Care Quality Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Telephone: 03000 616161
Fax: 020 7448 9311
www.cqc.org.uk

candourthresholdreview@dh.gsi.gov.uk
BY EMAIL

24 January 2014

Dear Sir

Duty of Candour – Review of threshold and proposals to adjust NHS LA contributions according to how candid a Trust has been

Thank you for inviting CQC to participate in your series of evidence sessions to inform your recommendation to the Secretary of State on the threshold for establishing a statutory duty of candour on organisations and proposals to adjust NHS Litigation Authority contributions according to how candid a Trust has been. Thank you also for bringing the Australian Open Disclosure Framework (Australian Commission on Safety and Quality in Healthcare, 2013) to our attention. We have reflected on this in our response.

In answer to your broad question of where the threshold should be set for enforcing a statutory duty of candour, it is the Care Quality Commission Board's considered and agreed view that the threshold should be set to include death, serious injury and moderate harm (see extract from minutes of meeting attached at Annex A). This is consistent with the existing contractual duty of candour, the guidance published in the 'Being Open Framework' (NPSA, 2009) and our interpretation of the term 'serious' in Robert Francis' recommendation 174.

We have arrived at our view based on the premise that we should first do what is right for patients and their families, and that we should deal with the consequences, i.e. the response by regulators, providers and commissioners as a secondary issue. This is in line with a number of patient representative organisations including Healthwatch England, Action against Medical Accidents (AvMA) and National Voices. This message is also reflected in the Australian Open Disclosure Framework, where the principle is to be open in all circumstances, including near miss and no harm events, but to vary the nature of the disclosure according to the effect, severity or consequence of the event.

We see no compelling reason to vary from this position. There is also the added advantage that providers are already familiar with the 'Being Open' and commissioning guidance[1] and will not have to adapt to another set of rules.

In saying that, we also want to emphasise that the system as a whole needs to determine how it will collectively incentivise the right values and behaviours that result in a culture where there is genuine openness and transparency with a view to learning and improvement as envisaged by Francis and Berwick. This includes having open and frank discussions with people who use services right from the start of their episode of care to ensure that there is a shared understanding of the likely outcomes and risks of proposed interventions, resulting in joint decision-making and genuine consent.

The key question is how? Criminal sanctions have a role to play, but are unlikely to be the strongest drivers for change by themselves. We recognise that we as the regulator have a vital part to play in setting expectations and that how we behave could have unintended consequences if we are not careful. We will work with other partners in the system to help develop our approaches to inspection and enforcement so that they focus on the right things and apply a palette of regulatory approaches to apparent breaches depending on the specific circumstances of the case in question, for example the degree of harm and the extent to which the breach was an act of omission as opposed to commission. We will not shy away from using the full weight of our powers when we have evidence of deliberate withholding or manipulation of information, but we will take a more proportionate approach when the situation is more ambiguous.

We also need to take a twin-track approach with our regulatory response to issues of under reporting of incidents and failing to learn from things that go wrong. We know that there is significant, as yet unquantified, scope for improvement in this area, particularly in primary care. We face a different set of challenges in adult social care.

CQC also has the responsibility to award ratings to providers on the quality of their services. These can act as a strong reputational lever to improvement and we can use this system flexibly alongside our enforcement powers to incentivise the right behaviours through a mix of hard and soft measures.

All of this is still very much work in development, but we will engage with others over the next few months in developing our approach to inspection, ratings and accompanying provider guidance, to help ensure we avoid any unintended consequences and help foster the right climate. There is also a job of work to do to determine the respective roles of the statutory bodies and professional regulators in relation to performance and improvement and how this can be aligned.

In giving our answer, you also sought our views on the following questions:

[1] NHS Standard Contract 2013/14: Service Conditions (NHS Commissioning Board, February 2013)

a) should the new duty of candour use the definitions that apply to the reporting of patient safety incidents in the existing National Reporting and Learning System (NRLS), and the existing contractual duty of candour?

We believe that the debate has become muddied by definitional issues, given that the current definition of severe harm in the National Reporting and Learning System (NRLS) only extends to permanent harm, whereas there are many cases where a patient may experience long-lasting, but non-permanent serious harm and equally deserves a full explanation, apology and necessary support. Many of these cases, along with those resulting in less serious harm, would be classified as experiencing 'moderate' harm within the NRLS definitions. In addition, we believe that the Duty of Candour should also extend to patients who are subjected to a Never Event, not all of which result in death or severe harm.

When the Care Quality Commission (Registration) Regulations 2009 were drafted we were keen that the regulations relating to the requirement to send statutory notifications of deaths and other incidents to CQC took a broader definition of serious harm (see Annex B), including non-permanent harm, such as impairment, physical pain or psychological harm lasting more than 28 days. While we were also keen to avoid establishing another reporting system for NHS providers, the existing definitions of severity of harm used by the NRLS did not quite equate to our notification requirements. This being the case, we have always included incident reports from the NRLS resulting in moderate harm along with those resulting in severe harm or death within our monitoring arrangements for regulatory purposes.

We therefore agree with working within the confines of the NRLS definitions to preserve the principle of reporting once and using for multiple purposes. However, we strongly recommend that the threshold for the duty of candour is extended "downwards" to include incidents classified as causing moderate harm, as we believe this will encompass what Francis and ourselves mean by "serious" harm.

We are also convinced that the definitions need simplifying so that everyone is talking the same language and there is less scope for ambiguity. We support Healthwatch England's position that any revised definitions should be developed with, and be as meaningful to, people who use services as much as they are to the professionals who provide them.

To extend the threshold for the Statutory Duty of Candour from severe harms and deaths to include moderate harms would not necessarily make any practical difference to the way in which CQC operates with respect to the number of incidents reported. However, it could potentially increase the volume of our enforcement work in relation to a Statutory Duty of Candour itself. That is because there is a commonly held view that there is a high degree of under reporting of incidents to the NRLS and CQC and that is more prevalent where the level of harm would be classified as moderate, low or no harm. Further research would be

needed to quantify this, but based on current reporting behaviours it could be a factor of 10-fold or more.

We are agreed that this should not be a deciding factor in arriving at our view on the threshold, but an issue where we must use our judgment in deciding upon the most effective regulatory response to positively incentivise a culture of transparency, learning and improvement.

This does raise a question over whether the reporting of moderate harms to CQC becomes mandatory to try and ensure that we have comprehensive coverage of the relevant incidents. However, this will not be necessary in most cases for NHS bodies as we have already put in place arrangements with NHS England whereby trusts report the majority of incidents once via the NRLS and we have secondary access to the data.

CQC will continue to monitor and assess the impact on incident reporting behaviours, with a view to encouraging fuller and more consistent reporting by providers. We would also wish to see more research done into the incentives and barriers to reporting, such as system constraints, definitional ambiguity and the social and professional factors affecting reporting behaviours.

b) what is your view on how incident reporting by an individual professional would be made to work best alongside the new statutory duty of candour on organisations?

CQC cannot see a rational argument for setting the thresholds for the statutory and contractual and professional duties of candour in a different place. However, there is an argument to encourage professionals to be more candid in all cases where a patient safety incident has occurred, regardless of the severity, in the interests of developing a more open culture where the patient is more actively involved in their care.

CQC has the power to take action against a registered person, that is the individual, organisation or partnership that is registered with us to carry on the regulated activity. We would not be able to take action directly against any individual employee failing in their duty, but would be able to respond to any provider who may have prevented that individual from observing their duty.

So, CQC's role is to hold registered providers to account for creating the right conditions that enable professionals to be candid. It is the more the role of professional bodies and regulators to determine how best to provide the necessary education, guidance and support to enable individuals working within a care service to be candid and to use their fitness to practice proceedings appropriately to address any alleged failings.

In the event of near misses, we feel there is more room for flexibility, but again the emphasis should be on being more rather than less open and the issues of being

candid should be separated from those of reporting. Nonetheless there is great room for learning from near misses and the default position should always be to disclose information at the patient's request.

If we don't manage to build the right incentives into the system at provider and at professional levels, we will inevitably get a rise in cases of whistleblowing, as we are already experiencing. When it gets to this stage it can become very unclear what the respective roles of the system and professional regulators should be.

c) what is your view on how the duty on the organisation to report an incident, which resulted in death or serious injury/moderate harm to a patient/family, may take account of incidents which have not been reported by a staff member or were not known at the time and were subsequently discovered to have occurred?

If a relevant incident was not reported at the time, but was later reclassified or 'discovered', we would expect the provider to report this as soon as possible and to explore the reasons for not doing so earlier as part of their root cause analysis. We would also expect the Statutory Duty of Candour to apply at the time the incident came to the attention of the provider and for the relevant person(s) to be informed that there is new information available. However, consideration also needs to be given to the patient/family and whether or not they wish to revisit the experience. They should certainly be informed that more information is available and given a choice about how much they wish to know.

Once again, where organisations are deliberately failing to report incidents and be open with patients, we might expect an increase in their staff raising whistleblowing concerns with CQC. This will be a key warning sign for us that the organisation does not have an open and transparent culture nor respond to staff and patient concerns.

d) how do you make a duty of candour work in primary care, e.g. for a single-handed practitioner?

CQC is of the view that the same rules should be applied in primary care as in other sectors, including for single-handed GP practices, but would like to see more discussion with the General Practitioners' Committee (GPC) and the Royal College of GPs (RCGP). The person registered with CQC to carry on the regulated activity will be accountable for any failure of the statutory Duty of Candour, and with a single-handed GP that will usually be that GP. This distinguishes between the practice and the practitioner.

However, even when they are single-handed, many practices will also have other salaried GPs, and all have some form of multidisciplinary team, including nurses, who will all have patient contact. We need to recognise that single-handed practitioners work under different 'environmental conditions' where they may operate in isolation, with less challenge to their day-to-day practice or incentives to maintain their professional development.

We also need to acknowledge that there is a very different reporting and learning culture within general practice. The barriers to reporting in smaller organisations are often more apparent, e.g. fear of the consequences. In addition, primary care has a higher rate of one-to-one care management compared with secondary care, potentially giving greater scope for under-reporting.

Indeed, there are very low levels of reporting to the NRLS from primary care and there is also a variable culture of significant event analysis (SEA), where discussion occurs within the team to promote learning and improvement. Good examples of SEAs include discussion with patients. This has been promoted by the RCGP and forms part of a GP's revalidation portfolio, with at least 2 SEA's per year being required as supporting information for quality improvement. This information is not readily available to CQC as the system regulator and we will need to give careful consideration to how we can monitor compliance in general practice.

On the other hand, patients may be more readily aware of near misses in general practice, but just as in secondary care, further guidance providing greater clarity on definitions would be helpful.

This will necessitate a more carefully phased implementation in primary care, focussing on improving reporting behaviours in general in the first instance to ensure the best chances of success of developing the right culture.

We will also need to consider how the duty can be made to work most effectively in adult social care services, particularly where many more people may lack mental capacity.

e) do you have any views on the proposal that the NHS Litigation Authority should adjust its contribution according to how candid a Trust has been, and require a contribution to the claim from the Trust?

We believe that there is great value in exploring as many levers as possible in the system to promote a culture of openness and transparency. There will be a number of issues that will need to be worked through, for example, determining the level of financial adjustment necessary to influence behaviours and how to deal with the time delays in claims coming to light/resolution.

It would be helpful to undertake a retrospective analysis of claims to inform a decision on whether to invest more time on this. The focus should not just be on whether the incident was reported in the first place, but also the identification of learning and service improvement as a result.

I trust that this submission proves helpful in reaching your conclusions and look forward to seeing the resulting report in due course. Please do not hesitate to contact me if you wish to discuss any of these matters further.

Yours sincerely

David Behan
Chief Executive

cc. Norman S Williams
David Dalton

Annex A Care Quality Commission Board Meeting 18 December 2013

Extract from Minutes of the Public Board Meeting
Finsbury Tower, London, EC1Y 8TG
18 December 2013 at 09.40

Present

David Prior (DP)	Chairman, Commissioner, Non-Executive Board Member
David Behan (DB)	Commissioner and Chief Executive Board Member
Louis Appleby (LA)	Commissioner and Non-Executive Board Member
Anna Bradley (AB)	Commissioner, Non-Executive Board Member and Chair of Healthwatch England
Paul Bate (PB)	Commissioner and Executive Board Member
Paul Corrigan (PC)	Commissioner and Non-Executive Board Member
Jennifer Dixon (JD)	Commissioner and Non-Executive Board Member
Steve Field (SF)	Commissioner and Chief Inspector of General Practice
John Harwood (JH)	Commissioner and Non-Executive Board Member
Steve Hitchins (SH)	Commissioner and Non-Executive Board Member
Michael Mire (MM)	Commissioner and Non-Executive Board Member
Mike Richards (MR)	Commission and Chief Inspector of Hospitals
Kay Sheldon (KS)	Commissioner and Non-Executive Board Member
Andrea Sutcliffe(AS)	Commissioner and Chief Inspector of Adult Social Care

In attendance

Hilary Reynolds (HR)	Director of Change
Claire Luxton (CL)	Corporate Governance Manager

ITEM 4 – CHIEF EXECUTIVE'S REPORT (REF: CM/10/13/03)

4 DB introduced the Chief Executive's update report, focusing on two areas arising out of the Care Bill, which had had its Second Reading in Parliament on 16 December:

4.2 Duty of Candour

DB explained that the Care Bill will include a statutory duty, in addition to any contractual or professional duty, to promote a more open, honest and transparent culture regarding safety and care. The Department of Health will be carrying out a 12 week consultation on the new quality and safety regulations, including a statutory duty of candour in January 2014. One of the key issues being debated is the threshold at which the statutory duty should apply. Initial proposals have suggested it should be restricted to patient safety incidents resulting in death of Severe Harm, which equate to about 11,000 incidents a year.

However the Francis Inquiry recommended the threshold should be set at death and serious harm, which potentially includes those incidents classified as causing moderate harm. This equates up to 100,000 incidents a year. This is serious and severe. A further review has been commissioned to inform the debate and consider the impact on reporting as it is thought that there is significant under reporting, particularly in the moderate and lower harm categories.

The Board agreed that the CQC's position must be that the threshold for Duty of Candour is set at moderate harm as this is the only approach that is clearly on the side of patients and allows them to understand what has happened in an open and transparent way.

Agree The Board agreed the CQC's position must be that the threshold for Duty of Candour must be set at moderate harm.

Annex B Care Quality Commission (Registration) Regulations 2009: Statutory Notifications of deaths and other incidents

Notification of death of service user

16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—

(a) whilst services were being provided in the carrying on of a regulated activity; or

(b) as a consequence of the carrying on of a regulated activity.

(2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—

(a) occurred—

(i) whilst services were being provided in the carrying on of a regulated activity, or

(ii) as a consequence of the carrying on of a regulated activity; and

(b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.

(3) Notification of the death of a service user must include a description of the circumstances of the death.

(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Patient Safety Agency(a).

(5) This regulation does not apply where regulation 17 applies.

Notification of other incidents

18.—(1) Subject to paragraphs (3) and (4), the registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

(2) The incidents referred to in paragraph (1) are—

(a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—

(i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,

(ii) changes to the structure of a service user's body,

(iii) the service user experiencing prolonged pain or prolonged psychological harm, or (iv) the shortening of the life expectancy of the service user;

(b) any injury to a service user which, in the reasonable opinion of a health care professional,

requires treatment by that, or another, health care professional in order to prevent—

(i) the death of the service user, or

(ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);

(c) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;

(d) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act;

(e) any abuse or allegation of abuse in relation to a service user;

(f) any incident which is reported to, or investigated by, the police;

(g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—

(i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,

(ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,

(iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and

(iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated

activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours.

(3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.

(4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to the National Patient Safety Agency.

(5) In this regulation—

(a) "the 2005 Act" means the Mental Capacity Act 2005(a);

(b) "abuse", in relation to a service user, means—

(i) sexual abuse,

(ii) physical or psychological ill-treatment,

(iii) theft, misuse or misappropriation of money or property, or

(iv) neglect and acts of omission which cause harm or place at risk of harm;

(c) "health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(b) applies;

(d) "registration requirements" means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;

(e) "standard authorisation" has the meaning given under Part 4 of Schedule A1 to the 2005 Act;

(f) "supervisory body" has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;

(g) for the purposes of paragraph (2)(a)—

(i) "prolonged pain" and "prolonged psychological harm" means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and

(ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.