for patient safety and justice

To the Care Quality Commission

4 September 2014

Dear Sirs

GUIDANCE FOR NHS BODIES ON THE FIT AND PROPER PERSON REQUIREMENT FOR DIRECTORS AND THE DUTY OF CANDOUR

Thank you for the opportunity to comment on your draft guidance. As you may be aware, AvMA is the UK charity for patient safety and justice and has done more than any other organisation to raise awareness of the need for the Duty of Candour. We remain passionately committed to ensuring the duty is implemented and reported in a way which will deliver much needed cultural change.

1 Duty of Candour.

1.1 The CQC's approach to the duty of candour

We are concerned by the statement in the consultation document *"we expect to mainly use the new regulations on candour to confirm or encourage good practice through the ratings we give, rather than enforce them directly"*. The duty of candour is one of the new fundamental standards and as such there is a legitimate expectation that the CQC will be proactive and robust in assessing compliance with the standard. This will mean amending the CQC's "key lines of enquiry" so that they specifically seek out evidence that the standard is being complied with (evidence that the guidance on compliance is being followed). This process should be applied to applications for registration/re-registration with the CQC; inspections; and when information comes to CQC's attention suggesting that an organisation is not complying.

The current 'ratings' process is too blunt a process to provide an assurance that the duty of candour is being complied with.

Clarity is needed as to which of the domains assessed as part of CQC's rating process will include assessment of compliance with the duty of candour. This should either be the leadership or the safety domain. A rating of "inadequate" in any domain should necessitate a rating of no better than "needing improvement" overall.

We question the comment that taking a proportionate approach involves *"taking account of the degree of harm"*. It should be noted that a notifiable incident as

defined by the regulations includes incidents that *"could result in"* harm. In other words, harm may not have materialised at all but there is potential that it will. Deliberate failure to ensure that any incidents that have caused or have the potential to result in significant harm are dealt with in accordance with the duty of candour is just as serious as failure to ensure compliance with regard to fatal cases.

Examples of specific evidence which the CQC should seek to test compliance with the duty of candour include:

- Reviewing a copy of the organisation's policy on 'being open'.
- Evidence that staff have been made aware of the policy.
- Evidence that all relevant staff have received training in the Being Open process and the requirements of the duty of candour.
- Evidence that appropriate support is available for staff involved in Being Open discussions.
- Evidence that the organisation regularly audits its incident investigations/ reports, complaints and claims to check that it has complied with the duty of candour.
- The CQC itself assessing a random selection of incident investigations/ reports, complaints and claims.
- A check with the Parliamentary and Health Service Ombudsman as to whether any complaints about the organisation which she has investigated involved a breach of the duty of candour.

We recommend that the CQC recruits and trains lay people ('experts by experience') to assess compliance with the duty of candour, as well as its own inspectors. AvMA would be happy to help both with training and recruiting 'experts by experience'.

The CQC ratings report on each organisation should contain an explicit statement as to whether the organisation has been found to be compliant with each fundamental standard, including the duty of candour.

1.2 The guidance itself

We think the guidance makes some very good points and are pleased to see some of our own suggestions are included. However, we believe the following suggested additions or changes are important.

We think that the guidance needs to do more to explain what is a "notifiable safety incident" as defined by the regulations. In particular it must be made clear that this includes incidents where the *"harm"* is potential rather than actual *("any unintended or unexpected incident that …… could result in, or appears to have resulted in …… harm"*).

This point is not widely understood and it is essential the guidance helps people understand that harm does not have to have materialised for the incident to be covered by the duty of candour. The guidance and summary of the regulations will need amending to reflect this. This will also need to be reflected in the organisation's own policies and training.

The "summary of the regulations" explains that the CQC can move directly to prosecution for failure to comply with the duty of candour with regard to individual incidents. However, it should say more about the other measures the CQC is more likely to take when an organisation is not doing enough to ensure compliance with the standard (for example: not making staff aware or not training staff). We believe that notices to improve, warnings and poor ratings are much more likely to be used and are powerful tools to drive improvement. Less emphasis should be given to possible prosecutions, which are likely to be extremely rare (and which in any case would only mean a £10,000 fine). The emphasis on prosecution is likely to "turn people off" or add to the perception of a "blame culture".

Under 20(1), the last bullet point should include the need to put the matter right (eg by telling the patient about the incident).

Under 20(1) there should be an additional bullet point: *"the provider regularly audits its incident reports, complaints and claims to assure itself that they have been dealt with in an open and honest way".*

Under 20(2) there needs to be a fuller explanation of the meaning of "notifiable safety incident" as discussed above. It is not sufficient to rely on the wording of the regulation itself.

Under 20(2)(a) the first bullet appears to be inconsistent with the regulation itself. The regulation makes no provision for not disclosing the incident because "it is felt counter-productive to disclose information". All notifiable safety incidents must be disclosed unless 20(5) applies*: "the relevant person cannot be contacted or declines to speak to the representative of the health service body"*.

Under 20(2)(b) we totally agree that it is vital that organisations are aware of relevant independent advice and support services, and we appreciate you recognise that information on AvMA in particular should be part of that. We would however suggest a different form of words, such as: *"providing the relevant person(s) with details of specialist independent sources of practical advice and support (such as Action against Medical Accidents – 'AvMA') or emotional support/counselling (such as Cruise Bereavement Care)".*

Under 20(3) we do not think that a "step by step" account is necessarily the best format. Often, the most salient points are missed or diluted by detailed step by step accounts of what happened.

Under 20(3)(d) we believe more guidance is needed about apologies. Where not enough is known about the reasons for the incident occurring, it may be appropriate simply to express regret or sorrow that the incident occurred ("we are sorry that this happened and regret the pain and suffering this has caused"). However, if the incident should have been avoided, a more meaningful apology acknowledging some responsibility for what happened is required. Simply expressing sorrow or regret in these circumstances would cause more harm than good and should not be confused with a genuine "apology".

Under 20(5) we do not think that a broad get-out clause such as believing disclosures of an incident would be "counter-productive" is acceptable or compatible with the regulations. However, we would like to see some flexibility in

rare and exceptional circumstances, where two health professionals record their consensus that it would not be in a person's best interests to disclose directly to them (even if they have capacity), for the disclosure to be made to another relevant person. However, we are not sure if the regulations as currently drafted would allow for that.

1.3 Other comments re Duty of Candour

To have the desired effect in underpinning genuine culture and behavioural change there needs to be good awareness of the new requirements and the guidance. We suggest an awareness campaign including use of the media, regional and national events aimed at health providers, and leaflets for staff and for patients. AvMA would be happy to help with this.

2 Fit and Proper Person Requirement

We agree with the intentions of the regulation and guidance. However, we believe that more clarity and guidance is required as to the practical aspects of complying with the regulation. In particular, we are unclear whether "serious misconduct" or "mis-management" is clearly enough defined, or that judging someone to have been responsible for or privy to these may not be challengeable in law if there has been no formal finding of such based on objective criteria. It is difficult to see how this can work without some form of regulation/assessment and register. We would also suggest the test applies to managers with significant responsibilities but who may not be managers.

We hope you find these comments helpful and would, of course, be happy to discuss in more detail.

Yours faithfully

Peter Walsh

Peter Walsh
Chief Executive