Consultation Response

Statutory Duty of Candour

January 2015

MPS's response to the consultation on 'Proposals to Introduce a Statutory Duty of Candour for Health and Social Care Services'

Overview

MPS fully supports a culture of openness in the NHS – a need for which was notably raised in the Francis Inquiry Report. We have long standing concerns that legal duties, such as a statutory duty of candour being proposed by the Scottish Government, fail to provide the impetus necessary for behavioural change. There is a risk that a legal duty of candour for health and social care services will encourage a bureaucratic, top-down, compliance-driven, blame culture which undermines a culture of transparency and learning.

MPS consistently raised concerns throughout the evolution of the statutory duty of candour in England and Wales, and similarly we have concerns with the proposals of the Scottish Government.

Problems with a legal duty of candour

A duty of candour will not create a culture of openness and learning

A statutory duty could prove counterproductive to the development of an open learning culture in healthcare. For any statutory duty to be effective, a system will be required to monitor compliance and apply sanctions. Any such system will inevitably distract from the original objective of ensuring openness with patients and learning from mistakes. This is why cultural change rather than legislation is the appropriate way of creating safe, responsive, patient centred care and high quality communication between professionals and patients. The legislation will instead result in a 'tick-box' reporting culture.

A recent survey of MPS members in Scotland found that 67% of respondents do not believe that a legal duty of candour will improve openness in healthcare.[1]MPS anticipates that the legislation will incentivise a box ticking attitude and create nervousness and fear amongst professionals. Furthermore, the requirement for subjective judgements will place undue pressure on practitioners.

Where a healthcare professionals reaction to incidents is one of fear, it should be changed into an eagerness to report, explain and learn, and this can only happen though cultural change. So while we welcome the Scottish Government's proposals for training and support to be a requirement for those staff involved in disclosure, MPS feels to do so alongside a statutory duty is counterproductive.[2]

The focus of the Scottish Government should be on fostering a culture of openness and trust. This will be achieved with mentoring, training and supporting staff to communicate effectively and sensitivity with patients when things go wrong and ensuring senior clinicians lead by example.

A statutory duty would be difficult to enforce

The proposals do not specify how compliance with the duty would be monitored and enforced and clarity is needed on that point.

In paragraph 10.1 of the consultation document, the Scottish Government states that its intention is for an organisational duty of candour to 'be monitored through the existing performance monitoring, regulation and/or scrutiny arrangements that apply to the organisation'.[3] While the function of Health Improvement Scotland (HIS), as a mechanism of the Public Service Reform (Scotland) Act 2010, is familiar to healthcare providers, greater clarity is still needed about how the Scottish Government sees an embedded statutory duty of candour sitting within its remit.

We question how a duty of candour can be effectively framed in statute and how it would be enforced. MPS's research shows that tracking and monitoring compliance has been particularly difficult in the seven states in the US that have introduced such legislation[4].

MPS cannot envisage it being possible for statue to properly define a requirement for genuine open communication and any statutory duty will inevitably become a 'box ticking' exercise. Weak

[1] MPS Member Survey (Scotland), Scottish Government proposals, December 2014. A total of 296 respondents, 199 of which responded 'No' to the question: *Do you believe that a legal duty to be open with improve openness in healthcare?*
[2] Scottish Government consultation document, pg 4, para 2.5
[3] Scottish Government consultation document, pg 17, para 10.1
[4] http://www.medicalprotection.org/uk/booklets/a-culture-of-openness.

organisations could, at best, merely fulfil the basic obligation and not address central issues of support and training. At worst they could look for loopholes in the legislation, manipulate their reporting procedures and do the minimum possible to comply.

The Proposed Legislation

We have identified several areas within the proposals where further consideration is needed. The problems we foresee are as follows;

1. The legislation may make healthcare providers fearful of breaking the law on candour and distract them from focusing on patient care;

2. The legislation mayl be inconsistently interpreted and applied, especially where the legislation relies on subjective assessments;

3. Ensuring compliance will be difficult and resource intensive. Organisations may be encouraged to manipulate their procedures and reporting mechanisms;

4. The statutory requirements will be difficult to enforce.

Proposals for definitions of 'Adverse Events Resulting in Harm'

MPS agrees that in order for organisations to implement effective arrangements for disclosure of episodes of harm, there needs to be clarity about the definition of harm that will be used to decide when disclosure is appropriate. As discussed above, the application of a subjective assessment would further encourage ambiguity.

The Scottish Government has acknowledged the need for definitions of types of harm to be established through dialogue with health and social care professionals. As an organisation representing more than 12,000 medical professionals in Scotland, MPS would welcome the opportunity to play an active role in that dialogue.[5]

Disclosable Events

[5] Total of 12,939 members – including, Medical, Dental and Associates, all of which either full-time, RDM or student.

The proposed definition of disclosable events does not adequately consider how its application would work in practice. MPS is concerned about the uncertainty that will inevitably come from an all-encompassing definition centred on both unintended and/or unexpected consequences.
We have considered the disclosable events listed and have provided examples below of why the application of the duty to disclose would be burdensome to medical professionals.

- ***Returns to surgery***

It is not clear what this means, especially as there is no timescale associated with it. There is a significant difference between a patient taken back to theatre within 24 – 48 hours of an initial procedure because of problems with that procedure and a patient who has surgery many years after an initial procedure. For example, a case where the patient has a stricture of the bowel which recurs two or three years after the initial surgery.

- ***An unplanned re-admission to hospital***

Similarly to the above, it is not clear what this means, especially as there is no timescale associated with it. For example, the difference is considerable between a patient who is admitted with unstable diabetes, stabilised, sent home and readmitted the following week and a patient who suffers from chronic obstructive airways disease, who is treated for their chest infection, sent home and readmitted the following winter with a further episode. Both of these could be an unplanned readmission, but with no clinical fault.

If in the first scenario the diabetic patient is readmitted after a week because they have not followed medical advice regarding diet and/or treatment, it is inappropriate that this should be classified as a disclosable event.

- ***A prolonged episode of care and extra time in hospital or as an outpatient***

Again, it is not clear what these ‘disclosable events’ mean as there is no explanation as to what would constitute prolonged or extra time. It seems particularly plausible for these ‘disclosable events’ that organisations could alter their procedures and reporting mechanisms to control the number of occasions when disclosure applies.

For example, if an organisation knows that the average time in hospital for a particular condition or treatment is three days, then half of patients could be expected to stay longer than three days. It

would be a burdensome requirement if this automatically is classified as a disclosable event. An organisation could, as a result, inform patients that for this particular condition or treatment they should expect to remain in hospital for four days. This would reduce the number of disclosable events but also reduce openness and honesty with patients.

- ***Cancelling of treatment***

This definition requires further qualification as it fails to give consideration to the different contexts in which treatment could be cancelled. For example, in the event of a major flu pandemic where routine treatments were cancelled as a part of a nationwide NHS plan, it would be inappropriate for hospital staff to spend time notifying patients as required by the legislation. This would waste resources that should instead be directed to addressing the pandemic – such would be the expectation of the public, and the desire of the medical profession.

- ***Transfer to another treatment area (Intensive Care)***

Again, it is not clear whether this means. For example, whether this refers to a transfer within a hospital or a transfer to another unit. There will be situations where admission for investigation shows that a particular unit must be involved in the patient's care because of the nature of the disease when it was diagnosed. It would be inappropriate for these circumstances to require disclosure as this is part of normal practise in a hospital.

- ***Prolonged pain and prolonged psychological harm***

There is no definition of 'pain' or 'psychological harm'. Pain, in particular, is highly subjective and it is inappropriate for legislation to rely on subjective assessments. Legislation should be clearly defined to provide certainty and clarity in duties.

It could be argued that minor discomfort or anxiety for 28 days might be included but it would be excessive for there to be a legal procedure requiring disclosure to a patient with this level of pain and anxiety. If circumstances such as this were captured by the legislation, compliance would be burdensome for medical professionals.

It is also unclear what the relevance of a 28 day period is or when, within a 28 day period, an assessment should be made as to whether pain is likely to be experienced. Furthermore, it is unrealistic and impractical for a healthcare professional to be required to assess the likelihood of a

patient's subjective experience of pain or psychological harm. Again, compliance by busy healthcare professionals would be burdensome and would distract them from their proper focus on patient care.

Questions

Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation?

While MPS believes a statutory duty of candour would be counterproductive, if the Scottish Government is minded to proceed it is important that organisations clearly communicate the policies and procedures to be followed so that all staff are aware of their duties under the legislation and how to comply. Statutory guidance alongside legislation would be essential.

Although MPS anticipates that different types/levels of training may be appropriate for different groups of staff, it is likely that the doctor responsible for a patient's care would ultimately be responsible for identifying and reporting when an adverse event occurs and then communicating this to patients and families.

It is noted that HIS visited all NHS boards in Scotland as part of the national programme supporting learning following adverse events. HIS's observations confirmed that there is variation across the country in respect of the rigour and standard of open disclosure and support for families and staff when harm occurs.

The introduction of a formal training programme and relevant policies and procedures will promote certainty and consistency amongst organisations by reducing the scope for misinterpretation of the legislation. It will assist leaders within organisations in reaching the correct decisions to ensure compliance. Also, it will allow those affected by disclosable incidents to understand how decisions are reached.

Since it is has been recognised that being candid is an advanced communication skill, it is vital that programmes are put in place to prepare health professionals on how to make disclosures and deal with a patient's reaction to that information.

Do you agree with the requirement for organisations to publicly report on disclosures that have taken place?

MPS supports open disclosure, and organisations should report on patient safety incidents. However, if the disclosable events were to remain as proposed in the consultation document, MPS would be concerned that the reporting of all the events, including those that form part of normal practice in hospitals, would be a source of unnecessary concern for patients.

Do you agree with the proposed requirements to ensure that people harmed are informed?

We agree with the spirit of the Berwick Report that people who are affected by serious incidents should be notified and supported. We do not, however, agree with the scope suggested by the National Framework for Adverse Events, which would include temporary harm or prolonged treatment intervention or required monitoring.

Do you agree with the proposed requirements to ensure that people are appropriately supported?

The proposals fail to provide guidance on what will constitute 'reasonable support' for the person harmed and relatives and staff who may have been involved with the event. Since HIS has already identified inconsistent approaches to defining adverse events and the subsequent levels of support given, a lack of guidance in the legislation will ensure this level of inconsistency continues, with different health boards applying varying interpretations to the definition of 'reasonable support'.

What do you think is an appropriate frequency for such reporting?

MPS does not believe that organisations should be required to publicly report on disclosures that have taken place. As the proposals stand, disclosable events may include unnecessary near misses, which would be worrying for the patient as well as burdensome for healthcare professionals. However, if the disclosure requirement is included in legislation then bi-annual reporting would seem to be sufficient.

What staffing and resources would be required to support effective arrangements for the disclosure of incidences of harm?

MPS cannot comment comprehensively on the administrative resources that will be required. However, we foresee that the burden on doctors will be considerable and will have an impact on the time available to provide patient care.

Do you agree with the disclosable events that are proposed?

MPS provided evidence to the Dalton Williams Review on the threshold of harm and we highlighted the risks for healthcare professionals in creating a duty of candour.[6] We consider that a threshold of harm set at death or serious injury should be included in order to mitigate the risks documented above.

For any statutory duty to be effective, a system will be required to monitor compliance and apply sanctions. Any such system will inevitably distract from the original objective of ensuring openness with patients and learning from mistakes. This is why legislation is not an appropriate way of creating safe, responsive, patient centred care and high quality communication between professionals and patients. The legislation will hinder the creation of the open, transparent, learning culture that the NHS needs and instead contribute considerably to the creation of a compliance and reporting culture.

MPS anticipates that the legislation will incentivise a 'tick-box' attitude and create nervousness and fear amongst professionals about compliance. Furthermore, the requirement for subjective judgements will place undue pressure on practitioners whose decision could create a statutory duty to report the incident.

Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings?

MPS does not consider that the disclosable events will be clearly applicable and identifiable in hospital care settings. As documented above, there are numerous examples of normal practice in hospitals which could require disclosure, such as admission to ICU for monitoring/investigations following major surgery. It would be inappropriate for these circumstances to require disclosure as this is part of normal practice in a hospital.

What definition should be used for disclosable events in the context of children's social care?

Not applicable.

What are the main issues that need to be addressed to support effective mechanisms to determine if an incidence of disclosable harm has occurred?

[6] Building a culture of candour: A review of the threshold for the duty of candour and of the incentives for care organisations to be candid. Sir David Dalton, Prof, Norman Williams http://www.rcn.org.uk/newsevents/news/article/uk/duty_of_candour_review_published ; MPSEvidence Submission, Duty of candour – review of threshold

In order to support effective mechanisms to determine an incidence of harm, policies and procedures containing obvious reporting lines will need to be introduced and communicated to staff.

As an advanced communication skill, adequate training will be required to support healthcare professionals who discharge this duty. Significant resources will be required to ensure that patient care does not suffer as a result of complying with the proposed legislation.

How do you think the organisational duty of candour should be monitored?

While MPS believes a statutory duty of candour would be counterproductive to an open culture in healthcare, if the Scottish Government is minded to proceed it would seem sensible for HIS to monitor the organisational duty of candour since they already exercise similar functions. However, as discussed earlier, greater clarity is needed about how the Scottish Government sees an embedded statutory duty of candour sitting within the remit of HIS.

What should the consequences be if it is discovered that a disclosable event has not been disclosed to the relevant person?

The consequences ought to depend upon the circumstances. If the spirit of the legislation is truly about reflection, openness and learning rather than fostering a blame culture, then organisations ought to be given an opportunity to address any failings. There are a number of factors to consider, such as efforts for remediation and numerous examples of normal practice in hospitals which could require disclosure under these proposals.

HIS should be tasked with providing support in rectifying any issues identified. MPS believes that sanctions should be a last resort.

Concluding remarks

A culture of openness is essential to ensure quality and safety in healthcare. We offer training and educational programmes, supporting medical professionals across Scotland to fulfil their obligations and to have an open and honest discussion with patients in the rare event that things go wrong. There is a risk that these proposals will encourage a bureaucratic, top-down, blame culture which undermines a culture of transparency and learning. Having studied the proposals closely, MPS does not believe that the Scottish Government should proceed with its plans.

About MPS

MPS is the world's leading protection organisation for doctors, dentists and healthcare professionals. We protect and support the professional interests of more than 290,000 members around the world. Our benefits include access to indemnity, expert advice and peace of mind. Highly qualified advisers are on hand to talk through a question or concern at any time.

Our in-house experts assist with the wide range of legal and ethical problems that arise from professional practice. This includes clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Our philosophy is to support safe practice in medicine and dentistry by helping to avert problems in the first place. We do this by promoting risk management through our workshops, E-learning, clinical risk assessments, publications, conferences, lectures and presentations.

MPS is not an insurance company. All the benefits of membership of MPS are discretionary as set out in the Memorandum and Articles of Association.

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