Action against Medical Accidents

APPENDIX:

SUPPLEMENTARY INFORMATION

Contents

1 Examples of erroneous information about complaints and litigation on NHS websites

A quick visit to a number of NHS websites on 17th December 2010 found the following examples:

Epsom and St Helier University Hospitals NHS Trust website:

"What about compensation for clinical care?

The complaints procedure, as described above, does not lead to compensation. In fact, the Regulations state that a complaint cannot be considered under this procedure if the person making that complaint states in writing that he or she intends to take legal proceedings".

NHS Croydon (Croydon PCT) website:

"Matters that cannot be complained about:

There are some cases that cannot be dealt with under the NHS complaints procedure. These include:

- Complaints about private medical or dental treatment
- Events requiring investigation by a professional regulatory body*
- Events about which you are taking legal action"

* Note: it is also incorrect that events requiring investigation by a regulatory body cannot be dealt with by the NHS complaints procedure

Leeds Teaching Hospitals NHS Trust website:

"As a point of information, if a complainant is seeking compensation as one of the outcomes of a complaint, we are unable to deal with such requests under the NHS complaints procedure …… For anyone who wishes to take legal action, once litigation has been set in motion, the complaints investigation will be discontinued".

2 **Examples of erroneous interpretation of regulations re: complaints and litigation by NHS bodies**

The following are copies of actual correspondence from NHS trusts to complainants/ their representatives:

Medway BS

NHS Foundation Trust

Medway Maritime Hospital
Windmill Road
Gillingham
Kent
ME7 SNY

Tel: 01634 830000

Extension 3108
Secretary direct dial: 01634 833881
Fax: 01634 829470
E-mail: Phillip.Elliott@medway.nhs.uk

2 August 2010

Messrs Fairweathers, Solictors
16 Station Road West
Canterbury
Kent
CT2 8AN

Dear Sirs

Yours and enclosure of 21 July 2010 refers.

Please note that this was not received until 26 July 2010, hence the delay in responding.

Having considered the facts, we have advised the Trust complaints department that a complaint investigation should not commence at the present time. The 'complaint[1] will, therefore, be put 'on hold' and addressed at the conclusion of the legal claim if your client then so wishes.

Given, however, that the subject matter of your client's 'complainf is the same as that of the claim being pursued, and the 'complainf letter is effectively an abbreviated Letter of Claim (albeit drafted by yourselves in the first rather than the usual third person), we will happily treat it as a protocol letter and address the Issues raised within the protocol period.
Shall we agree that receipt of details of funding arrangements, remedy sought and losses claimed from yourselves will trigger the protocol timetable?

Yours faithfully,

Phil Elliott
Solicitor
Head of Legal Services
Medway NHS Foundation Trust

Medway

NHS Foundation Trust

Medway Maritime Hospital
Windmill Road
Gillingham
Kent
ME7 5NY

Tel: 01634 830000

RESIDENCE 8
LEGAL SERVICES

Our Ref: PE.JB.455
& 427

Your Ref:
AT/H104/.2/NS

Extension No: 3108
Secretary direct dial: 01634-833955
Fax Number: 01634-829470
Reply to:
e-mail:

Canterbury,
Kent
CT2 8AN

29 July 2010

02 AUG 2!

MrAlexTengroth
Messrs Fairweathers, Solicitors
16 Station Road West

Dear Mr Tengroth

Yours of 23 July 2010 refers.

You have selectively quoted from the relevant Department of Health publication 'Clarification of Complaints Regulations 2009' published on 28 January 2010. I set out below the relevant section of that publication in Its entirety:

'Cases subject to litigation.
There is evidence that not all organisations are aware that the 2004 regulation, that excluded a complaint from consideration where the complainant has stated in writing that they intend to take legal proceedings, has been specifically excluded from the 2009 regulations.

The Department of Health's position was laid out in the consultation document 'Reform of health and social care complaints: Proposed changes to the legislative framework'published in December2008.

"The position in cases where legal action is being taken or the police are involved is slightly different. On receipt of a complaint in these circumstances, the Government will expect discussions to take place with the relevant authority (for example, legal advisors, the police, or the Crown Prosecution Service) to determine whether progressing the complaint might prejudice subsequent legal or Judicial action. If so, the complaint will be put on hold, and the complainant will be advised of this fact."

This envisaged approach has not changed. On receipt of a complaint in these circumstances, good practice is for discussions to take place with the relevant authorities (for example, local legal advisors or the NHS Litigation Authority) to determine whether progressing the complaint might prejudice subsequent legal action. The complaint should be put on hold only if this so, with the complainant being advised of this and given an explanation. In other words, the default position in cases where the complainant has expressed an intention to take legal proceedings would be to seek to continue to resolve the complaint unless there are clear legal reasons is not to do so.

A number of points arise:

The first of which is, of course, that I am the legal advisor to this Trust; you will be aware that I am a Solicitor of the Supreme Court and that I hold a current practicing certificate. Each and every case where there is possible conflict between a complaint and a claim Investigation is discussed with me and it is decided on its own merits.

When informing a 'complainant[1] of my decision, I explain the reasons for it; if you do not consider it sufficient to state that I believe it is prejudicial to the proper and effective conduct of the defence of the legal claim, then we must simply agree to differ.

In respect of the matters of **SKJiPfranoVHK** I have made the Trust's position clear and I see no reason to alter that view.

Yours sincerely)

Phil Elliott
Solicitor
Head of Legal Services
Medway NHS Foundation Trust.

PRIVATE AND CONFIDENTIAL

Our ref: JR/PS/SCH/10410 26 October 2010

Worcestershire

Acute Hospitals NHS Trust

Alexandra Hospital
Woodrow Drive
Redditch
Worcestershire
B98 7UB

Tel: 01527 503030 Fax 01527 517432

Dear

•Thank you-foryeuHetter of-10 October 2010. lam sorry forthe problems that you have experienced.

I understand that you have instructed solicitors in regard to your ophthalmology care and treatment and I am therefore unable to respond further to your concerns as part of this process.

With regard to your ophthalmology appointments) believe that you have spoken to Sue Willis, Directorate Support Officer for the Head and Neck Directorate, about the appointments and you were advised that the letters had crossed over with your visit to the department

If you have any further concerns or are unhappy with this response please do not hesitate to write to me or contact the Patient Services Department on 01527 512177. This should be done within 28 days following receipt of this letter. I would be happy to investigate your concerns, and it is our experience that in these circumstances a meeting with appropriate staff is often helpful in bringing these matters to a resolution. If you would like to take up this option please discuss it with the Patient Services Department

Yours sincerely,

Yours sincerely,

John Rostill OBE
Chief Executive

3 Examples of Parliamentary and Health Service Ombudsman's interpretation of her regulations re complaints and litigation

The following is correspondence from and with the Health Service Ombudsman:

You can contact me on: UJG0 061 4427 Our reference: EN-85851 /0053

sally.capper@ombudsman.org.uk

[redacted]

in Confidence **Parliamentary and Health Service** Ombudsman

20 July 2010

Dear

Your complaint to the Health **Service** Ombudsman

I am writing further to our recent conversations when we discussed your concerns about the care and treatment provided to your daughter by the Fairfax Group Practice (the Practice).

You explained that you are waiting to find out whether a charity you have approached is able to assist you in pursuing legal action against the Practice. As I explained, whilst there is the possibility that you may proceed with legal proceedings, we are unable to consider your complaint further. On this basis you agreed to withdraw your complaint for the time being until you know whether the charity is able to help you.

In the event that you decide not to proceed with any legal action and you would like us to consider your complaint again, please put your request in writing to me. As I explained, if you were to approach us again we would need to consider the circumstances of your complaint at that time. This would include the length of time passed since the matters you complain about took place so you should therefore contact us as soon as possible.

We have now closed your current enquiry, however, we will keep on file all the documentation you have sent us already.

I am sending a copy of this letter to your ICAS advocate, Tanveer Akhtar, for their information.

Please contact me if you have any questions.

Yours sincerely

Sally Capper ;
Assessor

22.06.2010 - Telephone call from Alana M in which she informed me that by pursuing legal proceedings I had put my mother's case out of their jurisdiction and that if I chose to pursue this action that they, the Health Service Ombudsman, would not be able to investigate the complaint further and the case would close. She clarified also that if I ceased all proceedings and did not accept any compensation or any form of remedy that they would continue.

Email 22.06.2010

Dear HlBBHlMBMM*

Further to our telephone conversation this afternoon, please find attached a copy of the Health Service Commissioners Act 1993.

It may be useful to explain that, although under the new NHS complaints regulations that you referred to in our conversation, the bar on dealing with complaints while legal proceedings are pending has been removed, the Ombudsman is not governed by those regulations but by the Health Service Commissioners Act 1993. Under that Act, the Ombudsman shall not investigate a complaint where the complainant has, or had, a remedy by way of proceedings in court, unless it is not reasonable to expect the complainant to resort, or have resorted, to that course of action.

As we discussed, I will wait to hear from you about the Trust's response to your settlement request, which I understand is not due until next week. In the meantime, I will discuss the issue with my Manager and obtain legal advice from our internal advisers, so that I can be sure of how we may proceed from here. I look forward to hearing from you in due course.

Kind regards

Alana McKaysmith
Health Investigator
Parliamentary and Health Service Ombudsman
Millbank Tower
Millbank
London
SW1P 4QP
Tel: 0300 061 3918
Fax: 0300 061 4196
Email: Alana♦McKaysmith@ombudsman.org.uk

Plus copy of

HEALTH SERVICE COMMISSIONERS ACT 1993 See Page 8

HSC_Act_1993.pdf

Email sent 13.07.2020

Dear Ms McKaysmith

Further to you email below I can now confirm that there has been no response to the part 36 request to the Trust for Settlement. It seems that their legal services are not prepared to comment until they have made their own enquiries and investigations or that they are obliged to respond within the given time limit. A final decision had to be

made last week as to whether I wished to issue the papers and continue proceedings against the Trust. I decided not to pursue the matter any further in preference to the continuation of the Parliamentary Health Service Ombudsman's investigation of my mother's case as discussed.

Please would you therefore now confirm to me that this is agreed with your manager and legal services and that the investigation process can now continue.

I look forward to hearing from you regarding this matter.

With kind regards

----Original Message ----
From: McKaysmith Alana [mailto:Alana.McKaysmith@ombudsman.org.uk]
Sent: 22 June 2010 17:48
To: 'Charlotte Radford'
Subject: Your complaint to the Health Service Ombudsman

Email 15.07.2010

Dear

Thank you for your email. I can confirm that as you have decided not to pursue legal action any further, we can now continue with the investigation into your complaint.

I am on annual leave from Friday 16 July 2010 until Monday 26 July 2010, after which I will be in contact with you to explain the next steps of the investigation.

Kind regards

Alana McKaysmith
Health Investigator
Parliamentary and Health Service Ombudsman
Millbank Tower
Millbank
London
SW1P 4QP
Tel: 0300 061 3918
Fax: 0300 061 4196
Email: Alana.McKaysmith@ombudsman.org.uk

--- Original Message-
From:
Sent: 13 July 2010 16:19
To: McKaysmith Alana
Subject: RE: Your complaint to the Health Service Ombudsman

Email from Dept of Health

Ourref:DE00000522113

DearMQMMH^

Thank you for your email of 9 July to the Department of Health about pursuing civil action and a complaint against the NHS concurrently. I have been asked to reply.

As you are aware, prior to the change to the NHS complaints regulations in 2009, a complaint against the NHS would not have been investigated even at local level where the complainant had indicated in writing that he or she intended to take legal action. The reform of the complaints procedure affected the local resolution and Healthcare Commission stages, the latter being removed entirely. However, the reform did not impact upon the Health Service Commissioners legislation.

In December 2008, the Department of Health published Reform of health and social care complaints: proposed changes to the legislative framework. This document introduced the idea of allowing the complaint to proceed if legal action is also being taken, subject to the complaint not prejudicing that legal action. It also makes clear that the necessary regulations would revoke the National Health Service (Complaints) Regulations 2004, as amended in 2006, but makes no mention of the Health Service Commissioners Act 2003.

I hope this helps to clarify the matter.

Yours sincerely,

Neil Gilmartin Customer
Service Centre Department of
Health

If you would like to view our performance against our quarterly service targets, please visit our website:-
http://www.dh.gov.Uk/en/ContactUs/DH_066319#_5

Solicitor s

250 Park Lane • Macclesfield • Cheshire SKI I 8AD
www.jobling-gowIer.cauk • Email: info@jobling-gowlcr.co.uk
Tel: 01625 614250 • Fax: 01625 614252
DX 25025 Macclesfield 2

Date: 5 October 2010
OurRef: RMJ.BC
YourRef:

AVMA DX
84207
CROYDON 1

6 OCT 2010

Dear Sirs

Re: **NHS Complaints & Litigation**

We would appreciate your advice in relation to a problem encountered when acting for a client who pursued a complaint herself, and a legal claim through this firm.

Our understanding was that the reform of the NHS Complaints Procedure in April 2009 brought about the removal of the bar on NHS complaints being investigated if a complainant has started litigation or has expressed the intention so to do. However, we now have cause to query that.

Our client's elderly mother died in an NHS hospital in March 2007. Our client was very unhappy with the nursing care her mother received whilst in hospital, and commenced a complaint in about May 2007. When she was not happy with the outcome of Stage 1 she asked the Health Service Ombudsman to consider the case.

Our client contacted us shortly before limitation was due to expire in connection with a legal claim. We advised her at that time about the need to issue protective proceedings if she wished to pursue a legal claim, and took instructions. We issued a Claim Form and obtained a nursing care report, which was supportive in identifying several areas of substandard nursing care. We then proceeded to obtain evidence on causation from a Consultant Physician.

Our client at around that period informed the Health Service Ombudsman that she was considering pursuing a legal claim and that a Claim Form had been issued. At that point she was informed that by pursuing legal proceedings she had put her mother's case out of the jurisdiction of the Health Service Ombudsman and that, if she chose to pursue the action, the Health Service Ombudsman would not be able to investigate the complaint further and the case would close. The Health Investigator apparently also confirmed that, if she ceased all proceedings and did not accept any compensation or any form of remedy, the investigation through the Health Service Ombudsman could continue.

In this particular case the expert medical evidence we obtained on causation was not supportive, and our client took the decision not to proceed with the legal claim and, in preference, to continue with the Health Service Ombudsman investigation of her mother's case.

It is however a grave concern of ours that it seems the bar to making a complaint when seeking legal action or pursuing a claim is not lifted once the matter proceeds to the Health Service Ombudsman.

We enclose copies of the emails that our client received on those points, for which we have been granted permission to disclose to you.

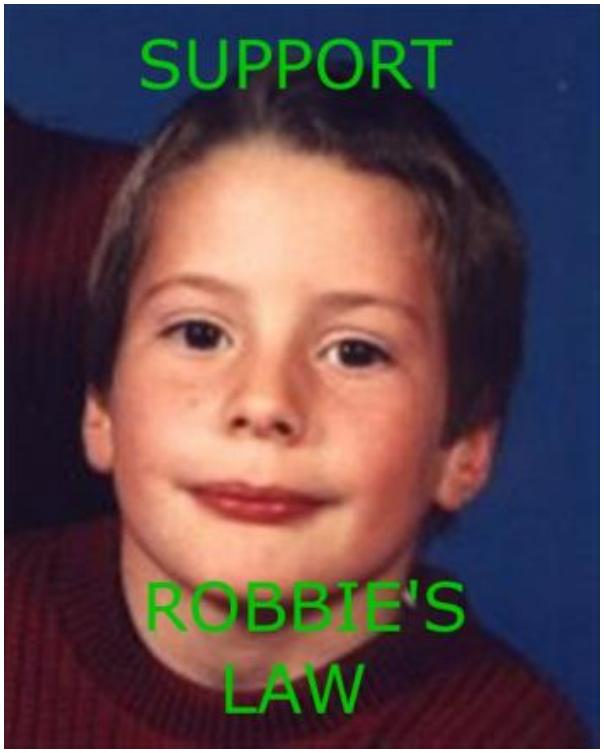
We should be grateful if you could consider the enclosures, and would appreciate any advice or information you have regarding the Health Service Ombudsman's role and the Health Service Commissioners Act 1993. We need to have the matter clarified so that any advice we provide to clients is accurate and up to date.

We look forward to hearing from you. Should you require any further information about this case or wish to discuss the matter, please do not hesitate to contact our Mrs Becky Jacobs.

Yours faithfully

Jobling Gowler LLP

THE NEED FOR A STATUTORY DUTY OF CANDOUR IN HEALTHCARE



Updated 17th August 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.

The new Government in its White Paper 'Liberating the NHS' says it will "require" hospitals to be open and honest when things go wrong. This stems directly from the Liberal Democrats manifesto. The Liberal Democrats supported our call for a statutory duty. However, there is still resistance from some quarters to introducing a statutory duty. Ministers are still prevaricating about whether such a duty will be brought in.

Not only is the Government still prevaricating over whether or not it will introduce a statutory Duty of Candour, but the previous Government pushed through controversial new registration regulations for the Care Quality Commission[1] 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 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 2005[2] revealed that only 24% of NHS trusts routinely informed patients of a patient safety incident and, astonishingly, 6% admitted to never informing patients.
- The Medical Protection Society (MPS) surveyed 700 members in 2008 and found that only two-thirds believed that doctors are willing to be open with patients when things go wrong[3].
- 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 _____

1 The Care Quality Commission (Registration) Regulations 2009, Statutory Instrument 2009 No:
2 **A Safer Place for Patients, National Audit Office, 2005**
3 MPS survey of 700 medical professionals conducted August/September 2008

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.
- 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:

- National Voices – the umbrella group for over 220 patients' and service user groups
- 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".

<u>What would a statutory Duty of Candour look like? How would it work?</u>

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

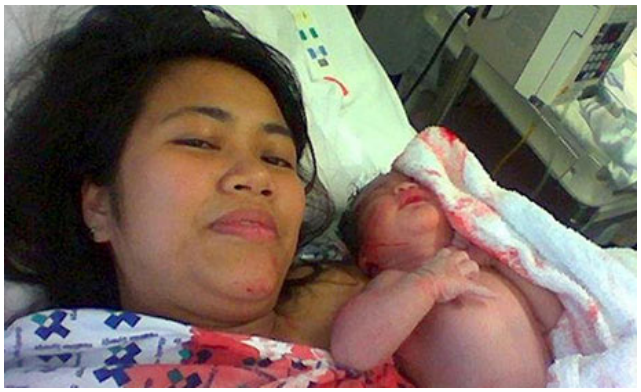
John Moore-Robinson (left) died in 2006 having attended the Mid Staffordshire NHS Foundation Trust following a mountain biking accident. He was discharged from the Accident & Emergency Department with suspected damaged ribs but later died as a result of damage that had been caused to his spleen. An internal 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 to 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.