The “DUTY OF CANDOUR” :

Briefing on why the current proposals need to be changed

NOVEMBER 2013

Background

The Care Bill was amended in the House of Lords to include a requirement to introduce a statutory Duty of Candour on healthcare organisations within the Care Quality Commission (CQC) regulations. (A duty to be open with patients or their families when things go wrong and cause harm). See clause 80:

"Duty of candour

In section 20 of the Health and Social Care Act 2008 (regulation of regulated activities), after subsection (5) insert—

***"(5A)Regulations under this section must make provision as to the provision of information in a case where an incident of a specified description affecting a person's safety occurs in the course of the person being provided with a service."* "**

Action against Medical Accidents (AvMA) has done more than any other organisation to raise awareness of the need for a statutory duty for healthcare providers to be open and honest when harm is caused to patients. We have called our campaign "Robbie's Law" in honour of Robbie Powell and his family. We very much welcome this new clause, which paves the way for the statutory duty we and many others have been calling for. This has the potential to be the biggest advance in patient safety and patients' rights in history. However, in introducing the amendment Earl Howe confirmed that the current intention is for the duty of candour to be framed in a way that restricts it only to cases of what the NHS defines as "severe harm" or death. (See below for a draft of the relevant CQC regulation which we understand the Department of Health plans to introduce).

We are firmly of the view that a Duty of Candour in this form would not be worthy of the name and would have the gravest unintended consequences. In effect, it would legitimise the cover up of all but the most serious incidents of harm. It would undermine existing established guidance (the *Being Open* guidance) which sets "moderate harm" as the threshold requiring open disclosure. It would be inconsistent with the existing contractual requirement on NHS organisations which also uses "moderate harm" as the threshold. It would go against the spirit of what Robert Francis QC advocated in his recommendations for a duty of candour and the recent Clwyd/Hart review of complaints. In short it would be a serious step backwards and hamper rather than help moves to bring about a more open and fair culture and full openness with patients when things go wrong. Our concerns are shared by a wide range of patients and professional groups, including National Voices – the national umbrella group for health and social care charities. This briefing explains in more detail why this would be the case and suggests an alternative approach.

What level of harm would meet the definition of an "incident of a specified description" under the current proposals?

Below (in italics) is a draft of the Duty of Candour regulation which at the time of writing we understand the Department of Health plans to introduce. Please note: this was only a draft; may have been changed subsequently; and the version which is eventually

published is likely to be worded differently. However, it is the only draft which we have seen and we understand that it is still the intention to limit the Duty of Candour regulation to only "severe harm" and fatal cases

"Duty of candour

1.*—(1) If a reportable patient safety incident occurs, or is suspected to have occurred, the service provider must, in accordance with this regulation, provide to the relevant person all necessary support and all relevant information in relation to that incident.*

(2) The registered person must, as soon as practicable, notify the relevant person that the reportable patient safety incident has occurred, or is suspected to have occurred.

(3) The notification to be given under paragraph (2) must—

(a) be oral and conducted in person by one or more representatives of the service provider (including where possible the clinician or other person responsible for the episode of care or treatment during which the reportable safety incident occurred), unless the relevant person cannot be contacted in person or declines to be contacted;

(b) provide all facts the service provider knows about the incident as at the date of the notification;

(c) where appropriate, include an apology;

(d) be accompanied by the offer of a written notification [and apology]; and

(e) be recorded in writing.

(4) The registered person must maintain full written records of any meeting or other contact with the relevant person in relation to the reportable patient safety incident.

(5) In this regulation—

"apology" means a sincere expression of sorrow or regret in respect of a reportable patient safety incident;

"reportable patient safety incident" means any unintended or unexpected incident that occurs in respect of a service user during the provision of a regulated activity that led to severe harm to, or the death of, the service user; and

"severe harm" means any injury that, in the reasonable opinion of a health care professional, appears to have resulted in—

(a) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
(b) changes to the structure of the service user's body,
(c) the service user experiencing prolonged pain or prolonged psychological harm,
(d) the shortening of the life expectancy of the service user, or
(e) the requirement for treatment by a health care professional in order to prevent the death of the service user or an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraphs (a) to (d)."

The Government's intended regulation (above) uses the same definition which is used elsewhere in the CQC regulations requiring the (anonymised) reporting of patient safety incidents by registered organisations to the CQC. (For NHS organisations this is via the *National Reporting and Learning System* (NRLS). This is based on the NHS definitions of harm used by the NRLS.

The NHS definition of "severe harm" is:

"Any patient safety incident that appears to have resulted in ***permanent*** *harm to one or more persons receiving NHS-funded care".*

The NHS definition of "moderate harm" is:

*"Any patient safety incident that resulted in a moderate increase in treatment and which caused **significant but not permanent harm**, to one or more persons receiving NHS-funded care."*

According to the NRLS figures for 2011-2012, "severe harm" and "death" cases totalled 11,036 of reported incidents. Cases causing "moderate harm" totalled 83,241 and there would be no requirement to disclose such incidents to patients under the Government's current plans. "Moderate harm" under the NHS definition would include serious injuries which at the time were not thought to have caused **permanent** disability. The official definition of 'moderate harm' includes "significant" harm. Most people would define such incidents as "serious" (the word used by Robert Francis QC). For example, a mistake could be made in surgery which leads to you being off work for a year as a result, you losing your career and being unable to care for dependents during that time, but if it was believed you would eventually recover, this would be defined as 'moderate harm' and the mistake would not have to be disclosed to you.

We strongly believe that any incident which may have caused "moderate harm" or worse (as defined by the NHS), should be covered by the Duty of Candour. See attached for our suggestions of what an appropriate Duty of Candour regulation might look like.

What are the problems with restricting the Duty of Candour to cases of "severe harm" or death?

Apart from being morally and ethically wrong to imply that a lack of openness about incidents short of severe harm or death can be tolerated, this would create massive inconsistency, confusion and bureaucracy.

- Restricting the remit of the statutory duty of candour to "severe harm" and fatal cases would mean that the vast majority of incidents causing significant harm, which most people would define as serious, are not covered.

- Organisations would not be in breach of any statutory rule if they systematically chose to cover up all incidents which cause serious harm short of the definition of "severe" or death. Lawyers would be obliged to advise organisations of their right to do this without fear of consequences.

- The existing Being Open guidance clearly states that all incidents of "moderate harm" and worse should be disclosed. This guidance would be rendered useless and create confusion.

- The "contractual duty of candour" for NHS bodies brought in in April this year stipulates that incidents of moderate harm and worse must be reported. The statutory duty would therefore be a step back from this and cause confusion.

- Primary Care practitioners like GPs are not covered by the "contractual" duty. Neither are private sector providers. This means there would be no duty, statutory or contractual, to disclose information about the vast majority of incidents which cause harm short of the definition of severe harm or death in these sectors.

- The recent review of complaints by Ann Clwyd MP and Professor Tricia Hart emphasised the importance of the Duty of Candour to underpin the way

complaints are responded to. The vast majority of complaints relate to incidents which are short of the definition of 'severe harm'. Even if a complaint were made, organisations would be under no statutory obligation to disclose information about the vast majority of incidents which cause significant or serious harm.

How could an organisation be sure what level of harm has been caused or will result?

Common sense and good practice would suggest that the best time to tell a patient or their family that something has gone wrong with their treatment or that harm may have been caused is as close as reasonably possible to the incident being known about. It is unlikely that the actual outcome (i.e. level of harm) will be known at that point. As currently drafted, the duty of candour in the CQC regulations would have the unintended consequence of encouraging organisations not to disclose anything about something that has gone wrong unless and until it was sufficiently clear that "severe harm" or death had been caused.

It is vital that patients or their families have the opportunity to input into any investigation that might arise to establish what harm has been caused or may result, and why. It should not rely on the organisation being sufficiently convinced that the level of harm is so severe before there is a requirement even to tell the patient that something may have gone wrong. This could provide organisations with a 'get out clause'.

Would the Duty of Candour as currently proposed change culture and behaviour?

The Duty of Candour as currently drafted only deals with the circumstances when an organisation may be held to account for a breach of the duty for not disclosing an incident. Whilst this is important, we have always argued that the opportunity should be taken to do much more to support a culture change. Just as important is requiring organisations to do everything practically possible to train and support staff in complying with the duty, including protecting them from any punitive action by the employer if they are "doing the right thing" by informing patients / their families about incidents that have affected them. This could be included in the regulations. Not to do so would be a massive missed opportunity to fully support and underpin the desired change of culture.

Will individuals be covered by a Duty of Candour?

Robert Francis QC recommended that a statutory duty of candour apply to individuals as well as to organisations. It is important that every individual with responsibility for communicating with patients/families needs to be covered. This will include people like complaints staff, lawyers and risk managers who may not be a regulated health professional. We believe Robert Francis QC's recommendations should be implemented. However, we do think that if proposed CQC duty of candour regulation is worded appropriately, it would go a long way to ensure individuals are fully aware of the serious implications for them if they do not act in accordance with the duty. For instance, organisations should be required to take appropriate disciplinary action, and/or refer to the appropriate regulator, if individual employees prevent the organisation from complying with its duty of candour.

Would the Government's current proposals put doctors and nurses in an impossible situation?

The professional codes for doctors and nurses clearly state that any incident where their patient has suffered harm should be communicated to the patient. Doctors and nurses are likely to be put in an impossible situation if the regulations governing their employer restrict the incidents which must be disclosed to patients as only the most severe and fatal cases. Some managers and lawyers working for the employer are likely to exert pressure not to disclose incidents below the threshold set in regulations. Doctors and nurses will have to choose between following their professional code which may put them into conflict with their employer, or working to the employers' instructions and putting themselves at risk of disciplinary action from the GMC or NMC. Given that organisations would be permitted by the current proposals to cover up incidents that have caused harm of a serious nature, when patients find out that a cover up had taken place they are very likely to want to refer any doctor or nurse involved in this to their regulator.

Doctors would also be caused extra work by the current proposals. Rather than simply doing what most would want and expect to do when something has gone wrong – explaining to the patient – they will be drawn into a time consuming unhelpful exercise of trying to assess what the seriousness of the harm that will result from the incident is and how long it will last. If they get it wrong and it eventually turns out that the harm was more serious or permanent than they had thought and they had not informed the patient, they again are likely to be subject to disciplinary procedures.

Far better to keep things simple and follow conventional common sense and good practice by requiring disclosure of any incidents that cause significant harm ('moderate harm' and worse using NHS definitions. This is what organisations are already used to doing (by implementing Being Open guidance and the 'contractual duty of candour' anyway. It is far easier to make a quick assessment of whether resultant harm is likely to be 'significant' or 'insignificant' than the tortuous exercise of assessing whether the harm would meet the more complex definition of 'severe harm' or 'moderate harm'. This is especially so as at the point where disclosure should be being made (as close to the time of the incident as reasonably possible), it is likely to be impossible to know the final impact on the patient.

Our suggested approach would build in a requirement on the employer to train, support and protect doctors and nurses in doing the right thing (see attached). These are essential to support the necessary culture change. The DH's current proposals simply define the circumstances where an organisation could be punished.

What are the arguments that have been put forward for limiting the scope of the Duty of Candour and are they credible?

There are two arguments that have been used to justify proposals to limit the scope of the Duty of Candour and leave the majority of patient safety incidents which cause harm outside the scope of any statutory rule.

- It has been suggested that organisations will not be able to cope with the extra work involved in communicating with patients' incidents which cause them harm.

- People are worried that the increased disclosure of mistakes which cause harm will lead to more litigation and cost the NHS money. It is argued, therefore, that it is in the public interest to continue to tolerate the cover up of such mistakes.

These arguments lack credibility not only on moral and ethical grounds, but for practical reasons. NHS organisations should already be disclosing all cases of suspected 'moderate harm'. This is the threshold used in the *Being Open* guidance, and also the contractual Duty of Candour. This has not led to any capacity problems. We are not aware of any evidence to suggest that there is very widespread failure to comply with this guidance. It is a question of dealing with the relatively small number of organisations and incidents where this does not happen, and it is important that the Duty of Candour ends this appalling practice. Sending a message that cover-ups of serious harm incidents short of the severe harm or fatal definitions would escape any regulatory action would lead to more, not less cover-ups.

It is well documented that a lack of openness when things go wrong is often the reason why people litigate when they otherwise would not have done. It is possible that increased honesty will result in more cases of negligence coming to light which result in compensation claims but this is likely to be more than offset by people accepting honest apologies and explanations and not taking legal action, and savings in legal costs due to compensation claims not being drawn out by unreasonable defence of the claim. Importantly, even if there were an extra cost involved, does anyone want to live in a society which consciously tolerates cover-ups of medical errors in order to save the State money? This would be in direct contradiction of stated policy including the NHS Constitution.

Continuing to tolerate cover-ups would also perpetuate a situation where error is not recognised, lessons not learnt, resulting in much greater cost to the State as well as human cost.

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What happens now?

The Care Bill has now moved to the House of Commons. Ministers have said that the Duty of Candour CQC regulations will later be the subject of public consultation and the 'affirmative' procedure in Parliament. However, in our experience it will be very difficult to shift the Government's position if it gets as far as a consultation or consideration of the secondary legislation. It is important to persuade Ministers to change their plans now and for there to be cross-party consensus if the introduction of the statutory Duty of Candour is to live up to its potential to be the biggest advance in patient safety and patients' rights in living memory.

Attached are our suggestions for how an appropriate Duty of Candour regulation might be worded.

AvMA SUGGESTIONS FOR A POTENTIAL REGULATION INTRODUCING A STATUTORY DUTY OF CANDOUR IN THE CQC REGISTRATION REGULATIONS:

Duty of Candour

1. The registered person must ensure, as far as practically possible, that:

(a) Service users or, where appropriate, their next of kin, are fully informed of any reportable patient safety incident which may have caused or may result in moderate or severe harm or death to the service user

(b) Relevant employees or agents are provided with training and support with regard to (a)

(c) Employees or agents who are involved in the provision of services which lead to a reportable patient safety incident are provided with all necessary support

(d) Employees or agents who are believed to have deliberately prevented the registered person from meeting its responsibilities in with regard to this regulation are referred to the relevant disciplinary or regulatory procedures

2. —(6) If a reportable patient safety incident occurs, or is suspected to have occurred, the service provider must, in accordance with this regulation, provide to the relevant person all necessary support and all relevant information in relation to that incident.

a. The registered person must, as soon as practicable, notify the relevant person that the reportable patient safety incident has occurred, or is suspected to have occurred.

b. The notification to be given under paragraph (2) must—

   i. be oral and conducted in person by one or more representatives of the service provider (including where possible the clinician or other person responsible for the episode of care or treatment during which the reportable safety incident occurred), unless the relevant person cannot be contacted in person or declines to be contacted;

   ii. provide all facts the service provider knows about the incident as at the date of the notification;

   iii. where appropriate, include an apology;

   iv. be accompanied by an offer to investigate the circumstances and causes of the incident further and to involve the service user in any such investigation

   v. be accompanied by the offer of a written notification [and apology]; and

   vi. be recorded in writing.

c. The registered person must maintain full written records of any meeting or other contact with the relevant person in relation to the reportable patient safety incident.

d. In this regulation—

"apology" means a sincere expression of sorrow or regret in respect of a reportable patient safety incident;

“all necessary support” includes the provision of information on sources of specialist independent advice and support

“reportable patient safety incident” means any unintended or unexpected incident that occurs in respect of a service user during the provision of a regulated activity that has led or may lead to moderate or severe harm to, or the death of, the service user; and

“moderate or severe harm” means any injury that, in the reasonable opinion of a health care professional, appears to have resulted in or may lead to—

(a) a prolonged impairment of the sensory, motor or intellectual functions of the service user,
(b) changes to the structure of the service user’s body,
(c) the service user experiencing prolonged pain or prolonged psychological harm,
(d) the shortening of the life expectancy of the service user, or
(e) the requirement for treatment by a health care professional in order to prevent the death of the service user or an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraphs (a) to (d).