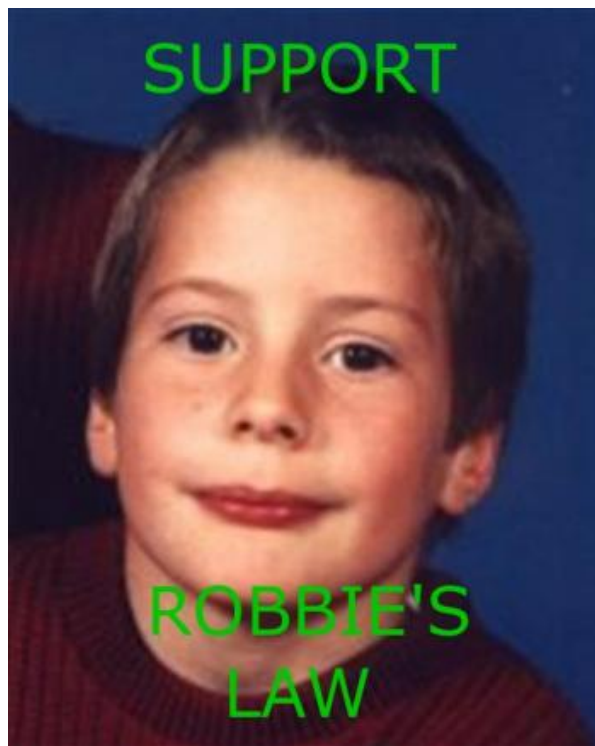




**THE NEED FOR A
STATUTORY DUTY OF CANDOUR
IN HEALTHCARE**



MARCH 2010

What is AvMA and why call for a statutory ‘Duty of Candour’ (‘Robbie’s law’)?

Action against Medical Accidents (AvMA) is the UK charity for patient safety and justice. For over 27 years AvMA has been campaigning for improvements in patient safety and providing vital advice and support to thousands of people each year who have been affected by things going wrong in healthcare (‘medical accidents’ or ‘patient safety incidents’). The recognition of patient safety as a top priority and the establishment of bodies such as the National Patient Safety Agency (NPSA) and the Care Quality Commission (CQC), as it is now known, came after years of AvMA’s campaigning and, tragically, after thousands of avoidable deaths in healthcare. As well as standing shoulder to shoulder with injured patients and their families, AvMA is proud to work in partnership, and to act as a critical friend when need be, with the health professions, NHS and private healthcare providers, the Departments of Health and national bodies like the NPSA and CQC. Our mission is to improve patient safety and to develop fairer ways of responding to medical accidents when they do happen.

Accidents will never be eradicated completely – healthcare is a very risky business, and health professionals are only human. Health professionals who are unintentionally caught up in things that go wrong in healthcare and cause harm to patients need to be supported and helped to cope with what must be one of the most difficult things that a health professional has to deal with in their career. No one goes into healthcare intending to harm patients. However, there has to be absolute clarity that anything less than complete openness and honesty when things go wrong is totally unacceptable in modern British healthcare. That is what we mean by a ‘Duty of Candour’. In our experience, failure to be dealt with openly and honestly when harm has been caused can often cause extreme harm and distress in itself, and is the most frequent reason why patients or their families turn to legal action or seek disciplinary action. Just imagine losing a loved one as a result of an avoidable error and then finding that it had been kept from you. To put it in the words of Sir Liam Donaldson, the chief medical officer in England,

“to err is human....but to cover up is unforgivable”

As far as AvMA is concerned, and the patients, families and other patients’ organisations with whom we work, tackling the current culture of denial and cover up is one of, if not *the* top priority needed to achieve a genuine patient safety culture. A statutory Duty of Candour is a vital part of helping to achieve that.

Why is this such a priority right now?

In spite of the need for a legal Duty of Candour having been discussed for years, and recent scandals such as Stafford Hospital underlining the need to tackle the culture of cover up and denial and rebuild public confidence, the English healthcare system has been plunged into further deep controversy which is likely to seriously damage public confidence still further.

Not only is the Government still prevaricating over whether or not it will introduce a statutory Duty of Candour, but it has pushed through controversial new registration regulations for the Care Quality Commission¹ which are due to come into force in April 2010 without consultation or debate. These regulations actually introduce a statutory duty for healthcare providers to report incidents which harm patients to the national

¹ The Care Quality Commission (Registration) Regulations 2009, Statutory Instrument 2009 No:

reporting system of the NPSA, but the Government has specifically excluded any duty to inform the injured patient or their next of kin. The NPSA system is anonymised and does not allow for investigation of the incident or informing the patient. It means that a hospital could be closed down or heavily fined if it did not send an anonymised report form about an incident which had seriously harmed you or a loved one to the NPSA, but has no statutory duty to tell you anything about it.

We believe most people would agree with us that this is totally unacceptable and sends out the most worrying of messages. We are not saying the Government intended to legitimise cover-ups but this is the effect, and it is a gross error of judgement. All we have been offered is discussions over the 'possibility' of introducing a Duty of Candour in the future. In the meantime, being open with patients will remain 'motherhood and apple pie' in 'guidance'. Everyone says it is the right thing to do, but it would appear the State is prepared to turn a blind eye where it doesn't happen.

This situation could so easily be turned into a 'good news' story if a corresponding statutory duty to inform patients (or their next of kin where appropriate) were to be introduced in the same regulations. This would be the statutory Duty of Candour ('Robbie's law') that AvMA and others have been seeking.

Evidence to support the need for a statutory Duty of Candour

- A National Audit Office report in 2005² revealed that only 24% of NHS trusts routinely informed patients of a patient safety incident and, astonishingly, 6% admitted to never informing patients.
- Recent NHS scandals such as Stafford have shown the consequences of a culture of cover up and denial in healthcare settings. See the case studies provided below.
- The Department of Health itself accepts that there is a 'culture of denial' in the NHS ('Safety First', Department of Health, 2006).
- There are estimated to be over 1 million patient safety incidents alone in English hospitals alone each year, 50% of which are estimated to cause avoidable harm. The National Patient Safety Agency receives hundreds of thousands of incident reports each year from NHS trusts where harm or even death has been caused. The NHS Litigation Authority regularly quotes figures of enormous potential liabilities (£9 - £10 billion) based on reports it receives from NHS trusts of incidents which are considered clinical negligence litigation risks. However, only 6,000 claims were received last year and only around 40,000 complaints about clinical treatment. This suggests that many people simply don't know, because they have not been told, that they or a loved one were involved in a patient safety incident which may have caused them harm – even if they are perceived as a potentially successful claimant.
- AvMA's casework regularly comes across examples of where there has not been open and honest reporting of incidents to patients or their families even after a complaint has been made, and even in the majority of clinical negligence cases which eventually settle in favour of the claimant, there has been a denial of liability and opportunities to be open and honest early in the process have been missed.

²

[A Safer Place for Patients, National Audit Office, 2005](#)

- There is a growing body of international evidence that as well as being the right thing to do morally and ethically, being open and honest when things go wrong can actually reduce litigation and complaints. Insurers in the USA even require open disclosure policies and practice by health providers to qualify for insurance. It is certainly AvMA's experience that not being dealt with openly and honestly is one of the biggest reasons why people take legal action or seek disciplinary action.

Is the call for a statutory Duty of Candour new?

No, there have been a number of calls for a statutory Duty of Candour over the years. The case of Robbie Powell who died in 1990 from a medical error which was then the subject of an alleged cover-up has been pivotal. It was the campaigning of his family which led to recognition of the need. This is why the AvMA's campaign for a statutory Duty of Candour is called 'Robbie's law'.

The chief medical officer for England, Sir Liam Donaldson, formally recommended the introduction of a statutory Duty of Candour in 2003 in his report *Making Amends*. There has never been a satisfactory explanation as to why the recommendation has not been implemented.

The all party Health Select Committee recommended in its report on Patient Safety (July 2009) that the introduction of a statutory Duty of Candour be reconsidered. In its response to the report, the Government wrongly claimed that a legal Duty of Candour already existed in the form of the professional codes for the various health professions. This had to be retracted when AvMA pointed out that this is incorrect. (The health professional codes are only guidance/standards, and in any case only apply to individual health professionals – not organisations). The Government response also sought to reassure the Committee that other measures were being considered to clarify a need to inform patients of incidents within the regulations for the Care Quality Commission. However, as explained above, quite the opposite has happened.

What do other stakeholders think?

The call for a statutory Duty of Candour to be introduced in the CQC regulations enjoys widespread support from all quarters. Just some examples include:

Harry Cayton, Chair of the Council for Healthcare Regulatory Excellence (the regulator of health professional regulators) said:

"We support the introduction of a duty of candour in the CQC's registration requirements, which would mean that the ethical responsibility of health professionals would be shared by organisations delivering healthcare services".

Ruth Marsden, Vice Chair of the National Association of LINks members (the local lay health & social care watchdogs), said:

"NALM is committed to the protection of patients in health care and believes that there should be a legal 'duty of candour' which places a duty of all health care professionals to be open and frank with patients. We are disturbed that the opportunity to introduce a legal 'duty of candour' has been side-stepped by Government, which has decided to introduce a requirement to report adverse events in health or social care in England to the regulator but not the patients and carers who should be at the centre of health care. We will be demanding that the Government amends the draft regulations for Care Quality Commission (CQC) laid before Parliament this week to include a duty of candour to patients as well as regulators".

Claire Rayner, President of the Patients Association and a former nurse, said:
"This is an issue that should have been dealt with years ago. As one who has personally suffered iatrogenic damage I know the sense of helpless anger it (failure to be open and honest) induces". Other patients groups' supporting a statutory Duty of Candour include:

- Sufferers of Iatrogenic Neglect
- Patient Concern

Professor Aidan Halligan, former deputy chief medical officer for England and currently Chief of Safety at Brighton and Sussex University Hospitals said:

"I am completely supportive of what you are proposing. I remember Don Berwick saying in relation to patients rights 'nothing about me without me'. In our privileged position as doctors and nurses, we should do to others as we would have done to ourselves. Honesty is the only policy"

Other prominent doctors publicly supporting a statutory Duty of Candour include:

- Sir Graeme Catto, immediate past president of the General Medical Council
- Sir Donald Irvine, past president of the General Medical Council

Sally Taber, Director of the Independent Healthcare Advisory Services said:

"This proposed law would require all healthcare providers to approach the level of the best. It would be an important driver for further improved patient safety in the independent healthcare sector".

What would a statutory Duty of Candour look like? How would it work?

AvMA does not employ parliamentary draftsmen, but our analysis of the way the Care Quality Commission (Registration) regulations 2009 are constructed suggests that a simple additional clause drafted in a way consistent with other existing clauses could relatively easily be added and would bring about the Duty of Candour ('Robbie's law) in England. Careful consideration would have to be given to the exact wording but one suggestion, consistent with the existing regulation on respecting and involving service users, would be:

“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 incident in their care which is suspected of having caused or may result in harm to the service user in the future
- (b) That staff are provided with training and support in reporting incidents
- (c) They have regard to any guidance issued by the Secretary of State or other appropriate expert body in relation to the matters referred to in paragraphs (a) or (b).”

This regulation would be backed up with more detailed guidance which the CQC has already drawn up. Each organisation registered with the CQC (every health & social care provider in England eventually) would have to demonstrate that they meet the criteria and could be heavily fined or have registration taken away if the CQC found that they were not meeting this requirement.

CASE STUDIES

We have chosen two case studies that convey poignantly and well why a statutory Duty of Candour is needed. However there are many other examples that we come across at AvMA as part of our work.

Case Study 1 – John Moore-Robinson, Mid Staffordshire NHS Foundation Trust



John Moore-Robinson (left) died in 2006 having attended the Mid Staffordshire NHS Foundation Trust following a mountain biking accident. He was discharged from the Accident & Emergency Department with suspected damaged ribs but later died as a result of damage that had been caused to his spleen. An internal report prepared by one of the A&E consultants for a coroner's inquiry found that the assessment and diagnosis at Stafford A&E was below standard and that better treatment might have saved John's life. However, a legal officer employed by the trust suppressed the report both from John's parents, Frank and Janet, and from the coroner. The Robinsons only found out about the cover-up when it was brought to their attention by lawyers running the independent inquiry into care at Mid Staffordshire last year. AvMA are now providing advice and support to the Robinsons and seeking a formal investigation of the affair and possibly, a new inquest. However, even the new regulations brought in by the Government in the CQC regulations would mean that the Trust were not in breach of any statutory regulation in covering up the information. However, the Trust could be fined or even closed down for not submitting anonymised data about such an incident to the NPSA.

Frank Robinson (pictured right) said:

"I am shocked and appalled by this. It is terrible enough to lose a son and have the reasons for it covered up, but to have the Government endorse a system where a hospital can do this so long as they send some anonymised data to the authorities is disgraceful."



Case Study 2 – Mayra Cabrera, Great Western Hospital, Swindon



Mayra Cabrera, 30, (pictured left) died of a heart attack one hour after giving birth to Zachary, a healthy 8lb baby, in May 2004 at the Great Western Hospital in Swindon, where she worked as a theatre nurse. A drip bag containing the powerful epidural painkiller Bupivacaine had been mistakenly connected to a line into her right hand instead of a saline drip. Although it became clear early on that the drug error had something to do with her death, and there was an internal investigation, Mayra's husband Arnel Cabrera was simply told that Mayra had died from a rare but natural event– from an embolism – and was given no idea that something untoward had happened. It was not until some fourteen months later, after a legal investigation had been instigated by his solicitors Seamus Edney (a specialist clinical negligence solicitor on AvMA's panel), that the circumstances were revealed. However, the records show that in May 2004 it had already been acknowledged internally that a “drug error” had been a contributory factor in Mayra's death (and even the post mortem report in May 2004 said that Bupivacaine toxicity was the cause of death). Yet no-one at the trust informed Mr Cabrera.

Frequently asked Questions and Misunderstandings

'Creating a statutory duty might make people more likely to cover up'

It simply is not credible to suggest that placing a statutory duty on organisations to do everything reasonably practical to ensure patients are dealt with openly and honestly will drive people to cover up. The proposal includes a requirement for organisations to treat staff fairly and support them. However, everyone needs to understand that it is simply unacceptable to allow dishonesty over medical accidents. Sending the message that cover ups may be tolerated (as the current arrangements do) can in no way support an open and fair culture.

'Doesn't the professional duty that all health professionals have to be honest with patients mean that a legal duty is unnecessary?'

The so-called 'professional duty' of health professionals contained in health professionals' codes of conduct only applies to health professionals. The duty should rest equally with health managers and boards as well. Also, the 'professional' or 'ethical' duty on health professionals is not a legal duty. It is guidance contained in their professional codes. Regulators have been inconsistent in how they use their discretion to enforce this duty. In the case of Robbie Powell, the GMC has maintained to this day that the strong allegations of attempted cover-up and forgery of medical records were not even important enough to waive their 'five year rule' and investigate.

'The NHS already promotes 'Being Open' through the guidance and training provided by the National Patient Safety Agency, and there is the NHS Constitution, so there is no need for a law'

The Being Open guidance produced by the National Patient Safety Agency (NPSA) is a useful tool and says the right things, but it is only guidance. This sends out the wrong message. NHS boards have many targets and other 'must do's' on their agenda and are unlikely to give this guidance top priority. Also, it only applies to the NHS whereas a legal duty would also cover private healthcare. The NHS Constitution also is restricted to the NHS, and whilst it makes a valuable statement of principle, there is no way of enforcing it.

'Making laws or rules is not an appropriate way to change culture'

It may be true to say that simply passing a law or a statutory regulation does not in itself change culture and behaviour. Obviously there will need to be lots of awareness raising, training and support as well. However, it can make a massive difference in helping bring about change. Take for example the effect of legislation on anti-discrimination; to ban smoking in public places; for the use of seat belts; and on drink-driving. It sends a clear and powerful message about what is and is not acceptable. Quite rightly, the Care Quality Commission regulations already include regulations which are designed to help change culture and behaviour. For example, they introduce a statutory duty to treat patients with dignity and respect.

'It is too complex or difficult to regulate something like candour/being honest'

The draft regulations for the Care Quality Commission and the Healthcare Standards for Wales already contain duties such as obtaining informed consent and treating patients with dignity and respect. These are complex and difficult to define also but, quite rightly, are a requirement of registration. The approach is to have a 'high level' requirement stated in the regulations themselves. The accompanying guidance will provide more detail on what is expected and how the Care Quality Commission will judge whether the requirement is being met. The Care Quality Commission has themselves said that they would be comfortable with regulating a statutory duty of candour.

"Would health providers have to report 'near misses'?"

No. It is accepted that discretion is needed as to whether it might do more harm than good to tell a patient about a 'near miss' in their care. It is proposed that the new duty only covers incidents which meet the NPSA definition of 'patient safety incident' which are known to have resulted in harm to the patient (or where it is possible harm will materialise in the future).

Why call it "Robbie's Law"?

Although there are many other cases where there has not been openness and honesty when things go wrong in healthcare, and even of deliberate 'cover-up', Robbie Powell's case has become a symbol for the need for a legal duty of candour. His family has campaigned tirelessly and courageously for nineteen years not only for justice for Robbie, but to ensure that other families do not have the same experience. It was Robbie's case which highlighted the absence of a legal duty of candour. Robbie's case has been the subject of a landmark judicial review challenge by AvMA of a General Medical Council decision not even to investigate serious, evidenced allegations of forgery as part of an attempted cover-up and ongoing dishonesty by doctors involved in Robbie's case.