

The Health and Social Care Act 2008 (regulated activities) regulations 2014: a litany of fundamental flaws?

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This paper argues that the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014¹ are fatally flawed. This criticism is often levelled at knee-jerk responses to policy crises created without the benefit of time and thought. Yet, these Regulations were the product of a sensitively executed public inquiry. I argue that the 2014 Regulations will fail because they rely too heavily on the rhetoric of criminal law while failing to take into account the competing norms for compliance and the impact of NHS budget constraints. They push the CQC towards a deterrence approach to enforcement, increasing hostility between regulatees and inspectors, and ultimately reducing the scope for developing the transparency about failures which is sorely needed in the NHS. This paper challenges the contemporary wisdom that it is primarily knee-jerk regulatory responses that suffer from fatal flaws of this nature.

(A) The 2014 Regulations

The 2014 Regulations enact the ‘fundamental standards of minimum safety and quality’² recommended by the Francis inquiry into the Stafford Hospital fiasco in the 2010s. This framework of standards is to be met by health and social care providers in England and Wales. Their aim is to protect the dignity of service users while ensuring a high level of safety across health and social care services. The 2014 Regulations encompass twelve minimum standards covering fourteen ‘regulated activities’. These activities make up the business of healthcare provision, including personal care; accommodation for persons requiring nursing or personal care; accommodation for persons requiring treatment for substance abuse; treatment of disease, disorder or injury; assessment or medical treatment for persons detained

¹ 2014/2936. Hereinafter, “the 2014 Regulations”.

² Robert Francis QC, Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Executive Summary 2013 at <http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>, table of recommendations

under the Mental Health Act 1983; surgical procedures; diagnostic or screening procedures; management or supply of blood and blood derived products; transport services, triage and medical advice provided remotely; maternity and midwifery services; termination of pregnancies; nursing care; and family planning services.³ They apply across all regulated activities, and providers must meet standards in relation to those activities that they engage in.

Many of the new standards are similar to those in place previously. The 2014 Regulations replace the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010⁴, all of which can be mapped directly onto the 2014 Regulations. Some of the 2010 Regulations map onto a single regulation in the 2014 Regulations, such as the care and welfare of service users⁵ which has become person-centred care⁶, or respecting and involving service users⁷ which has become dignity and respect.⁸ Some regulations have been merged to form a single new regulation in the 2014 Regulations, such as the new regulation on premises and equipment⁹ which is made up from the 2010 Regulations on cleanliness and infection control,¹⁰ safety and suitability of premises¹¹ and safety and suitability of equipment.¹² One of the 2010

³ Schedule 1, 2014 Regulations

⁴ 2010/781. Hereinafter, “the 2010 Regulations”.

⁵ Regulation 9, 2010 Regulations

⁶ Regulation 9, 2014 Regulations

⁷ Regulation 17, 2010 Regulations

⁸ Regulation 10, 2014 Regulations

⁹ Regulation 15, 2014 Regulations

¹⁰ Regulation 12, 2010 Regulations

¹¹ Regulation 15, 2010 Regulations

¹² Regulation 16, 2010 Regulations

Regulations, cleanliness and infection control¹³ has been split and now forms part of the new regulations on premises and equipment¹⁴, and safe care and treatment¹⁵. See figure 1 for a map of how the 2010 Regulations map onto the 2014 Regulations.

There are two important changes in the 2014 Regulations. First is the new duty of candour introduced in regulation 20. This requires health service bodies to ‘act in an open and transparent way’ about errors.¹⁶ This entails providing a full account and apology to the relevant individuals whenever a notifiable incident has occurred.¹⁷ The second important difference in the 2014 Regulations is the change in tone. The language has more imperative force than the 2010 Regulations. For example, regulation 11 (2010) provides that the service provider ‘must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse’. Regulation 13 (2014) provides that ‘service users must be protected from abuse and improper treatment’. Similar changes in tone are evident across all the new regulations. There is a move away from healthcare providers “ensuring” that certain things are provided, towards requiring that needs “must” be met. This is not just a rhetorical change. While both the 2010 and the 2014 Regulations make non-compliance with any of the regulations a criminal offence, the 2014 offence is more robustly framed than the 2010 offence. Regulation 27(2) (2010) provides that proceedings cannot be brought against a provider for failure to meet the requirements of any of the regulations unless the CQC has already issued a warning notice to the provider, alongside a timeframe for improvement, and they have not in fact improved. While it was possible for an offence to be committed, it was practically

¹³ Regulation 12, 2010 Regulations

¹⁴ Regulation 15, 2014 Regulations

¹⁵ Regulation 12, 2014 Regulations

¹⁶ Regulation 20, 2014 Regulations

¹⁷ Regulation 20(3), 2014 Regulations

difficult for the CQC to prosecute. The 2014 Regulations appear to have addressed the problem by removing these practical barriers.

(B) The Mid Staffordshire fiasco

Identifying a policy fiasco is difficult to do with certainty.¹⁸ On any measure however, the events at Stafford Hospital were a policy fiasco. The Healthcare Commission investigated unexpectedly high mortality rates at Stafford Hospital between 2005 and 2008.¹⁹ They found ‘deficiencies at virtually every stage of the pathway of emergency care’²⁰ including triage being performed by unqualified receptionists, shortage of doctors and nurses, and considerable pressure on staff to meet targets. Management had failed to notice the high mortality rates, or to scrutinise the hospital’s care. Robert Francis QC chaired a public inquiry in 2010-2013. The report found ‘appalling suffering’ and ‘an insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities’.²¹ Francis called for a fundamental change to NHS culture. The Mid Staffordshire NHS Foundation Trust, which managed Stafford Hospital, was dissolved on 1 November 2014, and its services were transferred to other NHS Trusts.²²

¹⁸ M Bovens, and ‘t Hart P, Understanding Policy Fiascoes (Transaction, London 1996), 1-19

¹⁹ Healthcare Commission, Investigation into Mid Staffordshire NHS Foundation Trust 2009 at <http://webarchive.nationalarchives.gov.uk/20110504135228/http://www.cqc.org.uk/_db/_documents/Investigation_into_Mid_Staffordshire_NHS_Foundation_Trust.pdf>

²⁰ Healthcare Commission, *ibid*, 7.

²¹ Francis note 2, 3

²² See ‘Mid Staffordshire NHS Foundation Trust’ at

<<https://www.midstaffs.nhs.uk/Home.aspx>>

The regulatory framework had failed to identify the substandard care at Stafford Hospital, which caused deaths and significant harm. Specifically, while the Healthcare Commission²³ was commended for its 2009 review identifying the problems, it was also criticised for its lack of independence from the Department of Health, its reliance on self-reporting in annual health checks of providers and its willingness to rely on assurances from the NHS Trust.²⁴ One problem was the ‘confusing mixture’²⁵ of applicable standards encompassing several different and conflicting concepts. Francis criticised the CQC for ‘over-bureaucratic’ guidance which ‘fail[ed] to separate clearly what is absolutely essential from that which is merely desirable’.²⁶ The situation at Stafford Hospital was highly complex. It implicated individuals at four different levels, caregivers, managers, supervisors and regulators. It further implicated the regulatory system itself. Failures can – and do – happen at all of these levels. Successful regulation must recognise and address failings across all these stages.

Crises are important for analysing regulatory change because they can punctuate the incremental nature of policy development, and lead to dramatic organisational changes.²⁷ One risk of regulating in crisis management mode is that it can result in ‘knee-jerk responses’ that leave ‘cumbersome and inappropriate regulatory

²³ The predecessor body to the CQC.

²⁴ Francis, note 2, 55

²⁵ Francis, note 2, 54

²⁶ Francis, note 2, 58

²⁷ A Boin and ‘t Hart P, ‘Public leadership in times of crisis: Mission impossible?’ (2003) 63 *Public Administration Review* 544-553; M Lodge and Hood C, ‘Pavlovian policy responses to media feeding frenzies? Dangerous dogs regulation.’ (2002) 10 *Comparative Perspectives* 1-13.

tombstones' after the crisis has faded.²⁸ Alternatively, it is argued that crises create a window of opportunity²⁹ for a government to implement a previously developed policy. It is evident here that the government did not have a ready-made policy waiting for implementation. It is also clear that the 2014 Regulations were not a knee-jerk response. Delegating responsibility for a public inquiry to Sir Robert Francis QC created breathing space for the government to decide on its response, since any policy would have to consider the Francis report. Instead, the effect was to lock the government into implementing Francis' recommendations. The question that arises is how a carefully considered, thoughtful policy change can be as flawed as a knee-jerk response.

To address this issue, I start by considering two case studies from the 2014 Regulations – the duty of candour, and the new criminal offence of causing or exposing patients to the risk of harm in relation to nutritional and hydration needs. These two types of provisions form the backbone of the 2014 Regulations. I show that the fundamental flaws in their substantive content stymie Francis' aim of raising standards across the board. Next, I consider two larger structural concerns with the 2014 Regulations – their reliance on criminal law and its expressive function to regulate as complex a field as healthcare. I argue that this fails to take into account enforcement practices, which have a dramatic effect on the success of new legal provisions. Drawing on notions of expressive power and regulatory enforcement theory, I offer a diagnosis of why a structured and considered public inquiry process might have produced seriously flawed regulations. I argue that this resulted from the political context surrounding the regulations, creating a tombstone to past disasters hindered by such shortcomings that they cannot accomplish the original aims. While

²⁸ Lodge and Hood note 27, 1

²⁹ J Kingdon, *Agendas, alternatives and public policies* (Harper Collins, New York 1995)

the literature on tombstones is more usually applied to knee-jerk responses, I demonstrate that it can offer some insight into the reasons carefully considered policy responses might also suffer from fatal flaws.

(A) The duty of candour and mandated apologies

Regulation 20 is a significant addition to healthcare regulation. The duty of candour requires health service bodies to ‘act in an open and transparent way with [patients or those acting lawfully on their behalf]³⁰ in relation to care and treatment provided’.³¹ Specifically, where there has been an ‘unintended or unexpected incident’ that did or could have resulted in the patient’s death or caused them to suffer moderate or severe harm, or prolonged psychological harm³² the health service body must notify³³ the patient or their legal representative about the incident and ‘provide reasonable support’³⁴. The Regulations require the notification to be ‘given in person’³⁵ and followed up in writing.³⁶ The in-person notification must be given as soon as reasonably practicable after the health service body became aware of the incident.³⁷ It must provide an account of the facts known,³⁸ advise the patient about the further enquiries to be made,³⁹ and include an apology.⁴⁰ The written follow up must contain

³⁰ Regulation 20(7), 2014 Regulations

³¹ Regulation 20(1), 2014 Regulations

³² Regulation 20(7), 2014 Regulations

³³ Regulation 20(2)(a), 2014 Regulations

³⁴ Regulation 20(2)(b), 2014 Regulations

³⁵ Regulation 20(3)(a), 2014 Regulations

³⁶ Regulation 20(4), 2014 Regulations

³⁷ Regulation 20(2), 2014 Regulations

³⁸ Regulation 20(3)(b), 2014 Regulations

³⁹ Regulation 20(3)(c), 2014 Regulations

⁴⁰ Regulation 20(3)(d), 2014 Regulations

information about the facts surrounding the incident,⁴¹ details about any enquiries that have been carried out,⁴² the results of those enquiries,⁴³ and an apology.⁴⁴ Apology is defined as ‘an expression of sorrow or regret’.⁴⁵ The duty of candour is backed by criminal sanctions. Failure to notify a patient about an incident which did or could have resulted in death or moderate or severe harm, and failure to apologise for that incident both amount to a breach of the regulation, carrying a penalty of a £2,500 fine following summary conviction.⁴⁶

This is the first time the law of England and Wales has required transparency about healthcare errors.⁴⁷ This complements information provision at the doctor-patient level. Montgomery held that patients should be informed prior to making a treatment decision about ‘material risks’ that a ‘reasonable person in the patient’s position would attach significance to’ and ‘reasonable alternative and variant treatments’.⁴⁸ There is an explicit move away from treating patients paternalistically by withholding information in their own interests. Instead, the law expects greater openness and transparency in information provision, enabling patients to be more autonomous when interacting with healthcare providers. Francis recommended a statutory duty of

⁴¹ Regulation 20(4)(a), 2014 Regulations

⁴² Regulation 20(4)(b), 2014 Regulations

⁴³ Regulation 20(4)(c), 2014 Regulations

⁴⁴ Regulation 20(4)(d), 2014 Regulations

⁴⁵ Regulation 22(3), 23(6), 2014 Regulations

⁴⁶ Legal Aid, Sentencing and Punishment of Offenders Act 2012. This is a fine at level 4 on the standard scale.

⁴⁷ The 2014 Regulations were made under the power found in section 20 of the Health and Social Care Act 2008, which applies in England and Wales only, see Health and Social Care Act 2008, s 1969.

⁴⁸ Montgomery v Lanarkshire Health Board [2015] UKSC 11, [87]

candour about post-treatment care⁴⁹ as a direct response to the failures at Stafford Hospitals, and in the absence of these failures, it seems unlikely that this duty would have been enacted.

Francis was clear that only a statutory duty of candour would solve the ‘culture of denial, secrecy and concealment of issues of concern’⁵⁰ evident in the NHS. The Inquiry found that the piecemeal candour regime in professional guidance was unsatisfactory. The various healthcare professions were subject to substantially different obligations and sanctions, while NHS managers had a vague obligation with no definable sanctions. Other parts of the NHS were under no obligation at all.⁵¹ A duty of candour had been considered in *Lee v SW Thames Regional Health Authority*⁵² and in *Naylor v Preston Area Health Authority*⁵³ but Lord Donaldson’s obiter comments did nothing to found any duty of candour, which would have been a dramatic expansion of tort law.⁵⁴ Subsequently, various recommendations were made about contractually or statutorily formalising a service-wide duty, by the Health Select Committee 1999⁵⁵, the Bristol Royal Infirmary inquiry⁵⁶, the Shipman Inquiry⁵⁷,

⁴⁹ Francis, note 2, 104

⁵⁰ Robert Francis QC, Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 3 at <<http://www.midstaffspublicinquiry.com/report>> [22.159] 1490

⁵¹ Ibid.

⁵² [1985] 2 All ER 385, 389 (CA)

⁵³ [1987] 2 All ER 353, 360

⁵⁴ See *Powell v Boldadz* [1998] Lloyds Rep Med 116

⁵⁵ House of Commons, Sixth Report: Procedures Related to Adverse Clinical Incidents and Outcomes in Medical Care (28 October 1999)

<www.publications.parliament.uk/pa/cm199899/cmselect/cmhealth/549/54902.htm>

⁵⁶ Bristol Royal Infirmary Inquiry, *The report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995: learning from Bristol* (Cm 5207, 2001)

the Chief Medical Officer⁵⁸ and the Health Select Committee 2011⁵⁹. None were explicitly acted upon. Instead, several different – non-complementary – policies were introduced by different bodies creating the piecemeal regime in place prior to the 2014 Regulations. The Francis Inquiry sought witness evidence on its effectiveness. The evidence suggested that the provisions should be effective, but actually failed to take into account human behaviour. The government's failure to back up guidance with enforcement meant that secrecy was being tolerated and perpetuated across the NHS.⁶⁰ Much of the witness evidence favoured a statutory duty, while the Department of Health was non-committal. Francis concluded that nothing short of a weighty statutory duty could overturn the ingrained culture of secrecy, such that candour would 'permeate and inform everything that is done when providing healthcare to the public'.⁶¹

Apologies are central to the duty of candour. Failure to apologise in person or in subsequent writing would breach the duty. Much research has explored the nature of

Recommendation 33, p 441

⁵⁷ Shipman Inquiry: The Fifth Report – Safeguarding Patients: Lessons from the Past – Proposals for the Future (9 December 2004) 916 [24.151], and 1146, [27.199]

⁵⁸ Sir Liam Donaldson, Making amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS: A report by the Chief Medical Officer (30 June 2003)

⁵⁹ House of Commons Health Committee, Complaints and Litigation Sixth Report of Session 2010–12 (23 June 2011), paras 80–82, Conclusions and recommendations paras 21–22

⁶⁰ Francis, note 50, 1486-1488

⁶¹ Francis, note 50, [22.160]

apologies, and their role in the legal sphere.⁶² O'Hara explains that 'an effective apology requires (1) identification of the wrongful act; (2) expression of remorse and regret for having committed the act; (3) promise to forbear from committing the wrongful act in the future; and (4) offer of repair.'⁶³ She suggests that an effective apology requires the transgressor to engage in self-humiliation, to 'place himself in a morally inferior position'⁶⁴ regarding the failure and its victim. Apologies which meet these conditions can help dissipate the victim's anger, and crucially, temper any inclination to bring legal action.⁶⁵ Adding apologies into the NHS complaints procedure might reduce the already significant burden of lawsuits. In 2014-2015, the NHS Litigation Authority paid over £1.1 billion to claimants and their legal representatives, with a third going to the legal profession. This is expected to increase to £1.4 billion in the next year.⁶⁶ The Chief Executive suggested that the

⁶² See for example, H Wagatsuma and A Rosett, "The implications of apology: Law and culture in Japan and the United States" (1986) 20 *Law and Society Review* 461; A Allan, "Apology in civil law: A psycho-legal perspective" (2007) 14 *Psychiatry, Psychology and Law* 5; M Bismark, 'The power of apology' (2009) 122 *The New Zealand Medical Journal* 96; L Taft, 'Apology and medical mistake: Opportunity or foil?' (2005) 14 *Annals of Health Law* 55; S McLennan, S Walker and LE Rich, 'Should health care providers be forced to apologise after things go wrong?' (2014) 11 *Journal of Bioethical Inquiry* 431; S Raper, 'No role for apology: Remedial work and the problem of medical injury' (2011) 11 *Yale Journal of Health Policy, Law and Ethics* 267.

⁶³ EA O'Hara, 'Apology and thick trust: What spouse abusers and negligent doctors might have in common' (2004) 70 *Chicago-Kent Law Review* 1055, 1064.

⁶⁴ O'Hara, *ibid*, 1065.

⁶⁵ D Wojcieszak, J Banda, and C Houk, 'The Sorry Works! Coalition: Making the case for full disclosure' (2006) 32 *Journal on Quality and Patient Safety* 344-450

⁶⁶ NHS Litigation Authority, Annual Report and Accounts, (HC293)

<http://www.nhsla.com/AboutUs/Documents/NHS%20LA%20Annual%20Report%20and%20Accounts%202014-15.pdf>> 4.

'emergence of non-specialist lawyers coupled with excessive claims for legal costs'⁶⁷ had had a significant impact on cost. While complaints are inevitable, these sums of money are not. Changes to the legal framework which might reduce the number of claims initiated could help lighten this burden.

The duty of candour applies to health service bodies, not individual staff members. But the CQC require health service bodies to ensure that there is a culture of openness and transparency amongst their staff.⁶⁸ This includes having a robust policy, appropriate training available, and a culture encouraging openness. This puts pressure on the individual to comply with the duty of candour, and non-compliance might amount to a disciplinary offence or an action outside the employment context which would entail a refusal of vicarious liability in any claim against the individual concerned. The regulations are concerned with the health service body's apology. Zwart-Hink et al argue that a public body's apology is significant because it acknowledges that the social contract has been violated.⁶⁹ The Stafford Hospital fiasco was compounded by the institutional failure to take responsibility. By mandating the institutional apology, regulation 20 mandates the institutional acknowledgement of errors. It sets no requirements about who must give the in-person apology, except that they must represent the institution.⁷⁰ It would be possible for institutions to augment the power of their apology by requiring the patient's consultant to make a personal apology alongside a member of hospital management

⁶⁷ Ibid, 6.

⁶⁸ CQC, Regulation 20: Duty of Candour: Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare March 2015 at <http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf> 10.

⁶⁹ A Zwart-Hink, Akkermans A, and Van Wees K, 'Compelled apologies as a legal remedy: Some thoughts from a civil law jurisdiction' (2014-2015) 38 U W Austl L Rev 100, 120

⁷⁰ Regulation 20(3)(a), 2014 Regulations

making the institutional apology. If the personal apology is sufficiently credible, with the appropriate levels of remorse and self-humiliation, it will give further impact to the institutional acknowledgement of the failure. If an individual health practitioner is to offer apologies, then it will be necessary for the institution to clarify the relationship and the individual's power to take responsibility for the institution.

If this duty becomes a de facto individual duty, or individual healthcare practitioners are required to make apologies on behalf of the institution, it places individuals under inappropriate pressure. Medical professional guidance does not mandate apologies instead leaving the decision to apologise to the doctor. GMC guidance in 2006⁷¹ required doctors to 'act immediately to put things right' where harm or distress was caused. Where patients complained they had 'a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology'. No guidance was offered on when an apology would be appropriate. This guidance continued in Good Medical Practice 2013,⁷² which provides that doctors 'must respond promptly, fully and honestly to complaints and apologise when appropriate'.⁷³ No further guidance is given on when an apology would be considered appropriate. If a doctor decided to apologise then section 2 of the Compensation Act 2006 provided that an apology was not an admission of negligence. Apologies by individuals are powerful. That power comes from both the sentiment and the reasons for it. This power is undermined by insincerity, since one purpose of an apology is the

⁷¹ General Medical Council, Good Medical Practice (2006) at

<http://www.ub.edu/medicina_unitateducaciomedica/documentos/Good_Medical_Practice.pdf

> [30]-[31]

⁷² General Medical Council, Good Medical Practice (2013) at <http://www.gmc-uk.org/guidance/good_medical_practice.asp> [61]

⁷³ General Medical Council 2013, at <http://www.gmc-uk.org/guidance/good_medical_practice/treat_fairly.asp>

forgiveness necessary to continue a relationship.⁷⁴ An expression of 'genuine regret, responsibility and intention to change can only be generated by the person concerned'.⁷⁵ Power comes from the personal connection, from the patient's understanding of the doctor's remorse, and from the doctor internalising that remorse. Mandating individual apologies undermines, and ultimately removes, the essential characteristic of genuineness. It undermines the patient-doctor relationship of trust and confidence. Where candour policies require an individual to make the apology, it is essential that the institution clarifies the limits of the relationship, and that the apologise is authorised to and is explicitly acting on behalf of the institution, rather than in a personal capacity.

The rest of the provision focusing on openness, transparency and honesty in communicating about failures, could do real good. A statutory duty to inform patients about failures is easy to fulfil, despite historical evidence to the contrary. The difficult part is taking responsibility. Giving factual information to patients promptly and honestly empowers them to make decisions about the future. It engenders trust in healthcare professionals as human beings since it reminds us that things go wrong. Lopez et al showed that disclosure of errors led to higher quality ratings of care.⁷⁶ While the law cannot instantly change cultures, this duty helps to embed explanations into healthcare provision. Ultimately, this should help to encourage a culture of openness throughout the NHS.

⁷⁴ Zwart-Hink note 69, 120

⁷⁵ McLennan, note 62, 433.

⁷⁶ L Lopez et al, 'Disclosure of hospital adverse events and its associations with patients' ratings of the quality of care' (2009) 169 *Quality of Care Archives of Internal Medicine* 1888

The duty of candour featured in 13 of Francis' 290 recommendations. Neither the word nor the notion of apology appears at all. Francis' duty of candour centred around full disclosure,⁷⁷ honest and truthful responses to questions,⁷⁸ and properly supporting patients receiving a disclosure.⁷⁹ His justification was that doing it properly 'requires insight into personal and organisational deficiencies' and 'a determination to put right what has gone wrong'.⁸⁰ While candour can have benefits for patients and healthcare provision generally, the Stafford Hospital fiasco showed that failings in candour had serious consequences, such as delays in bereaved relatives learning about their loved ones' deaths, and a general failure to correct deficient service.⁸¹ While the framework in the Compensation Act 2006 and the GMC's ethical duty of candour was good in theory, it had not worked in practice. Francis' challenge was to increase compliance. The parts of regulation 20 that relate to candour, ie, information provision, could be successful. The problem is that if institutional policies on apologising blur the boundary between personal and institutional apologies, it could lead to apologies appearing insincere, which could do considerable damage to the institutional position, and ultimately to the duty of candour itself.

(A) Meeting nutritional and hydration needs

The second significant development is the new criminal offence, committed by breaching fundamental standards relating to safe care and treatment,⁸² abuse and improper treatment,⁸³ or nutritional and hydration needs⁸⁴, and that breach results in:

⁷⁷ Francis, note 2, recommendation 174

⁷⁸ Francis, note 2, recommendation 173, and 175

⁷⁹ Francis, note 2, recommendation 174

⁸⁰ Robert Francis QC, Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 3 at <<http://www.midstaffspublicinquiry.com/report>> 1488

⁸¹ Francis volume 3, *ibid*, 1489

⁸² Regulation 12, 2014 Regulations

- (a) avoidable harm (whether of a physical or psychological nature) to a service user,
- (b) a service user being exposed to a significant risk of such harm occurring, or
- (c) in the case of theft, misuse or appropriation of money or property, any loss by a service user of the money or property concerned⁸⁵

It is punishable by a fine not exceeding £50,000 after summary conviction.⁸⁶

Hospital food provision is a useful context to explore this new offence. Regulation 14 provides that 'the nutritional and hydration needs of service users must be met'.

Needs are defined as:

- (a) receipt by a service user of suitable and nutritious food and hydration which is adequate to sustain life and good health,
- (b) receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional,

⁸³ Regulation 13, 2014 Regulations

⁸⁴ Regulation 14, 2014 Regulations

⁸⁵ Regulation 22(2), 2014 Regulations

⁸⁶ Regulation 23(4), 2014 Regulations, which applies where section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 is not in force on 6 November 2014, see regulation 23(3), 2014 Regulations. Section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 came into force on 12 March 2015, see Article 2 of The Legal Aid, Sentencing and Punishment of Offenders Act 2012 (Commencement No. 11) Order 2015.

- (c) the meeting of any reasonable requirements of a service user for food and hydration arising from the service user's preferences or their religious or cultural background, and
- (d) if necessary, support for a service user to eat or drink.⁸⁷

Regulation 14 applies where the service provider provides accommodation or an overnight stay, or where food and drink is provided as part of other services.⁸⁸ It does not apply where the service user refuses to accept food and drink provided, since care and treatment can only be provided with the consent of the service user⁸⁹ or where providing nutrition and hydration would not be in the service user's best interests⁹⁰ to be determined with reference to the Mental Capacity Act 2005.⁹¹

Prima facie, this offence is broad. Patients must receive nutritious and sustaining food, which meets their preferences, religious or cultural background, and be supported in eating if necessary. If this does not happen, and the patient suffers physical or psychological harm, or is put at risk of such harm, then the offence is committed. However, several of the criteria are subject to legitimate differences in interpretation, which could narrow its application.

First is the definition of 'nutritious and sustaining'. This appears to be an objective measure, since it is independent from the requirement that the food meets the patient's preferences. It is unclear how this will be measured. It could be assessed by considering whether there is an appropriate balance of important nutrients, such as

⁸⁷ Regulation 14(4), 2014 Regulations

⁸⁸ Regulation 14(2), 2014 Regulations

⁸⁹ Regulation 14(3)(a), 2014 Regulations

⁹⁰ Regulation 14(3)(b), 2014 Regulations

⁹¹ Regulation 14(5), 2014 Regulations

protein, carbohydrates, fibre, vitamins, and fat. It might be the number of calories provided, which could be referenced against the average recommended daily calorie consumption. It might also be important to take into account salt and sugar content, and the presence of E numbers. There are many different recommendations for the appropriate balance between the different nutrients. The 'eatwell plate' recommends plenty of fruit and vegetables, plenty of starchy foods such as bread, potatoes, pasta or rice, some milk and dairy foods, some non-dairy protein such as meat, fish, eggs or beans, and a small amount of foods that are high in fat or sugar.⁹² The three part scale – plenty, some, just a little – is mapped onto a plate to indicate how much space the food should take up. No specific figures or objective measures are provided. A second way might be to use the calorie count, but this is a flawed measure of nutritional value. It does not account for the processing that food has undergone. The calorie count for raw and cooked carrots are identical. However, more calories are available to the body in cooked carrot. Our bodies have to work harder to extract calories from raw carrot.⁹³ The best way to evaluate nutrition would be an amalgam of several measures, since no one single measure is sufficiently definitive. The choice of interpretation measure will narrow or broaden the application of the offence.

These measures provide a result for the average person. They do not take illness into account. Patients may have specific issues dictating specific nutritional needs, such as being under or overweight. Ill people need more calories to promote their

⁹² See 'The Eatwell Plate' at <<http://www.nhs.uk/Livewell/Goodfood/Pages/eatwell-plate.aspx>>

⁹³ See 'Have we been miscounting calories?' at <<http://news.sciencemag.org/evolution/2013/02/have-we-been-miscounting-calories>>

healing.⁹⁴ Even if a patient is otherwise healthy and eats a normal diet, the reason for their presence in hospital might indicate that a dietary change is necessary. One group of particular concern is the elderly, who have specific nutritional needs but may not feel motivated to eat. When elderly patients are admitted to hospital, they tend to become more ill, which is exacerbated by inadequate nutrition. Malnourished patients are also more likely to die earlier than well-nourished patients.⁹⁵ Perhaps the only way of approaching nutritional value is to reference it to the individual patient's needs. This makes it difficult to create a uniformly applicable standard.

The next definitional issue arises in relation to 'sustaining', which seems to mean something different from 'nutritious'. While 'nutritious' can be defined using objective measures, 'sustaining' implies a qualitative question of whether food is appealing, and whether it satisfies the emotional aspects of food consumption. Good food satisfies the body's need for fuel, and the mind's need for stimulation. Ultimately, whether food is nutritious and sustaining is a subjective question, which cannot be fulfilled with a simple calorie count, or other quantitative measure. This would not be an easy view for a court to reach, and doing so would create a significant burden of work for inspectors and providers. These practical issues might lead a court to choose an easily measurable and replicable objective scale, such as a straightforward calorie count.

⁹⁴ J A Windsor, G S Knight and G L Hill, 'Wound healing response in surgical patients: Recent food intake is more important than nutritional status' (1988) 75 *British Journal of Surgery* 135-137.

⁹⁵ K E Covinsky, G E Martin, R J Beyth, A C Justice, A R Sehgal and C S Landefeld, 'The relationship between clinical assessments of nutritional status and adverse outcomes in older hospitalized medical patients' (1999) 47 *Journal of the American Geriatrics Society* 532-538

Food must meet the reasonable needs of patients arising from their preferences, religious or cultural background. The issue here is reasonableness. People make accepted dietary choices – veganism – significantly limiting the food available to them in hospital. It is unclear how far these choices must be accommodated by the new fundamental standards. A more concerning conceptual problem is that regulation 14 appears to equate preferences with religious and cultural dietary rules. Arguably, there is a difference between a strict Muslim choosing only to consume Halal food, and a non-religious person choosing not to eat tomatoes. The religious rule appears to give the food preference greater weight. Reasonableness could be used to distinguish between them, such that preferences based in religious or cultural values are more likely to be considered reasonable than preferences which are not. However, food preferences also depend on taste. There is variation in the range of foods that people like, and it might not be unreasonable for a person to choose only to eat food that they enjoy.

There is significant room for manoeuvre within the definition of ‘nutritional and hydration needs’. Given this level of uncertainty, it is unclear whether it would be practically possible to find a breach of these standards, let alone prosecute.

The second stage is also open to interpretation, potentially increasing the breadth of the offence. First is the requirement that the patient suffers from avoidable physical or psychological harm. Avoidability implies that the failure to meet the patient’s nutritional and hydration needs caused the harm. An obvious harm would be dehydration caused by failure to provide sufficient fluids, or vitamin deficiency caused by failure to provide sufficient fruit and vegetables. A breach might occur if food exacerbates an existing condition. For example, a patient with gall bladder issues should avoid high fat meals that might trigger an attack, which can lead to further

problems.⁹⁶ If high fat food were eaten and it did trigger an attack, this would be avoidable harm. It is less clear regarding psychological harm. It may be successful if a person with a severe phobia of fruit was repeatedly provided with fruits, and this caused him to suffer anxiety and an exacerbation of his phobia. This psychological harm could have been avoided had his nutritional needs been met. In reality it will be difficult to satisfactorily meet this element of the offence. It depends on proving that a medical condition is avoidable, and that it would have been avoided except for the failure to provide appropriate food, or the provision of inappropriate food. This implies that there is a clear understanding of food's role in medicine. This is not the case.

The offence is also committed where the patient is exposed to the risk of physical or psychological harm. This broadens the offence by not requiring actual harm. This is open to interpretation. There is no indication what level of risk will amount to a breach. For example, failure to provide complete ingredient lists creates a risk that a patient will suffer from a serious allergic reaction, since they will not be aware whether the meal contains a particular allergen. This is a vanishingly small risk, albeit one with potentially harmful consequences. It might be easier to show a failure where the food provision could affect an existing condition. For example, failure to provide or adequately identify gluten-free menu choices risks exacerbating coeliac disease. The question is about the extent to which hypothetical or theoretical risks are included. It could be a broad, easily breachable standard.

Focusing on physical and psychological harm ignores harm that arises from failure to observe religious needs. Serving non-compliant food to strict practitioners is unlikely to cause or risk causing physical or psychological harm within the accepted definitions. It might be best described as an attack on personal or religious identity,

⁹⁶ Thanks to Aileen McHarg.

which is not caught by regulation 14. Treatment of this nature may fall at the intersection of regulations 14 and 10, requiring that service users should be treated with dignity and respect. Regulation 10 does not carry the same criminal provisions as regulation 14, indicating that this harm is not considered to be as serious as physical or recognised psychological harm. However, it may feel worse for the individual involved.

On its face, the new offence relating to food provision is more stringent than the 2010 offence. It carries a more significant penalty, and it is easier to bring a prosecution. However, the scope for considerable variation in interpreting the standards themselves is a concern. In the first instance, CQC inspections will establish the boundaries of the standards. A legal ruling will only be possible if a prosecution is brought, and a point of law is appealed to the High Court from the magistrates' decision. This seems unlikely.

(A) A litany of flaws?

These case studies illustrate the tone and potential impact of the new regulations. Understanding their impact relies on understanding the wider context surrounding their introduction. Stafford Hospital saw one of the worst healthcare failures in England and Wales. This was due to the actions of individual healthcare workers, and failures in the regulatory oversight mechanisms. Both the CQC and the Healthcare Commission were criticised for their parts in allowing the abuses to continue unchecked. This was a failure on all fronts. Any analysis of the 2014 Regulations must take this political context into account.

I have argued in the case studies above, that the focus on mandated apology undermines the duty of candour, which focuses on openness and transparency about errors. The scope for different interpretations of the criminal offence in the context of

nutrition and hydration means that the 2014 Regulations give no clear indication when and how the offence could be prosecuted. Both measures have fundamental flaws which could result in their individual failure. Taking the measures together, there are two further concerns that indicate that the regulations may fail. The first is the increased use of the criminal law to regulate complex issues of healthcare delivery, and the second is the CQC's capacity to effectively enforce the new regime.

(B) The criminal law

What is the purpose of invoking the criminal law to regulate healthcare provision? Francis seeks 'a relentless focus on the patient's interests and the obligation to keep patients safe and protected from substandard care'.⁹⁷ The 2014 Regulations' aim appears to be a general increase in the NHS standard of care. While both Quick⁹⁸ and Yeung and Horder⁹⁹ have argued that the role of the criminal law is its expressive function, it is unlikely to raise the general standard of care. Infrequent, high-profile prosecutions of egregious behaviour can set clear examples of what will and will not be tolerated, 'A criminal conviction amounts to a public proclamation that the conduct in question is seriously wrongful and worthy of condemnation and punishment, whether or not it leads directly to a substantial improvement in healthcare quality.'¹⁰⁰ They suggest that the reason for bringing criminal prosecutions for the events at Stafford Hospital is 'because [the criminal law] is the most powerful and important social institution through which we hold to account, and express public censure of, those who have mistreated others in a wholly unacceptable and highly

⁹⁷ Francis, note 2, 66

⁹⁸ O Quick, 'Regulating and legislating safety: The case for candour' (2014) 23 British Medical Journal Quality and Safety 614

⁹⁹ K Yeung and J Horder, 'How can the criminal law support the provision of quality in healthcare?' (2014) 23 British Medical Journal Quality and Safety 519

¹⁰⁰ Yeung and Horder, *ibid*, 523

culpable way.’¹⁰¹ Criminal prosecutions focus on the particular behaviour of the individual or institution. Wider social issues, and the potential impact of the prosecution, are expressly irrelevant to the prosecution itself. Prosecutions are brought because the person or institution acted in a culpable manner which deserves the censure of society.

Sunstein defines an expressive law as one that requires ‘certain forms of behaviour through statutory requirements accompanied by significant enforcement activity’.¹⁰² This might lead to a general raising of standards if it changes regulatees’ behaviour. Thornton, Gunningham and Kagan¹⁰³ considered the claim that a few high-profile convictions increased corporate compliance with environmental protection laws. They found the opposite. While the majority of firms reported taking different actions after hearing about prosecutions, they estimated that only 10-20 per cent of firms were actually responding to another firm’s prosecution.¹⁰⁴ While individuals who recalled more of the high-profile prosecutions did perceive a greater risk of being prosecuted for non-compliance, this did not translate into more compliance activities being undertaken.¹⁰⁵ They did not find a simple direct link between a few prosecutions and a general increase in standards. Instead, high-profile prosecutions merely reminded already compliant regulatees to remain so. Where a prosecution was unexpected, it allowed regulatees to reassure themselves that they were

¹⁰¹ *ibid*

¹⁰² C Sunstein, ‘On the expressive function of law’ (1996) *University of Pennsylvania Law Review* 2021-2053, 2032.

¹⁰³ D Thornton, N Gunningham and R Kagan, ‘General deterrence and corporate environmental behaviour’ 2005 Working Paper available at <https://escholarship.org/uc/item/4t7862s1>

¹⁰⁴ Thornton, *ibid*, 279

¹⁰⁵ *ibid*

compliant even where another firm was not.¹⁰⁶ At best, they found that regulatees had a greater perception of the possibility of prosecution, but this did not affect their behaviour, and there was no change to the general standards. Extrapolating to healthcare regulation, it is unlikely that a few high-profile prosecutions under the 2014 Regulations could improve standards. They will operate as a reminder that another Stafford Hospital fiasco will not be tolerated, while saying nothing about behaviour falling short. Most institutions are generally compliant with the rules, and they would be able to distance themselves from the widespread abuses at Stafford Hospital. It may not prompt them to examine their own performance, but instead simply confirm their compliance.

The criminal offences supporting regulation 14 and 20 may be the ‘significant enforcement activity’ required by Sunstein for an effective expressive law. However, the flexibility of regulation 14 makes it difficult to bring a prosecution or achieve a conviction. The CQC is clear that regulation 20 will be enforced where necessary, but since this is a new regulation and they are learning about how it will work, they will be taking a proportionate view on its application in different clinical settings.¹⁰⁷ Francis indicates that the CQC is expected to prosecute as a last resort only ‘in cases of serial non-compliance or serious and wilful deception’.¹⁰⁸ Since the fine for a single breach is £2,500¹⁰⁹ this could only be a significant penalty if the full fine was imposed for every breach. Neither of these amount to ‘significant enforcement activity’. At

¹⁰⁶ Thornton, note 103, 282

¹⁰⁷ Care Quality Commission, Regulation 20: Duty of Candour Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare March 2015, at http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf 10.

¹⁰⁸ Francis Volume 3, note 80, 1495

¹⁰⁹ Criminal Justice Act 1982, s37(2)

best, the expressive power is in the statement about the intolerability of behaviour caught by the regulations. To what extent can an expressive law not supported by 'significant enforcement activity' effect a general raising in standards? Sunstein argues that merely expressive laws rely on social norms. He considers cleaning up dog mess in the US.¹¹⁰ These rules are largely unenforced, and carry nominal penalties when they are enforced. People clean up their dog's mess because the presence of the rules indicates social disapproval of failure to clean up. Also, widespread advertising of these rules in places where dog fouling is most likely to occur increases the pressure by making it difficult to claim an unawareness of the rules. How might this apply in the case of healthcare provision?

Healthcare provision decisions might be made by an individual or a committee, but ultimately, people are responsible. People working in hospital management want their hospital to succeed, their patients to be well looked after, and their institution to be thought well of. They want to comply. If we look at Braithwaite and Braithwaite's study comparing care home regulation in the US and Australia¹¹¹, we see that a regulatory framework based around a small number of broad principles forced regulatees to think behind the principles and work out for themselves how best to meet them. This led to a more subjective service that better met the needs of residents. The 2014 Regulations take this approach. The provisions are broad, and the CQC guidance on how to comply urges providers to think about how the provisions will apply to their own institution. They harness the notion that providers want to engage and comply with the principles. There are relevant social norms

¹¹⁰ Sunstein, note 102, 2031

¹¹¹ J Braithwaite and Braithwaite V, 'The politics of legalism: Rules versus standards in nursing-home regulation' (1995) 4 Social and Legal Studies 307-341

within the community of hospital management that point towards compliance with the regulations, even where the potential for enforcement activity might be limited.

The circumstances surrounding the NHS differs materially from those faced by Braithwaite and Braithwaite's care home providers. The NHS faces an acute budgetary crisis. Thus these social norms compete with a need to control spending. In an ideal world, providers would want to provide outstanding care and meet the standards at the highest level possible. This world is not ideal. These social norms are not the only consideration. The NHS is expensive. Its budget is limited. The budgets of individual NHS Trusts are limited. It is not possible to provide a platinum standard of care on a brass budget. Hospital managers must get the best care they can for the money they have available, and this might mean cutting expenditure on food, to spend more on cardiac surgery. The obvious way to do this is to contract out. Contracts should effectively deal with the quality standards. Where the service fails to meet the terms, the institution would have an action in contract against the contractor. If there were a real prospect of CQC enforcement it would weigh in the balance in the compromise between high-quality services and cost-saving. Where there are these competing imperatives, the regulatory framework must provide a stark minimum level that must be met, and if it is to have any effect on the decisions made, it must limit, through the potential for enforcement action, the power that the imperative to cost-save has in any calculation. Regulation 14 fails to do that.

The interplay of norms surrounding the duty of candour is different. The social approval of openness and transparency about errors, and the social disapproval of secrecy expressed by regulation 20 is given greater weight by its history. The culture of secrecy at Stafford Hospital exacerbated the fiasco, and drew Francis' wrath. The duty of candour carries more weight than other regulations. The CQC are tentative about their enforcement agenda due to the newness of the provision, so there is

scope for providers to lead the way in compliance policies. Any credible attempt to comply will contribute to the CQC's understanding of how the regulation should be applied and enforced. For providers with clear views on how this should work, there is a strong incentive to work on their institution's approach early. An argument often made is that apology rules can help to reduce the amount of litigation brought, since patients will be satisfied with an apology and an assurance that this event will not happen again.¹¹² If this is the case, then this is another incentive in favour of having a robust policy favouring openness and apology. Balanced against this is the potential reputational damage coming from taking responsibility for poor practice outside the official complaints procedure or court proceedings. A high number of apologies might make it necessary to scrutinise institutional practices. Alternatively, the reputational damage associated with non-compliance might be more damaging than that linked to a review of practice. Arguably, the expressive influence of the duty of candour has the potential to be more successful than the food provisions in spite of its lack of significant enforcement activity, because the norms in favour of compliance outweigh any competing motivation not to.

These case studies show patchwork expressive power in the 2014 Regulations. The nutrition and hydration standards cannot succeed on their expressive power alone because the interplay of norms does not promote compliance. The duty of candour is different. It is Francis' magic bullet. The focus on openness and transparency brings symbolic power. It is being taken seriously – policies are being written, training is being given, and it is a topic of discussion throughout the NHS. The duty of candour may have sufficient expressive power to address the lack of transparency about failures in the NHS. But, lack of transparency is not the only issue that the 2014 Regulations are intended to address, and the duty of candour is not a panacea for all

¹¹² Wojcieszak note 65

ills. If I am right in arguing that the expressive power lies solely in the duty of candour, then it cannot effect the general increase of standards that Francis called for.

(B) Can the Care Quality Commission enforce the Regulations?

Ayres and Braithwaite's enforcement pyramid¹¹³ embodies the notion of responsive regulation and is used to argue that command and control sanctions are not the only method of enforcing standards. Instead, there is a hierarchy of available enforcement powers, starting with the least onerous at the bottom, rising to the most burdensome at the top. Most enforcement work fits at the bottom of the pyramid, but regulators can and should move up when appropriate. The most serious powers should be used sparingly, where necessary and proportionate. Movement through the pyramid can go both ways. Where regulatees have complied with a more serious enforcement measure, regulators can return to lower levels for future interventions.

The CQC has a raft of available enforcement measures.¹¹⁴ Figure 2 shows an enforcement pyramid illustrating the full range. There is no requirement to start at the bottom of the pyramid and work up. They may start at any level. Inspectors consider two questions, 1) whether the impact of the concern is minor, moderate or major, and 2) whether the likelihood of the events happening again is remote, possible or probable.¹¹⁵ The answers are combined to decide whether concerns are low, medium, high or extreme seriousness, and help choose the appropriate enforcement mechanism. A minor impact and a remote chance of repeat is low seriousness, and

¹¹³ I Ayres and Braithwaite J, *Responsive Regulation: Transcending the Deregulation Debate* (OUP, Oxford 1992), 35.

¹¹⁴ Care Quality Commission, *Enforcement Policy* (2015)

¹¹⁵ Care Quality Commission, *Enforcement Decision Tree* (2015) 10

merits a light touch response, such as an informal collaborative arrangement to improve standards. A major impact with probable repetition merits a more serious response, such as urgent deregistration procedures and prosecution. Urgent procedures entail cancelling a registration and closing down a health service provider quickly, and is used when serious harm is caused to service users. Enforcement actions need not be applied consecutively. The most serious problems would merit using civil enforcement powers alongside criminal enforcement powers. In most cases, there will be a gradual escalation of enforcement activities, starting with a warning notice and re-inspection, then imposing conditions on registration, and finally prosecution for non-compliance with the conditions, if necessary.

The 2014 Regulations enable CQC Inspectors to move more easily between levels of the pyramid. The 2010 Regulations provided that a prosecution could only be brought if a warning notice had been served alongside an improvement period.¹¹⁶ This made prosecuting difficult. The 2014 Regulations remove this requirement. Prosecutions can be a starting measure in the most extreme cases of failure. This adds weight to the top of the pyramid, especially with the unlimited financial penalties available for some offences. Removing the requirement to start with a warning notice gives the CQC greater control over their enforcement strategy in each case.

These changes fail to address institutional dimensions affecting enforcement. Particularly important are the institutional decision-making processes to draw the appropriate balance between compliance and deterrence measures. Hawkins¹¹⁷ has demonstrated that these affect the effectiveness of regulatory intervention in other

¹¹⁶ Regulation 27, 2010 Regulations.

¹¹⁷ K Hawkins, *Law as last resort: Prosecution decision-making in a regulatory agency* (2002 OUP, Oxford)

areas; yet the 2014 Regulations fail to deal with these dimensions. CQC inspector enforcement practices are as much a factor in the success of the new regulations as the provisions themselves. Neglecting ‘the inherent nature of the enforcement function’ contributes to regulatory failure.¹¹⁸ Inspectors necessarily have a great deal of discretion. Compliance methods – at the base of the pyramid – are more effective for managing ongoing relationships between the regulatee and the regulator, especially when breaches are not predictable. In the healthcare environment, the focus should be on correcting problems and creating a more stable approach for the future.¹¹⁹ The next failure is the bigger concern for patient safety. It is difficult to predict the next failure, especially where it falls outside the existing regulations. It is essential that institutions can disclose concerns to the CQC without fear of heavy handed prosecution, so that action may be taken to address potential future breaches. Compliance approaches to enforcement can help to foster this sort of openness.

Properly tailoring enforcement actions to each institution requires an understanding of why regulatees comply. Baldwin’s taxonomy of regulatees indicates that different enforcement approaches will suit different regulatees. For example, the well-intentioned and ill-informed regulatee is best dealt with through an educational and supportive approach, whereas the ill-intentioned and ill-informed regulatee is more likely to respond to a legalistic approach supported by the threat of the full weight of the law.¹²⁰ Allowing inspectors to tailor their enforcement approach to the type of regulatee is fundamental to the Regulations’ success.¹²¹ In the NHS context there is

¹¹⁸ C Diver, ‘A theory of regulatory enforcement’ (1980) 28 Public Policy 257, 298.

¹¹⁹ K Hawkins and J Thomas, ‘The enforcement process is regulatory bureaucracies’ in K Hawkins and J Thomas (eds) *Enforcing regulation* (1984 Kluwer Nijhoff, Boston) 3-22, 14.

¹²⁰ R Baldwin, *Rules and government* (1995 Clarendon Press, Oxford) 148.

¹²¹ Baldwin, *ibid* 152

another relevant class, the budgetary constrained regulatee. At the end of 2014/15 the NHS had a 'net deficit of more than £800million'.¹²² Hawkins argues that cash-strapped regulatees will not be motivated to go beyond basic compliance, doing only the minimum required.¹²³ Where there is a suite of standards to be complied with to different extents, regulatees might prioritise particular aspects, and focus on the regulator's particular concerns. The CQC is explicit in its focus on safety,¹²⁴ indicating that the non-safety standards may be less likely to attract enforcement action, thus regulatees can be a little less concerned about strict compliance.

In addition to understanding compliance, it is important to understand that non-compliance is not simply failure to comply. Kagan and Scholz suggest that non-compliance might be rational, principled or due to general organisational incompetence.¹²⁵ The Stafford Hospital catastrophe was due to a systematic failure of management and oversight, and the culture of secrecy surrounding errors. It is more important to know about the state of managerial competence in large organisations than it is to identify individual intentions. Even the most well-intentioned and well-informed team will fail to comply if they are situated in a culture of incompetence and non-compliance. Rather than engage in enforcement activity, inspectors may need to act as consultants working with the institution to create competent management. It is unlikely that CQC inspection teams have the necessary expertise or resources to do this. Alternatively, it may be that local enforcement action is pointless in this sort of crisis, and that engendering a culture of openness,

¹²² Care Quality Commission, *The state of health care and adult social care in England*, (2015, HC 483) 11

¹²³ K Hawkins, 'Enforcing regulation: Robert Kagan's contribution—and some questions' (2013) 38 *Law and Social Inquiry* 950-972, 963.

¹²⁴ Care Quality Commission note 122, 5

¹²⁵ Kagan and Scholz, *ibid.*

transparency and asking for help, through high-level policy change such as the duty of candour might be more successful. It might be even more successful if regulatees are included in forming enforcement policy.

There are historical reasons why a compliance approach may not be acceptable to the CQC itself. Francis identified the

systemic culture where organisations took inappropriate comfort from assurances given either by the Trust itself or from action taken by other regulatory organisations. As a result, organisations often failed to carry out sufficient scrutiny of information, instead treating these assurances as fulfilling their own, independent obligations.¹²⁶

The Healthcare Commission's compliance approach contributed to the Stafford Hospital fiasco. Insufficient scrutiny alongside a culture of secrecy meant errors and failings were missed or unreported. Had the Healthcare Commission scrutinised more closely and taken more serious enforcement action, the crisis may have been caught sooner and been less serious overall. The new criminal offences and the greater freedom to prosecute indicates the 2014 Regulations' aim to push a more deterrence-focused approach to enforcement, to prevent the possibility of regulatory capture. This strictness is a direct response to the failings of the more lenient 2010 Regulations. While the framework in the 2014 Regulations clearly permits a compliance approach to enforcement – making it easier to move between levels in the pyramid, and allowing inspectors to start at any point on the pyramid – the tenor of the provisions is that stricter enforcement practices are necessary to prevent another Stafford Hospital.

¹²⁶ Francis, note 2, 65

This creates a mismatch between the inspectors' role in maintaining ongoing relationships, calling for a compliance approach, and the 2014 Regulations, favouring a deterrence approach. The 2014 Regulations may push inspectors towards deterrence, even where compliance would be more appropriate. The deterrence approach assumes that regulatees are rational calculators, and that they comply to avoid penalties for non-compliance. The policy pushes inspectors to take this approach even where regulatees are differently motivated.¹²⁷ It brings a legalistic threat of prosecution to the forefront. Bardach and Kagan have argued that while this has positively affected compliance, increased legalism can cause perverse reactions.¹²⁸ It may lead to compliance experts taking up central management roles, moving focus from caring towards legalistic compliance. They argue that regulatees 'who think of themselves as trying to do a decent job are not likely to cooperate with an agency that in effect disregards their judgement and good-faith efforts or that even denies (by its actions) that they are to be trusted at all'.¹²⁹ This pushes regulatees towards a minimal compliance approach, removing any motivation to go above the standards set. This is problematic when the best patient care comes from a caring institution which is motivated to go beyond the minimum. The deterrence approach could turn the necessarily ongoing relationship between regulator and regulatee into one of hostility, further reducing the opportunity for the regulator to offer compliance advice, instead relying on prosecution and more formal measures. Hawkins argues that prosecution should be the last resort. Having to prosecute indicates 'a failure of regulatory control'.¹³⁰ Once a prosecution has been brought,

¹²⁷ See Kagan and Scholz, note **Error! Bookmark not defined.**, 69

¹²⁸ E Bardach and R Kagan, *Going by the book: The problem of regulatory unreasonableness* (1982 Temple University Press, Philadelphia) chapter 4

¹²⁹ Bardach and Kagan, *ibid*, 105

¹³⁰ K Hawkins, note 117, 416.

and relations have turned hostile, there is nowhere else to go. The regulator must continue to prosecute similar breaches or risk appearing arbitrary. This compounds the perception of regulator unreasonableness¹³¹ and cements the hostility. Bringing multiple prosecutions puts a significant financial burden on the regulator. Can the CQC can afford to follow the deterrence approach in the regulations?

The CQC have changed their method of work; specifically a new inspection model, entailing a mixture of announced and unannounced inspections, and a change in the constitution of the inspection team, to be led by a CQC manager, chaired by an NHS clinician or executive, and including staff, patients, carers and experts by experience. This mix of new perspectives increases the chances of inspectors seeing problems, and reduces their need to rely on assurances. This indicates a move towards a deterrence approach. The new inspections consider whether the service is 'safe, effective, caring, responsive to people's needs and well-led'.¹³² Each of these are rated inadequate, requires improvement, good or outstanding. Ratings are published on the CQC's website. The media are informed about inadequate and outstanding ratings and any enforcement actions and prosecutions.¹³³ It is possible that reframing the inspection process has made it more efficient, so there is more budget available for enforcement action. However, prosecution is expensive, and the deterrence approach creates a need for more prosecutions. There will come a point when it is not financially viable to continue to prosecute.

¹³¹ Bardach and Kagan, note 128, 105.

¹³² See 'Our new inspection model' at <<http://www.cqc.org.uk/content/our-new-inspection-model>>

¹³³ *ibid*

The ideal approach to enforcement is a mix between deterrence and compliance. There needs to be enough of a background threat of prosecution that regulatees feel bound to comply and to work collaboratively with the regulator, but also such that there is a reduced capacity for the regulatory capture. It is possible that the CQC's explicit focus on safety enables them to achieve this balance without compromising their ability to follow a compliance approach to enforcement. Safety is within the purview of the Health and Safety Executive ("HSE").¹³⁴ Since the CQC has responsibility for inspection and managing any ongoing relationship with its regulated providers, there is not the same impetus for the HSE to maintain an ongoing relationship. The HSE does not need to take a compliance approach. They can afford to bring prosecutions as a first rather than last resort. By aligning their priorities with the HSE, the CQC give themselves the freedom to follow a compliance approach to enforcement while relying on the threat of HSE prosecution to focus regulatees on meeting the standards. If the CQC's compliance approach does fail, the HSE provides a safety net to prosecute where there are significant safety failings.

(A) Do public inquiries offer a third way to successful policy change?

I have argued that the 2014 Regulations suffer from fundamental flaws which threaten their success in regulating important aspects of the NHS. Specifically, I have argued that the nutrition and hydration standards are too nebulous to be properly applicable, and that the duty of candour focuses to its detriment on apologies, undermining the necessary focus on transparency and openness. Taking these together, I have argued that the 2014 Regulations' reliance on the expressive power

¹³⁴ The HSE brought prosecutions under s3(1) of the Health and Safety at Work Act 1974 in respect of four deaths at Mid Staffordshire NHS Trust on 4 November 2015

'Stafford hospital deaths: NHS trust admits four charges' (4 November 2015) at

<http://www.bbc.co.uk/news/uk-england-34719361>

of criminal law cannot address the complex issues that are the regulations' targets without properly funded implementation of its deterrence-focused enforcement approach. This is unlikely to eventuate. How then, did such a flawed law come into being, and what are the implications for its success?

The literature on policy fiascos indicates two main responses available: the rapidly created 'knee-jerk' response which risks being unequal to the job required of it, and the pre-prepared response waiting for the necessary trigger or 'policy window' for its introduction. The second is acknowledged to have more success because it should be better prepared. A typical trigger for dramatic policy change is the dog bite.¹³⁵ It is a small event with significant consequences played out in the media, causing public outrage and demands to change the regulatory framework. Inevitably, Hood and Lodge's 'tombstone pattern'¹³⁶ follows. The public outcry leads to a rapid change in the regulation – whether by knee-jerk response or a pre-prepared policy introduced in a policy window – which appears to solve the problem. This regulatory tombstone focuses attention on and gives respect to the victims. Then, the problem leaves the public consciousness, and is not considered again until the next dog bite. At which point we find that the law is impossible to enforce and fails to solve the original mischief, or it creates a whole raft of new problems. The Dangerous Dogs Act 1991

¹³⁵ M Lodge and C Hood, 'Pavlovian policy responses to media feeding frenzies? Dangerous dogs regulation in comparative perspective' (2002) 10 *Journal of Contingencies and Crisis Management* 1-13

¹³⁶ Lodge and Hood, *ibid* 5

is a prime example.¹³⁷ The symbolic element of the regulation makes it more difficult to reform it further: 'tombstones may cast long shadows'.¹³⁸

When a dog bites a child, only a few people are involved, the child, their parents, the dog's owner. It is a one-off event. Other events acknowledged to be policy fiascos such as the banquet hall collapse in Jerusalem¹³⁹ which caused 23 deaths and injuries to over 400 others, are short-term one-off events. They are qualitatively distinct from big healthcare catastrophes. The Mid Staffordshire crisis continued for four years. Thousands were affected. This was the latest in a long line of protracted healthcare catastrophes causing considerable suffering. Before Mid Staffordshire there was Harold Shipman, the retained organs scandals at Bristol and Alder Hey hospitals, and the contaminated blood scandals. These events do not ever fall from the public consciousness. The shadow cast by the retained organs scandals at the end of the twentieth century still falls over the use of human tissue today. The shadow cast by Mid Staffordshire will fall over healthcare practice for much of the future. More importantly, the depth of feeling, and the temporal length of these shadows make it difficult to gain public or Parliamentary support for a knee-jerk regulatory response. In addition, the complexity of the issues make a true knee-jerk

¹³⁷ M Lodge and C Hood, 'Pavlovian policy responses to media feeding frenzies? Dangerous dogs regulation' (2002) 10 *Comparative Perspectives* 1

¹³⁸ M Dixon Woods, 'The tombstone effect: Long shadows and the pursuit of comfort' in R Dixon and M Lodge, *Explorations in Governance: A collection of papers in honour of Christopher Hood* (2014) 32, at <http://xgov.politics.ox.ac.uk/materials/pdfs/explorations%20in%20governance%20for%20web.pdf> > 33

¹³⁹ R Schwartz and A McConnell, 'Do crises help remedy regulatory failure? A comparative study of the Walkerton water and Jerusalem banquet hall disasters' (2009) 51 *Canadian Public Administration* 91-112

response unlikely. But, healthcare provision is already a highly regulated area, and the crises that lead to regulatory change are not ones that were foreseen. They were wholly outside the regulation in place at the time. The same is true of Mid Staffordshire. It is therefore unlikely that there is a pre-prepared solution waiting for the appropriate trigger.

Since neither of the options are available, the government must spend time creating a robust response which includes regulatory change where necessary. This is often done by establishing a public inquiry or a commission to investigate the crisis and make policy recommendations. Policy formation is contracted out to experts, which buys time, and provides the government with solid well-designed policy recommendations ready for adoption. This is tried and tested in the healthcare field. Sir Robert Francis QC headed the Mid Staffordshire public inquiry.¹⁴⁰ The Shipman inquiries were chaired by Lord Laming and Dame Janet Smith.¹⁴¹ Inquiries into retained organs at Bristol Royal Infirmary were led by Professor Sir Ian Kennedy,¹⁴² and at Alder Hey Children's Hospital by Mr Michael Redfern QC.¹⁴³ Professor Margaret Brazier chaired the Retained Organs Commission.¹⁴⁴ This moves the pressure to get the right solution away from the government and onto the inquiry's

¹⁴⁰ Francis note 2

¹⁴¹ The Shipman Inquiry

<<http://webarchive.nationalarchives.gov.uk/20090808154959/http://www.the-shipman-inquiry.org.uk/home.asp>>

¹⁴² Bristol Royal Infirmary Inquiry, note 56

¹⁴³ The Royal Liverpool Children's Inquiry, Report at

<<http://webarchive.nationalarchives.gov.uk/20060715141954/http://rlcinquiry.org.uk/download/index.htm>>

¹⁴⁴ 'The Retained Organs Commission' at

<<http://collections.europarchive.org/tna/20060802143339/nhs.uk/retainedorgans/>>

chair. Chairs are limited both by inquiry's terms of reference and by their experience. For example, the first Shipman inquiry was to report in public but to hear evidence in private. This decision was successfully judicially reviewed¹⁴⁵, and the second incarnation was to be held entirely in public. A similar thing happened with the Francis inquiries. Prior to the public inquiry, Francis had chaired an independent private inquiry with limited terms of reference.¹⁴⁶ While this might initially limit exposure it may not help the government to produce an appropriate regulatory response. If the terms of reference are sufficiently broad, the limiting factor is the inquiry chair themselves. Appointing a traditional doctrinal lawyer to chair a public inquiry may result in recommendations that are legalistic and rely heavily on command and control legislation. A behavioural economist will produce a regulatory framework primarily based around nudges and remedying cognitive bias. In order to get both the terms of reference and the chair appointment right, the government needs to have a clear idea of its expected outcomes. Most successful may be a balanced team of "chairs" bringing different experiences.

The root cause of the Mid Staffordshire crisis was the culture of secrecy and the Healthcare Commission's unwillingness to look behind institutional assurances. This compliance-focused approach to enforcement led to the Healthcare Commission's capture. The CQC complained that it was difficult to bring serious enforcement actions against institutions. The Francis recommendations and the 2014 Regulations has attempted to address this. The duty of candour is intended to reverse cultures of

¹⁴⁵ R v Secretary of State for Health ex parte Associated Newspapers and others [2001] 1

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¹⁴⁶ The Mid Staffordshire NHS Foundation Trust Inquiry, Robert Francis Inquiry into Mid-Staffordshire NHS Foundation Trust at

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113018>

secrecy. The 2014 Regulations make it easier to bring enforcement actions, and make the more serious actions more available. Recommendations were made about how the CQC could be more independent. However, the two case studies above indicate that the Regulations have the hallmarks of a legalistic response with heavy reliance on the criminal law. This pushes inspectors to take a deterrence approach to enforcement increasing the hostility in the CQC's relationships with its registered providers. Future failure is indicated in two distinct ways. The nebulousness of the food and drink standards and the limits of their application indicate failure due to under-regulation. The standards will catch the worst examples of poor hospital food, that which would endanger the health and life of the patients. They are unlikely to address the problem that food across the sector is generally poor and unappetizing since this would not have an impact significant enough to be caught by the regulations. Further, since the penalties are so stringent for failure to meet these standards, enforcement activity will only take place in the most serious of cases. This makes it unlikely that the food provisions can raise standards. The duty of candour regulations point to potential failure due to over-regulation. Its purpose was to embed transparency and openness in institutional approaches to errors and serious incidents. If the implementation of the duty transfers the burden to individual staff members it becomes a de facto individual duty to apologise, which inappropriately over-regulates individual behaviour, while deemphasising institutions. The focus becomes whether the individual healthcare professional was correct to apologise, and whether they have had training, rather than whether the institution has taken responsibility.

[A] Conclusion

The shortcomings of knee-jerk responses to policy fiascos are well known in the literature. By any standard, however, the 2014 Regulations were a cautiously framed measure. I have shown that the 2014 Regulations suffer from fatal flaws despite the

caution and effort that went into their making. There are problems of both under- and over-regulation highlighted by the case studies of the nutrition and hydration standards and the duty of candour. The centrality of criminal offences in the enforcement provisions pushes the CQC towards a legalistic deterrence approach to enforcement, increasing the potential for pushback from registered providers, and a consequent need to rely on the more burdensome and more expensive enforcement measures. Unless the CQC are properly resourced, it sets them up for greater impotence in their regulatory arena. Further, any attempt to lessen the focus on the criminal offences through reform of the regulations at a later date would undermine the symbolic importance of having serious penalties for similar failures. It is difficult to see what other direction the 2014 Regulations could have taken. The events at Stafford Hospital were terrible. The culture of secrecy was ingrained and unshakeable by anything less than the dramatic. The Healthcare Commission's compliance approach had failed. Sir Robert Francis QC is a serious doctrinal lawyer. The combination of these factors made the deterrence agenda inevitable, whether ideal or not. To make it work, the CQC have to be properly resourced to fulfil that agenda. If they are not, then there will be another serious healthcare crisis, which will necessarily lead to more stringent regulations, which will need further resources, for a restructured regulator. Lodge and Hood's 'tombstone pattern'¹⁴⁷ is perhaps better understood as a tombstone spiral, with ever increasing stringency.

¹⁴⁷ Lodge and Hood, note 135, 5