RESPONSE TO SCOTTISH GOVERNMENT CONSULTATION ON PROPOSALS TO INTRODUCE A STATUTORY DUTY OF CANDOUR

January 2015

Introduction

Action against Medical Accident (AvMA) is the UK charity for patient safety and justice (charity registration number in Scotland: SCO 39683). For decades, achieving more openness and honesty with patients or their families when things go wrong in healthcare has been a top priority for AvMA, based on our daily conversations with thousands of people affected by medical accidents each year. No other organisation has done more to raise awareness of the need for a 'duty of candour' and to make sure it comes about. Failure to be open and honest when things go wrong causes serious harm and distress in itself as well as being unfair and unethical. It also feeds a defensive culture in healthcare which mitigates against learning and patient safety. Yet, for the entire history of the NHS, there has been no legal or statutory requirement for organisations to tell patients about the harm they have been caused. Whilst a 'professional duty of candour' has existed for years in the codes of the GMC and NMC, it has been poorly promoted and inconsistently enforced. In effect, up to now, the system as a whole has frowned upon cover ups but has tolerated them.

The introduction of a statutory organisational duty of candour in Scotland, and the new found enthusiasm from health professional regulators to re-invigorate their professional duties of candour have the potential to change that. A change which, if properly designed and implemented, would be the biggest breakthrough in patients' rights and patient safety we have ever seen. We therefore warmly welcome the intention to introduce the Duty of Candour in Scotland, but we do have some very serious concerns about the current proposals in the consultation document. We believe the following changes are needed if the Duty of Candour is to be effective.

This document summarises our main suggestions to make the Duty of Candour effective in Scotland. Please also see the completed consultation response questionnaire which is an appendix to this document

OUR PROPOSALS FOR MAKING THE DUTY OF CANDOUR EFFECTIVE

The duty should apply to incidents are suspected to have caused harm or that have the potential to result in harm – not just when harm is already known to have resulted

We believe that it is vital that the definition of the "disclosable event" is changed so that it is clear that incidents that are suspected to have caused harm, or that have potential to result in harm must be disclosed. For example, if a baby is deprived of oxygen for too long at childbirth or a system failure occurs regarding diagnostic testing where the potential harm has not yet materialised. It would clearly not be acceptable to withhold this information from the parents/ patient in these circumstances.

The proposed definition in the consultation document only refers to incidents where harm is already known to have materialised because of the incident. The

consequence of this would be that patients/families may be denied information about incidents which eventually result in harm and, as is often the case now, them not having the opportunity to be involved in investigation of incidents. Incident investigations which exclude the patient / family perspective can often result in incorrect findings. Actually framing the definition in the way described in the consultation document could have the unintended consequence of making it easier for service providers to deny patients/families information about incidents that have serious long term implications for the patient but where the harm has not yet materialised, and to withhold any information about incidents which may have caused harm unless and until the service provider themselves are confident that harm has actually been caused. It must surely be the desired default position that if there is any doubt, the patient should be informed and have the opportunity to contribute to any investigation.

It should be noted that after meticulous discussion and debate, the regulations defining the statutory Duty of Candour for organisations in England define a notifiable patient safety incident as an incident which:

*" **could result in, or appears to have resulted in—**the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or severe harm, **moderate harm** or prolonged psychological harm to the service user "* (Our emphasis)

Whilst we agree that it is reasonable for 'near misses' and incidents which can only cause the most trivial harm are excluded from the statutory duty to disclose, we think it is important that it is clear that any potential "significant" harm incidents **must** be disclosed, whilst continuing to stress that it is good practice to disclose even near misses and minor harm that may have been caused.

We would also advise finding another expression as an alternative to "disclosable event" in order to avoid confusion with the legal disclosure process in litigation, and also to avoid implying that these are the only events that "are disclosable" (i.e. can be disclosed).

Patients or family members should also have the right not to be told everything

We think it is important that a patient or family member be given the opportunity to opt out of being told details of an incident if they wish to. The regulations in England allow for this. This can be achieved by notifying the people concerned that there has been a disclosable event which they have the right to know more about but respecting their wishes if they do not want to know the details. However, the details of what is known about the incident should be recorded in the patients' records for future reference .

Compliance with the duty must be rigorously monitored and robust action taken if it is not complied with

We understand that detailed consideration of how the compliance with the duty will be monitored and regulated is yet to be undertaken, but it is worth stressing that the way monitoring and regulation takes place is absolutely crucial. To be effective we believe that the appropriate bodies, presumably Health Inspectorate Scotland for healthcare organisations, will need to be proactive in seeking out evidence of compliance. For example, we believe the following are essential components:

- Evidence that staff are adequately trained and supported
- Named individuals with responsibility for ensuring compliance
- Audits of random samples of complaints, claims, and incident reports
- Investigating alleged breaches of the duty

Where organisations do not have sufficiently robust measures in place to comply with the duty they should be warned and required to comply within a set period of time. If they continue to fail to comply they should be put into special measures or ultimately have the Board replaced.

Where there is a deliberate breach of the duty, sanctioned by management, then organisation should be subject to a substantial fine, the responsible individuals disciplined / removed from their responsibilities and the organisation put under special measures / surveillance until it can satisfy the monitoring body that it has made the necessary adjustments to ensure compliance in future.

Whist we think it is right that the duty should be directed at organisations rather than individuals, employees of organisations need to be accountable through their organisation. Where an individual causes an organisation to breach the duty they should be subject to the organisation's disciplinary procedures and/or referred to their professional regulator if they have one. Organisations should need to be seen to be dealing with breaches by individual employees in this way, or themselves be in breach.

There needs to be a substantial awareness raising campaign about the duty and training and support for staff in implementing it

There remains a lot of misunderstanding and apprehension about the Duty of Candour where there is awareness of it, and far too little awareness. It is essential that awareness is raised with staff of how the duty will work in practice and that they see that there will be adequate training and support in implementing it. The way that information about incidents is communicated will be as important as the as the actual disclosure. A mechanistic, tick-box approach must be avoided.

Support for patients/families should include information on sources of independent specialist advice and support

The consultation document rightly points out that patients / families should be offered appropriate support, at what is an incredibly stressful time for them. Such support can take a range of different forms including a sympathetic approach from staff and offers of counselling, but should also always include information about where to access *independent* specialist advice and support. For example, agencies such as AvMA and the Patient Advice and Support Service. AvMA specialises in providing specialist advice and support when something has gone wrong in health care and can be particularly helpful to people in these circumstances.

Legislative changes

Changes to the legislation that underpin the role of Health Improvement Scotland and other regulators will be needed to enable the Duty of Candour to be treated as a fundamental standard and for them to be able to take sanctions against organisations who are not complying.

We believe that in addition, the Patients' Rights Act should be amended to incorporate the right of patients/family members to be told about incidents that may cause harm. This is a fundamental right which should have a place within this legislation as well as other legislation which is more about enabling regulators to enforce it.

The introduction of a statutory Duty of Candour in Scotland will fit well with the proposed "no-fault" compensation scheme, if it is introduced.