

Council, 3 December 2013

PSA report on candour

Executive summary and recommendations

Introduction

The Policy and Standards Department report included in the papers at the 17 September 2013 Council meeting outlined how the PSA had been commissioned by the Department of Health to look at what steps the regulators could take in encouraging registrants to be more 'candid' about mistakes which led or may have led to harm to patients.

The PSA has now published its advice to the Secretary of State (attached) and this includes references to the written information provided by the Executive to the PSA.

The Council previously discussed this topic at its meeting on 27 March 2013 in light of the publication of the final report of the Public Inquiry into the failings of Mid Staffordshire NHS Foundation Trust.

The Executive considers that there is a good case for strengthening the standards of conduct, performance and ethics to be more explicit about the principles underpinning a 'duty of candour', as well as about reporting concerns and whistleblowing, possibly through the creation of a dedicated standard. The Executive plans to draw on the PSA report during the course of the PLG to be established to review the standards of conduct, performance and ethics from 2014-2015.

Decision

This paper is to note. No decision is required.

Background information

Council, 27 March 2013. Duty of candour

<http://www.hpc-uk.org/assets/documents/10003F72enc07-dutyofcandour.pdf>

The research undertaken with registrants and service users by the Focus Group concluded that the standards might be strengthened to include the:

'...responsibility of a registrant...to report incidents and ensure the safety of the service user by responding appropriately and supporting and providing information to the service user where things go wrong.'

Council, 4 July 2013. Standards of conduct, performance and ethics – accessibility and understanding – outcomes of research with registrants and service users.

<http://www.hpc-uk.org/assets/documents/100040D7Enc29-researchreportonStandardsOfconduct,performanceandethics.pdf>

Resource implications

None

Financial implications

None

Appendices

PSA (2013). Can professional regulation do more to encourage professionals to be candid when healthcare or social work goes wrong? Advice to the Secretary of State for Health

Date of paper

21 November 2013

Can professional regulation do more to encourage professionals to be candid when healthcare or social work goes wrong?

Advice to the Secretary of State for Health

October 2013

About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care¹ promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament.

We oversee the work of nine statutory bodies that regulate health professionals in the UK and social workers in England. We review the regulators' performance and audit and scrutinise their decisions about whether people on their registers are fit to practise.

We also set standards for organisations holding voluntary registers for people in unregulated health and care occupations and accredit those organisations that meet our standards.

To encourage improvement we share good practice and knowledge, conduct research and introduce new ideas including our concept of right-touch regulation². We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care. We also undertake some international commissions to extend our understanding of regulation and to promote safety in the mobility of the health and care workforce.

We are committed to being independent, impartial, fair, accessible and consistent. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

¹ The Professional Standards Authority for Health and Social Care was previously known as the Council for Healthcare Regulatory Excellence

² CHRE. 2010. *Right-touch regulation*. Available at <http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation> [Accessed 10 September 2013]

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1. Letter to the Secretary of State

The Rt Hon Jeremy Hunt MP
Secretary of State for Health
Richmond House
79 Whitehall
London
SW1A 2NS

16 September 2013

Dear Secretary of State

How professional regulation can encourage registrants to be more candid

This report is a response to your commission to provide advice specifically on the *professional* duty of candour rather than a statutory or contractual duty. In considering how professional regulation is functioning in this regard and whether any improvements should be made, we have reviewed research evidence, mapped regulators' existing provisions, examined current activity and consulted with stakeholders in reaching our conclusions. We are very grateful for the input, interest and support from all those who have contributed to this work.

Regulators' standards inform and influence not only professionals' practice, but education and training providers, students, leaders and supervisors. As our paper describes in more detail, it is our view that the most effective approach would be for regulators, as a group, to improve the consistency and clarity of their standards around candour.

Improved consistency and clarity in standards could include all regulators developing a common standard, shared across the regulated professions (or at least common principles upon which specific standards can be based). As a minimum, it is our recommendation that regulators should unite to declare publically their support for the professional duty of candour and their shared expectation that health and care professionals meet it.

Alongside this work by regulators, we recommend that the Government should consider providing funding and support for studies that seek to understand the impact of the changes we propose and others that may be implemented around openness, transparency and candour, thereby helping to build an evidence base for the future.

There are a number of potential barriers to candour that cannot be addressed by professional regulation alone. Our own research and other feedback reinforced our belief, as described by right-touch regulation, that if reforms to professional regulation are to have any impact on this issue, complementary efforts will also need to be made by employers, service regulators, indemnity providers and professional bodies. The success of the approach we advocate in this paper will depend upon this.

We hope our advice will be useful to you and the Department of Health.

Yours sincerely

A handwritten signature in black ink that reads "Harry Cayton". The signature is written in a cursive style with a long, sweeping tail on the final letter.

Harry Cayton
Chief Executive

2. Introduction

- 2.1 This paper is our response to a recent statutory request for advice made by the Department of Health, a copy of which is reproduced in Annex 1. Our recommendations are therefore intended for the attention of the Secretary of State for Health and his Department. However we expect the underlying evidence and analysis presented here to be of interest to anyone interested in healthcare or social work and professional regulation, including the many individuals and organisations who contributed their time, experience and views to this project.
- 2.2 The themes of openness, transparency and candour are at the core of the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (the Francis Report).³ The Francis Report's recommendations in this area reflect both a need to be open with patients as a matter of course throughout healthcare treatment, and a specific need to be candid when harm has occurred. They also address the current disaggregated and independent approaches to the principles of openness, transparency and candour.
- 2.3 The Francis Report's recommendations are wide-ranging, and draw on a number of levers to influence behaviour and encourage more widespread and active demonstration of openness, transparency and candour. A statutory duty of candour on service providers and employed professionals is one of the levers the Francis Report recommends. Other recommendations rely on professional obligations and role-based commitments, such as those in the NHS Constitution.
- 2.4 In its initial response to the Francis Report, the Government committed to working with the professional regulators to understand what more could be done to encourage healthcare professionals to be candid with patients.⁴ It is essentially this question which we have explored in this paper, although, given our remit, it has been broadened to include social workers in England being candid with people who use social work services. We discuss the definition of candour used in this paper in section 3.
- 2.5 We oversee nine professional regulatory bodies and they are the focus of our advice. Between them these organisations regulate over 30 different professions working in the NHS, high-street health services, private healthcare and social services, as well as other settings. The regulators are:
- General Chiropractic Council (GCC)
 - General Dental Council (GDC)

³ *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*, chaired by Robert Francis QC 2013. Available at <http://www.midstaffpublicinquiry.com/report> [Accessed 10 September 2013]

⁴ Department of Health, 2013. *Patients First And Foremost: The Initial Government Response to the Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry (Cm. 8576)*, para 2.32. Available at <https://www.gov.uk/government/publications/government-initial-response-to-the-mid-staffs-report> [Accessed 10 September 2013]

- General Medical Council (GMC)
- General Optical Council (GOC)
- General Osteopathic Council (GOsC)
- General Pharmaceutical Council (GPhC)
- Health and Care Professions Council (HCPC)
- Nursing and Midwifery Council (NMC)
- Pharmaceutical Society of Northern Ireland (PSNI).

The professions they regulate are listed on page 37.

2.6 The regulatory bodies have four main functions and we have considered each of these in the analysis of potential areas for improvement. These functions are to:

- Set and promote standards that professionals must meet before and after they are admitted to the register
- Maintain a register of those professionals who meet the standards. Only those who are registered with these bodies are allowed to work as health professionals in the UK or as social workers in England
- Take appropriate action when a registered professional's fitness to practise has been called into question
- Set standards of education for those training to be a health professional in the UK or a social worker in England. In some cases they set standards for those who continue to train and develop as health professionals in the UK or social workers in England.

2.7 Our advice is based on evidence from a number of different sources:

- A review of academic literature on the topics of disclosing mistakes, whistleblowing, patient safety, adverse events, medical ethics, regulation, and behaviours, to try to understand what enables and impedes candour and what regulation can contribute. Our review is published alongside this report
- Responses to the request for information we sent to the nine regulators we oversee (see Annex 2)
- Responses to the call for information (Annex 3) we placed on our website and sent to our public and professional stakeholder networks and organisations and academics we felt may have an interest in the topic. We heard from 39 organisations (listed in Annex 4), 10 individual members of the public and 4 academics. We also invited comments from officials in the devolved administrations
- Meetings with the NHS Litigation Authority, the NHS England Patient Safety team and three education providers.

2.8 The stakeholders we engaged with expressed a variety of views about how the regulators could encourage candour and relevant factors they should take into account while regulating. We have summarised these views in Annex 5.

3. Defining candour

- 3.1 Candour, and duties associated with it, are not always consistently defined in public debates and discussion. For the purposes of this advice, the focus of our research and analysis is the appropriate professional behaviour in those situations where an individual has been harmed by a healthcare or social work service. This focus is taken from the Francis Report, which defines candour as:

‘Any patient harmed by the provision of a healthcare 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’⁵

- 3.2 In other words, we are interested in the professional’s reaction when they know or suspect a mistake in their practice has harmed a patient or service user. The appropriate professional behaviour in these circumstances is to be open with the patient or service user about what has gone wrong, as the Francis Report recommends:

‘Recommendation 174: Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.’⁶

- 3.3 In contrast to this relatively narrow definition of candour and the professional duty associated with it, debates and discussion about this topic are rarely as well delineated. These circumstances were reflected in the context within which the Francis Report made these recommendations (chapter 22) and also in the responses and feedback that we have received during the course of this project. Even when we are focused on the Francis Report definition of candour, there are relationships beyond that between the individual professional and the patient or service user they are caring for, where the principle of being candid is important:

- Employee – Employer
- Provider – Public
- Provider – Commissioner/Regulator
- Commissioner/Regulator – Public/Patient/Service User

- 3.4 In addition, the issue of candour is related to and interwoven with a range of other issues, such as:

- Whistleblowing, speaking up and raising concerns
- Complaints handling
- Being open with patients and service users, delivering patient-centred care

⁵ See footnote 3, para 1.176

⁶ See footnote 3

- Informed consent
- Patient safety
- Supporting colleagues who are raising concerns
- Supporting colleagues who have to be candid
- Being candid about the risks posed by one's own health or practice.

3.5 Our advice here focuses on the definition of candour provided by the Francis Report (see 3.1) applied to reflect the range of health and social care professions regulated by the organisations we oversee:

Our definition of candour

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

3.6 We have been asked for advice on how professional regulation can encourage candour and it is this professional duty to be candid with patients and service users that we discuss in this report. In drawing conclusions and providing advice, our report in places necessarily reflects on the broader context within which the professional duty of candour may apply, not least because of some of the issues that have been found to work against professionals fulfilling this duty in practice. However, our research and analysis has not considered other kinds of duties often associated with candour, such as a statutory duty on individuals, obligations under the NHS Constitution, or a contractual duty on organisations. Neither have we been asked in this advice to consider any proposal to introduce criminal sanctions for a failure to meet a duty of this nature.

4. What can we learn from research evidence?

4.1 In order to understand better the limits and potential for regulatory action in this area, we have explored literature on relevant topics including disclosing mistakes, whistleblowing, patient safety, adverse events, medical ethics, regulation, and behavioural sciences.⁷ It should be noted that the bulk of the relevant literature concerns doctors; other than a handful of studies on nurses, we found little that related to other healthcare professions or social work. Most of the research originates from the US and Australia. We summarise and discuss below the relevant findings of this research review. A more detailed separate report of the review has been published alongside this paper.⁸

The scope of impact of professional regulation

- 4.2 Our thinking should be understood in the context of the research we commissioned from Dr Oliver Quick in 2011 to try to understand the influence that professional regulation can have on the behaviour of professionals. While the regulators of products can exercise direct control through the specification of the equipment that is used every day, the influence of the professional regulators on the behaviour of their registrants is far harder to determine, both in terms of its nature and its scale. A *scoping study on the effects of health professional regulation on those regulated*⁹, identified that professional regulation was just one among many influences on registrants' daily behaviour, judgements and decisions, and it is probably true that the regulator is not overtly present in the small ethical decisions of everyday life.
- 4.3 Even if the nature of regulation's influence was known, it could not be assumed that it would be desirable for regulation to be able to exercise direct control of the behaviour of registrants. Professional regulation should support but not supplant the appropriate application of professional judgement in given situations. The power to mandate or authorise particular behaviours in too specific a way might engender deprofessionalisation and dependency on the part of registrants. Furthermore, research undertaken by Meleyal¹⁰ on the effects of introducing a statutory register of social workers on the behaviour of those regulated found (amongst other things) that professional regulation can have perverse, unforeseen, and unintended consequences on people's behaviour. So, it cannot be assumed that the purpose, role and influence of regulation as perceived and experienced by registrants is always that which the regulator intends.

⁷ Please note this was not a formal academic literature review.

⁸ Professional Standards Authority 2013. *Candour, disclosure and openness - Learning from academic research to support advice to the Secretary of State*. Available at www.professionalstandards.org.uk

⁹ Quick O, 2011. *A scoping study on the effects of health professional regulation on those regulated. A report for CHRE*. Available at <http://www.professionalstandards.org.uk/docs/scrutiny-quality/110516-literature-review.pdf?sfvrsn=0> [Accessed 20 August 2013]

¹⁰ Meleyal L. 2011. *Reframing conduct: a critical analysis of the statutory requirement for registration of the social work workforce*. Available at http://sro.sussex.ac.uk/7665/1/Meleyal%2C_Lel_Francis.pdf. [Accessed 20 August 2013].

- 4.4 The literature we reviewed suggests that while candour is almost universally acknowledged as ‘the right thing to do’, health professionals and social workers still struggle, for a variety of reasons, to be as open as they should when things have gone wrong.
- 4.5 People are no doubt held back by the common human reactions to these sorts of situations – the bystander effect¹¹, reluctance to acknowledge error, feelings of guilt, and so on – but prevailing cultures in different professions may also exert an important influence. Doctors and nurses, for example, appear to have different attitudes and approaches to disclosure, indicating that any regulatory responses may need to be profession-specific to address the different cultures, while attempting to establish common expectations across the professions.
- 4.6 Professionals can be swayed by feelings of loyalty towards their colleagues and their employer; organisational and institutional influences are also an important factor. For example, non-NHS practitioners may be put off being open about mistakes by clauses in their private indemnity insurance policies, while those in the NHS may find that employers are themselves discouraging openness by fostering a culture of blame rather than one of safety and learning. Such negative attitudes can fuel people’s fears about reprisals and damage to careers and reputations, and have a powerful deterrent effect.
- 4.7 The research indicates that professionals struggle to come to terms with their own mistakes, which is in itself an impediment to disclosure. They are more likely to report mistakes if they believe that this will prevent an error from recurring, or if they can themselves learn from the mistake. They are also unsure about what to report, when and how. These are all issues that employers should be trying to address through support systems, training and clear policies. However, they also point to an important role for pre-registration training, which can teach aspiring professionals about the realities of errors and the importance of candour, and equip them with the skills needed to come to terms with their own mistakes and disclose their errors to colleagues and patients sensitively and effectively.

The role for professional regulation

- 4.8 Professional regulators will need to take into account professionals’ sense of loyalty to their peers and employers, and their concerns about retribution, negative impacts on their career, and referral to the regulator. They will also need to be aware of undoubtedly justified concerns about the impact of candour on indemnity insurance.
- 4.9 In addition, it seems clear from this review that employers and the culture they foster – safety or blame – have the greatest influence. Not only do they set the tone with respect to disclosure and whistleblowing, there is also much they can do to encourage staff to be candid. They should be supporting them to come to terms with any mistakes they might have made, and ensuring that they know how to disclose or blow the whistle and are fully equipped and supported to do so.

¹¹ The phenomenon described in social psychology whereby when someone is in need of help, the more bystanders are present, the lower the probability that any one of them will act, due to ‘diffusion’ of responsibility.

- 4.10 It seems that alongside any professional regulatory developments, professional representative organisations, employers, service regulators, and indemnity insurance providers all have an important role to play to encourage candour. Such a joined-up approach could build some resilience into the system and help professionals, including sole practitioners, who do not benefit from the support structures that should be provided by employers.
- 4.11 Professionals should also be taught about candour as part of their professional training. This would give them the opportunity, at an early stage, to get to grips with the realities of professional error, and to assimilate the principles and skills relating to candour. There may also be a role for ethical training to reinforce the 'moral courage' necessary to combat some of the disincentives to candour.

Conclusions arising from research review

- In the face of the many barriers to candour, a standard relating to candour in professional codes might encourage some professionals to be candid in situations when they otherwise would not
- Having a common standard across the professions could help to redress some of the differences between the professions' approaches to candour
- Guidance on the new standard would reinforce messages about the primacy of candour
- The standard would underpin the introduction of a candour-related training in pre-qualifying education programmes
- The standard could encourage the development of post-qualifying learning opportunities
- Continuing compliance with the standard would be checked periodically through continuing fitness to practise mechanisms
- The standard would form the basis of fitness to practise decisions.

5. Encouraging candour by setting and upholding standards for registrants

- 5.1 The regulators are responsible for setting, promoting and upholding standards of competence and conduct. These are the standards for safe and effective practice which every health professional and social worker should meet to become registered and to maintain their registration. They set out the quality of care that patients and service users should receive from health professionals in the UK and social workers in England.
- 5.2 The names of these standards vary between regulators and include, for example, codes of ethics, standards of practice and standards of proficiency. In this report we refer to them simply as standards.
- 5.3 Respondents to our call for information and the stakeholders we met made a variety of comments about how the regulators’ standards could be improved in relation to candour and factors that they might need to take into account when drafting and applying them. These views are summarised in Annex 5.

Setting professional standards

- 5.4 Some of the regulators’ standards contain both explicit and implicit duties of candour whereas others only contain implicit duties.

Explicit duties of candour

- 5.5 Of the nine regulators we oversee, only the GMC and NMC’s standards *explicitly* require their registrants to be candid with people harmed by their practice. The relevant standards state:

GMC	‘You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should: <ul style="list-style-type: none"> a. put matters right (if that is possible) b. offer an apology c. explain fully and promptly what has happened and the likely short-term and long-term effects.’¹²
NMC	‘You must act immediately to put matters right if someone in your care has suffered harm for any reason. You must explain fully and promptly to the person affected what has happened and the likely effects.’ ¹³

¹² GMC, 2013 *Good Medical Practice*, paragraph 55. Available at http://www.gmc-uk.org/guidance/good_medical_practice.asp [Accessed 10 September 2013]

¹³ NMC, 2008 *The code: Standards of conduct, performance and ethics for nurses and midwives*, standards 54 to 55. Available at <http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/> [Accessed 10 September 2013]

- 5.6 The GPhC has a standard that requires their registrants to respond ‘appropriately’ when care goes wrong however it does not specify that this involves being candid with the patient. The relevant standard states:

GPhC	‘[You must] Make the relevant authority aware of any policies, systems, working conditions, or the actions, professional performance or health of others if they may affect patient care or public safety. If something goes wrong or if someone reports a concern to you, make sure that you deal with it appropriately.’ ¹⁴
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Implicit duties of candour

- 5.7 All of the regulators’ standards require their registrants to be honest with their patients/service users. Most also require their registrants to act in the best interests of service users or make patient care their first concern. It is arguable that, in most situations, these standards *implicitly* require registrants to be candid with anyone who is harmed whilst in their care.
- 5.8 The exception would be a situation where it would not be in the person’s best interests to tell them what happened. Such situations will be rare and in any event the registrant would still need to put matters right (if possible) and ensure the person’s carers or personal representatives are told what happened.

Promoting professional standards

- 5.9 In addition to stating the risks of non-compliance in the standards themselves, the regulators can also promote their standards in a variety of other ways.

Registration processes

- 5.10 Eight of the nine regulators require applicants for registration to confirm in their application that they have read and will follow its standards. The ninth, the GOSc, sends newly registered osteopaths a copy of their professional standards.
- 5.11 Five of the nine regulators require their registrants to reaffirm their commitment to complying with the standards each time they apply to renew their registration.

Continuing fitness to practise schemes

- 5.12 The GMC introduced its revalidation scheme for doctors in 2012 and the GOC launched its new continuing fitness to practise scheme in January 2013. The other regulators are at various stages of developing continuing fitness to practise schemes to suit to the professions they regulate. Some told us they were looking at incorporating into these schemes assessments or declarations of compliance with their standards which would include elements related to candour. It is too

¹⁴ GPhC, 2012. *Standards of Conduct, Ethics and Performance* standard 7.11. Available at <http://www.pharmacyregulation.org/standards/conduct-ethics-and-performance> [Accessed 10 September 2013]

early to conclude how effective this approach may be in influencing registrants' behaviour.

Awareness-raising activities

- 5.13 The regulators take a number of steps to publicise and explain their professional standards to their registrants, the public and employers. For example:
- The GMC is pursuing a programme of 'promoting professionalism', which includes events, partnership and the development of practical tools and training, for example the development of an app for doctors to record continuing professional development
 - The GOsC has developed some e-learning scenarios, which ask osteopaths to identify the relevant standards and consider how they apply in clinical scenarios. Further scenarios have been piloted and will be launched shortly
 - The GDC will hold events across the UK to launch its new professional standards which will take effect on 30 September 2013. They will also publish training materials on their website
 - In the last two years the GMC has set up its employer and regional liaison services which engage directly with those who oversee the delivery of frontline healthcare and medical education
 - In 2012 the NMC and GMC made a joint statement on professional values which among other things asserted that 'doctors, nurses and midwives are expected to (...) Be open and honest with people receiving care if something goes wrong.'¹⁵ In 2001 a similar kind of joint statement was produced by all the health professions regulators.¹⁶

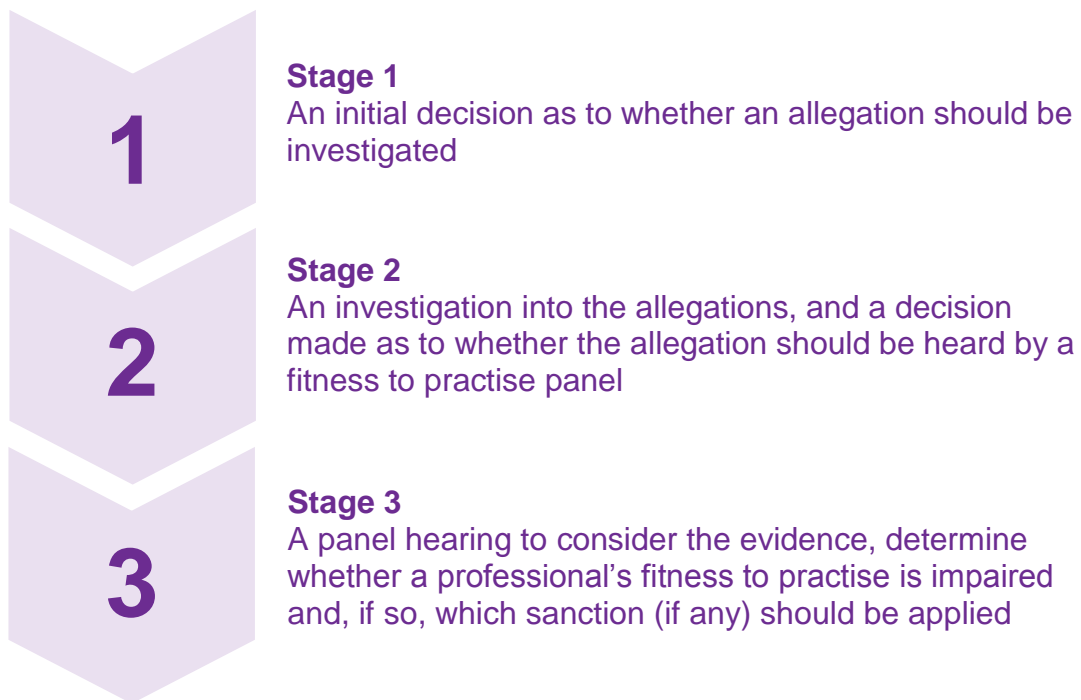
Upholding standards through fitness to practise proceedings

- 5.14 The regulators uphold professional standards through fitness to practise proceedings. Anyone, including members of the public, employers and the regulators themselves can raise a concern about a registered health professional's or social worker's conduct or competence if it calls into question their fitness to practise. When a concern is raised with a regulator about a professional who is registered with them, the regulator will follow the three stages of the fitness to practise process outlined in Figure 1 below.

¹⁵ Available at <http://www.nmc-uk.org/media/Latest-news/NMC-and-GMC-release-joint-statement-on-professional-values/> [Accessed 10 September 2013]

¹⁶ Available at http://www.gmc-uk.org/8a_UK_Health_Regulators__Statement_of_Common_Principles_for_Health_Care_Professionals.pdf_25398087.pdf [Accessed 10 September 2013]

Figure 1: An overview of the fitness to practice process



- 5.15 In certain circumstances regulators can take action to impose an 'interim order' on a registrant at any point in the process.

Examples of candour cases

- 5.16 Neither we nor the regulators have a 'candour' category in our existing information management systems for categorising fitness to practise cases.¹⁷ Identifying cases involving candour allegations would therefore involve manually sifting through thousands of dishonesty and competence cases. This has not been feasible within the timescale available for this project and resources available to us and the regulators.
- 5.17 We asked the regulators if they could identify any examples of fitness to practise cases involving allegations or findings that a professional had failed to be candid to a patient or service user about harm their practice had caused them. Some regulators suggested a lack of candour could be a constituent element within cases involving allegations of dishonesty or other professional misconduct or deficient clinical performance, however no relevant examples were identified.

¹⁷ The Authority keeps a database of all the final decisions made by the regulators' fitness to practise hearing panels because we scrutinise these decisions and, if necessary, refer to court any we consider are unduly lenient or do not protect the public.

Analysis

- 5.18 In the absence of relevant examples, it has not been possible to analyse the effectiveness of regulators' current approaches to enforcing a professional duty of candour through their handling of complaints about registrants at different stages of the process.
- 5.19 We cannot conclude from this absence of evidence that professionals rarely fail to be candid. The academic research and stakeholder responses to our call for information suggest that this is unlikely to be the case and anecdotally we are aware of cases involving clinical failings and an alleged 'cover-up' after the event.
- 5.20 We know that the effectiveness of fitness to practise as a mechanism to uphold professional standards is in part determined by the allegations and complaints that a regulator receives. Given the barriers to reporting highlighted by research evidence in Section 4 and stakeholder feedback in Annex 5, regulators may be unusually reliant on the public and employers to raise concerns about candour failures with them. To encourage reporting of candour failures, the regulators can:
- Set and publicise candour standards (as discussed above)
 - Refer to candour failures in fitness to practise referral guidance aimed at the public or employers.
- 5.21 The regulators can ensure they recognise and appropriately pursue candour failure allegations by:
- Including candour failure examples and issues in their training of fitness to practise case examiners, investigators and panellists
 - Clearly explaining in the decision making guidance used by their fitness to practise case examiners, investigators and panellists that a failure to be candid about harm caused to a patient or service is a clear failure of professionalism and should be taken seriously. For example, in light of the Francis Report, the HCPC has amended its Indicative sanctions policy in order to make clear how its fitness to practice panels should approach candour cases. The revised policy states: 'Registrants are expected to be open and honest with service users and, generally, Panels should regard registrants' candid explanations, expressions of empathy and apologies as positive steps.'¹⁸ We are aware the GDC has decided to make similar changes to its indicative sanctions guidance.
 - Monitoring for and auditing decisions that deviate from such guidance
 - Recognising that it could take time for failures to be candid to come to light and that therefore discretion may need to be exercised if a candour-related fitness to practise concern is raised beyond the timescale a regulator would normally accept.

¹⁸ HCPC, 2013. *Council meeting 4 July 2013, Indicative Sanctions Policy*, para 14. Available at <http://www.hpc-uk.org/assets/documents/100040C7Enc14-Indicativesanctionspolicy.pdf> [Accessed 10 September 2013]

Summary

- 5.22 Professional standards sit at the core of professional regulation. They should inform a registrant's practice throughout their careers. We are hopeful that in due course processes to assure registrants' continuing fitness to practise will offer an important opportunity to encourage and promote candour. The difficulty we have had in identifying fitness to practise cases suggest to us that until data is available to assess the effectiveness of fitness to practise processes in handling allegations of candour failure, we should refrain from claims about the effectiveness of this approach to enforcement. In the meantime, research evidence suggests that efforts to improve how professional regulation encourages candour will have a greater impact if focused on setting and promoting professional standards rather than enforcing them through fitness to practise.

6. Encouraging candour by regulating professional education

- 6.1 At the core of the regulators' work in education and training are a series of interconnected standards and associated assurance processes. Beyond this are a number of guidance documents that can also help to promote candour in students.
- 6.2 For the majority of regulators, their power to encourage candour among registrants through education and training is indirect, acting through education providers.¹⁹ In spite of this, research evidence points to the relatively strong influence that education and training can have on promoting and encouraging candour and it is worth considering the potential offered by these functions.
- 6.3 Respondents to our call for information and other stakeholders we engaged with made some suggestions about possible improvements to regulators' work in education and training to encourage candour. These are summarised in Annex 5.

Educating and training for candour

- 6.4 It is not the regulator's responsibility to set the curriculum or the detail of a particular pre-registration programme. The regulator's responsibility is to set the necessary standard to join the register – standards for new registrants – and the necessary complementary standards for education providers, students, teachers and mentors that arise from these. Some regulators also have responsibilities for post-registration education and training. Our analysis and conclusions on improvements would also apply in these circumstances.
- 6.5 The education providers we spoke to described a number of ways in which skills and behaviours to support candour can be embedded into pre-registration training. Ideally an integrated approach would be adopted throughout the education programme to allow this specific set of skills and behaviours to be acquired from different angles, including case studies, reflective learning, and direct teaching, to help them take decisions in difficult situations. For example:
 - 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
 - Providing support for students when concerns are raised.

¹⁹ The exception to this is the GOC, who have the additional opportunity to influence students directly through statutory registration. Although it should be noted the GOC is currently consulting on proposals to end student registration.

Setting and assuring standards of education and training

- 6.6 Regulators set standards for education providers that are linked to the outcomes that students need to achieve in their training, and the standards that registrants need to demonstrate when they practise. These may be published separately, for example, as in the GDC's *Preparing for Practice* and *Standards for the Dental Team* or as one document, as in the GMC's *Tomorrow's Doctors*. Table 1 (overleaf) provides an example of the interrelationship of these sets of standards with respect to the issue of candour from the HCPC. They set standards of education and training for education programmes. These draw on and refer to the standard of proficiency for an individual profession and the standard of conduct, performance and ethics for all registrants. Other regulators take a similar approach.
- 6.7 Alongside these different sets of standards are quality assurance activities that monitor how well education providers are delivering programmes. Some regulators discussed this in depth in their responses, and some stakeholders also said they regarded this as a useful lever for encouraging candour.
- 6.8 The GDC told us:
- 'Our quality assurance activity will consider a range of evidence provided to demonstrate achievement ... including relevant policies and procedures, communication mechanisms, records of concerns raised and actions taken. Inspectors routinely speak to students during the course of an inspection and are well placed to ask whether students feel able to raise concerns at this very early stage of their career.'*
- 6.9 The GOsC's approach to quality assuring education includes annual monitoring of complaints and student fitness to practise data to understand if candour-related issues are arising in education programmes. None have yet been reported.

Table 1: Example of interrelationship of regulators' standards in education – HCPC

Standards of education and training
<p>'4.1. The learning outcomes must ensure that those who successfully complete the programme meet the standards of proficiency for their part of the Register.'</p> <p>'4.5. The curriculum must make sure that students understand the implications of the HCPC's standards of conduct, performance and ethics.'</p> <p>'5.12. Learning, teaching and supervision must encourage safe and effective practice, independent learning and professional conduct.'</p> <p>'6.3. Professional aspects of practice must be integral to the assessment procedures in both the education setting and practice placement setting.'</p>
Standards of proficiency
<p>'2.1 understand the need to act in the best interests of service users at all times'</p> <p>'2.3 understand the need to respect and uphold the rights, dignity and values of service users'</p> <p>'2.4 recognise that relationships with service users should be based on mutual respect and trust'</p> <p>'8.1 be able to demonstrate effective and appropriate verbal and non-verbal skills in communicating information, advice and instruction and professional opinion to service users, colleagues and others.'</p>
Standards of conduct, performance and ethics
<p>'1. You must act in the best interests of service users...You are personally responsible for making sure that you provide and protect the best interests of your service users...You must protect service users if you believe that any situation puts them in danger. This includes the conduct, performance or health of a colleague. The safety of service users must come before any personal or professional loyalties at all times. As soon as you become aware of a situation that puts a service user in danger, you should discuss the matter with a senior colleague or another appropriate person.'</p> <p>'4. You must tell us (and any other relevant regulators) if you have important information about your conduct or competence, or about other registrants and health and care professionals you work with...You should cooperate with any investigation or formal inquiry into your professional conduct, the conduct of others, or the care or services provided to a service user, where appropriate. If anyone asks for relevant information in connection with your conduct or competence, and they are entitled to it, you should provide the information.'</p>

Supplementary education guidance and other activities

- 6.10 Many regulators publish guidance aimed at students. This may be a code of conduct and/or guidance on fitness to practise. For the majority this guidance is advisory rather than mandatory (as noted above, the exception to this is the GOC). The aim is to promote good professional behaviour among students and help education providers handle issues that may arise during the course of study. References to being open following a mistake that causes harm are rare, although the GCC's *Student fitness to practise guidance* does state that 'you must get help immediately if someone you are providing care for has suffered harm for any reason'. Otherwise, as with many standards for registrants, this behaviour is implied from a combination of clauses relating to patient-centred care, reporting and acting on concerns, good communication and being honest and trustworthy. For example:

GPhC	<p>2. Use your professional judgement in the interests of patients and the public</p> <p>As a student you must:</p> <p>2.1 consider and act in the best interests of the public.</p> <p>2.4 be prepared to challenge the judgement of others if you have reason to believe their decisions could compromise safety or care.</p> <p>6. Be honest and trustworthy</p> <p>6.7 Cooperate with formal investigations about you or others.²⁰</p>
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- 6.11 Stakeholders highlighted other opportunities in regulators' education and training standards to encourage and promote candour:
- An education provider pointed to the NMC's Standards to support learning and assessment in practice settings
 - A professional organisation identified standards for supervisors as an opportunity to promote candour among those with responsibility for education and training of registrants once they have initially qualified.
- 6.12 In other work, the GOsC have developed and piloted undergraduate professionalism e-learning programmes for students. Emerging findings suggest that students are not taking the falsification of records as seriously as they should be. If these results persist, they will be used to inform work between the regulator and education providers to target development of appropriate professional behaviours.

²⁰ GPhC, 2010. *Code of conduct for pharmacy students*. Available at <http://www.pharmacyregulation.org/sites/default/files/Code%20of%20conduct%20for%20pharmacy%20students%20s.pdf> [Accessed 10 September 2013]

Summary

- 6.13 Education and training provide a series of useful opportunities for regulators to encourage and promote a professional duty of candour to new registrants. Stakeholders expressed views on a number of ways to enhance current regulatory approaches to this issue. In our view, these would have a greater impact if delivered with improvements identified elsewhere for other parts of the health and care system.

7. Could professional regulation do more to encourage candour?

- 7.1 As we described in Section 3, our working definition of candour for the purposes of this advice is derived from the Francis Report:

Our definition of candour

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

This definition was adopted in the interests of expediency to meet the tight timescales for this work. For the specifics of professional regulation it may be necessary to explore whether this is the most appropriate definition to underpin the professional duty of candour. In particular greater clarity about the level and type of harm caused may be appropriate.

- 7.2 A professional duty of candour is focused on the individual's reaction (and, where appropriate, the team's reaction) when a mistake happens and harm occurs. There are three aspects to this:
- Recognising that harm has occurred or may have occurred
 - Proactively informing the patient or service user about what has happened
 - Offering an appropriate remedy and support²¹.
- 7.3 To these we would add a complementary obligation on all professionals to support their peers when they need to be candid and to play an active role in creating a climate where professionals feel able and supported to be candid. This would be especially important given the reality that care is often delivered by multi-professional teams. These four actions are integral to candour, and in our view, a professional duty of candour could not be said to be met if one or more is absent.
- 7.4 In addition to regulating individual professionals the GOC and GPhC also regulate businesses.²² 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.

²¹ The nature of appropriate and available remedy and support will depend to a certain extent on the circumstances in which the professional is working in as it brings into play matters of resourcing and redress.

²² The GDC could also regulate businesses if relevant provisions within its governing legislation were brought into force.

- 7.5 The impetus to promote and encourage candour in health professionals and social workers arises from a wider discussion in the Francis Report about the lack of openness and transparency within the Trust during the period investigated by the Inquiry. The Francis Report's aspiration of openness, transparency and candour for the healthcare system is in part rooted in the principles of honesty and truthfulness:

*'The culture of the NHS must embrace principles and practices that require the full truth to be told about the standard of care being provided in particular organisations'*²³

However, it is also driven by a wider concern about public trust in the NHS:

*'The public interest requires openness and honesty in relation to the maintenance of standards of service. Without this, public confidence in the system will drain away'*²⁴

So, not only must the health and care system ensure that the truth is told, it must also be seen to do so, for public confidence to be maintained.

- 7.6 The Francis Report's emphasis on openness, transparency and candour reflect one aspect of the need for culture change in healthcare that formed the Report's overriding recommendation. In our view, the proposals around candour, and the particular issue we have explored in this paper, is one expression of the desired change in culture. Better fulfilment of a professional duty of candour would also help to address the recommendation of *A promise to learn, a commitment to act* (the Berwick Report) that the NHS should become a system devoted to continual learning and improvement of patient care, to address patient safety problems and build a safety culture.
- 7.7 The Berwick Report suggested that current approaches across professional regulation may be sufficient to support a duty of candour:
- '... this duty is adequately addressed in relevant professional codes of conduct and guidance.'*²⁵
- 7.8 At one level this may be an appropriate assessment and some respondents to our call for information agreed. However, as we have seen in sections 5 and 6, it was not easy to identify relevant fitness to practise cases, and many respondents identified potential areas for improvement in professional regulation in the interests of encouraging and promoting candour. Some of these recommendations fall clearly within regulators' roles and responsibilities. Others reflect the influence of other organisations, agencies and individuals on the success of a professional duty of candour.

²³ See footnote 3, para 20.96

²⁴ *ibid*

²⁵ National Advisory Group on the Safety of Patients in England. 2013. *A promise learn – a commitment to act*, p34. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf [Accessed 10 September 2013]

7.9 Many of these comments from stakeholders mirror findings from the Francis Report about inconsistent references to candour in standards:

*'22.159: The ways in which that requirement is currently recognised are piecemeal and disjointed, and inevitably do not cover the whole of the ground which should be addressed. (...) Unless steps are taken to evidence the importance of candour by creation of some uniform duty with serious sanctions available for non-observance, a culture of denial, secrecy and concealment of issues of concern will be able to survive anywhere in the healthcare system.'*²⁶

This finding around piecemeal and non-uniform requirements about a duty to be candid was reflected in the views expressed to us via the call for information.

7.10 We have not taken a view on what level of harm warrants candour as this issue is beyond the scope of this advice. However we observe that different views exist about the appropriate trigger point:

- *'where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff'* (the Francis Report's candour proposals for healthcare organisations²⁷)
- *'patient safety incidents that led to moderate harm, severe harm or death'* (*Being Open*²⁸)
- *'if someone in your care has suffered harm for any reason'* (NMC²⁹)
- *'If a patient under your care has suffered harm or distress'* (GMC³⁰)
- *'Full information must be given to patients and their carers or representatives about any act or omission affecting their medical treatment and care which has caused harm (...) The duty should not be limited in any way, and all patients deserve candour, regardless of the injury suffered'* (patient advocate response to our call for information).

7.11 We also note that *Being Open* reports feedback from patients and healthcare staff that discussing 'near misses' and 'no harm' patient safety incidents with patients would, generally, be counterproductive and decisions about disclosing these should be made on a case by case basis guided by what is in the individual patient's best interests.³¹ This personalised approach is in tune with the regulators' general expectations that registrants exercise professional judgment in applying their standards, given that such standards can never be written in a way that anticipates every possible eventuality. Registrants will need to personalise their approach to candour to each patient and service user.

²⁶ See footnote 3

²⁷ See footnote 3, Recommendations 174 and 181

²⁸ National Patient Safety Agency, 2009. *Being Open, communicating patient safety incidents with patients, their families and carers*, p12. Available at <http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726> [Accessed 10 September 2013]

²⁹ See footnote 13

³⁰ See foot note 12

³¹ See footnote 28

7.12 Other evidence suggests a need to alter current approaches on candour. Data collected through the Authority’s 2012/2013 review of the regulators’ performance³² provides one small example of the difference of opinion that exists around this topic. We reported on a survey conducted by the Pharmaceutical Society of Northern Ireland in 2012. The PSNI asked employers and the public ‘*What do you think should happen to a pharmacist that failed to report concerns about other pharmacists or health professionals?*’ The contrast in the responses is interesting:

Table 2: PSNI 2012 survey results

What do you think should happen to a pharmacist that failed to report concerns about other pharmacists or health professionals?	Pharmacist employers (n=71)	Public (n=39)
Nothing – it is a matter of personal conscience	38.0%	15.4%
Issued with a warning	39.4%	33.3%
Refer to fitness to practise process	22.5%	51.3%

7.13 While the sample size is small and may not reflect the UK perspective as a whole or that of other professional settings, these results point to an expectation on the part of the public that a failure to report concerns should be addressed, which is not matched to the same extent by the employers who were surveyed. In this context employers may be self-employed pharmacists who may have been commenting on what should happen to them individually. It may also reflect the influence of commercial and business issues when professionals consider raising concerns.

7.14 Despite the sense that being candid is ‘the right thing to do’ from professional and public standpoints, evidence from academic research suggests that this is not the course of action that is always followed. In the light of this, and given the evidence above we suggest that improvements to professional regulation should be considered in the interests of the public, alongside corresponding reforms identified by the Francis Report and led by employers, systems regulators and others.

7.15 Professional regulators are only one part of the system supporting professionals to be candid with patients and to raise concerns with colleagues and employers when they think there are risks. Employers have a significant role to play to

³² Professional Standards Authority, 2013. *Performance Review Report 2012/2013*. Available at <http://www.professionalstandards.org.uk/docs/scrutiny-quality/performance-review-report-2012-13.pdf?sfvrsn=0> [Accessed 10 September 2013]

enable professionals to demonstrate the candour that is clearly expected of them. This is supported by the research evidence, and stakeholder responses also highlighted the important contribution that professional bodies, such as Royal Colleges and others, could play in emphasising and promoting candour and opportunities to learn from others mistakes. For example, if education and training offer the greatest potential to encourage candour, it is essential that students feel supported as they make the transition to becoming registrants, and are supported, by their managers, employers and professional organisations in the early stages of their careers.

- 7.16 Two regulators reported to us that indemnity insurance was a potential barrier to registrants fulfilling a professional duty of candour. This issue also arose in the research review and a few respondents to our call for information referred to it too. It is beyond the scope of this advice, but any improvements in encouraging and promoting candour that regulators pursue may be challenged by current indemnity insurance provisions which may prevent an individual professional from being candid when harm has occurred. Further investigation and review of the relevant terms and conditions of these insurance policies would be of benefit to professionals, regulators and service users. We understand Department of Health officials working on The Rebalancing of Medicines Legislation and Pharmacy Regulation Programme Board have been looking at the related issue of dispensing error offences inhibiting candour among pharmacists.

Areas for improvement

- 7.17 There is room for improvement in the consistency and clarity of the regulators' core standards for registrants. We found only two regulators made explicit the expectation that registrants should be being open and honest with patients when their mistake or error causes harm. For others, the expectation is less clear and implied through a combination of standards that emphasise different aspects of candour – such as communication, patient centredness, honesty, and raising concerns. As a group, the professional regulators we oversee could be clearer and more consistent in their guidance and standards around candour. This should include supporting colleagues who need to be candid and, where appropriate, creating a climate where colleagues feel they can be candid.
- 7.18 Given the research findings about the positive influence that pre-registration training has on candour, the concern about lack of clarity in some professional standards extends to their influence over education. At present, the standards for students and education providers predominantly focus on raising concerns and speaking out when risks are identified during an education programme. That may be appropriate, but clarity in professional standards about the behaviours expected of a registrant when a mistake happens and harm occurs would have a positive influence on the content and delivery of pre-registration education.
- 7.19 Furthermore, the language used by regulators in their standards and guidance could be clearer if they described appropriate professional behaviour *when*, rather than *if*, mistakes happen. The GDC's *Preparing for Practice* takes this approach to problems and it is also reflected in their *Principles of Raising*

Concerns guidance, in contrast to the style adopted by other regulators where the word *if* prevails.

- 7.20 A number of regulators also publish standards for registrants involved in educating, mentoring or supervising students and trainees. These present a useful and practical opportunity to embed, encourage and support candour. Similarly leadership and management guidance should emphasise the importance of creating a culture that supports candour.
- 7.21 Standards should be easy to access.³³ A practical issue arises when regulators rely on a combination of standards. For readers it means it is important that links between documents are maintained, especially when reading online. Re-designed websites can increase the risk that these links are lost, telling readers that the 'page is not found'.
- 7.22 In their responses a number of regulators indicated that they were planning revisions of their standards over the next year, and that the Francis Report would be reflected in these reviews. This presents a chance to improve current guidance for professionals. Moreover, it would be unfortunate if this opportunity for regulators to work together on improving standards so they are clear and consistent across professions was missed when joint action is needed.

A single common standard for all?

- 7.23 We have been asked to consider whether there should be a single common standard applied to all registrants by all regulators. It is an attractive proposal, and is in line with a number of responses to our call for information. It also reflects the multidisciplinary delivery of some health and care services across the UK.

'While all regulators do encourage their registrants to be open, honest and candid when something goes wrong; they do so in different ways and it would be helpful if there was a single approach taken by all health and social [care] regulators in this respect. ...We believe that there should be a common, agreed set of standards, codes and systems etc., that are applied by all professional regulators. It is only through this that there can be equity and consistency in the way regulators do their business and also provide assurance to the public about the professionals they regulate.' (Patient and public advocate)

- 7.24 The research evidence indicated some profession-specific differences in attitudes to raising concerns and there may be context-specific factors that need to be addressed in standards. Notwithstanding this variation, adopting a common objective through a standard would eliminate any uncertainty about the importance of candour, thereby helping to resolve tensions arising from divergent professional approaches. It could be supported by guidance as necessary, underpin the introduction of a candour-related outcome for pre-registration training, and encourage the development of post-qualifying learning

³³ CHRE, 2010. *The standards of good regulation*, para 3.2. Available at <http://www.professionalstandards.org.uk/docs/scrutiny-quality/performance-review-report-2012-13.pdf?sfvrsn=0> [Accessed 10 September 2013]

opportunities. Continuing compliance with the standard could be checked periodically through regulators' continuing fitness to practise mechanisms, it would inform fitness to practise decisions, and help to sustain consistency in handling complaints.

- 7.25 However, we are aware that in practice, it may be difficult to achieve a common standard across nine independent statutory bodies in a timely and effective manner. If this is the case the regulators should be encouraged to sign up to a joint statement declaring their support for and expectation that their registrants meet a common professional duty of candour, as described in the Francis Report derived definition in 7.1 to 7.3 above.

8. Advice to the Secretary of State

- 8.1 Our research and analysis has identified a number of potential areas where professional regulation could be improved to encourage registrants to be more candid. We conclude this paper with our advice specifically for the Secretary of State for Health.
- 8.2 In line with the scope of this project we limit our advice to the field of professional regulation. Clearly changes in professional regulation will not by themselves address the comprehensive and wide ranging candour-related recommendations in the Francis Report. Many other agents in the system have a role to play in encouraging candour: employers, service regulators, commissioners, the law, insurers and other organisations. The following advice should be viewed in this context.

Focus on the regulation of pre-registration education

- 8.3 Based on their current statutory roles and responsibilities, the regulators have the greatest potential to encourage candour, as defined in 7.1 to 7.3 above, among their registrants via their education and training responsibilities. To maximise this potential, **we advise the Secretary of State to work with the regulators to improve the clarity and consistency of candour standards for registrants and the education standards relating to them.** These improvements should reflect research evidence about the barriers and enablers of candour, and patient safety science.
- 8.4 Professional regulators should be included in any wider system plans to bolster the education and training system around candour, as the Berwick Report recommended:

‘The commissioners, regulators and providers of training and education for healthcare professionals (including clinicians, managers, Boards and relevant Governmental staff and leaders) should ensure that all healthcare professionals receive initial and ongoing education on the principles and practices of patient safety, on measurement of quality and patient safety, and on skills for engaging patients actively.’³⁴

Encourage greater consistency and clarity in professional candour standards

- 8.5 Greater consistency and clarity could be achieved by the development of a common standard applied across all registrants by all regulators. **The Secretary of State may wish to request that the regulators to begin working towards a common standard.** We are conscious that this may take some time to deliver however, so as a short-term measure, **we advise the Secretary of State that the regulators should be encouraged to sign up to a joint statement declaring their support for and expectation that their registrants meet a professional duty of candour with a commitment to moving towards a**

³⁴ See footnote 25

common standard over time. This could be delivered in a similar manner to previous joint statements (see 5.13).

- 8.6 Regulators have a clear role in promoting professional standards as part of the wider system of organisations influencing the quality and standard of care delivered to patients and service users. **The Secretary of State may wish to work with the regulators to increase the profile of professional candour standards to registrants and employers.** We consider that this would help to support cultural change in the delivery of health and care services emphasised in the Francis Report and in the Berwick Report.
- 8.7 Finally, we advise that if the regulators are unable to make the changes the Secretary of State considers necessary, there is the opportunity to explore changes to regulators' primary legislation. The Law Commissions' simplification review, due to report in February 2014, would provide a suitable opportunity to address lack of clarity and inconsistencies in the regulators' approaches to candour and provide for joint standards and guidance.
- 8.8 Beyond this, it is less clear that the regulators exert much influence over registrants' fulfilment of this duty. In theory processes developed by regulators to assure continuing fitness to practise could over time offer potential to promote candour, but it is too early to offer definitive conclusions on this. Data around the effectiveness of fitness to practise processes to enforce a professional duty of candour is not available without considerable further investigation. **Our advice is that no conclusion can be drawn on the effectiveness of fitness to practise as an enforcement mechanism at this time.**
- 8.9 As we have stressed throughout this paper, the limitations of professional regulation will be felt more keenly if well-documented barriers to candour are not addressed elsewhere. This includes employers adopting policies and cultures that allow employees to feel supported if they needed to be candid, or providing support for newly qualified registrants in the early stages of their careers. We have also highlighted the difficulties that indemnity insurance policies and the criminalisation of dispensing errors may pose to fulfilling a professional duty of candour. **We advise the Secretary of State to promote a co-ordinated and integrated approach to addressing the candour issues identified by the Francis Report.**

Support further research

- 8.10 We know that the nature and scale of the influence of professional regulation on registrants' behaviour is not well understood and that there is little research evidence available on this question. The system's response to the Francis Report, and in particular changes proposed to alter how professionals treat and care for patients and service users provide a useful evaluation opportunity. **We would advise the Secretary of State to consider providing funding and support for studies that seek to understand the impact of the changes we propose and others that may be implemented around openness, transparency and candour, thereby helping to build an evidence base for the future.**

9. Equality analysis

9.1 This equality analysis considers the likely impact of our recommendations in Section 8 on the three aims of the public sector equality duty³⁵. The duty requires most public bodies, including the Authority, to exercise their functions with due regard to the need to:

- Eliminate the discrimination, harassment, victimisation and other conduct prohibited by the Equality Act 2010
- Advance equality of opportunity between persons who share a relevant protected characteristic and other persons
- Foster good relations between persons who share a relevant protected characteristic and other persons.

9.2 To inform this analysis we have sought relevant information by:

- Reviewing the Department of Health's own equality analysis for the contractual duty of candour on healthcare providers³⁶
- Including a question about the equality implications of increased candour in our call for information (see page 38)
- Inviting some organisations with equality expertise to respond to the call for information. Namely the Equality and Human Rights Commission, Discrimination Lawyers Association and Employment Lawyers Association
- Arranging for the Equality and Diversity Forum to circulate the call for information to their members and non-governmental observers. The Equality and Diversity Forum is a network of national organisations committed to progress on age, disability, gender and gender identity, race, religion or belief, sexual orientation and broader equality and human rights issues
- Noting any equality issues raised in the academic research reviewed for the literature review referred to in section 4.

9.3 We also took account of relevant guidance published by the Equality & Human Rights Commission.

9.4 Based on this information our analysis is that if our advice about encouraging candour in section 8 were to be implemented:

- it is likely to support the first and second aims in the equality duty by leading to changes that discourage presumptions that disabled and older patients are too vulnerable to be candid with. We are assuming here that a) the regulators' guidance will encourage registrants to implement their candour

³⁵ Equality Act 2010, section 149

³⁶ Department of Health, 2010. *Equality Analysis, Implementing a 'Duty of Candour'; a new contractual requirement on providers*. Available at http://webarchive.nationalarchives.gov.uk/20130123195221/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_130442.pdf [Accessed 10 September 2013]

standards in a non-discriminatory personalised manner, b) registrants comply with this and c) their employer (if they have one) supports them with appropriate policies and resources

- It is likely to have no impact (positive or negative) on the third aim of the equality duty by neither encouraging nor discouraging good relations between persons who share a relevant protected characteristic and other persons
- It could not be improved in any way to better support the three aims of the equality duty.

9.5 Some respondents to our call for information suggested some registrants' ability or willingness to be candid may be influenced by the culture of the country where they trained (race), prevailing thinking about candour at the time they trained to join their profession (age) and disability related communication impairments. However we do not consider a professional duty of candour will unlawfully indirectly discriminate because if these disadvantages materialise the measures for encouraging candour we recommend would, in our view, be a proportionate means of achieving the legitimate aim of increased candour.

9.6 The above analysis assumes our recommendations do actually increase candour and have no unintended consequences.

10. Annex 1 – Commissioning letter

Mr Harry Cayton
Chief Executive
Professional Standards Authority

26th June 2013

Dear Harry

Request for advice: how professional regulation can encourage registrants to be more candid

In accordance with section 26A of the NHS Reform and Health Care Professions Act 2002, (the 2002 Act), on behalf of the Secretary of State I commission the Authority for advice arising from the recommendations made in the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry around the duty of candour, openness and transparency.

The Report made several recommendations around openness, transparency and candour covering their principles, implementation and enforcement (recommendations 173 – 184) so it would be helpful if your advice took these recommendations into account.

It would assist the Secretary of State, if the Authority, in presenting the advice:

- (i) take account of the views of the patient, service user and public representative groups, Regulatory Bodies referred to in section 25(3) of the 2002 Act, and healthcare practitioners and social work practitioners in England, and their employers
- (ii) explains how the Authority has complied with the public sector equality duty in formulating the advice
- (iii) clearly indicates the opinions of each of the groups with whom Authority engaged and of the Devolved Administrations.

The Francis Inquiry is clear in its recommendations and spirit that openness is a key element of healthy organisational cultures. The Government's initial response follows up on this by committing to introduce a statutory duty of candour on providers (this will be done via CQC's registration requirements) and acknowledging that there is an existing requirement to be open in the professional codes of practice for doctors and nurses. The response also commits DH to working closely with professional regulators to examine what more can be done to encourage professionals in their delivery of the duty of candour.

It is this aspect that we want the Authority's advice on, working with the regulators to inform DH's thinking into how the duty of candour could be implemented alongside existing frameworks.

Your advice should consider how the regulators' current requirements relevant to a duty of candour (or equivalent wording in their codes) are functioning and whether any improvements should be made in the interests of the public. It would be helpful if the response considered all regulators under the Authority's oversight, covered all relevant regulatory functions, and included:

- mapping of the regulators' current requirements on their registrants to be candid and open with their patients;
- how complaints/allegations about a registrant's failures to be candid are handled by regulators' fitness to practise processes, including if possible, analysis of decisions about candour failure taken at each stage of the fitness to practise process, and an assessment of the number and percentage of cases taken forward by each regulator in recent years (ideally since 2009)
- in the light of this analysis, views from the Authority, regulators and other stakeholders about the strengths and weaknesses of current approaches to enforcing a professional duty of candour (or equivalent) through fitness to practise procedures
- highlighting any examples of good practice that should be adopted by all regulators
- consideration of whether there should be a single common standard applied to all registrants by all regulators, in the interests of the public.

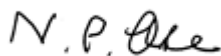
It would also be useful if the advice linked to the work you are taking forward with the regulators relevant to Francis Recommendation 235, if common themes emerge.

In respect of managing the process, I would require interim monthly written updates on the first day of each month, and a final report, for Secretary of State, by Monday 16 September 2013.

Once you have considered the scope of work needed to deliver the tasks please provide a breakdown of your costs for DH to confirm any additional funding.

I am copying this letter to colleagues in the Devolved Administrations and to the chief executives of the regulatory bodies.

Yours sincerely



Nick Clarke
Deputy Director Professional Standards

11. Annex 2 – Information request to regulators

11 July 2013

Dear Colleagues,

Encouraging candour

You will be aware of the request we have received from the Secretary of State for Health to provide advice on how professional regulation can encourage UK healthcare practitioners and social workers in England to be more candid when care goes wrong.

The request has arisen from recommendations 173 to 184 in the *Report of the Mid Staffordshire NHS Foundation Trust Public inquiry* about the principles of candour, openness and transparency.

The commissioning letter specifically asks us to include in our final report the views of the regulators we oversee and information about how existing professional requirements relating to candour are functioning and whether any improvements should be made in the interests of the public.

To help us meet this requirement we would be grateful for your response to the questions below by **Friday 9 August 2013**. We apologise for this tight timescale however it is determined by the needs of the Department of Health.

Questions

1. We enclose a table of the candour and honesty related standards we have identified in yours and the other regulatory bodies' current codes of practice/standards/guidance. Please can you confirm that we have identified the correct standards for you? Please tell us if you consider any of your other standards implicitly require registrants to be candid, open, transparent and/or honest about treatment or care that has gone wrong or incidents that caused harm or nearly caused harm.
2. Do you require registrants to declare they will follow your code of practice/standards/guidance:
 - a) when they register initially and
 - b) each renewal/retention thereafter?
3. How do your education standards and processes encourage education providers to satisfactorily prepare new registrants to be candid?

4. The Department of Health would like to understand the outcomes and frequency of fitness to practise hearings involving an allegation that a registrant has failed to be candid/open/honest about treatment or care that has gone wrong or incidents that caused harm or nearly caused harm. To assist with this please can you name any such cases decided at a final hearing since 1 January 2009? (This is the timeframe the Department of Health has requested information for.)
5. How frequently do you receive fitness to practise complaints/referrals about candour failures? What proportion of these is closed in the earlier stages of your FtP process (ie any stage before the final hearing stage)? It would be helpful if any data you can provide is organised by calendar year, from 2009 onwards. We appreciate that a full analysis of this nature may be difficult to deliver in the time available, so please state any the caveats relating to the data you can provide.
6. In your experience, what proportion of candour failure concerns/allegations is about a registrant's failure to be open with an employer or regulator? And what proportion is about a failure to be open with a patient, service user or carer?
7. In your experience how frequently are candour failure allegations/complaints accompanied by an allegation/complaint of professional incompetence and/or deficient performance?
8. Are there any general comments, feedback, observations you wish to make? In answering this question you may want to address the questions in the attached Call for Information which will be published on our website and circulated to other stakeholders in the next few days.

If you would like to discuss any aspect of this request before submitting your contribution please contact my colleague Amy Smith in the first instance at amy.smith@professionalstandards.org.uk or on 020 7389 8030.

We are required to submit our final report to the Department of Health by 16 September 2013. We will circulate the draft report to the regulatory bodies for fact checking on Thursday 29 August 2013 requesting feedback by Thursday 5 September 2013.

We look forward to receiving your response by Friday 9 August 2013.

Yours sincerely,



Harry Cayton
Chief Executive

Attached: Table of current candour and honesty related standards
Call for information

12. Annex 3 – Call for information

How can professional regulation encourage healthcare practitioners and social workers to be more candid when care goes wrong?

A call for information

Responses required by 9 August 2013

The Professional Standards Authority is an independent body accountable to Parliament. Our primary purpose is to promote the health, safety and well-being of patients, people who use care services and other members of the public.

The Department of Health has recently asked us to advise how professional regulation can encourage UK healthcare practitioners and social workers in England³⁷ to be more candid about incidents that harm or could have harmed patients or social care service users.

This project has arisen from the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*³⁸ which recommended that:-

- Where poor care has caused, or may have caused, death or serious harm to a patient, the patient or their representative should be fully informed of the incident and offered appropriate support.³⁹
- Statutory duties should be introduced that require healthcare providers and professionals to be candid about treatment or care they believe or suspect has caused death or serious injury to a patient.⁴⁰
- In certain circumstances it should be a criminal offence to breach these duties or obstruct another from performing them.⁴¹

In its initial response to these recommendations the government has said it will introduce a statutory duty of candour on health and care providers in England. It also stated that it will work closely with professional regulators to examine what more can be done to encourage professionals to be candid with their patients at all times.⁴²

To help inform our advice to the Department of Health we would like to hear from anyone with views on how any of the nine regulators we oversee could encourage the

³⁷ The social worker element of the Department of Health's request is limited to England because responsibility for government policy about the regulation of social workers in Northern Ireland, Scotland and Wales rests with their respective governments.

³⁸ TSO (2013). Available at <http://www.midstaffpublicinquiry.com/report> [Accessed 10 September 2013]

³⁹ Recommendation 174

⁴⁰ Recommendation 181

⁴¹ Recommendation 183

⁴² *Patients First and Foremost*. Department of Health (2013). Paragraph 2.32. Available at <https://www.gov.uk/government/publications/government-initial-response-to-the-mid-staffs-report> [Accessed 10 September 2013]

professionals they regulate to be more candid about mistakes they or colleagues have made. The regulators we oversee and the professions they regulate are listed below.

Regulators we oversee	Professions they regulate
General Chiropractic Council	Chiropractors
General Dental Council	Dentists Dental hygienists Dental therapists Clinical dental technicians Orthodontic therapists Dental nurses Dental technicians
General Medical Council	Doctors
General Optical Council	Dispensing opticians Optometrists ⁴³
General Osteopathic Council	Osteopaths
General Pharmaceutical Council	Pharmacists in Great Britain Pharmacy technicians in Great Britain
Health and Care Professions Council	Arts therapists Biomedical scientists Chiropodists Clinical scientists Dieticians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists Orthotists Paramedics Physiotherapists Podiatrists Practitioner psychologists Prosthetists Radiographers Social workers in England Speech and language therapists
Nursing and Midwifery Council	Nurses Midwives
Pharmaceutical Society of Northern Ireland	Pharmacists in Northern Ireland

⁴³ The GOC also regulates student dispensing opticians and student optometrists

We would particularly like to hear views from:

- Organisations that represent the interests of patients, people who use social care services or carers
- Members of the professions listed above and their representatives, employers and insurers.

We would like to hear any views you have on the following questions:

1. In your view, are all the regulators listed above effective at encouraging the professionals they regulate to be candid when something goes wrong?
2. What could the regulators do differently to encourage the professionals they regulate to be more candid/open/honest about treatment or care that has gone wrong or incidents that have caused harm or nearly caused harm? For example are there any improvements you think should be made to
 - a. Their codes of practice and how they support professionals to be open
 - b. Their fitness to practise/disciplinary investigation and adjudication processes
 - c. How their education standards and processes encourage education providers to satisfactorily prepare new professionals to be candid
 - d. How their registration and registration renewal processes work.
3. What good practice is there in this area, either from overseas or here in the UK, that we could learn from?
4. Are you aware of any reasons why a duty of candour on professionals may benefit or disadvantage patients, people who use social care services, carers or professionals differently depending on their age, gender, disability status, transgender status, ethnicity, nationality, sexual orientation, marital or civil partnership status, religion or belief?

Responses need to reach us by **Friday 9 August 2013** preferably by email to policy@professionalstandards.org.uk or alternatively by post to The Policy Team, Professional Standards Authority, 157–197 Buckingham Palace Road, London, SW1W 9SP.

We will store all feedback that we receive securely. However, you should be aware that any information you provide is disclosable under the Freedom of Information Act 2000. We will consider requests for non-disclosure on merit and, as necessary, in accordance with legal advice.

If you have any queries about this project please email us policy@professionalstandards.org.uk or call the policy team on 0207 389 8030.

13. Annex 4 – Stakeholders who responded to the call for information

Action against Medical Accidents (AvMA)
Association of Personal Injury Lawyers (APIL)
British Association for Counselling & Psychotherapy (BACP)
British Association of Social Workers (BASW)
British Dental Association (BDA)
British False Memory Society
Care Quality Commission (CQC)
Chartered Society of Physiotherapy
Children’s Rights Director for England
Dental Schools Council
Department for Health and Social Services, Welsh Government
Department of Health, Social Services and Public Safety, Northern Ireland
Directorate for Chief Nursing Officer, Patients, Public and Health Professions, Scottish Government
Durham County Council
Employment Lawyers Association (ELA)
Federation of State Medical Boards of the United States of America (FSMB)
Health Foundation
Healthcare Improvement Scotland
Independent Healthcare Advisory Services (IHAS)
Medical and Dental Defence Union of Scotland (MDDUS)
Medical Protection Society (MPS)
Ministry of Social Affairs of Estonia
NHS England Patient Safety team
NHS Litigation Authority (NHSLA)
Northern Ireland Social Care Council (NISCC)
Older People’s Commissioner Wales
Open University Department of Nursing
Optical Confederation
Osteopathic Alliance
Patient Concern
Royal College of Anaesthetists (RCoA)
Royal College of Midwives (RCM)
Royal College of Nurses (RCN)
Royal College of Obstetricians and Gynaecologists (RCOG)
Royal College of Pathologists
Royal College of Radiologists (RCR)
Skills for Health
The College of Social Work (TCSW)
The Portuguese Medical Chamber - Ordem dos Médicos

Plus ten individual members of the public, four academics and the nine regulators we oversee.

14. Annex 5 – Stakeholders' views

14.1 Respondents to our call for information and the stakeholders we met made a variety of comments about what the regulators could do to encourage candour and relevant factors they should take into account while regulating. We have summarised these into themes below.

Views on how the setting of professional standards of candour could be improved

14.2 Professional standards should contain clear explicit candour requirements, (professional regulator, member of the public, devolved administration, royal college, professional organisation)

14.3 There should be greater consistency in the regulators' candour standards (professional organisation, devolved administration)

14.4 A professional's ability to be candid depends on their workplace culture and environment (professional organisations)

14.5 The standard should take account of the National Patient Safety Agency (NPSA) *Being Open* framework in England (royal college, patient advocate) and the *Putting Things Right* regulations in Wales (devolved administration)

14.6 As recognised in *Being Open*, being candid about harm is a process and not a one-off conversation. Any professional duty of candour should adopt this philosophy (NHS organisation)

14.7 A professional who has made a mistake which has harmed a patient is often not the right person to inform the patient (NHS organisation)

14.8 The standard should require professionals to support colleagues who need to be candid and create a climate where people feel they can be candid. This element of the standard should be clearly reflected and supported in any leadership or management guidance the regulators produce (defence organisations)

14.9 The standard should take account of the wide range of contexts and environments professionals work in and avoid situations arising where a team of professionals are each queuing up to be candid to the same patient (NHS organisation)

14.10 The standard should avoid including the words candour or candid as these are not widely understood words and/or mean very different things to different people (professional regulator, professional organisation)

14.11 The words candour, candid or duty of candour should be included in the standard (royal college, devolved administration)

14.12 The standard should recognise that being candid can be difficult and stressful (systems regulator, NHS organisation) and because of this the regulators should

consider providing support to registrants who are candid (professional organisation)

- 14.13 There should be no scope for the standard to be misinterpreted as a requirement to 'go public' about errors in a way that leads to affected patients first hearing about the problem in sensationalist news reports (system regulator)
- 14.14 The standard should extend to being candid with a patient/service user's family if psychotherapy or counselling leads to false memories about childhood abuse (carer advocate, member of the public)
- 14.15 An apology is not an admission of liability (devolved administration, NHS organisation)
- 14.16 Being candid about a mistake could invalidate insurance cover and lawyers may advise professionals against being candid (professional organisations)
- 14.17 There may be helpful lessons to learn from colleagues in the Scottish Government involved in the no fault compensation scheme and the compensation schemes in Australia, France and New Zealand (devolved administration)

Views on how the promotion of candour standards could be improved

- 14.18 Fitness to practise cases involving a failure to be candid should be widely publicised as an example of the importance of candour and as a deterrent to others (patient advocate)
- 14.19 Build references to candour standards into continuing fitness to practise (revalidation) processes (royal colleges, patient advocate, professional organisation)
- 14.20 Provide clear guidance and support to revalidation Responsible Officers to help them handle the potential conflict between their obligations to the GMC and to their employer (defence organisation)
- 14.21 Produce guidance about candour for registrants' supervisors, leaders and managers (professional organisations, defence organisation, employer)
- 14.22 Take more active steps to explain professional standards to employers and, in particular, their implications for the duties and workloads employers ask professionals to undertake (professional organisation)
- 14.23 Work with patient advocate organisations to develop training about candour that includes patients, families and professionals real experiences of a lack of candour (patient advocate)
- 14.24 Promote awareness of professional standards through 'roadshows', podcasts aimed at students and more user-friendly websites (education provider)

Views on how fitness to practise procedures should deal with candour issues

- 14.25 Enforcement of a duty of candour could be counterproductive because it risks creating fear which is toxic to the open learning culture needed for safety and improvement (system regulator, royal college, professional organisation)
- 14.26 Where a professional duty of candour is breached serious sanctions should be applied. Unless there are truly exceptional extenuating circumstances this should usually mean a striking off (patient advocate)
- 14.27 Where there is evidence suggestive of a breach of a professional duty of candour the regulator should always investigate. No time bar or 'five year rule' should apply⁴⁴ (patient advocate)
- 14.28 Being open about adverse events should be a mitigating factor against disciplinary action. This could operate in a similar way to apology laws which exist in several jurisdictions, for example Canada (defence organisation, professional organisation)
- 14.29 Regulators should have processes and guidance in place that facilitate the discussion about any pressures in the workplace that may have contributed to an untoward incident and representations such pressures should not be seen as either the registrant having a lack of insight into their own responsibilities or as an 'excuse'. (professional organisation)
- 14.30 Fitness to practise cases, including candour cases, need to be progressed more quickly (professional associations, education provider)
- 14.31 The fitness to practise process should involve greater provision for and use of informal means of discussing candour and other issues. For example preliminary meetings or mediation (professional organisation)
- 14.32 The Professional Standards Authority should produce guidance for the regulators about how candour issues should be taken forward (devolved administration)

Views on how regulators could encourage candour through their education and training functions

- 14.33 Provide clearer guidance on when to be candid, with consistency across different types of standards, in education and practice, and across all regulators, given the multidisciplinary nature of care (royal colleges, professional organisations)

⁴⁴ Some regulators set a time limit for bringing an allegation against a registrant. For example, at the General Medical Council, an allegation cannot proceed if more than five years have elapsed since the most recent events giving rise to the allegation. The exception is if 'it is in the public interest, in the exceptional circumstances of the case, for it to proceed' (General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004 No 2608, r 4(5).1)

- 14.34 Use standards to support the role of supervisors, mentors and trainers to encourage them to model desired behaviour (professional organisations, royal colleges)
- 14.35 Involve service users and patients in education and training (patient representative)
- 14.36 Reflect on existing good practice for the frontline, such as *Being Open* in education standards (patient organisation)
- 14.37 Integrate teaching of necessary skills and competencies in the curriculum, do not isolate as a separate module (professional organisations)
- 14.38 Support registrants immediately post-registration as they gain experience (education providers, defence organisations)



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