work closely with the systems regulators and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. Full access to the Care Quality Commission information in particular is vital.*

19. The Government accepted this recommendation in part, especially around the NMC working together with other regulators. However, the response noted that the NMC does not wish to be a systems regulator as the CQC already has that function.

20. Our proposals to reform business regulation are designed to enable us to tackle systemic concerns through the way we regulate optical businesses.

> *227 The Nursing and Midwifery Council needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues. It may decide to seek the cooperation of the Care Quality Commission, but as an independent regulator it must be empowered to act on its own if it considers it necessary in the public interest. This will require resources in terms of appropriately expert staff, data systems and finance. Given the power of the registrar to refer cases without a formal third party complaint, it would not appear that a change of regulation is necessary, but this should be reviewed.*

21. The Government accepted this in principle, though noted that the NMC is taking a different approach to achieving the recommendation – working with the CQC and others to address serious complaints in a systemic way.

> *229 It is highly desirable that the Nursing and Midwifery Council introduces a system of revalidation similar to that of the General Medical Council, as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. It is essential that the Nursing and Midwifery Council has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.*

22. The Government has accepted this and the NMC is committed to introducing a 'proportionate and effective revalidation' model.

23. The Government came out against the suggestion that the NMC could establish minimum standards for appraisal and support (recommendation 194), noting the benefits of revalidation.

> *230 The profile of the Nursing and Midwifery Council needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed, by those providing treatment or care, of the existence and role of the Nursing and Midwifery Council, together with contact details. The Nursing and Midwifery Council itself needs to undertake more by way of public promotion of its functions.*

24. The Government has accepted this recommendation; a number of the other healthcare regulators are also taking this suggestion seriously and considering how they might raise their public profile.

> *231 It is essential that, so far as practicable, Nursing and Midwifery Council procedures do not obstruct the progress of internal disciplinary action in providers. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. This may require a review of employment disciplinary procedures, to make it clear that the employer is entitled to proceed even if there are pending Nursing and Midwifery Council proceedings.*

25. The Government has accepted this. The NMC are clear that their procedures should not obstruct internal action, however they are reviewing their guidance to patients and employers to ensure this is clear.

> *233 While both the General Medical Council and the Nursing and Midwifery Council have highly informative internet sites, both need to ensure that patients and other service users are made aware at the point of service provision of their existence, their role and their contact details.*

26. The Government has accepted this. The response notes that the GMC is piloting meetings with complainants to ensure they fully understand the GMC's processes.

> *235 The Professional Standards Authority for Health and Social Care (PSA) (formerly the Council for Healthcare Regulatory Excellence), together with the regulators under its supervision, should seek to devise procedures for dealing consistently and in the public interest with cases arising out of the same event or series of events but involving professionals regulated by more than one body. While it would require new regulations, consideration should be given to the possibility of moving towards a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.*

27. The Government accepted this in part. The response noted that the Law Commissions review will give regulators powers for joint working. It also notes there will be the power for regulators to share tribunal services, however 'the full implications of this will need to be considered further'.

28. On 4 July 2013, the PSA led a meeting of the UK regulators to consider recommendation 235 of the Francis Inquiry. Four key areas were identified where further work may be beneficial:
    - employers' perceptions and expectations;
    - pooling data to identify hot spots and advising third parties of the need for action;
    - standardisation of investigative processes where practicable; and
    - information to the public.

Other key recommendations

29. **recommendation 2** – the Government accepted the recommendation that the NHS and all who work for it must adopt and demonstrate a shared culture in

which the patient is the priority in everything done. This requires:

- a common set of shared core values;
- leadership at all levels from ward to the top of the Department of Health;
- a system which recognises and applies the values of transparency, honesty and candour;
- freely available, useful, reliable and full information on attainment of the values and standards; and
- a tool or methodology such as a cultural barometer to measure the cultural health of all parts of the system.

30. **recommendations 3-8** – in these recommendations the Government is fully supportive of the need for patients' needs to be the first priority for everything the NHS does.

31. **recommendation 13** – the Government accepted Francis' recommendations of having three tiers of standards in the NHS:
    - fundamental standards of minimum safety and quality. The DH will consult soon on new regulations to provide for these standards. The Government also accepted recommendation 28, that there should be a zero-tolerance approach to failure to meet these standards.
    - enhanced quality standards. It notes that these *"Such standards could set requirements higher than the fundamental standards but be discretionary matters for commissioning and subject to availability of resources."*
    - developmental standards which set out longer term goals for providers. Francis sees that, *"These would focus on improvements in effectiveness and are more likely to be the focus of commissioners and progressive provider leadership than the regulator."*

32. **recommendation 19** – the Government rejected the floated idea of having *single regulator dealing with both corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts.* The response does, however, suggest a single regulatory process with clear roles and responsibilities.

33. **recommendation 35** – *"Sharing of intelligence between regulators needs to go further than sharing of existing concerns identified as risks. It should extend to all intelligence which when pieced together with that possessed by partner organisations may raise the level of concern. Work should be done on a template of the sort of information each organisation would find helpful."*

34. The Government accepted this regulation, specifically mentioning that professional and systems regulators should share information to identify and act upon risks.

35. **recommendation 38** – *"The Care Quality Commission should ensure as a matter of urgency that it has reliable access to all useful complaints information relevant to assessment of compliance with fundamental standards, and should actively seek this information out, probably via its local relationship managers. Any legal or bureaucratic obstacles to this should be removed."*

36. The Government accepted this recommendation. The CQC already have an operational protocol with the GMC about information sharing, and are in various stages of developing one with the NMC, HCPC and GDC.

37. **recommendation 43** –"Those charged with oversight and regulatory roles in healthcare should monitor media reports about the organisations for which they have responsibility."

38. This recommendation was accepted, and also specifically mentioned as a recommendation for professional regulators in recommendation 222. This is something we already started in summer 2013 and we have so far investigated four potential complaints following information reported in the local media – two concerning criminal convictions and two concerning poor clinical care.

39. The response also puts a lot of emphasis on information sharing between regulators and education providers. We should ensure that we communicate regularly with education providers about any trends that may represent patient safety issues.

40. The Government accepted the recommendation that the GMC should seek feedback from students and tutors on providers' compliance with patient safety standards and the quality of education provision more generally. The DH accepts that patient safety should generally be the primary focus in all healthcare education.

41. **recommendation 61** – the Government rejected the suggestion of merging system regulatory functions between Monitor and the CQC.

42. **recommendation 109** – the Government accepted the recommendation that there should be multiple gateways for registering complaints, leading to a uniform process for handling them. We could consider how we might create more avenues for patients to raise concerns with us.

43. **recommendations 111 and 112** – the Government accepted the recommendation that providers should constantly promote their desire to receive feedback and learn from complaints, and to treat non-complaint feedback as seriously as complaints. We could include something to this effect

in our revised business code to encourage optical businesses to embrace this learning culture.

44. **recommendations 116** – the response goes into some detail about how making a complaint can be a stressful process. We are already accounting for this; for example, our FTP team recently undertook training with the Samaritans on supporting witnesses. Our continued efforts to speed up the FTP process should also help to reduce the stress on both registrants and complainants.

45. **recommendations 119 and 120** – the Government mainly accepted recommendations for local HealthWatch and commissioners to be able to access information about complaints (with respect for patient confidentiality). This is in respect of hospitals, with no mention of it extending to professional regulators.

46. **recommendation 160** – the Government accepted the recommendation that more should be done to encourage openness and professionalism on the part of trainee healthcare professionals. The GMC are running professionalism events at all medical schools each year and are highlighting the issue of bullying of trainees.

47. **recommendation 172** - The Government accepted recommendation 172 that medical practitioners should be proficient in the English language. They remain keen to extend it to all healthcare professionals subject to a change in EU law.

48. **recommendation 173** – the Government accepted the recommendation that, *"Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful."*

49. The DH noted that professional regulators' codes already enshrine this but the CQC will ensure that organisations act transparently. As optical practices do not have to be CQC-registered though, this duty will not apply to them.

50. **recommendation 174** – in response to Francis' recommendation about candour in the event of death or serious harm, a contractual duty of candour is being inserted into NHS standard contracts for NHS trusts. However, in response to recommendation 178, they will not be inserted into contracts of employment, as the Government feels the recommendation can be delivered through appraisal and revalidation.

51. **recommendation 181** – in response to the call for a statutory duty of candour, the DH is clear that professional regulators should lead on this for individuals:

> *"The government agrees that the professional values of individual clinicians are critical in ensuring an open culture in which mistakes are reported, whether or not they cause actual harm. The General Medical Council and Nursing and Midwifery Council will be working with the other regulators to agree consistent approaches to candour and reporting of errors, including a common responsibility across doctors and nurses, and other health professions to be candid with patients when mistakes occur whether serious or not. The Department of Health will ask the Professional Standards Authority to advise and report on progress with this work. The professional regulators will issue new guidance to make it clear professionals' responsibility to report 'near misses' for errors that could have led to death or serious injury, as well as actual harm, at the earliest available opportunity and will review their professional codes of conduct to bring them into line with this guidance. The professional regulators will also review their guidance to panels taking decisions on professional misconduct to ensure they take proper account of whether or not professionals have raised concerns promptly."*

52. **recommendation 183** – the Government rejected the proposal to make it a criminal offence for a healthcare practitioner to make an untruthful statement to a regulator.

53. **recommendation 185** – the Government accepted the recommendation that nurses' training and education should have an increased focus on the practical requirements for delivering compassionate care. It notes that the NMC have introduced new education standards and admissions criteria. The DH accepted recommendation 188 in principle, that aspiring nurses should have a values-based aptitude test on entry to the profession.

54. **recommendation 201** – the Government has accepted the recommendation that the Royal College of Nursing should split its 'Royal College' role from its trade union/employee representative role.

55. **recommendation 215** – *"A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and steps taken to oblige all such staff to comply with the code and their employers to enforce it."*

56. The Government accepted this recommendation, noting that the PSA's standards for members of NHS boards and Clinical Commissioning Groups provide the basis for standards for board-level leaders and managers. We could

consider these principles as part of our own reviews of standards and business registration, to apply them where it would be proportionate.

57. **recommendation 238** – *"Department of Health officials need to connect more to the NHS by visits, and most importantly by personal contact with those who have suffered poor experiences. The Department of Health could also be assisted in its work by involving patient/service user representatives through some form of consultative forum within the Department."*

58. We have already taken this recommendation on board to ensure our own staff and lay members are connected to the front line of the profession. Our induction programme now includes a section on the role of optometrists and dispensing opticians and in November 2013, all staff and members had the opportunity to learn more about sight-threatening conditions when RNIB's 'Eyepod' visited. We continue to attend a variety of optical event where we directly engage with registrants.

The Berwick Review

59. In August 2013, the Government published a patient safety review led by Professor Don Berwick, an international patient safety expert. The Berwick Review examined patient safety learning points from the NHS and other healthcare systems around the world.

60. Berwick notes that in most cases individuals are not to blame for patient safety failings – rather it is systems and the working environment that are to blame.

61. The report's suggestions include a review of health regulation by the end of 2017. As part of this, Berwick floated the idea of merging some systems regulators such as the Care Quality Commission (CQC) and Monitor. However, he also notes that large-scale structural reform is not desirable at present.

62. The review makes two specific recommendations for professional regulators and educators:
    - assure the capacity and involvement of professionals as participants, teammates, and leaders in the continual improvement of the systems of care in which they work; and
    - embrace complete transparency.

63. The review makes ten overall recommendations:

Recommendation 1: The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.

64. While this includes registrants learning, which we are strongly encouraging through enhanced CET, it is also vital that the GOC itself continues to wholeheartedly embrace an ethic of learning.

65. This means continuing to fully understand the environment our registrants operate in through close engagement with stakeholders and an effective programme of research and intelligence-gathering.

Recommendation 2: All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.

66. The narrative behind this point further advocates the importance of leaders being connected to the front line of the profession. It also notes the importance of cultural change coming from what leaders do – important as we consider as part of the strategic plan whether we need to show more leadership in the profession.

67. The report notes that, "All leadership bodies of NHS-funded health care providers should define strategic aims in patient safety, and should regularly review data and actions on quality, patient safety and continual improvement at their Board or leadership meetings."

Recommendation 3: Patients and their carers should be present, powerful and involved at all levels of healthcare organisations from wards to the boards of Trusts.

68. The Berwick Report places a high emphasis on the importance of involving patients and the public in our work. The report notes that:

> *"Government, CQC, Monitor, TDA, HEE, NHS England, CCGs, professional regulators and all NHS Boards and Chief Executives should include patient voice as an essential resource for monitoring and improving the safety and quality of care."*

Recommendation 4: Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Healthcare organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.

69. The report says, *"Staffing levels should be consistent with the scientific evidence on safe staffing, adjusted to patient acuity and the local context."* It would be worth considering in the business regulation and standards projects whether our business code of conduct needs to include something about giving registrants the time and resources needed to do their job properly.

Recommendation 5: Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.

Recommendation 6: The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.

70. The report contains a specific recommendation for professional regulators in relation to these overarching recommendations:

> *"Professional regulators (such as the GMC and NMC) should continue and build upon their good work to date with undergraduate and postgraduate education providers and Health Education England to ensure that medical and nursing undergraduates and postgraduates become thoroughly conversant with and skilful at approaches to patient safety and quality improvement."*

71. We ought to satisfy ourselves that our core competencies and training programmes are adequately preparing registrants in this area.

72. The Berwick Review also reiterates the emphasis from Francis on collaborating and sharing information with other bodies.

Recommendation 7: Transparency should be complete, timely and unequivocal. All data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.

Recommendation 8: All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.

73. The report reiterates the importance of sharing data and trends under this point, including professional regulators in its assertion that:

> *"Government, CQC, Monitor, TDA, HEE, NHS England, CCGs, professional regulators and all NHS Boards and chief*

> *executives should share all data on quality of care and patient safety that is collected with anyone who requests it, in a timely fashion, with due protection for individual patient confidentiality."*

Recommendation 9: Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.

74. Berwick calls for an "in-depth, independent review of structures and the regulatory system [which] should be completed by the end of 2017, once current proposed changes have been operational for three years."

75. He provides considerable detail here about how he sees regulation working.

> *"Delivering safe care is first and foremost the responsibility of providers, but having no regulation is not an option. Regulation should make clear the expectations that providers must meet, detect failings early, and take appropriate action when sub-standard care is found.*
>
> *"The most effective regulation comes from a mixture of princi-ples-based standards (developed by a process involving patients, carers and the public) and technical specifications where appropriate, supported by an inspection regime with true experts who are able to apply thoughtful judgement and the right actions in response.*
>
> *"The current NHS regulatory system is bewildering in its complexity and prone to both overlaps of remit and gaps between different agencies. It should be simplified.*
>
> *"The system needs to be agile, responsive and proportionate. This cannot be achieved through a series of prescriptive, technical standards that attempt to delineate between "acceptable" and "unacceptable" according to a tick-box or list. It can be achieved only through a well-resourced, highly coordinated, integrated and expert regulatory system employing intelligent and thoughtful inspection, able to apply both qualitative and quantitative judgement and take effective action when necessary. The same principles apply to oversight and performance management by commissioners and other supervisory bodies.*

> *"A high level of coherence is required across the system, with clear and fully aligned goals and incentives focused on the interests of patients at every level. All bodies involved in the oversight of health care providers need to actively avoid the creation of 'priority thickets' where providers become increasingly unclear about what they are doing and why, and where the goals they are supposed to achieve compete, conflict, or fail to cohere.*
>
> *"Safety and quality stand the best chance when all of the drivers in the system – financial incentives, policies, regulatory strategies, use of competition, commissioning decisions, training, and organisational and professional norms – point in the same direction."*

76. It also makes the specific recommendation that:

> *"CQC, Monitor, TDA, professional regulators, HEE, professional societies, Royal Colleges, commissioners and others should streamline requests for information from providers so that they have to provide information only once and in unified formats. The same is true of inspections."*

Recommendation 10: We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.

77. In noting that recourse to criminal sanctions should be extremely rare, the Review goes on to note that:

> *"We believe that legal sanctions in the very rare cases where individuals or organisations are unequivocally guilty of wilful or reckless neglect or mistreatment of patients would provide deterrence whilst not impeding a vital open, transparent learning culture. Our proposals aim to place wilful or reckless neglect or mistreatment of all NHS patients on a par with the offence that currently applies to vulnerable people under the Mental Capacity Act."*

78. He goes on to note that increasing the skills and knowledge of the many will have a far more positive patient safety impact than punishing the few. The review suggests a new offence that: "of wilful or reckless neglect or

mistreatment applicable both to organisations and individuals" but strongly urges against criminalising unintended errors.

79. Berwick does suggest that withholding information in relation to quality and safety of care be a criminal offence. However, he believes there is no need for a statutory requirement to report serious incidents as this is already covered by professional codes of conduct.

The Cavendish Review

80. In July 2013, the Cavendish Review was published. In the wake of Mid-Staffs, this review by Camilla Cavendish looked at unregistered staff in the NHS.

81. Cavendish's review found a 'disconnected landscape' where the NHS operates in silos. She advocates a system with reduced complexity and duplication with common standards across the NHS.

82. Cavendish notes that healthcare assistants (HCAs) have no compulsory or consistent training and a wide variety of job titles which can confuse patients. In optics, a comparison can be made to optical assistants.

83. Cavendish makes a number of recommendations for HCAs to have a standardised qualification which would allow them to use 'nursing assistant' as a protected title. This stops short of calling for statutory regulation as called for by Francis, an idea that the Government rejected.

84. Cavendish calls for regulators, employers and commissioners in health and social care should define a single common dataset for their purposes, and commit to using it, to relieve the pressure on first line managers and other staff.

85. She called for the Secretary of State for Health to commission the PSA for advice on how employers can be more effective in managing the dismissal of unsatisfactory staff, the legal framework around this, and the relationship with referrals to professional regulators.

86. Cavendish also notes the importance of healthcare professionals having 'time to care'.

The Keogh Review

87. This review by Bruce Keogh, Medical Director of the NHS, was published in July 2013, looking into the quality of care and treatment provided by 14 hospital trusts in England. The main barriers to delivering high quality care that Keogh identified were:
    - not listening to or engaging with staff and/or patients;

- difficulties in using data when it is complex and fragmented across the health system;
- some trusts are operating in an isolated location;
- lack of value and support being given to frontline clinicians; and
- transparency being used for blame and accountability rather than support and improvement.

The Clwyd/Hart review

88. The Government commissioned Ann Clwyd MP and Tricia Hart (Director of Nursing and Patient Safety at South Tees Hospital) to conduct a review into the complaints process in the NHS. They published their report in October 2013. Key points they identified included:
    - in some NHS trusts there is a culture of delays and denials when it comes to complaints, arising from a conflict of interest when a Trust investigates itself;
    - people often feel intimidated when making a complaint and find the complaints system confusing and difficult to navigate;
    - the report described a 'toxic cocktail' of people being reluctant to complain and staff being defensive and reluctant to listen to concerns;
    - many people who tried to ask for help or raise concerns are treated with a lack of compassion and sensitivity, and do not receive adequate support; and
    - many staff lack the skills to deal with complaints and dedicated complaints handling staff often lack the required training or seniority to act effectively.

89. The NMC and GMC have pledged to act on the findings of the Clwyd-Hart review.

90. The NMC has pledged to:
    - ensure the duties of registrants in relation to communication with patients and raising concerns are adequately highlighted in its revised Code of Conduct and standards, which they intend to publish soon;
    - take more immediate steps to raise awareness of these duties;
    - provide more information and support to patients and complainants during fitness to practise proceedings; and
    - work more closely with other regulators to share data and intelligence.

91. The GMC has pledged to:
    - examine how the skills required to communicate with patients and handle complains can be better reflected in postgraduate training and CPD – they intend to run a consultation early in 2014;

- research how well prepared medical graduates feel to deal with patient concerns and complaints in a positive way;
- look at how the role of patient feedback in revalidation can be further developed; and
- support patients more during fitness to practise cases, including using tailored face to face meetings to explain the process and outcomes – a final evaluation of a pilot programme will be received at the end of 2013.

PSA report on duty of candour

92. On 16 September 2013, the PSA wrote to Secretary of State for Health Jeremy Hunt with their view on how professional regulators can encourage healthcare professionals to be more candid. The DH had commissioned this advice.

93. The introductory letter states that they believe the most effective way for this to happen is for the regulators to collectively improve the clarity and consistency of our standards around candour. This could improve common standards, or at least common principles on which standards are based.

94. The paper also notes that any such changes would have to be complemented by work outside of professional regulators' remit, with employers, service regulators, indemnity providers and professional bodies.

95. The PSA define candour as:

> *"Any patient or service user harmed by the provision of a health or care service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it."*

96. Research they conducted felt that it is hard to determine the effect of professional regulation on registrants' day-to-day behaviour. The report also notes that different professions may have differing cultures, requiring profession-specific solutions.

97. The report notes that although candour is seen as 'the right thing to do', there are still barriers to healthcare professionals putting it into action. Professional regulators have to take these barriers into account.

98. The review notes that employers and the culture they foster have the greatest influence over professionals and their candour. This is particularly pertinent in light of our ongoing review into business regulation and the report specifically notes that *"we would expect their business standards to require those*

businesses to create a climate where professionals and others feel able and supported to be candid."

Standards

99. The benefits that the PSA see in having a common standard across the healthcare professions include:
    - redressing the difference between different professions' approaches to candour;
    - the ability to have guidance reinforcing messages about candour;
    - underpinning candour-related education and training;
    - encouraging post-qualification learning, which could be continuously checked through continuing fitness to practise schemes (such as enhanced CET); and
    - the standard forming part of FTP decisions.

100. The report notes that currently, only the GMC and NMC have standards which explicitly require candour, with the other regulators only having an implicit requirement. The report also notes the value of regulators proactively promoting their own standards to registrants, including specific case studies, where a lack of candour has caused problems.

101. The report struggled to quantify how many FTP cases relate to a lack of candour, as none of the regulators listed candour as a specific complaint category. It was felt that it was likely to be a contributory factor in a variety of other types of complaint but the lack of robust evidence makes it hard to analyse the effectiveness of regulators' current approaches to candour.

Education

102. The PSA's evidence points to education and training having a relatively strong influence over candour. The report notes though, that regulators can only affect this in an indirect way, as regulators only set the standard for joining the register rather than the specific curriculum. Education providers who the PSA spoke to suggested the following examples to help embed candour into future registrants:
    - Modules on professionalism and professional values;
    - Communication skills and assertiveness training;
    - Placement preparation focusing on values, policies and behaviours;
    - Mentors and educational staff modelling professional behaviour; and
    - Providing support for students when concerns are raised.

103. Regulators are also able to publish supplementary guidance for students, even though it is advisory rather than mandatory because (apart from the GOC) they don't register students.

Should regulators do more?

104. The report points to research by the Pharmaceutical Society of Northern Ireland (PSNI) which points to a large gap between the views of employers and the public as to what should happen to a pharmacist who failed to report concerns about another pharmacist. 51.3% of the public felt they should be referred to FTP whereas only 22.5% of employers felt the same.

105. Although based on a relatively small sample size (71 employers and 39 patients) it does point to a gap where public expectation may not be being met.

106. Two regulators reported to the PSA that indemnity insurance is seen as a barrier by some registrants to being candid where harm has occurred. The PSA noted that this was beyond the scope of their review but that the DH had been looking at the issue in the context of dispensing errors in pharmacy (which have recently been decriminalised).

107. The PSA also call for regulators' guidance to be clearer in describing professional behaviour *when,* rather than *if,* mistakes happen. They also note that standards should be easier to access and confusion can arise when they come from multiple sources.

Conclusion

108. The PSA presented the Secretary of State with three overarching recommendations:
    - focusing on regulation of pre-registration education;
    - encouraging greater consistency and clarity in professional candour standards; and
    - supporting further research into the effect of professional regulation on candour

Annex 2 – Francis Inquiry action plan Steps agreed by Council, May 2013

	Action	Implementation	Responsibility	Date	Progress
1	Work with the Professional Standards Authority (PSA) and other regulators to improve our information sharing about the complaints we receive. Consider how we may address fitness to practise (FTP) issues more proactively, for example by spotting trends that lead to complaints.	The PSA hosted a regulatory seminar on 4 July 2013 to address this point. The seminar identified various ways in which regulators might collaborate to improve performance in this area.	Head of FTP	Ongoing	Have already attended a PSA seminar on taking this forward. Details on next steps in relevant section of Council paper. PSA to take lead on taking this forward. We are now using our media monitoring tool to proactively find instances of registrants receiving convictions or cautions. Have already brought four potential complaints.
2	Continue to engage with the UK Law Commissions over any changes to regulators' investigation, FTP and adjudication processes.	Continue current level of engagement; consider current need for any additional legislative changes.	Director of Policy and Communications	Ongoing	We continue to work closely with the Law Commissions on their draft legislation in line with their required deadlines. We are participating in a regulators' forum to ensure a co-ordinated approach to the development and implementation of the legislation.

	Action	Implementation	Responsibility	Date	Progress
3	Satisfy ourselves that the support and guidance we provide to complainants and witnesses through the FTP process does not need to be strengthened.	FTP to review suitability of current guidance.	Head of FTP	Ongoing	Collaborated with other regulators and the Samaritans near the end of 2013 to train FTP staff in dealing with vulnerable witnesses.
4	Consider our position on any potential successor to the Office of the Health Professions Adjudicator (OHPA) as an independent tribunal service for ours and other healthcare regulators' FTP hearings.	Ultimately a decision for Council but FTP and Policy teams can provide updates and guidance. Continue to engage closely with PSA and other regulators to monitor attitudes towards such a tribunal.	Director of Policy and Communications		More likely to come back on to agenda following Law Commissions review when regulators share same legislation.
5	Consider, through our standards review and potentially other means, whether we need to strengthen our existing rules, guidance, education and support in respect of registrants raising concerns.	Standards review taking place during 2014. Continue to engage with PSA and other regulators about joint mechanisms for candour. Need to account for PSA advice to Government on duty of candour.	Head of Education and Standards	Consulting during 2014	Project team in place, planning to consult on new standards framework during 2014. Participating in regulators' working group to ensure a consistent approach.

	Action	Implementation	Responsibility	Date	Progress
6	Consider whether, and if so how, we ought to show more leadership in respect of promoting an open and transparent culture among our professions and the wider health service.	This would be best considered as part of the next strategic plan and reflected in our stakeholder engagement strategy.	Director of Policy and Communications	2014-17	New strategic plan places more emphasis on proactively promoting higher standards. Proposed stakeholder engagement strategy prioritises the need to clarify our role and responsibilities, and the need for us to take more of a leadership role in relation to standards.
7	Satisfy ourselves in our forthcoming standards review that the Codes of Conduct and/or the core competencies place sufficient emphasis on care and compassion.	Standards review taking place during 2013/14. Continue to engage with PSA and other regulators about joint mechanisms for candour and heed PSA advice on candour.	Head of Education and Standards	Consulting during 2014	Project team in place, planning to consult on new standards framework during 2014. Participating in regulators' working group to ensure a consistent approach.
8	Satisfy ourselves that our core competencies provide sufficient training in working with vulnerable groups such as older people, children or patients with disabilities.	Consider as part of standards review	Head of Education and Standards	Consulting during 2014	Project team in place, planning to consult on new standards framework during 2014. Consider visits or professionalism sessions such as those being undertaken by the GMC.

	Action	Implementation	Responsibility	Date	Progress
9	Consider whether the working environment for registrants and other staff should form part of our reviews of business registration and/or standards (specifically the business code of conduct).	Business regulation consultation takes into account the risks to the public arising from business practices, including the environment in which registrants work. For example, it examines how tensions between clinical issues and commercial incentives are managed. Standards review taking place in 2013/14.	Head of Education and Standards	Consulting on standards during 2014, including businesses Code of Conduct.	Project team in place, planning to consult on new standards framework during 2014. Council decided in November now register all businesses carrying out protected functions, regardless of title, along with a revised code of conduct. The new business code will consider this issue.
10	Satisfy ourselves that our rules and/or guidance around what constitutes effective supervision are suitable as part of our reviews of standards, business regulation and student regulation.	Currently being considered as part of student and business consultations. Standards review taking place during 2014.	Head of Education and Standards	Standards review during 2014	Standards review during 2014. Important to capture learning from student consultations.

	Action	Implementation	Responsibility	Date	Progress
11	Consider to what extent, and if so how, we ought to raise our public profile.	Considered a priority in strategic plan.	Director of Policy and Communications	2014-17	Strategic plan has given priority to 'increased trust and awareness'. Part of that includes working with stakeholders to raise awareness of our role. This is addressed in our stakeholder engagement strategy.
12	Consider whether we ought to take more steps to ensure that staff and lay Council and committee members are connected to front line of the profession.	Explanation of the role of registrants now part of induction for staff and Council members. First session took place in July with good feedback. Communications team to explore possibility of more staff having the opportunity to interact with registrants at events.	Director of Policy and Communications	More staff to be given the opportunity to attend stakeholder events during 2014.	New induction session has already taken place, receiving positive feedback from staff. Staff and Council members both had the opportunity to visit RNIB 'Eyepod' to learn more about sight-threatening conditions. We will explore other opportunities in the coming months.