RESPONSE TO

DEPARTMENT OF HEALTH

CONSULTATION ON A

"DUTY OF CANDOUR"

JANUARY 2012

1 OVERVIEW

Action against Medical Accidents ('AvMA' – the charity for patient safety and justice) has been at the main protagonist in pushing for openness with patients when things go wrong in healthcare for years. AvMA welcomes the recognition by government that something very different and more serious needs to be done than anything else to date to achieve this. **However, whilst AvMA welcomes the concept of embedding a 'Duty of Candour' in contractual arrangements with NHS organisations as one of a variety of means to support a change in culture and practice, we are convinced that without introducing an underpinning statutory duty of candour on all healthcare providers this measure would be woefully inadequate.** Openness with patients needs to be given the same status as any other essential standard of quality and safety and not to do so seriously undermines the whole concept. We also believe there are very serious practical difficulties with relying on a contractual arrangement. These include: the capacity of commissioners to monitor and enforce the so-called requirement; the fact the duty would only apply to incidents which have already been reported to the official systems; and the fact that by the Government's own admission, it can not guarantee that the duty would apply to general practitioners or the commissioners themselves.

AvMA is deeply disappointed with the approach of the Department of Health in restricting this consultation to comments on its proposal to restrict its so-called duty of candour to a contractual arrangement. In discussions with stakeholders prior to the Department announcing this it was clear that there was no enthusiasm from stakeholders for this mechanism on its own and strong support, particularly from all patients' organisations consulted, that a meaningful duty of candour needs to have statutory force. It also received this message loud and clear in the responses to the listening exercise on the Health and Social Care Bill. If the Department was unconvinced, the least it should have done is to consult all stakeholders, including the public, on which option for a duty of candour they favoured. AvMA strongly disputes the Department's rationale for its decision to opt for a mere contractual arrangement, which lacks credibility and smacks more of an ideological resistance to introducing any new statutory regulation. A detailed briefing on why this is the case is provided at the end of this response. However, we have also responded, below, to the consultation questions set by the Department.

It is not too late to change direction. There is overwhelming support for a **statutory** duty of candour. It was clear from the closing submissions at the Mid Staffordshire NHS Trust Public Inquiry that the inquiry itself was not necessarily convinced by the Department's contractual proposal, and it will have something to say on the matter. The subject is also being debated in the context of the Health and Social Care Bill. It would be reasonably simple to introduce a clause in the Care Quality Commission's registration regulations to give such a duty statutory force and put it on a par with other essential requirements. Statutory duty and contractual requirements are not mutually exclusive. A statutory duty together with contractual arrangements would be extremely powerful and mark the biggest advance in patients rights and patient safety since the NHS began.

Even if the Government continues to ignore the clear wish of patients that openness when things go wrong be made a statutory duty, there are very significant weaknesses in the current proposals for a 'contractual' duty which will need to be addressed if it is to have a meaningful impact. Most notably, the duty should not be restricted, as currently proposed, to patient safety incidents which are reported to local risk management systems / the National Reporting and Learning System. There are serious patient safety incidents which are not reported through this route even where they are known about. It is widely acknowledged that there is very significant under reporting of incidents. Restricting the duty in the way proposed would mean there would be no way of taking action against providers over failing to be open about these unreported incidents even

where this is brought to Commissioners' attention. This makes a nonsense of the so called duty. Perversely, it could actually incentivise non-reporting.

2 ANSWERS TO CONSULTATION QUESTIONS SET BY THE DEPARTMENT

1 Do you think the contractual mechanism described here including the requirement for a declaration or commitment on openness, provides an effective effective mechanism for requiring openness?

No, absolutely not, without an underpinning statutory duty. Openness with patients needs to be given equal status with any other essential standard of quality and safety. The most logical, practical and consistent way to achieve that is to introduce a duty into the registration requirements of the Care Quality Commission. If this were in place, the proposals for a contractual mechanism would be an extremely useful and welcome complementary measure. We also strongly object to the restriction of the proposed duty to patient safety incidents which have already been reported through official systems (see answer to Q6).

2 Do you think there should be a range of consequences available for use depending on circumstances?

Yes. In addition to the consequences envisaged a vitally important one would be reporting to the CQC, with the CQC having the power to take regulatory action as a consequence of non compliance.

3 Do you have any suggestions for what the consequences should be – either as a range or as a single consequence?

Yes. In addition to the consequences envisaged a vitally important one would be reporting to the CQC, with the CQC having the power to take regulatory action as a consequence of non compliance. Note: it should be a given that a breach of the contractual duty is in itself serious enough to require bringing to the attention of the CQC. We object to the assumption in the impact assessment that only perceived "serious" breaches of the requirement would result in this.

4 Should the level of escalation include suspension / termination of the contract?

Yes. Plus there needs to be reporting to CQC.

5 Do you think a requirement should be placed on primary care contractors and if so how might this be achieved?

Yes. This is absolutely essential. It should not be a question of negotiation over the national contract. It must be non negotiable. By far the most practical and effective way to achieve this is to make the requirement a condition for registration with the CQC, with whom GPs will need to register from 2013.

6 Are these requirements reasonable and clear, including the 5 working day deadline?

No. It is completely unreasonable and counter productive to restrict the duty to relate to patient safety incidents which are reported to local risk management systems or the National Reporting and Learning System. There are serious patient safety incidents which are not reported through this route even where they are known about. It is widely acknowledged that there is very significant under reporting of incidents. Restricting the duty in the way proposed would mean there would be no way of taking action against providers over failing to be open about these unreported

incidents even where this is brought to Commissioners' attention. Perversely, it could actually incentivise non-reporting.

7 Is there anything that should be included that isn't?

Yes, provision of evidence in a public statement that:

- providers have a suitable Being Open policy in place and that this is promoted within the organisation
- an ongoing programme of training on Being Open for clinical and non clinical staff who communicate with patients in these circumstances is in place
- monitoring complaints about providers and the responses for openness with patients
- periodically monitoring cases which have been the subject of litigation and analysing them to see if there has been any lack of openness with patients/ their relatives
- reporting any serious or systemic failures to promote and deliver openness with patients to the CQC
- reporting individual health professional breaches of professional standards with regard to openness which come to their attention to the appropriate regulator

8 Do clinicians, including GPs, feel able to assist their patients in identifying cases where there has been a failure to be open, and then either supporting their patient in raising these concerns, or simply referring the concern to the commissioner to investigate?

For clinicians to answer, but independent, specialist advice and support must be available to patients and their families.

9 What support and advice do clinicians feel would assist them in this?

We believe that there should be compulsory training in Being Open. There should also be a lead person (a board member) in each organisation with responsibility for overseeing compliance with this requirement.

10 What additional support and advice would assist patients in raising concerns that could be made available through Local HealthWatch services?

It is vital that the replacement service for Independent Complaints Advocacy Services (ICAS) is readily available to patients by contacting their local Healthwatch organisation. This is best achieved if such a service is part of an easily identifiable local 'one-stop shop'), with the staff providing such advice being part of Healthwatch itself. It is also important that this generic local complaints advice service has close links and access to more specialist independent advice services capable of dealing with more complex clinical cases and cases that may require regulatory action or with medico-legal implications. Rather than duplicating what already exists in the voluntary sector by developing such specialist services as part of Healthwatch itself, National Healthwatch should be resourced to commission such specialist services from suitable existing providers, to work closely with local Healthwatch.

11 Does a 'road map' or 'flowchart' of 'What To Do When Things Go Wrong' sound like a useful tool for patients?

Yes. AvMA has already done some work with CHRE on such a flow chart. That would be a useful starting point.

12 Are there any equalities issues with this proposal? Will any groups be at a disadvantage and therefore less likely to receive openness[1]?

Yes. Anyone can be kept in the dark over whether there has been a patient safety incident which has caused harm. However, there are particular dangers that people who lack capacity, who are elderly, confused, or have learning difficulties will not understand when this is the case. There will need to be a particular drive to ensure these patients' care is monitored and where there are issues that these are appropriately explained including family members or next of kin where appropriate.

13 Are the expectations on Commissioners clear and reasonable?

Whilst the expectation on Commissioners to monitor providers and seek reassurance that providers are abiding by essential standards of quality and safety and the NHS Constitution is reasonable, we question whether it is reasonable or practical to expect Commissioners to effectively take on a role more suited to the national regulator (CQC). Commissioning and contracts have an important role to play, but it is not appropriate for Commissioners to be the sole regulator of what essentially should be a core national requirement for any provider of healthcare. Neither will Commissioners have either the resources or the know how to effectively enforce a core quality and safety standard such as openness with patients, whereas the regulator has. If it were the case that openness with patients could be enforced purely through the contractual/commissioning process, then this would be the case for all the essential standards of quality and safety which currently are included in the CQC regulations.

14 Should Commissioners be expected to do anything else?

The Commissioners should take reasonable steps to monitor and check that providers are meeting this obligation including:

- requiring evidence that providers have a suitable Being Open policy in place and that this is promoted within the organisation
- checking that there is an ongoing programme of training on Being Open for clinical and non clinical staff who communicate with patients in these circumstances
- monitoring complaints about providers and the responses for openness with patients
- in particular, analysing complaints which are referred to the Ombudsman for any evidence of breach of this condition
- periodically monitoring cases which have been the subject of litigation and analysing them to see if there has been any lack of openness with patients/ their relatives
- reporting any serious or systemic failures to promote and deliver openness with patients to the CQC
- reporting individual health professional breaches of professional standards with regard to openness which come to their attention to the appropriate regulator

Commissioners should involve independent external reviewers in evaluating their approach to monitoring and enforcing this requirement.

15 Are the public reporting requirements clear and reasonable?

Yes, in as far as they go.

3 OTHER ISSUES NOT ADDRESSED IN THE CONSULTATION

- Given that the responsibility for monitoring and taking action where appropriate over breaches of the requirement occur will rest with Clinical Commissioning Groups there is also clearly a role for the NHS Commissioning Board in ensuring that CCGs take on this responsibility, monitoring their performance in carrying it out, and taking action when necessary.

- There need to be clear guidelines on the responsibilities of CCGs with regard to complaints which will be made to them about breaches of the duty and about the CCG's failure to deal with reported breaches appropriately. The CCGs themselves should be under an obligation to report publicly on what they are doing to support compliance with the duty and to monitor and take action when appropriate.

- The definition of 'moderate' or 'severe' harm which defines the nature of the incidents which are covered by the duty need to be better explained. In particular, incidents such as failures in diagnostic procedures (for example breast screening) which have the potential to result in moderate to severe harm should be included. It should not be possible to keep information from patients affected by such failures which expose them to the risk of such harm and still to be compliant with the duty. 'Low' harm should be defined as so low as to be very superficial and temporary. Guidance should make clear that even if not covered by the duty, it is usually good practice to be open even about low or 'no harm' incidents. Where a decision is made not to disclose such incidents the decision and its rationale should be recorded in the patients' records.

- Whilst we do not agree that this duty should be restricted to incidents which are already reported through the official reporting systems, we do agree that it is intolerable that even these incidents do not necessarily get explained to the patient / their family. One small and practical step that should be taken to address this, notwithstanding anything that happens over the proposed duty, is to ask reporters of incidents to declare on the reporting form whether the patient/their next of kin have been informed through a Being Open process.

4 ANALYSIS OF THE DEPARTMENT OF HEALTH'S RATIONALE FOR OPTING FOR A 'CONTRACTUAL' DUTY AND REJECTING A STATUTORY DUTY

- On a positive note, there now seems to be consensus that something really serious needs to be done to guarantee that patients and families are dealt with openly and honestly when things go wrong. The well intentioned words in the NHS Constitution; various guidance and the health professionals' codes of practice are not enough. Current arrangements have proven to be insufficient to ensure openness and honesty and a stronger more focussed approach is required.

- However, the Government heard loud and clear in its Listening Exercise on the Health & Social Care Bill, mostly from patients' groups but from other experts as well, that what was needed was a statutory "Duty of Candour" reflected in this Bill – not the so-called "contractual" duty of candour which they recently announced and are consulting on the detail of. This is paying lip service to the notion of a genuine 'duty of candour' and has been soundly rejected by the leading voices on this topic – notably, Action against Medical Accidents ("AvMA" – the charity which has championed the cause of patient safety and justice for nearly 30 years); National Voices (the umbrella group for over 200 patients' charities); and the National Association of LINks Members.

- Failure to commit to a more meaningful measure in the form of a stautory duty – one which would be worthy of the title "Duty of Candour" – will not only fail to have the desired effect, it is a snub and an insult to patients and patients' groups, and other experts. This is an opportunity to show that patients really are being listened to.

- We believe a "contractual" duty is woefully insufficient on its own, and why a statutory, enforceable duty is required. Note: we are not against the standard clause in providers' contracts which is proposed, it is simply that that measure on its own can not have the desired effect and, as we will discuss, is riddled with practical difficulties.

- Essentially, this is a question of just how seriously the Government takes its commitment to "require" openness with patients when things go wrong and cause harm. If this is really an essential and fundamental principle which we want any provider of NHS care to live up to, it is reasonable to expect to find it where all other essential core standards are – in the registration requirements with the Care Quality Commission. These are reflected in the statutory CQC regulations, making it a statutorily enforceable requirement for any provider to meet these standards.

- Not only is a requirement to be open with patients not reflected in the CQC regulations at present, but quite bizarrely the regulations do make it a statutory requirement to report incidents which cause harm (anonymously) to the CQC. This sends out completely the wrong message about how important being open with patients is taken. The Government's current proposals do nothing to address this.

- In addition to this, AvMA and others point out that the Government's proposals of a mere contractual duty on its own simply cannot have the desired effect. It is worth nothing that the Government itself admits in its consultation document, that

  "We are not certain of the precise mechanism that will be added to contracts".

  The primary elements of the proposed contractual duty seem to be a standard clause in providers' contracts, and a requirement to make an annual declaration that the clause is being complied with. If that is not a "tick box" exercise, one wonders what is.

- If the Government agrees that the requirement to be open really is fundamental and essential, why on earth would a different approach be taken to this essential requirement with it being left to the commissioning process? Commissioners simply aren't equipped to regulate issues of this kind. If one accepts the argument that this is the appropriate way to proceed, then all of the core standards currently in the CQC regulations could simply be dealt with in the standard contract for providers.

- Another key weakness in the Government's proposal is that "providers' contracts' only relate to NHS contracts with trusts, PCTs and private/voluntary providers of NHS services. This would not include primary care practitioners such as GPs. The Government admits in its consultation document that they are subject to different arrangements, and the duty could only be brought in in negotiation with their representing organisations. Very significantly, the BMA General Practitioner Committee have already stated that they will not sign up to a 'duty of candour'. This is not something which should be negotiable. A duty is a duty. The Government's proposed contractual duty of candour would be weak even where it did apply, but simply would not cover where so much NHS care is undertaken – in primary care. An advantage of a statutory requirement in the CQC regulations is that it would cover primary care and also private providers of healthcare.

- It is not just patients and patients' groups who advocate a statutory duty of candour. AvMA present an impressive list of leading clinicians and organisations who support it. Just recently, at the Mid Staffordshire Public Inquiry, Sir Liam Donaldson, the ex-Chief Medical Officer for England and internationally renowned champion for patient safety reiterated his long held belief in a statutory duty of candour when asked directly. He said:

"I have always personally agreed that there should be a statutory duty of candour. I have favoured it because I am of the view that professionals should be encouraged to take responsibility when they have done something wrong, rather than withhold instances of harm"

In closing submissions, both the chair and counsel for the inquiry made it clear the chair is likely to comment on this matter, and that the Government's proposed 'contractual' duty is not necessarily considered sufficient.

- As recently as June of this year, MPs on the Commons Health Select Committee looking at "Complaints and Litigation" recommended that a duty of candour be included in the licensing arrangements with the Care Quality Commission (precisely what AvMA and others are arguing for).

- The Government say in its current consultation document that it wished to avoid a "bureaucratic" or "tick box" arrangement. However, its proposal amounts to just that. The Care Quality Commission's Registration Regulations and the CQC's regulation of the care requirements within them is clearly the appropriate place to place a duty of candour. To imply that somehow the CQC could not cope with regulating this is simply not credible. It would suggest they are incapable of regulating all the other core requirements in its regulations. A good start would simply be to check that organisations are complying by examining the reports of incidents sent to them under the existing requirement. This would not be onerous.

- No doubt the CQC is under a lot of pressure and has a natural desire to argue that it needs additional resources. It may not welcome an additional requirement in its registration regulations with enthusiasm. However, it is its job to regulate matters which are essential in healthcare. If the CQC were unable to regulate a 'duty of candour' it is not credible to suggest that commissioners could.