Regulating and legislating safety: the case for candour

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INTRODUCTION

Public inquiries into healthcare-associated harm have a depressing sense of déjà vu. The past 12 years have seen (among others) exhaustive and expensive inquiries into the failures of paediatric heart surgery,[1] systems for obtaining informed consent,[2] the killings of Harold Shipman,[3] and now the story of neglect and maladministration at Mid Staffordshire NHS Trust,[4] where mortality rates were persistently higher than expected over the period 2005–2009. Indeed, the vast three-volume Francis Report echoes the findings of the first major NHS public inquiry into events at Ely Hospital as far back as 1967.[5] While these different events have their own histories and causes, they tell similar stories of ineffective regulation and weak safety cultures. The Francis report is reminiscent of the Kennedy inquiry report into Bristol[6] in observing closed hierarchical systems, fear of blame and punishment, toleration of bad practices, and a failure to learn from patient and staff feedback. Robert Francis QC is clear (and surely correct) that the fundamental problem lies in the prevailing culture of healthcare organisations. However, the report tends to gloss over some of the complexities of culture.[7] Thus, whilst heavy on detailed recommendations (there are an unmanageable 290), only four are specifically made in relation to culture.[8] Instead, the report gives much detail of—and places much faith in—the capacity of law and regulation to improve the safety of patients. This short paper evaluates the recommendations made in relation to reforming the legal and regulatory landscape around patient safety, and focuses on the potential that a legal duty of candour has for contributing to an improved safety culture in healthcare.

REGULATORY FAILURE?

Mid Staffordshire is a story of regulatory failure. This *should* be surprising given the seemingly robust structures in the 'pluralistic regulatory landscape'[9] that surrounds healthcare. Professional regulators, such as the General Medical Council, used to dominate their domains but are now overshadowed by a super-regulator (the Care Quality Commission) and overseen by a meta-regulator (the Professional Standards Authority for Health and Social Care). They are joined by Monitor, which assesses whether Foundation Trusts are well led in terms of efficiency and quality considerations, and countless other agencies that exercise some sort of regulatory influence in a complex and confusing arena. There appears to be little method in the madness of multiple agencies performing similar tasks yet leaving organisations and individuals confused and often conflicted in how to respond.[10] Constant change to the remit and legal responsibilities of regulators, as well as regular name changes, cannot help them in their task of making an impact with the regulated. It has been demonstrated that such a crowded and complex system of regulation contributes to the failure of organisations to develop clear goals.[11] The story of Mid Staffordshire is testament to this.

According to Francis, 'Regulation cannot be effective if it does not challenge claims of compliance made by the regulated organisations, and its prime purpose in protecting patients cannot be served by such a passive approach.'[12] However, evidence on the effectiveness of different types of healthcare regulation is thin on the ground.[13] Understanding how any *one* type of regulation affects behaviour is sufficiently challenging given the lack of research evidence and the difficulty of disentangling it from myriad sources of influence such as civil and criminal law, guidelines, employment contracts, peer support and pressure. Perhaps this dearth of material reflects the reality that the quality of medical work has only relatively recently become a focus for regulation and governance. Only during the last decade has professional regulation begun to move away from its ineffective past[14]

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with attempts to foster a new style of professionalism.[15]

What is the formula for effective regulation? Regulation scholarship, albeit from other sectors, has shown that achieving regulatory objectives—in this case continually improving the quality and safety of healthcare—is more likely if a combination of methods all point in the same direction. To help ensure effectiveness, the message from various sources of regulation, whether through ethical codes of conduct or legal obligations, should be clear and consistent. This so-called smart regulation is responsive to the relevant context and should begin with soft supporting nudges and be slow to utilise command and control measures such as legal penalties.[16] The spirit of smart regulation is welcomed by patient safety champions who have consistently called for more empathy and less blame directed to those at the sharp end of patient safety incidents. However, while this is generally seen as desirable, there is currently little evidence to support a claim that this smart regulation improves quality and safety.[17]

MORE LAW AND REGULATION?

It is perhaps unsurprising that Robert Francis QC, a distinguished barrister, leans on additional legal mechanisms for providing accountability. Those who despair at the tendency of modern day governments to over-criminalise will question whether more criminal law is an appropriate regulatory response to the problem of patient safety. For some, it is a blunt tool for dealing with a small amount of gross error and misconduct, and incompatible with attempts to foster an open culture.[18] In short, Francis is unconvinced by this argument. The report recommends that organisations could be prosecuted where breaches of fundamental standards leads to death or serious harm.[19] This zero tolerance policy towards breaches of minimum standards sounds attractive but is it realistic? The inclusion of a due diligence defence where all 'reasonably practicable steps have been taken to prevent a breach' might suggest that it isn't. While this zero-tolerance approach is laudable, some prefer a more pragmatic approach where regulators abandon the pursuit of perfection in favour of keeping behaviour within a 'band of variation', and focus on 'governing rather than erasing' the gap between expectations and performance.[20]

Francis invokes the precautionary principle by urging regulators to use wide-ranging interim powers to intervene in the name of patient protection. And managers who make intentional or recklessly false statements about compliance with such standards would also be open to prosecution as would similar bad faith in the signing off of quality accounts.[21] The post-Francis review led by Donald Berwick, focusing on the lessons for quality and safety, while generally eschewing blame and punishment, supports the call for an offence of wilful neglect.[22] This would apply to the sorts of callous acts of cruelty laid bare in the Francis report and for which criminal law does not currently cater. The case for such an offence is strong[23 24] and would be in line with existing offences that protect the mentally incapacitated.[25] The Department of Health has taken this recommendation for a new offence of ill-treatment or wilful neglect forward, and it seems inevitable that such an offence will be enacted shortly.[26] Such an offence (which will apply to both organisations and individuals) is intended to apply to instances of deliberate or reckless behaviour, rather than medical errors, although there are bound to be (as always) some grey areas calling for prosecutorial discretion. A likely source of contention in debating this offence is whether it will include a harm element or whether it will merely focus on the conduct in question.

While the horrors of Mid Staffs make it difficult to argue against a stronger regulatory response, we can legitimately question the long-term impact of such changes. The overall regulatory picture remains one that is overly complex, at times inconsistent and likely to leave individuals and organisations unclear about which practices and policies to prioritise. Arguably, a much more basic, yet fundamental task is required before amending the powers and responsibilities of regulators. In a recent thought paper, Douglas Bilton and Harry Cayton have called for the identification of a shared set of values of safe care on which all regulators can agree and communicate consistently. This would be a first step in moving to a system that looks and feels like a single regulatory force, albeit with different elements.[27] One element that is currently missing is a legal duty of candour to patients and their families about medical harm, the case for which will now be discussed.

A STATUTORY DUTY OF CANDOUR?

In another echo of the Kennedy report into Bristol,[28] Francis calls for a statutory duty of candour in healthcare. This would place a legal obligation on professionals and organisations to be honest with patients and their families about incidents causing medical harm. The campaign to create such a duty has been powerfully put by Mr William Powell, following the death of his son Robbie in 1990, with the support of the medical charity Action Against Medical Accidents (AVMA).[29] The absence of a legal duty of honesty *should* be a matter of surprise. Courts have long considered the possibility that professionals ought to be under such a duty but have stopped short of recognising this.[30] Despite the resistance to creating such a duty, it should hardly be considered radical—after all, existing legal duties now endorse the 'prudent patient' test for determining the standard of care in relation to information disclosure *before* medical intervention,[31] so why not extend this to include communication

after treatment? The ethical case for disclosure is clear: it is about truth telling and respect for persons,[32] and this should be reflected in a clear legal obligation to be honest.

However, disclosure is not easy. Proponents of candour cannot ignore the medicolegal context, which has the effect of discouraging openness. Survey research in the USA and Australia confirms the suspicion that the fear of medicolegal consequences is the main barrier to the practice of open disclosure.[33 34] In Australia, this is despite the presence of 'apology laws' and qualified privilege laws, although these do not protect professionals from litigation in terms of all aspects of what they might disclose.[35] In the UK, the statutory assurance that an apology or offer of redress is not an admission of liability or breach of statutory duty[36] is unlikely to reassure professionals into disclosing. Many medics also lack the necessary communication skills to be comfortable and effective at disclosing, which is unsurprising given that it has not featured prominently in medical education.[37] Part of the response to this must be better ethical training, which would (hopefully) lead to a stronger culture of openness around patient safety.[38]

While most accept the moral case for candour, many stop short of supporting a legal duty, instead preferring to leave this as a matter for regulatory codes of conduct. However, given that ethical and policy guidance has largely failed to encourage greater disclosure,[39] it is legitimate to consider a stronger statutory duty which should be taken more seriously.[40] The most recent reform in this respect—a contractual duty of candour as a service condition of the NHS standard contract for 2013/14[41] is inadequate and fails to do justice to such an important issue. To relegate the need for honesty into a contractual clause understates its importance. The ethics and emotion of the professional–patient relationship seem to have been forgotten here.

Robert Francis QC is surely correct in calling for a direct obligation to patients and their families and not just to NHS commissioners (as is the case under the contractual duty). His general recommendation for candour is widely drafted in stating that patients or their representatives *should* be fully informed when acts or omissions of the organisation or its staff may have caused death or serious harm. However, the proposed statutory duty of candour in recommendation number 181 is narrower in two respects. First, disclosure is limited to events that have *caused death or serious injury*. As causation is notoriously complex, one can foresee arguments that it was the patient's condition, for example, and not any healthcare error or negligence that caused the death or serious injury. Secondly, only healthcare providers (and not the professionals involved) are obliged to inform patients about an incident. Professionals would only be expected to report concerns to their employer, rather than directly informing patients. This seems a missed opportunity given the potential of open disclosure for altering the dynamics of patient–professional relationships. Contrary to widespread perception, the honesty and care displayed by open disclosure has the potential for strengthening and not weakening trust relationships.[42] In terms of enforcement, prosecution by the Care Quality Commission is envisaged, but only as a last resort for serial non-compliance or serious and wilful deception.[43] The reference to intentional deceit and dishonesty would render any such prosecutions hard to prove.

The initial Government response to the Francis report promised to deliver a statutory duty alongside the contractual duty on providers.[44] The Department of Health had initially intended (in line with the Francis recommendation) that such a duty would be limited to cases where *death or serious harm* was caused. However, intervention by Action Against Medical Accidents persuaded the Secretary of State for Health to commission a review on whether the threshold for the duty should be lowered to include moderate harm. Debating the degree of harm necessary to trigger a legal duty to tell the truth is somewhat unedifying, as is the prospect of hospitals waiting to discover the outcome of sub-standard care before disclosing. The case for being candid should not depend on whether the harm caused is classified as serious or moderate. It should be noted that the term 'moderate harm' is actually misleading given that the official NHS definition refers to 'significant but not permanent harm.'[45] While extending this duty to include near misses is generally seen as disproportionate,[46] a growing consensus (The Care Quality Commission, The Royal College of Nursing, The Patients Association and AVMA) has supported a threshold of moderate harm. On a practical note, it would also be consistent with the existing contractual duty of candour and the National Patient Safety Agency issued guidance.[45] Happily, the review led by Sir David Dalton (Chief Executive of Salford NHS Foundation Trust) and Professor Norman Williams (President of the Royal College of Surgeons) has strongly recommended that the duty should apply to harm currently defined as moderate.[47] This has been accepted by the Department of Health[48] and will be put before Parliament later this year.

This is not to suggest that a legal duty of candour is in any way a solution to problems such as those that caused the failures at Mid Staffordshire. It is part of the broader question of what is the optimum amount and type of law and regulation for helping to secure safer healthcare. While candour is only one piece of this broader puzzle, it is arguably a very significant one. For example, while change is likely to come from locally led initiatives and teams of professionals engaging with the science of patient safety, nevertheless, law has a role in setting standards. And in the

spirit of smart regulation, legal duties should be consistent with ethical responsibilities. Behavioural change is more likely when various sources of influence such as law, regulation and ethical guidelines repeat the same message.[49] Ideally, this reform would be introduced as part of a package of measures designed to improve the system of redress for victims of medical harm—for example, a no-fault compensation scheme, akin to those operating in New Zealand and the Nordic countries, or via a proposed system of 'Health Courts'.[50] However, the unlikely abolition of clinical negligence actions should not prevent reform signalling the importance of candour. It is more realistic to expect that professionals and providers of care will comply with such a duty safe in the knowledge that they will not be unduly penalised for their honesty. Realistically, we can only expect professionals to disclose harmful events with assurances that they will not face disciplinary or legal action unless the conduct in question suggests criminal behaviour or a continued risk to the safety of others. Furthermore, a legal duty should require that organisations provide training and support for staff in how to comply with the duty, alongside existing efforts by professional regulators.[51]

CONCLUSION

Regulating patient safety is not easy. The task is not helped by the dearth of empirical evidence on the impact of different types of regulation. But we can confidently predict that the current overly complex system is likely to confuse rather than clarify matters for those subject to regulation. Robert Francis QC is right to demand a zero-tolerance approach to compliance with fundamental standards as a bare minimum in terms of quality and safety. There is also a need for a unified system of regulation with a shared set of values. But might we need more? Can we be confident that more of the same—more law and regulation—will make any lasting impression? Or will the Francis report merely be the latest in a long line of inquiry reports that make a short-term impact but not the lasting change intended? It remains to be seen whether the new inspection regime established after these recommendations, led by a Chief Inspector of Hospitals, is sufficiently resourced, independent and trusted to make any headway here.[52]

Does law help or hinder attempts to encourage safer healthcare? This is a difficult question to answer, not least because law includes an array of approaches ranging from the 'hard' law of civil and criminal mechanisms, to statutory duties and 'soft' law such as policies and guidance. Patient safety scholars tend to be suspicious of law, viewing it as counterproductive to the pursuit of an open learning culture. However, the relationship between legal mechanisms of accountability (mainly via civil and criminal negligence) and the safety of care is not well understood. There is a danger of all legal approaches being lumped together and perceived as one and the same, when they can be designed and enforced differently. Francis is right to reject the argument that law is necessarily incompatible with efforts to foster the openness and cooperation necessary for a safety culture. Culture is notoriously difficult to change, and external controls such as law and regulation are limited in their capacity for achieving change. Nevertheless, it would be wrong to rule out any relationship between law reform and cultural change. In this respect, it is vital that such a duty includes an obligation on organisations to train staff in how to disclose, and to support them through this process. Furthermore, while the proposed statutory duty of candour will only apply to organisations rather than individuals, its success will require the active involvement of healthcare professionals. An important practical point to be worked out is who will inform patients about incidents that have caused them harm. Arguably, this should come from someone involved in the care of that patient rather than an envisaged candour-compliance officer. Receiving an explanation and apology from someone unconnected to the delivery of care is less likely to satisfy patients or help encourage the required cultural change in patient–professional relationships. It is hoped that, in designing guidance for implementing the duty of candour, the Care Quality Commission gives careful thought to the question of who discloses to patients and their families and how they do it.[53]

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