“DUTY OF CANDOUR”

The case for including all incidents of significant harm within the remit of the duty

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Background

In the Government's response to the Mid Staffordshire Public Inquiry recommendations, the Secretary of State for Health confirmed that a statutory Duty of Candour upon organisations will be introduced. It had been intended that this duty only apply to fatal cases and those of severe harm resulting in permanent disability. However, directly as a result of representations by Action against Medical Accidents (AvMA), the Secretary of State has agreed to consider including all incidents of significant harm to patients within the remit of the Duty of Candour. He intends to make a decision about this by the end of the year.

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 the Government's acceptance at long last that a statutory Duty of Candour is needed. This has the potential to be the biggest advance in patient safety and patients' rights in history. However, we are firmly of the view that a Duty of Candour which was restricted to fatal and severe harm cases 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 and it would lead to increased confusion and bureaucracy. It would contradict the *NHS Constitution* which pledges that patients will be told about any harm caused to them and undermine 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. This briefing explains in more detail why this would be the case and suggests an alternative approach.

Our view that the Duty must cover *any significant harm* is shared by a wide range of patients' and professional groups, including:

- The Care Quality Commission (CQC – the very body that will responsible for regulating the Duty of Candour, however it is finally defined)
- The Royal College of Nursing
- The General Medical Council
- The Nursing & Midwifery Council
- Healthwatch England – the official voice of patients in England
- National Voices – the national umbrella group for health and social care charities
- Patients First – the NHS whistleblower support group
- Ann Clwyd MP and Tricia Hart – ceo of South Tees Hospitals NHS Foundation Trust - co-authors of the recent report on NHS Complaints

What level of harm should be covered by the statutory Duty of Candour ?

The Secretary of State is reconsidering the Government's original plan to restrict the Duty of Candour to fatal and 'severe harm' cases and whether to extend it to cases of so-called 'moderate harm'.

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 original 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). These incidents can be devastating and life-changing. 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.

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 harm” or death. Lawyers would be obliged to advise organisations of their right to do this without fear of regulatory 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 they would not be covered by either 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.

- 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’. If the Duty of Candour were restricted only to cases of “severe harm” or death, 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. Restricting the duty of candour to severe harm and death 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’.

Will the Duty of Candour be framed appropriately to do enough to change culture and behaviour?

The Duty of Candour should not only deal 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.

Should 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. The Secretary of State for Health has confirmed he does not accept this recommendation. However, we suggest 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 restricting the Duty of Candour 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 to 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. These are essential to support the necessary culture change. The eventual CQC regulations must do more than simply define the circumstances where an organisation could be punished.

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

The Secretary of State for Health has said that he needs to be clear about any "unintended consequences" that might arise from including all cases of moderate harm and worse in the remit of the Duty of Candour. There are two possible "unintended consequences" that have been suggested. These are discussed below:

1. It has been suggested that organisations might not be able to cope with the extra work involved in communicating with patients' incidents which cause them harm / that it would cause unnecessary "bureaucracy"

Not only is it disappointing that being open about harm caused to patients can be seen as 'bureaucracy', but this argument lacks credibility. The vast majority of healthcare organisations are already disclosing all cases of suspected 'moderate harm'. Not only is this the obvious right thing to do - this is the threshold used in the *Being Open* guidance, and also the NHS contractual Duty of Candour. We have asked for, but not been provided with, any evidence that this has led to any capacity problems. Good healthcare organisations do this as a matter of course and also keeping a record of the incident. This has been confirmed by senior widely respected figures in healthcare we have spoken to including Professor Tricia Hart, chief executive of South Tees Hospitals NHS Foundation Trust; Dr Umesh Prabhu, medical director of the Wrightington, Wigan & Leigh NHS Foundation Trust. 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 where it does exist. Sending a message that cover-ups of significant harm incidents thought to fall short of the "severe harm" or fatal definitions would escape any regulatory action would lead to more, not less cover-ups. For the reasons explained above, restricting the Duty of Candour to fatal and severe harm cases would cause more work and bureaucracy, not less, than continuing with the well-established principle that details of all significant harm incidents ('moderate harm' and worse) must be disclosed.

2. Some 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.

This argument lacks credibility not only on moral and ethical grounds, but for practical reasons. 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 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. Furthermore, the CQC has confirmed that it has never had to defend a Judicial Review of its decision not to take regulatory action. See below.

How would the statutory Duty of Candour be regulated / enforced?

General fear and unease about the statutory Duty of Candour including 'moderate harm' seem to be based on misunderstandings of how it would work in practice. The Duty of Candour will form one of the 'fundamental standards' which are required to be met for registration with the CQC and the CQC would be able to take regulatory action against the organisation if it had evidence that the organisation was subsequently failing to meet the standard. Just as with the other CQC standards, the prime objective is to promote good practice and incentivise compliance with the standard – not to catch people out and punish them. Of course it is important that the CQC has the power to take firm regulatory action where the standard is not being met and continues not to be met. The notion that healthcare organisations would suddenly be clobbered by the CQC over some isolated or minor departures from the Duty of Candour is completely unfounded. For example, the CQC quite rightly has standards on obtaining consent and on patients' privacy & dignity. We know that practice in these areas is not ideal. However there is no epidemic of organisations being prosecuted by the CQC over breaches of these (or other) standards. Where CQC becomes aware of failure to fully meet a standard it has a range of regulatory powers at its disposal. Almost always, a first stage would be to issue a formal warning and give the organisation time to comply with the standard.

CQC will not be acting as 'policeman' investigating individual allegations of 'cover-up' or breach of the Duty of Candour. Rather, as with the other standards, it will be looking for evidence that the organisation is doing everything reasonably practical to ensure the standard is being met. Of course, in a particularly egregious case of cover up where management of the organisation were complicit one would expect serious, immediate action. If there were a pattern of individual cases that were brought to the CQC's attention, one would expect them to look further into it and take regulatory action if necessary. Likewise if an individual case shed light on systemic failure by the organisation to take all reasonable steps to ensure compliance with the duty. However, for the most part the CQC would be seeking evidence that the organisation has appropriate policies and procedures in place; that it promotes these policies and procedures and trains and supports its staff in the practice of *Being Open*; that it monitors how well *Being Open* is being practised within the organisation; and that if individual members of staff step out of line or prevent others from abiding by the Duty of Candour, that the organisation takes appropriate disciplinary action and/or refers to a professional regulator where appropriate. CQC has complete discretion about how it uses its powers and there is no reason to believe that it would not take a reasonable and proportionate approach depending on the gravity of the departure from the duty. Individual patient/complainants have no right to instigate or force CQC to take regulatory action over their individual case. CQC have confirmed that they have never had to defend a Judicial Review of a decision they have made not to take regulatory action. Recent case law concerning the Health & Safety Executive confirms our view that such an action would be nigh on impossible. So, fears of unhappy or angry individuals causing problems for organisations or creating a 'lawyers' charter' are unfounded.

.**What happens now?**

The Secretary of State for Health has asked David Dalton (chief executive of Salford NHS Foundation Trust) and Mr Norman Williams (President, Royal College of Surgeons) to advise him about the pros and cons of including all incidents of “moderate harm” and worse within the remit of the Duty of Candour. A decision is expected by March 2014.