Duty of Candour Consultation
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Dear Jeremy

Thank you for the opportunity to respond to your consultation on the draft Care Quality Commission regulations on the Duty of Candour. As you know, AvMA has made a huge contribution to discussions and debate around the need for a Duty of Candour and how it should work. We are delighted that the main thrust of our arguments has been accepted at long last and are now Department of Health policy. However, the success of the Duty of Candour is of such importance to the charity and the people we serve that we do need to point out some serious concerns about how the regulations are currently drafted. These are set out below with suggestions as to how they can be amended to achieve what we believe to be our shared objectives.

Definition of "Notifiable Safety Incident" / Omission of incidents which could result in moderate or severe harm or death

Our understanding is that, as currently drafted, the regulations would not require that a patient be notified about a known safety incident which could result in significant harm or even death, but has not yet done so. We believe this is a very serious omission and that it is an oversight rather than Ministers' policy intention. It would mean, for example, that a healthcare provider would be under no statutory duty to notify the patient (or their family) that there had been a safety incident in their care where:

- *There had been a known delay in delivering a baby or ensuring that the baby received its oxygen supply, leaving the baby at risk of suffering from learning disabilities in future life. The 'harm' may not be detectable for some time to come, but the healthcare providers would know that there was a significant risk that it would eventually. It cannot be right that the healthcare provider is not required under the Duty of Candour to tell the parents what has happened and what the consequences might be.*

- *It is discovered that there has been an earlier misdiagnosis or a delayed diagnosis of cancer resulting in a delay in treatment being commenced. At this stage it may be impossible to say that moderate/severe harm or premature death will result from the delay even though it is known there is a significant risk of this. Surely the healthcare provider should be required to explain to the patient what has happened and what the implications might be?*

These are just two examples. It should be borne in mind that misdiagnosis or delayed diagnosis is a very common safety incident resulting in significant harm. According to the last full year figures (October 2011 – September 2012) there were over 60,000 reported incidents of this nature in England reported to the national reporting and learning system (NRLS). As currently drafted, the Duty of Candour would not apply to these incidents unless significant harm already appeared to have been caused.

The Solution

We believe these serious unintended consequences can be avoided by:

1 Redefining "Notifiable Safety Incident" as "a safety incident which in the reasonable opinion of a health care professional appears to have resulted in, or ***could*** result in, moderate or severe harm or death to the service user".

We are mindful that the Department may be worried that use of the word "could" in this context may be too wide a definition. However note that it would only apply if in the opinion of a health professional this was the case. An alternative might be to use the word "likely" and to use the guidance to describe the circumstances more fully.

2 Making it explicit in the guidance around the Duty of Candour that the duty applies to "omissions" in care or treatment such as misdiagnosis, delayed diagnosis or delayed treatment as much as it does other "errors".

Other important suggested changes to the Regulations

1 There is an inconsistency between the definition of "notifiable safety incident" for social care services and healthcare services in that an incident resulting in "prolonged pain" is a notifiable safety incident in social care but not in health care. We assume that this is an error in the drafting, and that prolonged pain caused by incidents in healthcare should be covered by the Duty of Candour. This can be easily rectified by adding to the definition of "moderate harm"
"(d) prolonged pain"

2 We believe that the requirement to train and support staff and make them aware of their responsibilities in helping registered organisations comply with the duty is stated in the regulations themselves rather than left to the guidance. A clause should be added along the lines

"the registered person must take all practical steps to ensure that all of its relevant staff or contractors are aware of the requirements under the organisations Duty of Candour set out in clause 3, and provided with appropriate training and support".

We know that colleagues in the Department of Health agree that training and support of staff will be an essential element of the Duty of Candour being effective in changing culture and behaviour, and that it is intended that this is dealt with in guidance. However, this is too vital an issue to be left to the guidance. The CQC needs to be able to take regulatory action if this is not happening, which may not be possible if it is just in the guidance. This is a fundamental part of the fundamental standard.

3 We also believe the regulations should require organisations to take appropriate action over individuals who prevent the organisation complying with the Duty of Candour. We suggest inserting a clause along the lines of:

"The registered person, upon learning that an individual or individual employees or contractors have prevented the registered person from acting in accordance with clause (3), must initiate disciplinary action against the individual(s) and/or refer the individual(s) to an appropriate regulator".

4 We believe the regulations should require the organisation to provide, on request, any information which the CQC needs to assess the organisation's compliance with the Duty of Candour. We suggest a clause along the lines

“The registered person, upon receipt of a request from the CQC, must provide the CQC with information the CQC requires in order to make an assessment of the registered person’s compliance with these regulations”.

The guidance should stipulate the kind of information which the CQC will require and should include: evidence of the members and function of staff who have received appropriate training; evidence that the organisation audits complaints, patient safety incidents, and litigation cases to ensure that the duty is being complied with.

Yours sincerely

Peter Walsh

Peter Walsh
Chief Executive