New criminal sanctions: will they generate the cultural change required for a safer NHS?
Examining the Government’s initial response to the Francis Report

The Government has accepted some, but not all, of the recommendations made by Robert Francis QC to introduce new criminal law sanctions. While the Government do not challenge the basic premise that sticks are better than carrots in changing culture, they do reserve their position in respect of individual liability and whether this would create a culture of fear.

Nevertheless the Government has been persuaded that criminal penalties are the answer in four areas:

- New “fundamental standards” to be enforced by the CQC’s new Chief Inspector of Hospitals.
- A “statutory duty of candour” on providers to inform people if they believe treatment or care has caused death or serious injury.
- The HSE will be asked to investigate serious cases with the Department of Health and the Department for Work and Pensions required to ensure that they have the capacity to act.
- In addition, penalties for withholding or wilfully generating misleading information are being considered.

Introduction

Politicians are good at rhetoric. They have to be to become politicians. When faced with a scandal the size of Mid Staffordshire it is incomprehensible to think they could stand back dispassionately and respond in a careful and measured way. More often, out comes the sledgehammer and new laws seek to crack the problem once and for all. The last Labour government introduced more than 3,000 new criminal offences during its nine-year tenure, one for almost every day it was been in power, criminalising everything from selling non-native animals to failing to nominate a key-holder to come and turn your burglar alarm off whilst you are on holiday.

Three days after the publication of the Report of the Mid Staffordshire Public Inquiry, in an interview with The Daily Telegraph, the Secretary of State for Health Jeremy Hunt was quoted as saying that it was "absolutely outrageous that potentially more than 1,000 people lost their lives because of poor care and not a single person has been brought to book."

At the same time, they were resolutely standing behind the NHS Leadership. Yet, as Robert Francis QC himself was at pains to point out that there was “serious systemic failure” and concluded that the tendency to try and seek someone out who can be blamed for what occurred prevents us from moving away from the culture of blame, that perpetuates the cycle of defensiveness, concealment, lessons not being identified and further harm.

---

1 Blair’s “frenzied law making”: a new offence for every day spent in office, The Independent, 16 August 2006
The Government say in their own response that:

“The key is that boards and leaders need to create environments where staff feel supported to cope with the day to day risks and challenges of health and care work. This also enables openness: mistakes will sometimes happen – staff need to know it is safe to admit them. It also enables compassion: under stress, anyone can find it hard to be caring – staff need to know it is safe to ask for the support they need to really be there for patients.”

The Government does appear to have some reservations over the benefit of criminal sanctions as they have deferred judgment on whether an individual will be criminally liable for a failure in care or be caught by the duty of candour. However, it is still hard to see immediately how the introduction of several new criminal offences will bring about a common culture of putting patients first and supporting staff.

**Fundamental standards**

Breach of the existing “Essential Standards” by a healthcare provider is already a criminal offence. However, prosecutions are rare and non-existent in the NHS as providers voluntarily take action to improve when found wanting by the CQC.

Few would support the standards themselves; an odd collection of requirements, first put together for use in nursing homes and care homes, not acute hospital wards or GP surgeries. New evidence based and clinically supported standards will clearly be welcomed. However, what is not clear is exactly how they will be enforced. Patients First and Foremost suggests that they should have a similar status to ‘never events’ and yet the examples put forward still require a complex web of interconnected procedures and individual action and are open to much interpretation. Take one example put forward:

“People are getting the medicines they have been prescribed at the right time and the right dose, including appropriate pain relief”

On a hospital ward this involves many people, including pharmacy wholesaler delivery drivers, hospital pharmacy staff, porters and nurses on the ward. Will any deviation be permissible? How many minutes are allowed to elapse before the drug is said not to have been given at the right time? Does it matter what else the nursing staff were doing at the specified time? What if the prescribed dose is wrong, will a failure to give that dose be an offence?

The Regulations setting out the current “Essential Standards” actually allow some leeway to organisations, containing a defence if the organisation can demonstrate that it has taken all reasonable precautions and exercised all due diligence to avoid the commission of an offence by the organisation or any person under his control. This is a question of fact as to whether the defence has been made out, and not law. It is a question of fact in every case to enquire whether what the relevant individual organisation has done constitutes due diligence.

It is not clear whether the government proposes to retain this defence in the new “Fundamental Standards” especially given the “zero tolerance” rhetoric. However, if you are a board member how can you really ensure that your organisation meets the fundamental standards every time?

---

2 See Executive Summary, paragraphs 106-108.
3 The initial Government Response to the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Paragraph 1.4.
The Government recognise that safe care is about ‘… both systems and people: ensuring organisational structures, policies, procedures and practices are delivering reliably safe care … and ensuring that staff’s decisions and behaviours and the effects of these are promoting safer care and avoiding risk and harm’.

Therefore strict liability on the part of the board for the individual actions of all staff will not really help and could in fact become a perverse disincentive. What is the point in having the best system in the world if you are going to be guilty anyway? A due diligence defence will still be a high threshold and will protect those doing the right thing. If it is not included, just think of the number of staff required on the front line to make sure that no patient ever waits to be taken to the lavatory, the net result of one of the other examples given.

Duty of Candour

The Government’s response to the “campaign” for a statutory duty of candour is interesting. It begins by setting out a defence of what is already in place, by talking about the publication of individual outcome data, quality accounts and the existing guidance on “Being Open”. It also sets out the rationale for the using the contractual mechanism to place an onus on organisations “to create a supportive culture in which people can admit mistakes.” It comes as a little bit of a surprise then, that for all the measures already in place to ensure transparency, they feel it necessary to introduce a new statutory duty after all. The document itself does not say why.

No detail is provided save that it will be for “care providers to inform people if they ‘… believe treatment or care has caused death or serious injury and to provide an explanation!’” This definition itself leads open the question of whether there needs to have been an actual error or mistake and still leaves it to the organisation to determine whether there has been any harm. In many cases the real reason that patients are not taken to one side and told that they have been harmed is that it is often very difficult to tell if that is the case or not. That’s also why most clinical negligence claims require expert evidence on breach of duty (was there a mistake?) and on causation (did it cause any harm?).

Personal experience, including my time in the early 1990’s working in the Complaints and Litigation department of a busy acute hospital, tells me that there is not as much of an issue regarding candour as perhaps Robert Francis QC makes out. He extrapolates quite a lot from a single case involving disclosure to a Coroner rather than demonstrating any widespread conspiracy to cover up mistakes. In fact, good practice in all serious incident investigations is to involve patients and their families and some Trusts even automatically share the incident report form with patients as a matter of course, as soon as it is completed.

Where there has been an obvious error (never events for example) patients are almost invariably told straight out. However, there will always be a large rump of cases in the middle ground where it is not easy to say whether treatment or care has caused harm, let alone whether that is “serious harm”. Many medical procedures have side effects, are they covered by this duty or not?

There is also no link between the duty and what is expected in patient safety terms. What would be far more effective than a duty to tell patients of an incident is a requirement for them to go beyond the rather trite ‘lessons learnt’ stage and take real action to prevent recurrence. The NHS is still far too reactive, relying on incidents to drive safety improvements rather than investing in designing safety in from the outset.

Distilling something workable and useful out of such an aspirational objective such as “candour” will be difficult. I expect that providers will encourage a conservative and non committal approach, telling patients when they ‘might’ have suffered harm as a result of the care provided. Otherwise the duty of candour could become an industry of its own.

4 Ibid paragraph 1.38.
own with experts being retained to review treatment decisions and outcomes on a regular basis to decide whether the duty is triggered or not.

HSE to use Criminal sanctions

One major concern that Robert Francis QC had was the reluctance of the Health and Safety Executive (HSE) to concern itself in healthcare. While the HSE have successfully prosecuted NHS organisations in respect of the clinical care of patients (R (HSE) v Southampton University Hospital and R (HSE) v Berkshire Healthcare NHS Trust for example) it does not see healthcare as an enforcement priority, partly because of the presence of other regulators (although for the NHS this is only really true of the past two years) and partly because of a perceived lack of expertise.

There is no other industry where the HSE takes the same approach and the Government appears to have called their bluff. No changes to the law are proposed as the all encompassing nature of the Health and Safety at Work Act 1974 and its associated regulations provides more than enough power to cover any situation in a healthcare setting. Instead, they will be encouraging the CQC to refer cases to the HSE for inspection and will ensure that they have adequate ‘capacity’ to investigate.

We can still expect this to be the exception rather than the norm, but more frequent HSE consideration of clinical settings and the application of proven risk management methodology may have quite profound consequences. For example, the standard required by the Health and Safety at Work Act 1974 is complete safety. If a patient is harmed, the onus is on the defendant to prove that they did everything that was reasonably practicable to prevent that harm occurring. This means demonstrating that the hazard had been identified and assessed and that appropriate control measures were implemented. This is not currently the way in which clinical governance operates in the NHS, but there is much to commend, as stated above, a more proactive approach with less reliance on incident investigation.

The other thing to say is that there is very clear individual criminal liability under the Health and Safety at Work Act 1974 for both Directors and individuals on the ground. Where managers have turned a blind eye or individuals have clearly flouted safety rules, they can expect to find themselves in court on their own account.

Misleading information

The final area where the government potentially sees criminal sanctions operating as a powerful deterrent is in terms of knowingly supplying wrong information. There have been recent stories of ‘doctored’ target data that may well be playing on minds. However, like with the HSE above, there are plenty of existing criminal powers available, such as the catch all ‘misconduct in a public office’ where it is really necessary to bring criminal charges.

Individual criminal sanctions

The extent to which any or all of these new criminal sanctions will apply to individuals as opposed to the corporate body is still to be determined. Before introducing “… criminal sanctions at an individual level for staff providing NHS services we would want to ensure that this does not unintentionally create a culture of fear” say the Government. This issue will be reassessed following Don Berwick’s review of safety.

Summary

As always, changes to the law of itself will not drive change. The way in which current and new laws are enforced will have more impact. Whether greater criminal law accountability and the fear it will create in others will be the most effective way of changing behaviour, is still to be proven. Experience in Denmark suggests that to the contrary, providing an amnesty for individuals reporting incidents might be a more effective approach. The Danish Patient Safety Act, provides a notable difference in emphasis:
“A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts”

Evaluation of the impact of this legislation found high level of reporting and confidence in the system and concluded that the reporting system has had a “considerable impact on the development of a safety culture in Denmark”.

They like carrots in Denmark. Maybe we should try some.

Duncan Astill
Partner
for Mills & Reeve LLP
+44(0)1223 222477
duncan.astill@mills-reeve.com

5 http://www.health.org.uk/blog/protection-or-prosecution-learning-from-denmark/?utm_source=Email+Alert&utm_medium=email&utm_campaign=New+content+on+Health+Foundation+website%3A+Protection+or+prosecution%3F+Learning+from+Denmark