

# The need for a regulatory rethink: a perspective from Australia

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## ABSTRACT

Traditional 'hierarchical' regulation involves checks and balances and external accountability and review bodies. There have been high profile failures of this approach in England (Mid Staffs) and Australia (Bundaberg, Queensland). The regulatory framework needs to be transformed to recognise the increasing use of market and market-like mechanisms in health care. Improvement in the ability to measure quality and safety of care using routine (already collected) data facilitates this. New regulation needs to ensure quality and financial incentives are aligned. New instruments such as incorporating safety/quality measures into service descriptions, use of patient reported outcome measures, and making information about expected outcomes of care to patients available, ought to be used more widely. Improved data capture, including whether a diagnosis was present on admission, will help in improving quality and safety of care and its measurement.

**KEYWORDS:** Quality, safety, pay for performance, routine data

## Background

Australia's new government elected in 2013 is following the practice of conservative governments elsewhere in conducting a war on 'red tape'. In Australia, this is taking the form of a 'repeal day' where legislation considered to be outmoded, superseded or out of favour will be introduced into parliament. Two 'repeal days' will be scheduled each year.

'Red tape' is a term of derision, but one person's 'red tape' may be another's necessary safeguard. Crises beget regulations and they are layered on health (and other policy) systems like geological sediments, so an occasional spring cleaning may be worthwhile.

## The place of regulation

The objective of public policy is typically to shape the behaviour of individuals, communities and organisations. There are a number of top-down instruments or levers that governments can use: provision of new services; financial levers (taxes,

incentives, setting up markets); rules, laws, organisational changes and system targets; information provision; rhetoric; and changing values and culture (usually by a combination of the previous five and through initial education).<sup>1,2</sup> Adherence to rules and targets can be accompanied by various levels of sanctions or 'terror'.<sup>3,4</sup> Bottom-up pressure for change can be manifest by governments adopting consumer empowerment or market-like strategies designed to achieve this.<sup>5</sup>

In general, each specific behaviour or target of policy requires a distinct policy instrument,<sup>6</sup> partly explaining their accretion over time. Ideally, they will be aligned and work in the same direction. It is undesirable to create either policy instruments that the regulator expects the regulated to ignore, or complexity by instituting one policy instrument to counteract the unintended effects of another. Not all behaviours (or situations) can be predicted with certainty, which means that specification of what is expected is necessarily incomplete,<sup>7</sup> creating uncertainty in the regulatory frame.

The relative balance across different instruments will vary over time, and according to the nature of the problem being addressed. Oliver Williamson, awarded a Nobel Prize in 2009, developed transaction cost economics to predict when different forms of interactions between a firm and its supply chain may be optimal.<sup>8</sup> In brief, he identified the conditions under which a firm should go to market to acquire supplies or should produce them internally. This is termed the 'make or buy' decision. The choice is also characterised as being one between markets and hierarchies.<sup>9</sup>

Reliance on hierarchical controls, regulation and 'red tape' is out of fashion as a way of influencing behaviour, supplanted by market mechanisms and financial incentives. In the health sector, this has been made possible by advances in our ability to describe health services. A market cannot function when the products to be bought or sold cannot be defined adequately. The great advance in defining 'products' of hospital care was the development of diagnosis-related groups (DRGs) as a measure to control for the mix, or clinical heterogeneity, of hospital cases.<sup>10</sup> In England, activity is measured using healthcare resource groups (HRGs).<sup>11</sup> HRGs (and other case-mix measures) are incomplete descriptors of inpatient activity because they implicitly assume homogeneity of outcomes. As outcome measurement has improved, this assumption is increasingly questioned.<sup>12</sup>

The various policy instruments applied to healthcare have their impact by reinforcing or responding to the motivations

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or values of hospitals and their staff. Such motivations include professionalism, service to the local community, the financial health of the organisation, work satisfaction and maintenance of reputation. Different incentive designs have different impacts on these motivations, influencing the salience of the instrument.<sup>13</sup>

Contemporary regulatory approaches increasingly rely on ‘self-regulation’ and graded pyramidal interventional hierarchies, where greater levels of infringement lead to increasing intervention.<sup>14</sup> The lower levels of the regulatory hierarchies involve the so-called ‘light touch’ approach and assume that strong internal motivations and professionalism, coupled with the threat of reputational risk if infringements are identified, are sufficient to ensure compliance.

### Regulatory failure

Although inadequacies of standards of safety and quality rarely have a single cause, one contributing factor to recent system failures in both Australia and England may be regulatory in origin. The UK Francis Report is replete with stories of how the central regulators failed in their missions.<sup>15</sup> But a more compelling narrative is that of failure of regulatory design, not of implementation.

The Mid Staffs story is one of failure to ensure alignment of instruments: the financial incentives on the Trust were in conflict with professional norms and values, and with the rules and regulations administered by ‘quality’ regulators.<sup>16</sup> The system of potential financial rewards and penalties created perverse incentives in the Trust to cut corners, tolerate understaffing, and dispute or ignore warning signals, resulting in what one commentator called an ‘extraordinary muddle’.<sup>17</sup>

The same factors were at play in Queensland’s safety scandal involving Bundaberg Base Hospital.<sup>18–21</sup> Bundaberg Base Hospital is one of Queensland’s network of regional hospitals, located 360 km (225 miles) north of the state capital, Brisbane. Queensland has had a lower per capita graduation rate of medical graduates than the rest of the country: contrast South Australia at around 14 new medical graduates per 100,000 population each year with a rate of 7 per 100,000 in Queensland. Queensland has had difficulty in recruiting Australian-trained doctors to work outside the south-east corner where Brisbane is located, which has meant a heavy reliance on internationally trained medical graduates to staff its rural and regional services.

These recruitment difficulties provided the environment in which American surgeon Dr Jayant Patel was recruited to provide surgery at Bundaberg Base Hospital. The first very serious complaint about Dr Patel occurred within 8 weeks of his starting. There were 22 complaints against Dr Patel during the 24 months of his employment at Bundaberg: taking into account periods of leave there was about one formal patient complaint or formal staff report for each month that he actually worked. Action was eventually taken only after a nurse who worked in Bundaberg Base Hospital blew the whistle, and her story was doggedly pursued by a journalist.<sup>22</sup> Independent investigations subsequently confirmed that many of these complaints raised valid, serious questions about the competence of Dr Patel, including his clinical decision-making.

Dr Patel was a hard-working (and possibly over-confident) surgeon, who was willing to undertake surgery on patients whom other local surgeons would have declined to recommend for surgery or referred to larger centres. A number of patients on whom Dr Patel operated had serious adverse outcomes.

A critical issue in Bundaberg was not a problem of identifying aberrant poor practice but rather of acting on this knowledge. At the time, Queensland hospitals had a financial incentive to undertake additional activity to reduce waiting lists so Dr Patel’s work generated significant additional revenue for the hospital. This partly explained the lack of action on complaints against Dr Patel.

The response to the Bundaberg scandal included a regime change at Queensland Health (minister, director-general and the senior leadership departed) and the introduction of a comprehensive programme of culture change and statistical process control monitoring of the safety of care.<sup>23–25</sup> (The author was recruited to Queensland Health as part of that process.)

Up until recently, medical registration in Australia was a state responsibility. State laws generally allowed wide discretion to boards to approve registration for practitioners to work in ‘areas of need’ who might not be approved to work in areas with a better supply of medical practitioners.<sup>26</sup> Perversely, this meant that the weakest practitioners were approved to work in the areas with the weakest supervision, creating well-documented system problems.<sup>27</sup> In smaller states, the registration boards did not work fully independently, suffering a form of regulatory capture where they were overly swayed by local health system exigencies to approve registration. As part of wider regulatory reform, medical registration is now national, removing some of the regulatory capture risk (Table 1).

**Table 1. Australia: health system regulatory processes**

Dimension	Early 2000s	Current
Professional registration and regulation	State based	National
Safety monitoring	Ad hoc, limited	Audits of surgical mortality established in all states Statistical monitoring introduced in some states
Monitoring of hospital standards	Voluntary accreditation scheme operated nationally	Voluntary accreditation schemes operate nationally Many states require participation in a form of accreditation National standards developed by Australian Commission on Safety and Quality in Health Care

An issue in policy design is the potential for unintended or perverse responses.<sup>28</sup> This was evident in both Mid Staffordshire and Bundaberg, where perverse responses to financial incentives created safety issues. As mentioned above, policy instruments are aligned ideally, but, in these two instances, the financial incentives created responses that were counter to inherent culture and values of professionalism, and to formal regulatory rules, overwhelming the longer-term impacts (eg sanctions from the regulator) and more subtle internalised values. This created the environment in which warning signals were ignored by local management, a situation common to other safety scandals around the world.<sup>29</sup>

### Directions for regulation in a developing healthcare market

An easy response to failures of regulation is to apply more, or to rearrange the regulatory deck chairs. Such changes create the impression of action, and allow politicians to appear to respond to concerns until public attention and sentiment have moved on. Unless policy instruments are aligned, similar problems are bound to emerge again.

Our thinking about regulation of healthcare is still framed by the 'hierarchy' period of health policy thinking and has not adapted properly to the market forces approach to provision. Although in theory hospitals might compete on quality to attract market share, the evidence that this leads to improved care is still scant, and mixed at that.<sup>30,31</sup> Even high-profile scandals don't appear to have a lasting impact on patient flows.<sup>32</sup>

In the hierarchical period of service delivery organisation in countries such as Australia and the UK, hospitals were creatures of the state with direct line accountability as the mode of ensuring service responsiveness to the needs of patients and voters. Professional self-regulation was assumed to assure quality of care. Although these are seen by some as the halcyon days, the system was not fit for purpose and patient neglect, both procedural and caring,<sup>33</sup> abounded, some evidenced in external enquiries after high-profile system failures.<sup>34</sup>

The move towards more market-like sector organisation has not been accompanied by a sufficient rethink of how regulation ought to occur.

Regulation framed in the hierarchical mode is set up as part of a 'checks and balances' approach, attempting to constrain managers from acting in an economically rational, albeit perhaps morally inappropriate, way. 'Hierarchical' regulation is generally slower to respond than the more immediate gratification provided by price signals. External 'audit' bodies, of variable effectiveness, have been added, attracting criticism for their added regulatory burden.<sup>35</sup> The regulatory responses in this newly marketed sector need to be quicker, built on a wider range of policy instruments than hierarchical organisations, laws, external inspections and regulations.

An underlying problem of markets stems from the incomplete specification of the product being bought and sold, especially the implicit assumption of outcome or quality homogeneity. Better specification of policy objectives allows development of price signals for other ('adjunct') policy objectives relating to waiting times and other aspects of service quality.<sup>36</sup> In particular,

developments since DRGs/HRGs were originally constructed allow incorporation of quality measurement into price signals (and/or product definition), thus helping to align volume-related incentives and quality incentives.

The first new regulatory development should be to strengthen the use of quality measurement in payment design. There are a number of ways in which quality can be incorporated into pricing signals, including 'pay for performance' (P4P) or, more widespread in policy implementation, 'no pay for non-performance'. The evidentiary basis for both types of initiatives is still weak<sup>37</sup> and, in their first manifestations, little money is shifted around. However, both types of initiatives appear to be having an impact on behaviour, partly because of reputational risk (hospitals don't like being seen to have been penalised for poor quality) and partly because penalties evoke disproportionately stronger responses than rewards ('loss aversion').<sup>38</sup>

In England, a hesitant toe has been dipped into the P4P water with payment-by-results, 'best practice' pricing strategies in four areas: cholecystectomy, hip fractures, cataracts and stroke. In the USA almost all contemporary implementations of funding reform involve a blend of efficiency and P4P aspects.<sup>39</sup> In the US's Medicare system, for example, a limited list of hospital-acquired conditions (so-called 'never events') is excluded in the assignment of cases in its case-mix classification algorithm. This effectively penalises hospitals where these events occur, because, in the absence of such an exclusion, the adverse event (say catheter-associated infection) would have potentially led to assignment to a higher DRG and hence a higher payment.<sup>40</sup> Queensland has gone further than other Australian states with P4P, rewarding performance on a list of clinically developed indicators and penalising, with zero payment, six 'never events'.<sup>41,42</sup>

Results from the broader collection of patient-reported outcome measures could be incorporated into pricing structures, alongside more clinical measures. This would increase the salience of patient-experience in quality measurement and overcome barriers to their use as part of internal hospital improvement efforts.<sup>43</sup>

Improved use of existing information should be the second strand of regulatory reform, which can also involve strengthening the hands of consumers. The full potential of the information currently collected about hospital performance should be used to inform patients about the potential outcomes of their treatment and for hospitals to monitor their own performance.

Feedback to Mid Staffs about its relative performance resulted in denial – the first of the Kübler–Ross grief stages.<sup>44</sup> This response may have been evinced because of fear of penalties or punishment. An external accountability environment that was more supportive, focusing on what a hospital has done to change its practices (rather than just more punitive data analyses), may have led to more in-hospital 'ownership' of the signals.<sup>45</sup> It would also be more consistent with the contemporary view that quality improvement is fostered by creating a 'just and trusting culture'.<sup>46,47</sup>

There is increasing recognition of the potential for routinely collected data to contribute to health system improvement. In addition to their potential for facilitating use in research, such data can provide a rich source of feedback and the potential

for a ‘continuous learning health system’.<sup>48,49</sup> Hospitals should be encouraged and supported to analyse their own patterns of adverse events as already collected in the routine data.<sup>50</sup>

Routine data can also be used to provide patients with better information about the pattern of adverse events and likely outcomes of care, specific to their own circumstances and the experience of their treating clinician(s). Rather than generalised information about the potential outcomes of care, informed patient consent should be based on the specific local experience in terms of patterns of outcomes, preferably tailored to be age and sex specific.

The full potential of routine data sets will be garnered only if the UK catches up with other countries and incorporates a flag into its coding rules to indicate whether a diagnosis was ‘present on admission’.<sup>51,52</sup>

Clinical hubris contributes to clinicians predicting better outcomes of care than the average – the Lake Wobegon effect.<sup>53</sup> A way around this is to collect information from clinicians about their perception of likely outcomes and compare this with actual results. Over time either clinicians will become more accurate in reporting likely outcomes or an optimism factor could be used to discount their advice.<sup>54,55</sup>

These suggestions for updating the regulatory approach need to be accompanied by a renewed emphasis on reinforcing good professional values and a safety-oriented NHS culture. This is what the Berwick report sets out to do, partly relying on rhetoric to reinforce desirable cultural attributes.<sup>56</sup> Whether anyone will hear is a moot point.<sup>57</sup>

Streamlining the existing regulatory over-burden is also required. The problems identified at Mid Staffs and Bundaberg are not new. Nor are the responses proposed in the enquiries that these events stimulated.<sup>58</sup> Walshe has conducted a meta-review of both the English reviews and international ones, identifying common themes and synthesising strategies that might prevent recurrence.<sup>59,60</sup> To date, these lessons have been ignored. They should be dusted off and implemented.

## Conclusions

Although there has been a waxing and waning of market language in the British NHS, the reality has been a slow but steady increase in use of market and market-like instruments over time. This has been facilitated by an improvement in the ability to define what is being provided, in turn facilitating pricing of those system outputs.

Over the last few years there has been an improvement in the ability to describe system outcomes as well. This development has not led to systematically incorporating outcome or quality measurement into the pricing framework. As a result, pricing incentives have created environments in which quality goals have been relegated to second place. Quality regulation has been a ‘pimple on a pumpkin’ supplement, to be avoided or circumvented in the pursuit of the monetary goal dangled in front of hospital leadership.

What is required is to augment current systems of quality regulation by new approaches that better align pricing and quality goals. This new approach transforms the improved ability to measure safety and outcomes of care into a policy instrument that hopefully will bring quality objectives into equal status (at least) with financial goals. ■

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