

# The Governance of Health Safety and Quality

## A Discussion Paper



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& Dr Kathryn Dwan

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This document is intended to stimulate debate on how to improve the governance of health care safety and quality in Australia. The views expressed in this discussion paper do not necessarily represent the views of the Council, or of the Australian Government.

Copies of this document, and further information on the work of the Council, can be found at [www.safetyandquality.org](http://www.safetyandquality.org), or from the Office of the Safety and Quality Council on telephone: +61 2 6289 4244, or email to: [safetyandquality@health.gov.au](mailto:safetyandquality@health.gov.au).

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## Foreword

Significant system and cultural change is necessary if Australia's health care system is to continue to provide safe, high quality health care.

The Australian health care system is complex, involving large numbers of public and private providers working in a range of community and institutional settings in eight separate jurisdictions, each with its own governance responsibilities, and each responding to local circumstances and conditions in which health care is delivered.

The Australian Council for Safety and Quality in Health Care (the Council) believes that governance at all levels of the health care system is one of the most important influences on the safety and quality of care. Good governance is reflected in strong systems of leadership and accountability. With good governance, the capacity for innovation and responsiveness to new technologies, challenges, and opportunities are retained within a system in which safety and quality is valued and protected.

Throughout the Australian health care system, governance action should be directed towards ensuring that each organisation and individual is engaged actively in comprehensive processes of systems review, risk management, and systems improvement. Concerted and coordinated action involving each element of the health care system is required - from individual clinicians, through to health care organisations, and jurisdictions.

Where self-regulation of the health care system is effective in achieving safe, high quality care, it should be supported. Where active regulatory strategies are necessary, they should be designed to establish conditions that are conducive to, and foster, good governance at the appropriate level in the system, so that responsibility and accountability can be maintained.

This paper was commissioned by the Council and prepared by the Australian National University, Regulatory Institutions Network (RegNet). It presents concepts of regulatory thinking that are designed to stimulate debate on how to improve the governance of health care safety and quality in Australia.

Since this paper was commissioned, RegNet has been awarded an Australian Research Council grant to research regulatory strategies for improving health sector performance, in partnership with ACT Health and the Council. This ongoing research will make an important contribution to understanding how to deliver best practice governance in the Australian health care system. This is an essential element in achieving sustainable best practice in health care safety and quality.

I commend this paper to you.



Professor Bruce Barraclough AO  
Chair

Australian Council for Safety and Quality in Health Care

## Executive summary

### Patient safety

Industrialised countries are seeking ways to improve the quality of their health care and, in particular, to make it safer. Accidents and “medical errors” do occur - whether by commission or omission, through people and/or systems failures, and through *iatrogenic*<sup>1</sup> injuries, as well as through *nosocomial* infections. The question is to what extent are these incidents preventable? *Adverse events* can be defined as incidents in which a patient is harmed, and include infections, falls, pressure ulcers, medication and equipment errors, as well as other errors in procedures. While there is no certainty as to the exact number of adverse events, let alone “near-misses”, current estimates suggest that about 10 percent of patients experience some type of adverse event in hospital, while 1-2 percent of patients suffer serious consequences. While it is also unclear how many of these events are preventable, perhaps one-third to one-half, it seems that deaths in hospital from preventable adverse events exceed the road toll. This is not to suggest that medical errors occur only in hospitals; just that there are no reliable statistics from other areas of health care.

In response to the dawning realisation that medical errors are a common occurrence, recent years have seen a proliferation of regulatory actors and regulatory strategies. For example, the United Kingdom has established the Healthcare Commission; the United States the National Quality Forum; Canada has set up the Canadian Patient Safety Institute, while Australia has set up the Australian Council for Safety and Quality in Health Care. A major shift in regulatory thinking is under way to find the best ways to ensure better and safer health care. Much effort has been directed at quality improvement, but safety issues now dominate this larger reform agenda. The abatement or control of risks to society, a key purpose of *regulation*, has emerged as central to health regulation. The medical profession has a long tradition of self-regulation, but the complacent approach of “leaving it to the doctors” is being challenged. There is also more interest in using external regulatory levers designed to improve performance within organisations, rather than to assume that the remedies lie solely in voluntary behavioural change by individual professionals.

### An ideas paper

This ideas paper is intended to stimulate debate on how to improve the *governance* of health care safety and quality in Australia. We illustrate the ideas with some successes and failures drawn from the multiplicity of regulatory initiatives, and consider emerging approaches to health sector regulation. The paper argues that regulatory thinking must transcend the polarised choice between persuasion and punishment. Given the dramatic growth of regulation over the last decade, it is time to draw together research and experience from health and other sectors, and to begin to formulate an evidence base for choosing between regulatory strategies. The paper calls for an holistic approach to regulation that entails considering the complementarities and incompatibilities of different kinds of external and internal levers for change.

<sup>1</sup> Italicised terms are defined in the glossary and the concepts are discussed in the text.



We argue that the idea of *responsive regulation* offers a productive framework for choosing regulatory approaches that can escalate upwards as required from “soft” to “hard” instruments. We consider the promise of *networked governance* as opposed to reliance on top-down government action. While there is certainly a place for the direct enforcement of rules, we argue for the addition of *meta-regulation* where the conduct of self-regulation is monitored by an external third party. This approach ensures that health care providers have effective safety and quality programs in place and also promotes an expectation of continuous improvement and a culture of safety. Additionally, we discuss other promising possibilities such as *restorative justice*, which offer a means of addressing the tragedies that may strike in health care where there are victims with compensation due, and where emotional scars remain to be healed.

## Regulatory strategies

Regulatory strategies are not just about enforcing law, but cover a range of options that can be categorised in ascending order of intervention under five types of policy instruments. *Voluntarism* is based on an individual or organisational undertaking to do the right thing without any coercion. *Self-regulation* is where an organised group regulates the behaviour of its members (eg. by establishing an industry-level code of practice). *Economic instruments* involve supply-side funding sanctions or incentives for health care providers, and also demand-side measures that give more power to consumers. *Meta-regulation* involves an external regulatory body ensuring that health care providers implement safety and quality programs and practices. *Command and control* involves enforcement by government (eg. ensuring compliance with rules for licensing facilities).

The main argument of this paper derives from the concept of *responsive regulation*, which maintains that regulators are more likely to succeed by using mechanisms that are responsive to the context, conduct, and culture of those being regulated. Escalating sanctions can be invoked; that is, soft words before hard words, and carrots before sticks. Since a single regulatory mechanism is seldom sufficient, the weaknesses of one mechanism are complemented by the strengths of another. The ideas of responsive regulation can be depicted in a *regulatory pyramid* with market mechanisms at the base (eg. quality incentive payments); followed by voluntarism (eg. clinical protocols); self-regulation (eg. industry standards); meta-regulation (eg. compulsory incident reporting); and command and control at the apex of the pyramid (such as criminal penalties). Thus, successive and more severe sanctions can be invoked ranging from a warning letter to licence revocation.

## Context of health regulation

Regulation has become more common, not less, with the growth of private entrepreneurs and the introduction of market mechanisms into the public sector. The term “*new regulatory state*” was coined to describe the parallel development of privatisation accompanied by the establishment of new regulatory bodies. These new bodies are seeking flexible, participatory, and devolved forms of regulation, in addition to traditional enforcement such as inspections. These new strategies are possible given the changes in the nature of organisational life in the information age, with widespread and rapid communication, as well as complexity and flux among competing organisations. Further, the nature of government is changing with the pluralist proliferation of stakeholders in public and private sectors, as well as multiple and decentralised sites of government power. Both government and private actors must now seek to mobilise networks of power to get things done and, in this light, the Australian Council for Safety and Quality in Health Care is part of *networked governance*, a health partnership that seeks to recruit key actors who can pull together different strands of a network to bring about change.

## Current approaches to health care regulation

Regulation in the health sector has traditionally been “soft” and largely a matter of voluntary compliance by individual doctors, backed up by professional self-regulation in instances of glaring incompetence. The exceptions are the *licensing* of health professionals, a “hard” instrument of command and control, and the licensing of facilities through *standards inspection*, a common approach to improving quality. While some matters are best regulated by command and control mechanisms, we argue that in an era of networked governance, meta-regulation offers promise, especially since many of the voluntary and self-regulatory approaches that predominate in the health sector can be transformed into effective meta-regulation.

One challenge to improving safety and quality is the lack of information on what constitutes minimum acceptable standards, let alone “best practice”. But information is very limited on the extent of adverse incidents and near-misses. *Error reporting systems* are not widely established, despite efforts to set up adverse events registers, and to document and analyse “*sentinel events*”. This lack of information constrains the use of *benchmarking*, defined as a continuous process of measuring performance against a standard, and which can serve as the basis for *continuous quality improvement*. The issues surrounding error reporting include whether it should be compulsory or voluntary, identifiable or anonymous, external or internal, and whether substantial under-reporting can be overcome. If professionals do not report errors, for reasons including fear of litigation and professional solidarity, then consumer complaints procedures become more important, and various initiatives are under way to enhance the capacity of patients to monitor their own health care.

Health sector organisations prefer internal rather than external regulatory strategies. Further, the adoption of safety oriented practices within an organisation is largely voluntary, whether it be continuous quality improvement, incident reporting, benchmarking, *performance indicators*, *clinical protocols*, or *peer reviews*. The problem is that a voluntarist approach treats an organisation, such as a hospital, as though it exists in isolation from its environment. But the behaviour of a hospital and its staff is influenced by the interaction between external pressures and its organisational structure and culture, and if the external environment does not generate pressure to improve safety and quality, the hospital may have little reason to strive for better performance. For example, a hospital may have an excellent continuous quality improvement program, but if the funders/purchasers are only interested in getting the lowest price possible for a service, it will be difficult to sustain its commitment to excellence no matter how motivated the organisation.

*Accreditation* of health provider organisations, and *league tables* that compare rankings on performance indicators for professionals and/or hospitals, are both examples of external review mechanisms that generate controversy for political and technical reasons. While the public disclosure of league tables offers an opportunity to purchasers and patients to choose the “best performer”, *market approaches* to regulation have not been successful in improving clinical practice. In the United States, for example, the most privatised and most expensive health sector among industrialised countries, health care providers compete less in curing the sick and poor than in creaming the worried and wealthy well, and compete less in cost reduction than in cost shifting. In response, one United States analyst urges more micro-level competition in improving safety and quality.

## **New approaches to health care regulation**

Three regulatory approaches that have been shown to work in other sectors hold out promise for the health sector: namely, meta-regulation, restorative justice, and responsive regulation.

### **Meta-regulation**

In a world of networked governance, it is imperative that organisations not only manage their own risks, but also manage how their partners manage their risks. This calls for the external evaluation of an organisation’s self-evaluation of its safety and quality systems. Here, we note examples from the nuclear industry and the nursing home industry.

The near-meltdown of a nuclear reactor at Three Mile Island in the United States in 1979 forced a major rethink of regulation. Nuclear power plant operators had become rule-following automatons rather than strategic thinkers about risk management systems, and when something went wrong that was not covered by a rule, operators lacked the risk analysis intelligence to think about what needed to be done. In response to this near disaster, the regulation paradigm changed to being less about government inspectors checking compliance with rules, and more about scrutiny of risk management systems - a *meta-risk management strategy*. The relevant points for the health sector are, first, that professionals must be able to respond to emergencies creatively and rapidly, and second, that external scrutiny should ensure that appropriate and flexible safety systems are in place.

Our second meta-regulation example is from the United States nursing home industry where the federal government required every home to choose a health quality problem each year to improve and to evaluate its ensuing quality intervention program. Given the appalling level of restraint of elderly residents (with over 40 percent physically or chemically restrained), many nursing homes targeted this issue and brought down restraint levels sharply. This was not accomplished by command and control that set and enforced a standard, but by the industry's own efforts to find better ways to manage patients. In a regulatory strategy that harnesses creativity to deliver continuous improvement, leaders can raise the standards of the industry as a whole: by motivating the leaders, you may ultimately pull up the laggards.

### Restorative justice

Restorative justice is based on the notion that because injustice hurts, so justice should heal. In the area of criminal justice, for instance, a *restorative justice conference* brings together all of the people affected by a crime: the offender, the family of the offender, the victim, supporters of the victim, the police, and so on. This circle of people discusses who has been hurt by the crime, what repair might right the wrong, and ultimately agrees upon a plan of action signed by all who give undertakings. There is often an apology and its acceptance, and the evidence is that these improve long term outcomes for both parties.

The health sector is moving towards a policy of *open disclosure* in relation to a serious adverse event. A meeting might be held between health professionals and family, with guidance from the National Standard for Open Disclosure that sets out principles that contain elements of restorative justice. When restorative justice works, an apology fosters a culture of forgiveness, which is more conducive to learning from mistakes than a culture of defensiveness that kills off learning by tolerating cover up. Further, the evidence is that apologies from health practitioners that are perceived as sincere do reduce tort litigation (ie. suing doctors and hospitals).

A variety of approaches under the rubric of a *learning model* seek to learn from, and remedy, the causes of adverse incidents. Shift from a culture of blame to a learning culture is not easy. One problem is that it makes victims angry to learn that the institutional philosophy is that no one is to blame. A full investigation of a serious adverse incident in health care might involve the following processes: first, a *critical incident analysis* of what happened and when, and who was involved, and second, making a decision as to whether to take the next step with a *root cause analysis*, which seeks to ascertain the chain of cause and effect. These learning opportunities are constrained, however, by staff fears that they will be "named, blamed and shamed", and that the information collected may be used later in disciplinary proceedings by the employer, or in litigation by the patient.

## Responsive regulation

To conclude, this summary returns to the concept of responsive regulation. The idea is that regulators can be responsive to those they seek to regulate when deciding on a soft or a hard intervention. The base of the pyramid represents a dialogue-based approach for securing compliance with a just rule or standard where rewards rather than sanctions apply. This may involve a restorative dialogue about repairing harm, as well as how to prevent future harm. The pyramidal presumption of persuasion gives the cheaper and more respectful option a chance to work first. For most of us, a tap on the shoulder is enough to put our socially responsive self forward, and suppress our less motivated, self-interested self.

As we move up the pyramid, more demanding and punitive strategies are invoked. Persistent infractions elicit a formal request to remedy problems, and possibly entail repeat inspections and the public disclosure of failure to meet standards. Closure or removal of license are a last resort, and signal the failure of both the regulator and the regulatee (the person/organisation being regulated) to ensure that the public is well served. The empirical experience in business regulation is that persuasion works in most cases. The more costly punitive steps are thus held in reserve for the minority of cases where persuasion fails. The regulatory pyramid thus encompasses soft persuasion at the bottom end, but also hard enforcement at the pointy end. For responsive regulation to work, those regulated must believe in the *inexorability of sanctions*. Polite requests followed by threats only work when everyone knows that non-compliance will result in an inexorable progression up the enforcement pyramid. In essence, we seek a regulatory approach that encourages and values trust and transparency.

# The Governance of Health Safety and Quality

## Improving patient safety

Many industrialised countries, including Australia, are seeking ways to improve the quality of their health care and, in particular, to make it safer and more effective. While Australia compares well internationally with respect to health care and health outcomes, more attention is being paid to safety and quality issues (Hilless and Healy 2001; Australian Institute of Health and Welfare 2004). While there are certainly concerns about out-of-hospital health care, most attention has been concentrated on hospitals – because better data is available, and because the consequences of *medical error*<sup>1</sup> tend to be greater. While hospital patients generally receive safe and effective treatment, the delivery of health services is complex and involves known risks, as well as unanticipated and sometimes adverse consequences.

The public expects a high standard of care from their twenty-first century hospitals. The last half century has seen dramatic progress in hospital treatment given advances in technology, and in medical and surgical knowledge and techniques. But greater scrutiny of hospital performance, and more media interest in their failings, has shaken public confidence. Hospitals are not always safe places – accidents and medical errors do happen, and the question is to what degree are these preventable? There is increasing concern about the number of medical errors that occur in hospitals, whether by commission or omission, and whether as a result of people and/or systems failures. In response, the last few years has seen a proliferation of regulatory actors and regulatory strategies that aim to reduce such adverse events.

Adverse events are defined as incidents in which harm resulted to a person receiving health care. They include infections, falls and other injuries, and medication and medical device problems, some of which are preventable.

(Australian Institute of Health and Welfare 2004: 292)

These adverse events may involve *iatrogenic* injuries and *nosocomial* infections. While some adverse events may not be preventable, others are – if systems and/or people failure can be prevented. Improving the safety and quality of clinical performance is a major challenge, however, given the many possible reasons for failures and sub-optimal performance, and the many ways in which improvements may be sought.

<sup>1</sup> Italicised terms are defined in the glossary and the concepts are discussed in the text.

## Beginnings of a regulatory response

While it has long been recognised that harm can result from medical care, complacency about the wonders of modern hospital care was shaken in the 1990s. A Harvard team study of New York State hospital patients reported that 3.7 percent of admissions resulted in injury from medical error (Brennan et al 1991). A later report by the Institute of Medicine extrapolated national numbers from the Harvard Study and other studies to estimate that between 44,000 and 98,000 United States hospital patients die each year, and more than one million are injured as a result of medical error (Institute of Medicine 2000). A small survey in British hospitals found that 11 percent of patients experienced an adverse event with a third of these events involving moderate to severe consequences, while about half of all events were preventable (Vincent et al 2001).

Although the scale of medical error is substantial, there is no certainty on numbers in the absence of any systematic measure of adverse events either in overseas or Australian hospitals; most studies extrapolate national figures from small samples. The Quality in Australian Health Care Study (using the 1991 Harvard study methodology) based on an analysis of over 14,000 medical records, estimated that 18,000 Australians die each year because of medical error and 50,000 suffer permanent disability – in other words, 16.6 percent of hospital admissions were associated with an adverse event (Wilson et al 1995). As Richardson has pointed out, assuming that 25 percent of deaths from adverse events are preventable, the 4500 preventable deaths estimated from the 1995 Australian study are equivalent to 13 Jumbo jet crashes per year (Richardson 2003). While the number is arguable, the hospital toll is certainly more than the road toll of 1634 deaths nationally in 2003 (Australian Transport Safety Bureau 2003). A more recent and lower estimate is that 10 percent of patients experience an adverse event in hospital, while 2 percent of patients experience serious effects (Runciman et al 2000). This latter proportion translates into large numbers given that in 2001-02, there were nearly 6.4 million admissions to Australian hospitals.

A second method, although imprecise and an underestimate, uses data collected on hospital separations (discharges) according to International Classification of Diseases (ICD-10) codes. On this measure, 4.1 percent of hospital separations were associated with an adverse event (the following numbers do not add up because some are multiple events): 1.1 percent involved an adverse drug effect, 0.1 percent a misadventure (such as an accidental laceration during surgery), 3 percent involved complications arising from a procedure, and 2.3 percent of adverse events were due to complications of medical and surgical care (such as an infection or post-operative haemorrhage) (Australian Institute of Health and Welfare 2004: 293).

Many hospitals now collect data on hospital-acquired infections. While health professionals had thought that the battle against hospital-acquired infections had been won, antibiotic-resistant micro-organisms are fighting back with a rise in multi-drug resistant strains. In the United Kingdom, for example, one in eleven people contract an infection in hospital, resulting in an estimated 5000 deaths per year, as well as huge costs to the National Health Service partly because patients who acquire infections spend twice as long in hospital (National Audit Office 2000).

Whatever the precise figures, it is clear that patients may encounter significant threats to their safety while in hospital – additional to any known risks associated with their treatment. The fifth annual report from the Australian Council for Safety and Quality in Health Care summarised five main areas of known harm where the need for patient care improvements is most urgent: medication, health care associated infections, blood, patient falls, and pressure ulcers:

#### Medication:

Misuse, under-use, and adverse reactions to therapeutic drugs result in 140,000 hospital admissions each year and cost \$380 million, while 10-20 percent of all adverse events are estimated to be medication-related and most are potentially preventable.

#### Health care associated infections:

The estimate is that about 150,000 health care associated infections occur each year and significant numbers are preventable.

#### Blood:

There is substantial inappropriate clinical use of blood products.

#### Patient falls:

Falls are a leading cause of injury and death among people aged 65 years and over, accounting for increased lengths of stay and higher health costs, and many are preventable.

#### Pressure ulcers:

Between 15-25 percent of patients in the health system develop pressure ulcers – and almost all are preventable.

(Australian Council for Safety and Quality in Health Care 2004: 19).

These alarming findings on the extent of adverse events occurring in hospital, let alone the *near-misses*, as well as critical verdicts on clinical performance by health professionals both inside and outside hospitals have resulted in the establishment of new regulatory bodies in several countries (McLoughlin et al 2001). Among other bodies, the United States established a National Forum for Quality Measurement and Reporting (known as the National Quality Forum) in 1999 following a recommendation from a Presidential Commission (President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry 1998). The United Kingdom, building upon previous initiatives, established the National Patient Safety Agency in 2001 and the Healthcare Commission in 2004. The Canadian Patient Safety Institute was established in 2003. Australia set up the Australian Council for Safety and Quality in Health Care in 2000.



## An ideas paper

The purpose of this paper is to foment ideas and stimulate strategic conversations about how to craft a research and policy agenda to improve the *governance* of Australian health safety and quality. Wellington (2004a) argues that *clinical governance* calls for health care governing entities to respond to the following challenges:

- ensure that effective systems are in place to safeguard and continually improve the safety and quality of clinical care;
- ensure that those systems support the creation of environments which foster a high level of professional involvement in, and responsibility and accountability for, clinical safety and quality; and
- monitor the performance of those systems, demonstrate a high degree of accountability to stakeholders for their performance, and respond effectively to any under-performance.

Our ongoing research partnership aims to fundamentally rethink these challenges. The partners in this collaborative venture are the Regulatory Institutions Network (RegNet) based at the Australian National University, the Australian Council for Safety and Quality in Health Care, and the Australian Capital Territory (ACT) Health. This three-year study, planned for 2005-2007, will be funded by a Linkages Project grant from the Australian Research Council (ARC), and by contributions from the research partners.

This ideas paper, the first step in this collaboration, draws upon regulatory theory and practice, and contemporary thinking on *networked governance*. We consider where *command and control* is still the most cost-effective strategy, and where less coercive strategies deserve our research attention. The health sector has a long tradition of *self-regulation*, although the complacent approach of “leaving it to the doctors” is now under challenge. To understand why these strategies deserve our attention, we first need to understand wider macro-sociological changes in the nature of governance that provide the context in which health *regulation* takes place. Key changes include the rise of the *regulatory state* in the 1980s, and the emergence of networked governance in the 1990s.

## Macro-context of health regulation

### The regulatory state

In quite fundamental ways, the nature of the contemporary state has changed to become a regulatory state. The first scholars to use the expression “*new regulatory state*” were the eminent health policy thinkers from the University of Bath, Rudolf Klein and Patricia Day, in the 1980s. They were referring to the Thatcher reforms of British health services, with separate purchasers and providers and much contracting out of health service delivery to the private sector, which left health authorities with the task of regulating by contract the quality of those services. In the 1980s, it was standard to speak of Western economies as entering an era of privatisation and deregulation which, in retrospect, was instead a decade of privatisation and regulatory growth. For example, when the Thatcher government shifted the provision of nursing home beds from the public sector to the private nursing home industry (Day and Klein 1987), 200 little nursing home inspectorates were set up in district health authorities around the country. These have now been combined under a huge national Commission for Social Care Inspection with over 2600 staff. Education is another area that started on a market trajectory under Prime Minister Thatcher. *League tables* on the teaching performance of schools by the Office of Education Standards (Ofsted), and comparable approaches to the performance of universities, became key regulatory tools so that consumers would have data to help them decide where to send their children.

What was called the “New Public Management” in Britain was called “Reinventing Government” in the United States (Osborne and Gaebler 1992). The slogan of the Clinton administration was that government should do “less rowing and more steering”. The nightwatchman state of classical liberal theory (Nozick 1974) and the Keynesian welfare state are both phenomena of the past. Jordana and Levi-Faur (2004:11) see the nightwatchman state, in which most steering and rowing was done in civil society, as the dominant model from the nineteenth century until the end of the Great Depression of the 1930s. The welfare state was the dominant model from 1945 to the 1970s when the state did much of both the steering and rowing. In contrast, the contemporary model of the regulatory state, in which civil society does most of the rowing with the state concentrating on steering, emerged after 1980 (see also Majone 1994; Loughlin and Scott 1997; Parker 1999; Braithwaite 1998). The United Kingdom regulatory state came into being because Mrs Thatcher would privatise a public utility, such as telecommunications, and then create a new regulator – the Office of Telecommunications (Oftel). Even the supply of water was partially privatised and then regulated by the Office of Water Supply (Ofwat). Fortunately, when rail was privatised, the new regulator was not called Oftracks because that is what happened when the regulator of privatised British Rail was under-resourced!

In Australia, the Keating Labor government also adopted aspects of economic rationalism (Pusey 1991) and moved privatisation into the heartland of the Keynesian welfare state. When it privatised the Commonwealth Employment Service, however, it also created an Employment Service Regulatory Authority. When John Howard's new government believed its own rhetoric on privatisation and deregulation in 1996, it continued the privatisation but without a new regulatory agency, and soon found itself embroiled in fraud scandals involving private providers of job placement services. In many other areas, however, the Howard government fell into line with other Western nations in building a bigger regulatory state. It partially deregulated nursing home inspection then substantially re-regulated it. Howard was a vociferous critic of Allan Fels' Australian Competition and Consumer Commission (ACCC), but once in government, substantially increased ACCC powers and resources. Just as the pages of regulatory laws, and the budgets and staffing of regulatory bureaucracies, increased under both the Reagan and Thatcher administrations (Tramontozzi & Chilton 1989; Ayres and Braithwaite 1992: Chapter 1), so this has continued under John Howard's conservative government. In 2002, for example, the Commonwealth Attorney-General's Department estimated that there were 1800 Commonwealth Acts in force, with 170 of these promulgated in 2001, and 148 in 2002. But more tellingly, the number of rules per Act, as well as their complexity and length, are increasing. For the 1990s, the number of pages of law per Act was twice the number for the 1980s, and three times the quantity for the 1970s (Argy 2003). Tax law is probably the most extreme example with a 27-fold increase in pages of law since 1970 (Inglis 2003).

The new institutions emerging in the era of the regulatory state involve a different kind of regulation from the command and control approach that first emerged from the New Deal in the United States before World War II. Command and control inspection of hospitals or factories still has a place; it still works to improve health and safety in some important contexts (see Gunningham and Johnstone 1999: Chapter 1; Gunningham and Grabosky 1998: 42-3). But in many contexts, regulatory administrations have found command and control to be counterproductive. In these situations, more flexible, participatory and devolved forms of regulation show promise. Exploring the potential of such strategies to improve the safety and quality of health services in Australia is the main purpose of this paper. The reason these strategies show promise is that the nature of organisational life has changed with the advent of an information economy. The information age, with widespread and rapid communication and most especially the Internet, has ushered in an age of networked governance. We must understand this development if we are to design better structures and strategies for the governance of health quality.

## Networked governance

Governmental capabilities have been devolved in many different directions. The strategic planning conducted by government departments must now take into account the plans of multiple pluralised nodes of governmental power and private sector interests if those departments wish to be relevant and effective. There is no point in a Commonwealth or State Health Department purporting to wield power that it does not possess. It can only plan meaningfully by taking into account other levels of government, the pharmaceutical industry, the hospital industry, a galaxy of health professions, global health research funding networks, myriad *accreditation* bodies, and the like. Governments mobilise networks of power to get things done. This approach is evident in the establishment of the Australian Council for Safety and Quality in Health Care (Box 1). The Council can be conceived as part of networked governance, or indeed as a *node of governance*, which brings together actors with influence over many different health system levers.

### Box 1. Australian Council for Safety and Quality in Health Care

The Council was established in January 2000 by the Australian Government Health Minister, with the support of health ministers from all states and territories, in order to lead national efforts to improve the safety and quality of health care. A policy advisory body, its secretariat is based in the Australian Government Department of Health and Ageing, and it reports annually to the Australian Health Ministers' Conference. Its terms of reference (until July 2006) stress its national leadership role and mandate to develop working partnerships with public and private sector stakeholders. The Council has an independent chair, Professor Bruce Barraclough, and its approximately 30 members include a nominee from each state and territory, as well as clinicians, consumers, quality experts, private and public health facility chief executives, and a representative from the New Zealand Ministry of Health. The Council works closely with a forum of state officials, and Council has working groups with co-opted extra members in order to oversee work in key program areas. A review of governance arrangements for safety and quality is being undertaken by a team appointed by AHMAC with recommendations to be made to the Health Ministers in July 2005.

Source: Australian Council for Safety and Quality in Health Care 2004

The concept of networked governance is particularly apt in the pluralist health sector with its multiplicity of interest groups and potential regulatory actors (see Figure 1). This recourse to collaboration by government is why networked governance is a major theoretical theme in contemporary social science disciplines (e.g. Rhodes, 1997; Bevir and Rhodes 2003; Clegg 1989; Slaughter 1997). The most ambitious re-theorising of state and society in network terms is the three volume magnum opus by Manuel Castells (1996, 1997, 1998) on *The Rise of the Network Society*. For Castells (1996: 500), “Networks constitute the new social morphology of our societies...the power of flows takes precedence over the flows of power.” By this he means that the way to govern others in such a society is to harness the right networks to your governance project. This, for example, is how comparatively powerless Washington legal entrepreneurs managed to build a network to launch repeated assaults on Australia’s Pharmaceutical Benefits Scheme (Drahos with Braithwaite 2002). Networked governance also implies more collaboration across the whole of government to tackle problems from drug abuse to security against terrorism. Cross- sector collaborations have profound possibilities for enriching democracy through learning by monitoring between government, the professions, non-government organisations and consumer groups in civil society.

**Figure 1. Types and levels of regulatory actors**



The federal system of government, and the pluralist nature of the health care field, means that a networked governance approach has been readily adopted by Australian governments. The number and variety of advisory groups, forums, and partnerships (the terminology varies), has multiplied dramatically over the last decade. The function of these bodies has also evolved from one of offering advice to government, to being a means of bringing coherence into the field and of organising stakeholders so that they can play a real role in governance. There are many examples of these inter-sectoral groups in the health field, but one of the best documented is the National Public Health Partnership (Box 2).

## Health partnerships

With complex issues like heart disease or medication error, and in the context of the pluralist health care field, public sector organisations at both the state and federal level realise that they cannot devise their strategic plans in isolation from the private and not-for-profit sectors. On medication error, for example, government needs to partner with the pharmaceutical industry. Government has the power to require warnings on package inserts and on advice to prescribers and pharmacists, and can collaborate with suppliers of pharmacy services and technologies (such as medication management and packaging systems).

### Box 2. National Public Health Partnership

Set up in 1996 by the Australian health ministers in tandem with the Public Health Outcome Funding Agreements, this Partnership pioneered an approach to coordinating intergovernmental population health policy and practice. An intergovernmental coordinating body that reports to the health ministers via the Australian Health Ministers' Advisory Council (AHMAC), it brings some policy coherence to the diverse area of population health, provides a forum for debates over funding, and helps set performance indicators to measure progress towards achieving public health objectives. The Partnership is serviced by a small secretariat in Melbourne and its membership comprises the chief health officers or directors of public health in each state and territory, the head of the Population Health Division in the Australian Department of Health and Ageing, a representative from both the National Health & Medical Research Council and the Australian Institute of Health and Welfare, and an observer from New Zealand. The Partnership also has an advisory group of non-government organisations and professional associations.

Sources: Lin and King 2000; Lin 2002

Government also needs to work in partnership with the medical profession, who prescribe and can educate and monitor patients, and with consumer groups and the media who can inform the public through consumer networks and media outlets. The aged care industry is an especially important target because it is mostly older people who are the victims of medication errors and over-prescribing. It follows that health regulation involves monitoring and evaluating the results of such partnerships.

## Nodal governance of networks

Shearing and colleagues have developed the theme of nodal governance (Shearing and Wood 2003; Drahos, Burriss and Shearing 2004). Because a network is more fluid and complex than older structures of government, like parties and ministries, understanding how governance unfolds is more challenging. The concept of nodal governance offers a way of thinking about possibilities for strategic regulatory action. A node is a place where resources, ideas, deliberative capability, and leadership are available to make networked governance buzz. The Australian Council for Safety and Quality in Health Care, the National Public Health Partnership and the National Obesity Taskforce (Boxes 1, 2 and 3) are also examples of nodes of governance. The questions are what type of node is likely to energise a network and where can they be found? These nodes are the focus of attention in this theoretical tradition, because a synoptic understanding of how a whole network and sets of networks operate is beyond our grasp.

Each of us only understands those bits of a network that we are able to monitor directly, but we may be able to grasp whether nodal governance can mobilise networks and link them together. Nodal governance means recruiting key actors who control different strands of governance, who can collaborate at a particular node, and who can tie these strands together into an effective web of controls. This is an old idea in Eastern philosophy. Around 89 BC, Sima Qian quotes the following exchange with Confucius:

“Do you think me a learned, well-read man?”

“Certainly,” replied Zi-gong. “Aren't you?”

“Not at all,” said Confucius. “I have simply grasped one thread which links up the rest.”

(Quoted in Castells 1996: 1)

A nodal partnership can connect strands of governance to produce action that can be monitored (albeit imperfectly) in order to assess its effects. Each strand of a web of controls that seeks to govern some persons or some phenomenon may be weak, and we may have only a dim understanding of this complex web of governance. If we pull the right strand at the right time, however, we might find that the entire fabric of the web of controls tightens to become quite strong. Conversely, if we pull the wrong strand at the wrong time, the entire fabric of control can unravel. Learning how to pull the right strand at the right time, according to Shearing, is accomplished by studying strategic nodes of networked governance. Nodes of public-private governance can apply the strategies discussed in this paper, such as *responsive regulation*, just as traditional government bureaucracies can apply them.

### Networked partnerships with the private sector

The reality of the new forms of public management in the information age reflects not just a hollowing out of the state with the growth of government by contract. Corporations, as the key partners of governments, have themselves been transformed into networks. Top-down design of strategy invites failure in the face of diverse market dynamics. Information technology now allows the decentralised retrieval of information about market dynamics from different points in space and time, and the integration of this information into flexible strategy-making and production systems. Small and medium-sized businesses increasingly link across borders with large corporations to form endlessly adapting networks. “Thus, the actual operating unit becomes the business project, enacted by a network, rather than individual companies or formal groupings of companies” (Castells 1996: 177). This logic also applies to health: for example, reducing medication error may be usefully viewed as a project that transcends the boundaries of companies, hospitals, and governments. Companies that fail to adapt to these new possibilities in the networked economy cease to compete successfully in global markets. Similarly, states that fail to adapt to the possibilities for networked governance fail to make it work to achieve objectives like good health outcomes.

The Australian health system encompasses a substantial private sector, including generalist and specialist physicians, laboratories, hospitals, and health insurance funds (Hilless and Healy 2001), and indeed a defining feature is its multiplicity of public and private sector interest groups (Sax 1984). Further, public sector organisations are finding it hard to resist the flexible production imperatives of their private partners. The distinction between private and public organisations is also becoming increasingly blurred. Thus, a hospital can no longer be categorised as either public or private but may, for example, be a public hospital co-located with a private clinic, or have been built with private capital (Bloom 2000). This means that a hospital can be classified along a continuum ranging from a government entity to an autonomised, corporatised, or privatised hospital (Jakab et al 2002). Public-private partnerships and networked partnerships consequently have become increasingly important. For example, a recently established partnership to tackle the growing problem of obesity in Australia with its adverse health consequences includes several representatives from the private sector, including the fast-food multinational, McDonalds (see Box 3).

### **Box 3. National Obesity Taskforce**

In 2002, the Australian Health Ministers agreed that overweight and obesity are significant public health problems for Australia. The terms of reference for a National Obesity Taskforce were announced in early 2003 – principally, the Taskforce was to develop a national action plan and to “lead communication within sectors and jurisdictions about implementation of the action plan”. The Taskforce reports to Health Ministers via the Australian Health Ministers Advisory Council (AHMAC). The Taskforce is chaired by the Secretary of the Australian Government Department of Health and Ageing, with members from several state health departments (currently New South Wales, Victoria, and Tasmania), chairs of three other partnerships (the National Public Health Partnership, the Strategic Intergovernmental Nutrition Alliance, and the Intergovernmental Forum on Physical Activity and Health), and a scientific adviser. The Taskforce has a Scientific Reference Group, and a Consultative Forum comprising representatives from 24 interest groups, including the community (eg. the Australian Consumers Association), experts (eg. the Australian Divisions of General Practice) and the private sector (eg. McDonalds). The Taskforce has a high level of commitment from the national government (chaired by the Secretary of the Department) and is advised by a wide-ranging Consultative Forum including seven private sector representatives out of a total of 24 taskforce members.

Source: National Obesity Taskforce 2003



## Democratic experimentalism

Democratic institutions that require transparency (ie. observation of others' *benchmarks* and errors, and public reporting of *continuous improvement*) become fundamental to effectiveness in safety and health. Dorf and Sabel's (1998) concept of "democratic experimentalism" is an emergent pragmatic form of management with its origins in the complexity and flux of the information age. They argue that production systems in developed economies now require the decentralised and collaborative design of innovations. The upshot is a world where the private-public divide is increasingly blurred, where steering collaboration is everything, and where undertaking actual production is less important.

Perhaps the most crucial element of democratic experimentalism is that public policy becomes more evidence-based. Here the health sector has pioneered the paradigm with the Cochrane Collaboration: a web-based network of knowledgeable researchers who focus on a particular therapeutic intervention, and who use the Internet to provide a continually updated account of what works, what doesn't, and what's promising. The Regulatory Institutions Network (RegNet) is also actively involved in developing a parallel Campbell Collaboration to foster evidence-based regulatory administration and policy science.

In the health sector, there is a long-term opportunity for a government-university collaboration with business and civil society that will allow Australia to become an international leader in evidence-based health safety and quality improvement. This ambition to be democratically experimental, as opposed to governments being cautious, allows the private sector to bear some of the burden for making the mistakes that go with innovation. Other opportunities arise through research collaborations between government and public sector partners. One such example is our three-year Australian Research Council (ARC) research project for 2005-07, a collaboration between RegNet, the Australian Council for Safety and Quality in Health Care and ACT Health, aimed at identifying successful regulatory strategies for improving the safety and quality of health care for patients. One aim of this partnership is to study strategically selected "islands of innovation", then to reflect on the regulatory strategies that might expand these islands and their national and international relevance. Another such example is the Centre for Research Excellence in Patient Safety based at Monash University that has been established by the Australian Council for Safety and Quality in Health Care, which intends to promote and develop resources to improve patient safety, and to build health services' research capacity.

An ambition for Australian health policy makers could be to initiate a research process that would trigger investment from health funders and international foundations to conduct strategic randomised controlled trials of regulatory interventions to improve health safety and quality. The Australian Government has only recently begun looking to education and health as sectors that are assets to the economy through their export of services and goods. Government does not have a strong record in biomedical research and development (R&D), although some health sector export examples include the bionic ear, the broad-spectrum anti-flu drug Relenza, and information technology such as the Diagnostic Related Groups (DRG) software for *casemix* funding and the analysis of hospital patient costs. The expectation should be that Australia could look to exporting procedures for improving the safety and quality of health care.

## Current approaches to regulatory mechanisms

### Ordering of regulatory mechanisms

Issues of governance resonate within the Australian health sector, characterised as it is by a tradition of medical autonomy, its many public and private providers and occupational groups, and its split Commonwealth and State powers. *Responsive regulation*, as discussed later, is proposed as a paradigm that transcends the regulation-deregulation dichotomy by allowing “win-win” solutions in regulatory design (Ayres and Braithwaite 1992). The rationale is that regulators are most likely to achieve their goals by using a variety of strategies, and by invoking escalating sanctions. Regulation in the health sector has traditionally been “soft”; essentially non-interventionist and reliant upon self-regulation by doctors, backed up by the sanction of professional bodies in instances of glaring incompetence. There are, however, a multitude of regulatory strategies available to public agencies, in addition to the “hard” options that specify rules and punish their infringement.

As a “steward” of the nation’s health (World Health Organization 2000), government has a central interest in optimising health outcomes and minimising harm. A key purpose of regulation, the abatement or control of risks to society (Sparrow 2000), has emerged as central to health regulatory strategies in Australia. The Australian Council for Safety and Quality in Health Care has thus been charged with finding ways to reduce risks to patients (Barraclough 2001). The government’s responsibility as a steward of the nation’s health extends its purview beyond the bounds of the public sector to ensuring that the private sector also does not place the public at risk.

The push for safer health care represents a major challenge to professional self-regulation. In the United Kingdom, a series of medical scandals led the editor of the *British Medical Journal* to proclaim that the old system of relying solely upon self-regulation was dead (Smith 1999). We go on to argue that professional self-regulation need not be dismissed as totally worthless for maintaining safety and quality, but we do propose that a credible system of *meta-regulation*, (ie. the external regulation of self-regulation), provides a relatively low-cost way of ensuring that health service providers are cognisant of, and capable of, meeting their professional obligations.

The last few years have seen a dramatic expansion of interest in safety and quality issues in Australia and other industrialised countries, and with it, the emergence of more regulatory actors and a proliferation of regulatory strategies intended to improve safety and quality. The regulatory actors (see earlier Figure 1) may involve government, the market, the voluntary sector and the public. Gunningham & Grabosky (1998: 424-6) identify four categories of policy instruments: command and control regulation, economic instruments, self-regulation, and voluntarism. *Command and control* involves direct regulation or enforcement by the state (eg. licensing professionals and facilities, and enforcing performance standards). *Economic instruments* may be wielded by government (eg. controlling supply-side incentives under Medicare), by health care purchasers (eg. buying the safest and best health services), or by consumers (eg. who use information to make informed decisions on the safest hospitals). *Self-regulation* is where an organised group regulates the behaviour of its members, and might involve an industry-level organisation or a professional association setting rules, standards, and codes of practice relating to the conduct of its members. *Voluntarism* is based on the individual firm, or individual professional, undertaking to do the right thing without any basis in coercion.

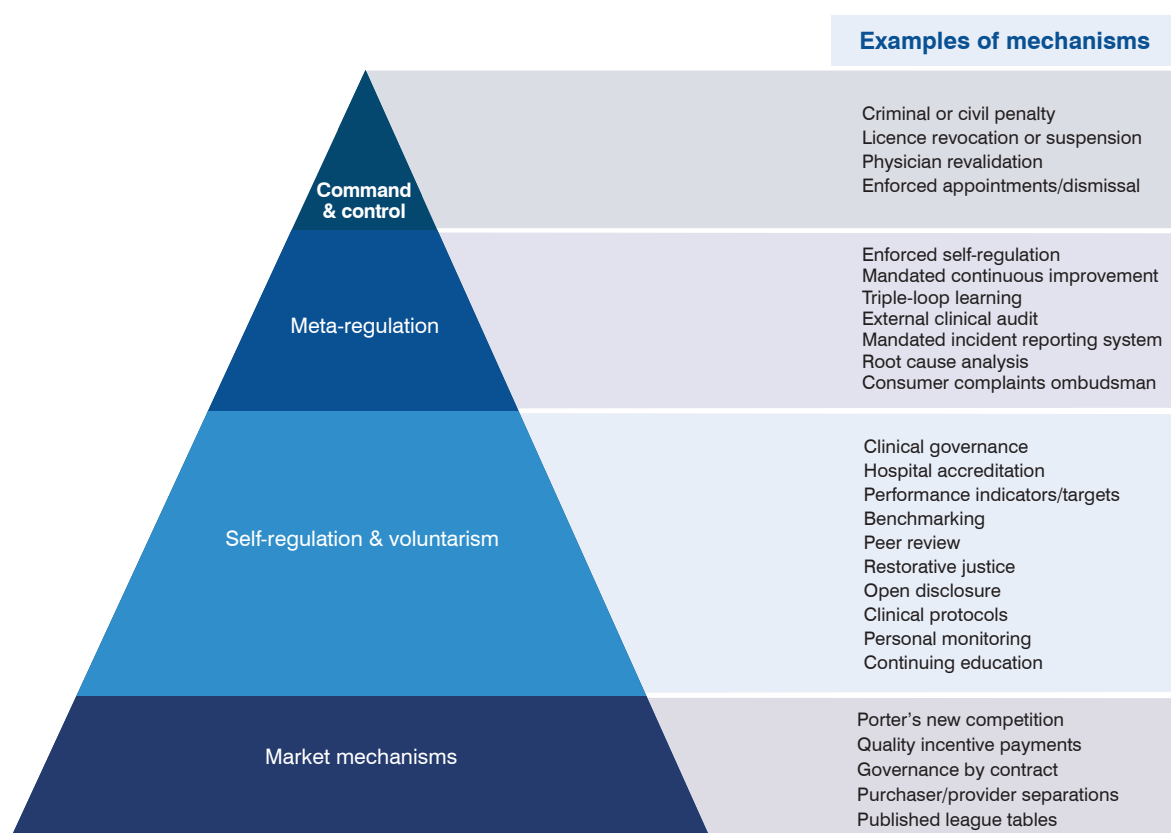
Figure 2 groups the regulatory strategies that we will consider in this paper within a responsive regulatory framework. At the base of the pyramid, neo-liberal governance has a definite preference for attempting to govern health and safety using market mechanisms, including consumer preferences. We will argue that market mechanisms are often unsuccessful in protecting consumers. For example, the impact on quality of funding mechanisms intended to improve cost-effectiveness in hospitals is not clear (eg. Diagnostic Related Groups - DRGs). Other caveats are that health care is a public good as well as a commodity, and that consumer choice is often limited. For example, the concentration of technology in large facilities combined with large geographic catchment areas limits consumer choice and competition between large regional hospitals – except in large cities where hospitals are historically and inequitably centrally concentrated.

Government by contract, as opposed to regulation by rules, continues to be a dominant strand of neo-liberal thought about health. Purchaser/provider separations that replace provider monopolies with competition to supply health services have been abandoned as failed reforms in many places, including the Australian Capital Territory (Webster 2004). We will see later in this paper, however, that recent work on a new strategy for health competition holds out promise for market-driven improvement in health safety and quality.

Health and safety could be delivered without government intervention if consumers really were sovereign. But when markets fail, we are prepared to escalate up the pyramid to more interventionist and costly forms of government regulation until safety and quality is secured. At the peak of the pyramid in Figure 2, the most interventionist strategy is regulatory command and control.

We will argue toward the end of this paper that there remain some challenges that are best regulated by command and control strategies, such as cancelling the licenses of incompetent health providers. But the thrust of this paper is that, in an era of networked governance, we will see more failures of command and control strategies, of economic instruments, and of voluntaristic self-regulation. But there is promise in a variety of forms of regulated self-regulation – meta-regulatory strategies. These include the external audit of the quality of internal clinical audits, continuous improvement strategies, and others. All self-regulatory strategies shown to be effective when implemented successfully can be transformed into effective meta-regulatory strategies.

**Figure 2. Regulatory pyramid and health care safety and quality mechanisms**



### Monitoring safety and quality

Networked governance means a shift in both the private and public sector from Fordist control of a systematically specialised production system (Henry Ford's Detroit production line), to post-Fordist steering of more volatile systems that are partially contracted-out and partly contracted-in. Health systems are also subject to postmodernist pressures towards complexity, with a shift away from collective to pluralist services, given increasing demands from more diverse populations and consumer groups for services that are responsive to their particular preferences and needs (Healy and McKee 2004). In a volatile market, shifting collaborative producer groups compete for contracts. According to the "democratic experimentalism" identified by Dorf and Sabel (1998), this competition is part of the error-detection system; groups watch for flaws in the work of competitors so they can show how their output can surpass the benchmark.

Excellence is grounded in collaboration, and the detection of poor performance in competition – or at least the promotion of an open and more transparent health care system. Everyone is learning how to continuously improve by monitoring everyone else. Monitoring and steering is, therefore, not only top-down. Current production methods institutionalise more participatory and complex forms of self-regulation in the production of public goods, as well as private ones. Consumer input is therefore crucial, especially given the explosion of information (eg. on the Internet). An increasing policy emphasis on public information and citizen participation means that consumer groups are better placed to demand better quality health care (as discussed later in Box 6).

## Benchmarking

In a volatile market, one of the first things firms do as they explore how to improve their efficiency is to benchmark: survey promising products or processes that are superior to those they use.

*Benchmarking* is designed to disrupt expectations of what is feasible by a comparison of actual performance, and to spur exploration of new possibilities. Independent units then collaborate with others to engineer competing visions. This throws up quite a steering challenge when selecting which group will become the producers of the final design that integrates the best components. Dorf and Sabel (1998) see successful firms as accomplishing progress through “learning by monitoring”.

A benchmark, defined as “a standard or point of reference for measuring quality or performance”, and benchmarking, defined as “a continuous process of measuring quality or performance against highest standards” (Australian Institute for Health and Welfare 2004: 486), have been adopted as tools for improving performance in the Australian health care system. There are many examples of benchmarks set in the health sector - one being age-standardised participation targets set for screening women for cancer. One difficulty in setting benchmarks for safety and quality, however, is the lack of statistical information on *adverse events* (as discussed in Box 4).

### Box 4. Monitoring statistics on adverse events

There are no accurate statistics on the number of preventable adverse health events in Australia. The National Health Information Group, which was established in 2003 and reports to the Australian Health Ministers' Advisory Council (AHMAC), noted this information gap in its 2003 report. While some imprecise data can be gleaned from hospital statistics, little is available from other areas of health care, such as general practice and aged care. The Group therefore supports the objectives of the Australian Council for Safety and Quality in Health Care in promoting the collection and analysis of information on adverse events. The Council has called for reporting on a common set of sentinel events, for better use of hospital data to report adverse events, and supports the use of electronic clinical records.

Source: Australian Institute of Health and Welfare 2004: Chapter 7

## Continuous quality improvement

Private sector management models intended to improve performance have also been adopted by the public sector. *Continuous quality improvement* (CQI) and total quality management (TQM) principles and techniques have proved popular. Compared to a command and control model, managers are freer of public service rules although there is more monitoring of outcomes.

Quality improvement programs have been heavily promoted in the health sector over the last decade. Such programs usually are left to health providers to adopt voluntarily, and the results from implemented programs have been disappointing. Walshe (2003: 7) and others (Shortell et al 1995; Blumenthal and Kilo 1998) argue that the limited progress made by total quality management and continuous quality improvement programs in the United States is partly explained by a failure to recognise the limits of intra-organisational improvement efforts, in an environment that is at best uninterested, and at worst, actively hostile towards quality improvement. Pressure upon Australian hospitals over the last decade or so to contain costs also has been unrelenting and this has meant that quality issues have received less attention.

Despite considerable and varied attempts at dissemination in the United Kingdom National Health Service, the take-up rate of best practice by health professionals is not encouraging. There has, for example, been a time-lag of several years in prescribing thrombolytic drugs in the treatment of post-heart attack patients (cited by Freemantle 2002). Such evidence of sub-optimal performance, coupled with medical scandals, prompted the United Kingdom to move towards externally enforced requirements to institute clinical governance in hospitals, and to require doctors to submit to regular revalidation. General practitioners also are being held to account for patient health and safety. Therefore, they will require support, including the information technology to interrogate patients' histories, to detect adverse drug interactions, to receive emailed warnings on recalls or epidemics, and to consult the databases that underpin evidence-based health care.

### Error detection

Crucial questions for the regulatory thinker are “How can risks to patients be monitored?”, and “Who manages the reporting to monitor continuous improvement?” The health sector has sought to draw lessons for hospital safety from the aviation industry (Australian Council for Safety and Quality in Health Care 2004a). This industry has an *error reporting system* that seeks to document events, including near-misses, caused by system failure and not just human failure. The aim is to identify and then analyse the things that go wrong in health care delivery in order to prevent future occurrences. As noted earlier in Box 4, there is limited information on the incidence of adverse events involving patients in Australian hospitals, let alone near-misses. Many health care providers, therefore, have undertaken to collect and transmit reports for a register of adverse events (see Box 5). The problem is that under-reporting is endemic for various reasons, and there are a number of policy issues that need to be resolved, including: whether reporting should be compulsory or voluntary; whether it should be confidential; the consequences for an identifiable individual; the sample size needed to draw statistical conclusions; and whether reporting actually does result in improved patient care.

## Box 5. Adverse events registers

Many hospitals have adopted the Australian Incident Monitoring System (AIMS), as have several States. A preliminary analysis of Victorian data on sentinel events, however, suggests substantial under-reporting (Runciman 2004), as has a South Australian study (Smith et al 2004). The United Kingdom National Health Service has set up a voluntary reporting scheme for adverse events and near-misses (Donaldson 2000). The biggest hospital accreditor in the United States, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), requires its members to report on adverse sentinel events – but the data still suggests significant under-reporting.

Source: Donaldson Report 2000; Conference Papers 2nd Australasian Conference on Safety and Quality in Health Care, Canberra, 2004

The challenge in improving reporting, analysis, and action is to move “beyond blame” and to develop a “culture of safety”, or a “just culture” (Wellington 2004b). This requires the adoption of a “systems approach” to error which recognises that human error, more often than not, is the consequence of systems failure rather than the failure of an individual (Reason 2000). Thus “naming, blaming and shaming” an individual does not improve safety and quality when the systems problems are ignored. Moving beyond a culture of blame, however, does not mean an escape from accountability. Accountability entails, among other things, a commitment to investigating and understanding the underlying systemic factors that contribute to adverse events, and a commitment to providing personal and professional support to staff and patients (Wellington 2004b:np). A just culture, therefore, is one with “appropriate accountability [measures] but no presumption of moral culpability when things go wrong” (Wellington 2004b: np). Moving beyond a culture of blame means a move from passive to active responsibility. Passive responsibility means holding someone responsible for something that has happened in the past. Active responsibility means voluntarily taking responsibility for putting things right in the future. Active responsibility is a virtue nurtured in a culture that values learning. Immediate recourse to blaming and shaming allows people to accept passive responsibility that kills off active responsibility. We go on to argue in this paper that *restorative justice* is one strategy for encouraging active responsibility (Braithwaite 2002).

### Consumer perspectives

The substantial under-reporting of adverse events by health professionals, whether under a compulsory or voluntary system, suggests that more errors might be picked up if health care users also were encouraged to report adverse events. The state expects that health care providers should inform patients on their rights, including the right to complain (see Box 6). Vincent and Coulter (2002) point out, however, that it is striking how little attention the safety movement has paid to the patient’s perspective. The health care system should educate patients to expect reasonable standards and to ask good questions of health professionals. Patients are often not in a strong position, however, to monitor safety and quality. They often lack the information necessary to make an informed treatment choice, or to monitor the quality of care they are receiving. They may be vulnerable because of illness, and they may be in an unfamiliar and very confusing hospital environment (Australian Council for Safety and Quality in Health Care 2001; 2003c).

## Box 6. Consumer complaints procedures

Many countries have signed up to international treaties that have consequences for patients' rights. In addition, a number of documents, while not legally binding, carry moral authority including principles on patients' rights enunciated by the World Health Organization. Australia also has passed legislation that formalises the relationship between physicians and their patients, including the right to informed consent. Most Australian States and Territories have an ombudsman or commissioners external to the health system to whom patients can take their complaints. Patients' rights have been defined formally in charters drawn up by health administrators in many jurisdictions, although their adoption by health care providers is voluntary – except in some States in the United States where they have legislative force. Many hospitals have patients' complaints procedures in place, some have an internal ombudsman, while most hospital boards seek representation from citizens who could then voice any safety and quality concerns. Patient surveys are an occasional mechanism for taking patients' views into account. Some countries pay systematic attention to patient complaints by: including complaints data in audit programs; by offering patients access to a register of adverse events; and in the United Kingdom, by taking patients' complaints into account in the revalidation of doctors.

Source: Healy & McKee 2002: 134-136

Consequently, regulators and consumer groups seek to redress the unbalanced power relationship by safeguarding patients' rights through legislation, by including citizen participation on management boards, through the promulgation of service standards, and by establishing complaints procedures that are either internal or external to an organisation. The potential influence of the patient can be considered in terms of “exit” and “voice” (Hirschman 1970). Voice is a political concept that refers to a person's ability to influence an organisation while continuing to use its services – the citizen participation model. Exit is an economic concept that refers to a person's ability to leave an organisation and to seek services or products elsewhere – the market model (McKee and Healy 2002: 135).

### Internal and external mechanisms

A striking aspect of the health regulation literature on health safety and quality is that it is overwhelmingly about what Walshe (2003: 5-8) calls “internal” approaches to improvement. Further, the normative assumption is that the adoption of techniques for improving performance is voluntary on the part of health professionals; whether it be continuous quality improvement, incident reporting, benchmarking, or following *clinical protocols* (see Box 7). For example, considerable effort goes into developing clinical protocols that are left to doctors to consult voluntarily, and then to exercise their professional judgement. Compared to traditional medical practice, doctors are no longer expected to rely solely on their own clinical judgement, or to apply received wisdom from their seniors or teachers (handed down perhaps twenty years ago) – but instead, to practice evidence-based medicine – or at least to consult the guidelines on what should be standard practice.



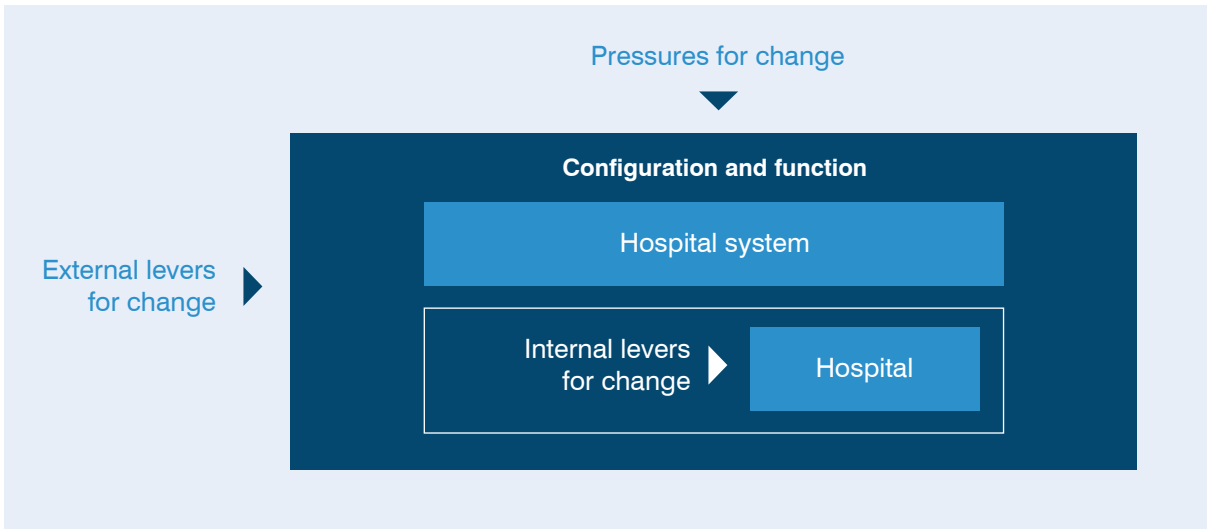
Walshe argues that the problem with this “soft” and voluntarist approach to health regulation is that it treats an organisation as if it exists in isolation from its environment, oblivious to the institutional, social, and economic pressures that drive organisational willingness to contemplate internal reforms. In the case of a complex organisation, such as a hospital, it should be seen as an open system that interacts with its environment to secure the resources necessary for survival, adaptation, and growth (see Figure 3). Thus, there are external levers available for improving hospital safety and quality, as well as internal levers in the hospital that arise from its structure, functions, and culture (McKee and Healy 2002).

**Box 7. Clinical protocols**

Clinical protocols, also termed care pathways, are developed to guide the treatment of a specific condition. A protocol recommends what should be done and how, and when it should be done to achieve an optimal health outcome. These clinical protocols have been developed by professional associations, by large employer organisations such as hospitals, by research institutes, and by departments of health. This process has been aided enormously by the Cochrane Collaboration, an international collaboration that has established a procedure for undertaking and disseminating systematic literature reviews of the effectiveness of a range of health care interventions, with the database available on the Internet ([www.cochrane.org](http://www.cochrane.org)). This database is free to all Australians via various health websites. The United Kingdom Department of Health was a pioneer in developing a guideline in 1998 for the management of cardiovascular disease, and the National Institute for Clinical Excellence (NICE) now issues regular guidelines as well as “national service frameworks” that are compilations of evidence on the overall management of certain conditions spanning prevention, treatment and rehabilitation. The value of clinical protocols and frameworks is that they offer a standard against which to assess the safety and quality of clinical performance.

Source: McKee and Healy 2002.

**Figure 3. The hospital as a system (Source: McKee and Healy 2002 Figure 1.1)**



Hospital performance is influenced by the interaction between its external incentives and its organisational structure, and if the external environment does not generate pressures to improve safety and quality, the hospital may have little reason to strive for better performance (Preker and Harding 2001; Jakab et al 2002). Even with well-directed external pressures, however, the hospital's response may be moderated by its organisational structure, as Walshe (2003: 7) explains:

For example, a hospital may have a superb continuous quality improvement programme, but if the purchasers are only interested in getting the lowest price possible for a service, then however motivated the organisation, it will be difficult to sustain its commitment to excellence. In another setting, healthcare providers might be striving to collaborate using "breakthrough" methodologies to learn from best practice elsewhere and bring about improvement, but if they exist in a highly competitive marketplace, the pressures upon them are highly likely to prevent the open sharing of innovations that confer competitive advantage, thereby undermining the whole concept of collaborative improvement. Internal approaches to improvement implicitly assume that the organisation is not the way it is because of the financial, commercial or political environment in which it operates, and that the organisation can swim against the tide of that environment. Organisational theory suggests that both assumptions are highly suspect (Cook et al 1983).

Internal approaches need to be complemented by external ones, especially in regulation. Accreditation is an example of a regulatory mechanism that has achieved consensus on the need for an independent and external review (see Box 8). Accreditation involves an independent body evaluating the degree of compliance by an organisation against previously determined standards and, if the organisation is adequate, awarding a certificate. The "best" type of hospital accreditation system remains a matter of debate internationally. Accreditation has two different but related goals. The first is to provide a guarantee that an organisation meets a defined minimum standard; the second is a developmental process through which best practice is promoted. It appears axiomatic that accreditation meets the first goal, but there is little empirical evidence on whether accreditation is a cost-effective strategy for raising performance standards.

### Box 8. Accreditation

The Australian Council on Health Care Standards was established in 1974 as an independent not-for-profit body, is the major accreditor of hospitals, and had 741 accredited public and private health facilities as at June 2003. A developmental approach has been taken in enrolling applicants in a quality improvement program (EQuIP) as part of accreditation, but from January 2005 applicants are also expected to meet mandatory criteria for accreditation. The other main accreditation agencies are: the Quality Improvement Council that accredits mainly community health and welfare agencies; Australian General Practice Accreditation Ltd that accredits general practices; and the Aged Care Standards and Accreditation Agency that accredits residential aged care. The Australian Council for Safety and Quality in Health Care has proposed the establishment of a national framework and a national body to coordinate accreditation.

Source: Australian Council for Safety and Quality in Health Care 2003b; McKee and Healy 2002; Scrivens 2004.

The first issue is that hospitals are seldom “failed”, since Australian accreditation bodies have preferred to act as “coach rather than referee”, and because the consequences of losing accreditation are considerable. A second issue is whether accreditation should be voluntary or compulsory. Originally a voluntary system, most Australian public hospitals now seek accreditation, some States require all public hospitals to be accredited, while private insurance funds pay higher reimbursement to accredited facilities. A third issue is the extent to which accreditation is moving towards scrutinising performance and health outcomes - not just the adequacy of the facility. A fourth issue is whether a national accreditation system is needed in order to produce uniformity across jurisdictions and across public and private organisations.

### Performance indicators

Walshe (2003) condemns crude economic approaches to regulation that assume that the introduction of competition into a health system will automatically translate into internal reform. For example, the public disclosure of rankings of the clinical outcomes achieved by doctors and hospitals, often referred to as “league tables” (see Box 9), has aroused interest as a strategy both for improving standards and for informing consumers. The expectation is that standards should rise after public disclosure, while “naming and shaming” would prompt failing health professionals and failing hospitals to improve. The second rationale is that such public information should enable patients, and the referring health professionals, to make choices about specialists and hospitals – assuming that such choice exists. One adverse outcome of public rankings is that providers may attempt to “cream” patients who are likely to have good health outcomes, and pass on the hardest cases in order to move up the league table.

#### Box 9. League tables of clinical performance

Many countries now publish various *performance indicators*, such as hospital waiting times and surgical success rates. Several North American states publish death rates for individual surgeons, while the Department of Health in England has published league tables on a set of criteria for NHS hospitals since the late 1990s. This allows hospitals and the public to compare hospital performance. These rankings are contested on technical and managerial grounds, and there is disagreement over whether “real” improvements result (McKee and Healy 2002: 132-4). However, the United Kingdom Healthcare Commission plans to publish performance ratings, as well as “star ratings” for top performers. So far in Australia, performance information is used mainly for internal comparisons within professional groups or within groups of hospitals. The Australian Health Care Agreement between the Commonwealth and the States and Territories for 2003-2008, however, requires the collection and publication of performance indicators for the public hospital system.

Another problem is that the use of soft measures can trigger litigation from those who get bad results. The result is that the more reliably measurable can drive out the more important. Another concern is that providers may practise defensive medicine (eg. ordering excessive diagnostic tests), in order to protect against risks that might drive them down a league table.

### Standard setting

In the mid-1980s, the state of Illinois introduced a system of rewards (higher Medicaid payments) for nursing homes graduated according to the quality of care delivered (the Illinois Quality Incentives Program). Some other North American states, including Michigan and Massachusetts, also experimented with this approach. The Illinois Quality Incentives Program won an Innovation in Government Award from Harvard's Kennedy School of Government and the Ford Foundation. But in the early 1990s, the program was abandoned as a failure. The reason was revealed by an ethnographic study of United States nursing home regulation (Braithwaite 1994): when rewards were put in place for increasing the number of residents participating in activity programs, the researchers noted sleeping residents in wheel chairs being wheeled into the room where an activity was going on, such as craft or a game, so that they could be recorded in the head count as participating.

One very important standard related to the existence of a "homelike" environment. To what extent could residents domesticate their little piece of institutional space? This kind of empowerment could take many forms – rearranging the bed and other furniture, carpets, even keeping a beloved pet. Counting the pictures on the wall is the easiest quantitative way to operationalise this standard. And, of course, quantitative measures that can be calibrated unambiguously are what inspectorates like when ratings can be contested in a court of law. Sure enough, nursing home staff told the researchers that the observed large numbers of pictures of movie stars, often torn from the same magazine, had been slapped up around the nursing home on the instructions of management in anticipation of the arrival of the inspectors.

The fieldwork even revealed nursing homes where pot-plants on short-term hire were returned as soon as the inspection was completed. The bigger the incentive, the more complex the phenomenon regulated, the more creative health administrators can become in fabricating an appearance of quality to outflank economic instruments of regulation (see Braithwaite 2001).

Regulatory strategies fail when they ignore the subtleties of organisational behaviour and the cultures of the professions being regulated (Aiken and Sloane 2002). They fail when naïve, universal assumptions are made that the mechanics of change are simple. One size fits all strategies that appear rational at the macro-level can turn out to be arbitrary and inappropriate at the micro-level of application for a specific service provider.

## Competition and quality

The world's leading thinker on competitive strategy, Michael Porter of the Harvard Business School, sees a paradox in the fact that the United States has the most aggressively competitive health care system in the world, but a system that delivers much less cost-efficiency and poorer outcomes than less competitive systems (Porter and Teisberg 2004). How, they muse, could it be that in a competitive market it takes 17 years on average for the results of clinical trials to become standard clinical practice. Surely the market would drive providers who failed to adopt the improved practice out of business? The paradox arises because, at the micro-level, North American health care organisations seek to compete less in curing the comparatively sick and poor, and more in creaming the comparatively healthy. They seek to compete less in cost-reduction and more at cost-shifting (eg. shifting costs from payer to patient, from health insurer to hospital, from hospital to doctor, from insured to uninsured, and so on). So insurer payments foster competition in the provision of cheaper treatments, rather than more effective or innovative ones. If the treatment fails, the hospital gets another admission and another payout.

Porter and Teisberg's (2004) diagnosis of the United States health system is that competition occurs at too macro a level – at the level of insurers, networks, and hospital groups. In Australia as well, it could be contended that competition occurs more at an institutional level than at the level of service delivery. To improve safety and quality at reduced cost, competition needs to occur at a more micro level – disease by disease, patient by patient. Porter and Teisberg (2004: 4) cite the accomplishments of the Texas Heart Institute in achieving surgical costs one-third to one-half lower than other providers despite taking on the most difficult cases. They achieve this by specialising in a disease in which they both “learn to do it right the first time”, and learn to innovate:

Providers should compete to be the best at addressing a particular set of problems, and patients should be free to seek out the providers with the best track records given their unique circumstances. In the current environment, where patients' treatments are determined by the networks they are in, network providers are all but guaranteed the business.

(Porter and Teisberg 2004: 4)

Internally oriented reformers for health safety and quality are thus too micro in their orientation, and the external reformers (especially the health economists) are too macro. What is needed is more micro-macro synthesis. Regulatory theory provides an alternative path to such a synthesis, particularly through the idea of meta-regulation. We will see that meta-regulation is about macro-regulation of micro-regulation, and the external regulation of internal regulation.

## New approaches to health regulatory mechanisms

### Meta-regulation

In a world of networked governance, wherein private and public organisations get things done by forging new partnerships, it is imperative that organisations not only manage their own risks, but also manage the way in which their partners manage their risks. Drawing together longstanding themes in the regulation literature with more recent writing on neo-liberal governance, Grabosky (1995) developed the theme of meta-regulation, which he called “meta-monitoring” – government monitoring of self-monitoring, and he elaborated on these ideas with Gunningham (1998) in *Smart Regulation: Designing Environmental Policy*. Parker, in *The Open Corporation: Self-Regulation and Corporate Citizenship* (2002), used this approach to explore notions of meta-regulation and meta-evaluation, that is, the evaluation of corporations’ self-evaluations of their compliance systems. Another version of meta-regulation is found in Morgan’s (2002) analysis of National Competition Policy in Australia. In this section we draw upon these ideas, but with a risk-management orientation applicable to health safety risks.

According to Beck’s (1992) influential book, *Risk Society: Towards a New Modernity*, societies have become more reflexive about risk. One of the earliest shifts of this kind was with nuclear safety regulation after the near-meltdown of the nuclear reactor at Three Mile Island in 1979 (Rees 1994). Nuclear power plant operators had become rule-following automatons rather than strategic thinkers about risk management systems. When something went wrong that was not covered by a rule, operators lacked the systemic wisdom – the risk analysis intelligence – to think about what needed to be done. In response to this near-miss (or near disaster), the nuclear regulation paradigm changed to being less about government inspectors checking compliance with rules, and more about regulatory scrutiny of risk management systems, as well as re-integrative shaming, where necessary, within the nuclear community of companies. Within a decade, SCRAMS (safety-related automatic shut-downs of nuclear plants) fell from 7 per-unit-per-year to average less than 1 per year in the United States and then, in the next decade, fell to 0.1 per year (Braithwaite and Drahos, 2000: 302). The huge improvements in Western nuclear safety in the 1980s were put at the disposal of the former Soviet nuclear industry after the Chernobyl disaster. Every problem nuclear plant in Russia, for example, was partnered with a Western European (mostly German) plant with highly developed risk management sophistication.

Another important shift of this type occurred following the Piper Alpha disaster in 1988 when 165 people lost their lives on a North Sea off-shore oil rig. Following the recommendations of Lord Cullen’s Enquiry on the disaster, regulation of off-shore oil and gas production worldwide became based on the rig operator developing a “safety case” (a safety management system) that it submitted to the regulator for analysis and approval (Cullen 1990). Instead of government inspectors directly enforcing rules, they moved to checking that the operator was both self-enforcing its safety management system, and continuously improving it.

The most recent debate about this regulatory paradigm shift occurred after the Asian financial “meltdown” of 1997-98. The twentieth century approach to ensuring that banks did not collapse was to insist upon a certain ratio of loans to gold in a bank vault – enough capital to withstand a run on the bank and non-repayment of loans. Over time, the required capital ratios became more complex. Bonds of an OECD government counted for more than bonds in a private company. But in a crisis, these capital adequacy ratios did not always make sense. In the midst of the Asian financial crisis, for example, were General Electric or Microsoft bonds really less secure than bonds with the South Korean government – an OECD member that was bankrupt? Many experts believed it would be better to require banks to disclose their risk management systems and also the risk assessments of their portfolio of reserves to national and international regulators. Moreover, the banks should test whether these systems could cope with major shocks. For example, the regulator might ask: “Run your risk-management software and prove to me that you will be solvent if there is a 40 percent fall in the value of the yen at midnight tonight”. While the complexity and volatility of financial risk in a world of derivatives and rapidly fluctuating currency markets would seem to make this regulatory paradigm shift vital, in practice, regulators are finding it difficult to design a reflexive system for evaluating the assessment of financial risk which will work with both sophisticated global banks and banks with lesser risk analysis capabilities. Nevertheless, it seems this is the direction prudential regulation will move (Mayes et al 2001). Analogies in the health sector are how a hospital health safety system would cope with a sudden influx of patients exhibiting Severe Acute Respiratory Syndrome (SARS), or with an outbreak of a particularly virulent multi-drug resistant strain of *Staphylococcus aureus*.

Braithwaite (2005) has analysed the application of meta-risk management by the Australian Taxation Office. One example of meta-risk management (and of responsive regulation discussed in the next section) is The Transfer Pricing Record Review and Improvement Project. Companies involved in international trading were required to put in place their own risk management systems to prevent tax avoidance through shifting profits into low tax jurisdictions or tax havens. For every million dollars of tax office resources put into this intervention, Braithwaite (2003) concluded that an extra billion dollars in tax was raised. While this is far from a definitive study, it suffices to show that regulated self-regulation is a strategy with promise.

### Meta-risk management of health care

Pharmaceuticals regulation is one area in the health sector with a history of meta-risk management. Rules relating to research on human subjects require researchers to submit a risk management plan to their institution’s ethics committee. In a sense, this is meta-meta-risk management because the NHMRC risk manages the risk management of laboratories through institutional ethics committees. The reason command and control – enforcement of ethics rules – was never embraced here was that, at the frontiers of science, we should expect new risks to emerge that rule writers of decades past would never have conceived. Since many of us have experienced either how perfunctory or how clumsy ethics committees can be in Australia, we know that meta-risk management is no panacea. It requires wisdom and sensitivity in thinking systemically about health risks.

One of the hopes for well crafted meta-risk management, in contrast to command and control, is that it will foster creative approaches to continuous improvement. A meta-risk management strategy was one reason United States nursing homes achieved remarkable results more than a decade ago in reducing levels of physical and chemical restraint of elderly residents (which had been much worse than in Australia). In the late 1980s in the United States, the percentage of nursing home residents who spent their days tied down in physical restraints was over 40 percent nationally, and over 70 percent in the worst states, according to figures supplied by the Health Care Financing Administration from annual nursing home surveys. By 1993, levels of physical restraint in most states had halved and chemical restraint had also fallen (Braithwaite 1994) - improvements that have continued nationally in the decade since.

### Enforced quality improvement

An interesting change to the United States regulatory process after 1990 was that individual nursing homes were required to identify their greatest health quality problems, and to then choose one to improve each year. They were required to design a quality improvement intervention, and measure the targeted quality outcome before and after the intervention. Because the appalling level of restraint of the elderly was such an obvious and huge problem, many nursing homes targeted this issue for their quality improvement study and brought down restraint levels very sharply. This was not accomplished by a command and control rule that said a 40 percent level of restraint was above the industry norm and therefore unacceptable. It was accomplished by the industry's own management creativity in finding better ways to manage patients without doping them or tying them into a chair or bed.

There is a deeper philosophical shift in this kind of move away from command and control.

The command and control idea is that there is a level of health quality that is so poor that it cannot be tolerated. A problem with legally defining a floor below which no health provider is allowed to slip is that it is hard to set the floor above the average existing industry performance. Doing so induces general industry revolt against the impracticality of the standard; the upshot is widespread industry non-compliance where they are all protected from vigorous enforcement by safety in numbers. But in a situation where the industry norm in 1988 was something as appalling as 40 percent of the institutionalised elderly being tied up, setting a minimum standard at something worse than that is morally unacceptable.

If you have a regulatory strategy where the management creativity is harnessed to deliver continuous improvement in quality, leaders can pull their standards up through a ceiling (Gunningham and Sinclair 2002). In time they may pull up the standards of the whole industry with them so that both the floor and the ceiling rise. By motivating the leaders, you may ultimately bring along the laggards. The "Untie the Elderly" campaign led by NGOs in the United States at the end of the 1980s energised the "can-do" nursing home administrators to prove that they could run a "zero restraint" nursing home. Obviously, when the leaders were finding ways of managing even their most unmanageable residents without restraint, it became difficult for nursing homes operating with most of their residents restrained to withstand consumer, professional and governmental reproach. A strategy of regulated self-regulation challenged innovators to lift up the performance of industry and to lift up the floor below which standards are viewed as unacceptable.



## Enforced self-regulation

Enforced self-regulation is a specific form of meta-risk management where some issue requires both the management problem-solving creativity of self-regulation, and the assurance that a minimum standard of performance is being met (Ayres and Braithwaite 1992: Chapter 4). This is the concept that underlies the framework of clinical governance introduced into the United Kingdom in the National Health Service (NHS) in the late 1990s after the inquiry into the high rates of deaths and injury among children after heart surgery at the Bristol Royal Infirmary. The government placed a statutory duty on NHS organisations, and in particular the chief executive, to seek quality improvements which meant giving much higher priority to quality issues. This required a hospital, for example, to integrate the elements of financial control, service performance, and clinical quality (Sally and Donaldson 1998). The Healthcare Commission now regularly reviews the progress of NHS health providers in implementing quality improvement mechanisms and in achieving better performance outcomes.

An example of enforced self-regulation is a requirement that each hospital must have an infection control plan. While the plan is crafted by the hospital to respond to the particular risks and circumstances it confronts, government requires the plan to meet a minimum standard, which might be defined by measurable outcomes or by performance principles. The plan must be submitted to the government in advance to ensure that it meets the minimum standard; alternatively government could provide a default set of standards. Hospital administrators who are unable or unwilling to think about the particularities of their own risk environment can simply use the default standards. Innovative hospital administrators are permitted to design their own standards, so long as they can make a good case to government that their standards are better than the default standards. Dynamism can be built in to enforced self-regulation to prod lazy managers by requiring continuous improvement. This means that each year, managers are required to do something to make infection control better than last year. The tough part about enforced self-regulation is that, unlike voluntary self-regulation, it is legally enforceable. Hence, if a hospital fails to meet one of the privately written but publicly ratified rules in its infection management plan, the corporation and its managers can be held accountable for that failure. This enforced self-regulation strategy attempts to simultaneously secure the creativity, flexibility, and cost-effectiveness of moving away from command and control, while retaining the public assurance of full enforcement credibility.

Research work to specify the conditions where enforced self-regulation might be effective in hospital safety regulation would be an example of a worthwhile future project. This could be followed by process evaluations of some pilot programs, followed by randomised controlled trials if the pilots were promising.

## Restorative justice

Restorative justice is about the idea that because injustice hurts, justice should heal. It takes healing as a therapeutic value into the foreign domain of jurisprudence and regulatory enforcement. Australia and New Zealand are world leaders in restorative justice research, while New Zealand leads innovations in restorative practices. Together, the Antipodes have been at the “healing edge” of R&D restorative justice innovation. The restorative justice conference has been the particular New Zealand contribution, and has now been subject to encouraging (although not uniformly so) randomised controlled trials on effectiveness in three continents (Braithwaite 2002). Such a conference brings together all the stakeholders affected by a crime – the offender, the family of the offender, the victims, supporters of victims, the police, school representatives if the incident was one of school vandalism, and so on. This circle of people discusses who has been hurt by the crime, what relationships have been damaged, what trust has been breached, and then what repairs might right these wrongs. The final act is an agreed plan of action that is signed by the offender, the victim, and other key stakeholders who all give separate undertakings. There will often be an apology communicated with some emotion in response to the revelation of how others have been hurt, and an acceptance of the apology. The evidence now suggests that an apology and its acceptance improve outcomes (Braithwaite 2002).

Braithwaite has observed many exit conferences after inspections of nursing homes in the United States and Australia where inspectors, managers, proprietors, staff representatives, representatives of the residents’ committee and the relatives’ committee sit around a table to first discuss the health and safety risks that exist in the facility, then any trust that has been breached and relationships damaged by allowing these risks to exist. They then move on to discuss a plan of action to fix the problem, to provide symbolic reparation (eg. an apology), and to offer material reparation (eg. compensation payment) to residents or staff who have been adversely affected.

Some health services already operate in a restorative way, unsurprisingly given the pre-eminence of healing as a value in the health professions. But this happens unsystematically rather than programmatically, and there have been no randomised controlled trials to parallel the 17 trials that appear in the Campbell Collaboration report on restorative justice (Strang and Shearing, forthcoming). Hospital staff do, of course, have considerable experience in dealing with anxious patients, and anxious or grieving families. Such encounters are especially delicate in cases where a patient has been seriously affected, or has died as a result of an adverse event. Health institutions and health professionals are now moving towards a policy of open disclosure in such family conferences, and this national standard contains elements of a restorative justice approach (see Box 10).

## Box 10. Open Disclosure

Open disclosure is the process of discussing incidents that resulted in harm to a patient as a result of the care s/he received. The primary aim is to facilitate effective communication after an adverse event. At a minimum, it should result in an apology to the patient and, hopefully, enduring systemic improvement that ensures such an event is less likely to take place in the future. This approach is consistent with a “just culture” (Wellington 2004). Some commentators maintain that honest and timely disclosure of medical error to patients is “ethically, morally, and professionally expected of clinicians” (Oakley & Cocking 2001; Lamb 2004; Irvine 2004). Furthermore, the evidence is that doctors who take an open approach to medical mishaps are less likely to be sued (Gallagher et al 2003). Legislative provisions in some Australian jurisdictions now encourage an apology by preventing its use as evidence of fault (eg. the New South Wales Civil Liability Amendment (Personal Responsibility) Act 2002). Some people perhaps sue health providers “to prevent the same thing happening again” rather than to obtain significant compensation (Lamb 2004). However, fear of litigation does attenuate support for open disclosure among clinicians, health organisations, and their lawyers (Gallagher et al 2003).

Veterans Affairs in the United States has taken the position that it ought to remain an ethical caregiver and notify the patients adversely affected, and this has had the unanticipated financial benefit of reducing its malpractice burden (Kraman & Hamm 1999). The principles set out in a *National Standard for Open Disclosure* (Australian Council for Safety and Quality in Health Care 2003a) encourage: acknowledgement when an adverse event has taken place; expression of regret as early as possible; recognition of the reasonable expectations of patients; creation of an environment that enables staff to recognise and report adverse events, and to learn from them; improvement of integrated risk management systems; good governance; and confidentiality.

There are good theoretical grounds for believing that such incipient restorative justice processes could be effective in improving health safety and quality outcomes. Braithwaite is currently working on a book to argue just this based on fieldwork observation of such practices in nursing homes. The evidence is that apologies from health practitioners that are perceived as sincere do reduce tort litigation (Gallagher 2003). The evidence from RegNet’s research on 1285 criminal trials in Canberra is that restorative justice doubles the chances of an apology, and then doubles the prospects of apologies being perceived as being sincere by victims (Sherman et al 1998). Thus, restorative justice has a pragmatic appeal in terms of legal risk management.

When restorative justice works, an apology helps to foster a culture of forgiveness. This is more conducive to learning from mistakes than is a culture of defensiveness. When employees know that their organisation rewards the “owning” of responsibility for mistakes so that organisational growth can occur, it becomes possible prior to a restorative justice process for the facilitator to say to an employee “Is there even a little piece of responsibility that you are willing to own voluntarily so that this can become a constructive process rather than one with mutual recriminations?” If this person confesses that if only he had met his responsibility and done this or that, things might have been different, then there is the prospect that others will reciprocate with statements like: “It’s not right that you take the blame for this. While this is not all my fault either, I bear more responsibility than you and I don’t want to see you taking all the responsibility.” The strategy is for the facilitator to spread active responsibility for making things right. Part of the philosophy of restorative justice is a shift from passive responsibility – holding someone responsible for the past – to active responsibility. Active responsibility is a virtue; it is the virtue of taking responsibility for making things right in the future (Braithwaite and Roche 2000; Braithwaite 2005). Being forward looking is conducive to learning.

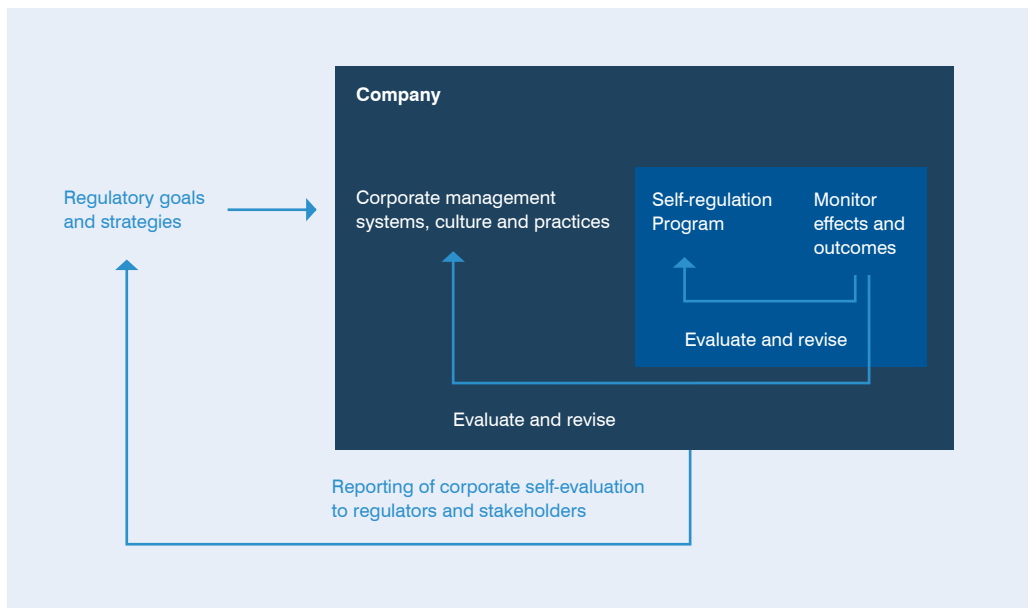
## Learning model

### Triple-loop learning

Parker’s (2002) idea of triple-loop learning in self regulation both permeates, and is permeated by, regulatory ideals in the public sphere (see Figure 4). The first loop occurs when a good self-regulatory innovator monitors his/her own effectiveness at improving an outcome (see also Box 11). The second loop is that this policy learning is then monitored by senior managers of the responsive firm, who change their corporate management systems, culture, and practices in response to the learning. The third loop occurs when government learns from monitoring the company’s double-loop learning, and evaluates and revises its regulatory goals and strategies for the whole field. International regimes can foster a fourth loop by assisting the world community to learn from a nation, such as Australia, which has a rich experience of triple-loop learning in the health sector. Triple-loop learning is a strategy for spreading islands of innovation throughout health systems.

Think about a hospital in terms of multiplying the loops of learning on how to improve safety and quality. Hospital managers might require the professional staff on each ward to meet annually to identify and discuss their biggest safety problems, and then to design one improvement project for that ward and measure its outcomes. One point in doing this ward by ward is that different kinds of wards have different kinds of problems. Sometimes, however, the targeted problem will be of general import, like infection control. If a ward comes up with a simple way of improving infection control, hospital managers can spread the success story to all the wards of the hospital and hopefully, achieve hospital-wide success. The accreditation agency for the hospital or government can learn from this and spread the story of this hospital’s success across the country. The fourth loop of learning might come when a researcher evaluates and publishes the results of this Australian infection management program in an international journal.

**Figure 4. Triple-loop learning (Source: Parker 2002:278)**



### Box 11. Triple-loop learning: specialist training

Specialist training offers many examples of a learning model approach. Australian anaesthetics registrars, for example, undertake the Early Management of Severe Trauma, or the Effective Management of Anaesthetic Crisis, as part of their training. This is done via simulation training that uses an artificial representation of real-world processes with a focus on patient safety. The simulation demonstrates performance in evolving clinical situations, and the subsequent self-assessment is guided by trained facilitators. The feedback process, both viewing one's performance and receiving guidance, is an example of single loop learning; that is, professionals monitor, evaluate, and learn from their own performance. Double-loop learning requires the profession, as a whole, to monitor the standards of its members and to identify what changes to make on the basis of this performance. The Australian and New Zealand College of Anaesthetists grant points for Maintenance of Professional Standards to those undertaking simulation training. The government's role in triple-loop learning could be in detecting patterns and problems and prompting a professional group to improve its management of safety and quality. This would require the Colleges to provide data to allow external learning from its members' performance, including their own capacity to self regulate, in order to enable triple-loop learning to take place. Given the high value attached to professional independence, this may not be easy to negotiate. Triple-loop learning would involve taking new knowledge and disseminating it within the wider health system.

Source: Parker 2002; Interview with Dr Brendan Flanagan, Barwon Hospital, Melbourne.

## A learning culture

An alternative approach is a shift from a blame culture, to a learning culture and a just culture (Australian Council for Safety and Quality in Health Care 2003: iv; Wellington, 2004b). This is the philosophy that has underwritten the incredible accomplishments of the twentieth century in making air travel (even with the risks of terrorism) so much safer than travel by road. If a pilot has a near-miss, say a simple separation error, where she observes her aircraft flying more closely to another than is desirable, in the culture of air safety there will be no-blame placed on the pilot for voluntarily reporting the incident. Indeed, she will be rewarded for being the kind of pilot who helps the organisation to learn from such incidents and who has prevented something serious from going wrong.

Health care organisations might also benefit from a shift from a defensive culture to a learning culture. Generally, health professionals do not discuss their most serious mistakes when they conduct training programs (Wilf-Miron et al.2003: 36). Nor, (as discussed earlier in Box 5), do they necessarily report adverse events. In the Internet Age, moving from blaming to learning should be easier to make work in large health systems than it is in smaller airline systems. Thus, a general practitioner can anonymously report a near-miss to an Internet reporting system that records full details of the case (Suresh et al 2004). In the United States, the Institute of Medicine (2004:226) estimates that near-misses are 7-100 times more frequent than adverse events – near-misses are the “main game” of opportunities to learn. Obviously, it is much harder to preserve anonymity in near-misses and plane crashes. Aviation and medicine are said to share three key safety principles:

- 1) errors inevitably occur and usually derive from faulty system design, not from negligence;
- 2) accident prevention should be an ongoing process based on open and full reporting; and
- 3) major accidents are only the “tip of the iceberg” of processes that indicate possibilities for organisational learning.

(Wilf-Miron et al 2003: 35)

One problem is that it makes victims angry when they learn that the institutional philosophy is that no one is to blame. It might follow that the no-blame philosophy is only best in medical near-misses that are analogous to air safety near-misses. A no-blame approach does not apply in air safety regulation when an air disaster takes lives. Instead, there is a full and frank investigation that seeks to hold all responsible who are responsible (Fisse and Braithwaite 1993).

A comprehensive investigation of an adverse incident, known as root cause analysis (see Box 12), is becoming widely accepted in Australia as a tool for learning from errors in health care (New South Wales Department of Health 2004). First, this involves undertaking a *critical incident analysis* of what happened and when, and who was involved, and second, making a decision whether to take the next step with a root cause analysis, which seeks to identify the chain of events and to ascribe cause and effect. This analysis often is constrained, however, by staff fears that they will be “named, blamed and shamed”, and that the information collected may be used later in disciplinary proceedings by the employer, or in litigation by the patient.

### Box 12. Root cause analysis: the case of falls prevention

A root cause analysis is a systematic process whereby the factors that contributed to an incident are identified (Australian Council for Safety and Quality in Health Care 2003). Once the root cause/s of the problem has been identified, possibilities for redress and improvement emerge. Falls in hospital are frequent, accounting for over one-third of all adverse events reported on the Australian Incident Monitoring System (Rigby et al 1999), and of which over 60 percent are preventable (Wilson et al 1995). The Commonwealth Department of Health and Ageing therefore has made falls among older people a priority for action (Strategic Injury Prevention Partnership 2001). St George Hospital in Sydney has undertaken an internal analysis of falls (Donoghue et al 2003; Donoghue et al 2003a). The studies identified both the intrinsic patient characteristics (age, gender, ethnicity, history of falling), and the extrinsic circumstances (such as date and time, location of fall, patient activity at the time, and consequences, etc) of all the falls that took place over a three month period in 2001. The key factors were time and location in explaining where, when, and why falls occurred.

Another example is the ACT Falls Prevention Program begun in 2001. Having established its falls baseline and identifying an appropriate benchmark partner, Calvary Health Care introduced a falls risk assessment tool and implemented a falls intervention pathway. The result was a 43 percent decrease in falls in the pilot ward. The Canberra Hospital also achieved a considerable reduction in patient falls among elderly patients after introducing a risk assessment tool, by increasing staff awareness through regular education sessions, and by distributing information. Ongoing effort is required, however, since a re-evaluation of a falls program in an acute medical area five years after initial implementation revealed that the falls rate had returned to pre-program levels (Dempsey 2004).

When victims have suffered, or have died leaving grieving relatives behind, restorative justice is a better strategy than a no-blame strategy. It will not always lead to sequences of remorse, responsibility taking, emotional reparation, voluntary compensation, apology and forgiveness. But when it does, there is the prospect of policy learning superior to that constrained by a culture characterised by defensiveness and cover-up. Defensive medical cultures lead to over-servicing, where practitioners protect themselves with the argument that they did everything that could possibly be done. Defensiveness also leads to “scapegoating”. Fisse and Braithwaite (1993) found empirically that top managers in large organisations are very resourceful in ensuring that blame will pass to a junior fall guy. Better still, they can sometimes define lines of responsibility so that everyone is in a position where they can blame someone else. This phenomenon was well illustrated recently by the defensiveness of several Western governments in relation to the intelligence failures associated with both September 11, and the War in Iraq. This strategy of developing a smokescreen of diffused responsibility deters policy learning that might prevent a recurrence of such failures. During interviews

at multinational pharmaceutical corporations in the United States, for his book *Corporate Crime in the Pharmaceutical Industry* (1984), Braithwaite encountered three executives who were described to him as the “Vice President responsible for going to jail”. These employees were promoted to a vice presidency on the understanding that they would protect the CEO from blame. After a period of faithful service as the vice president responsible for going to jail, they would be promoted sideways to a safer vice presidency. In Westminster governments, Prime Ministers often have loyal minions who, if things get hot enough with major untruths, will assume the mantle of the scapegoat.

We suggest that a no-blame approach that flows from a culture of learning may be the best option for health care near-misses. Where patients are hurt and ongoing underperformance is identified and can be attributed to an individual or to systems failure, however, legal and moral imperatives require that remedial action is taken (Wellington 2004b: np). Here, a restorative justice approach offers a way to transcend blame. In the next section on responsive regulation, we will also hypothesise that when both no-blame and restorative justice approaches fail to elicit active responsibility, public policy should escalate to a legal accountability approach. These are all hypotheses that could, and should, ultimately be addressed by research designed to produce evidence-based health administration.

### **Responsive regulation**

The basic idea of *responsive regulation* is that regulators (usually government or its agents) should be responsive to the conduct of those they seek to regulate when deciding whether a more or less interventionist response is needed (Ayres and Braithwaite 1992). Responsive regulation acknowledges that one regulatory strategy is not, and cannot be, applicable across all situations, and that some strategies will work better than others depending on the circumstances. Hence, the choice among regulatory strategies should be pragmatically grounded, rather than ideological (Sparrow 2000).

Contrasting this approach with regulatory formalism is instructive. Formalism defines in advance what problem requires which response and then writes rules to mandate the response. Formalism seeks consistency and thus, responsive regulation is criticised for lack of consistency in enforcement, particularly by those used to public sector accountability requirements. Interestingly, the idea of responsive regulation arose out of the actual experiences of private firms; specifically, dissatisfaction with the business regulation debate. Some argue that business people are rational actors who only understand the bottom line and who, therefore, must be consistently punished for their lawbreaking, while others assert that business people are responsible citizens and can be persuaded to comply. There is a lot of truth in both positions, depending on the context. Neither consistent punishment or consistent persuasion, however, have proven effective in the long term. For a start, it is costly to resource the stringent enforcement of regulation. But more problematically, a consistent strategy of deterrence may backfire and result in poorer outcomes (Braithwaite 2002: 102-110). In business regulation circles these days, few contest the conclusion that consistent punishment of business non-compliance is an ineffective and potentially damaging policy; persuasion is normally perceived to be the better approach when there is reason to think that cooperation will be forthcoming.



Responsive regulation challenges the presumption that one can accurately foresee all possible problems, let alone determine a corrective strategy in advance. To be efficacious, regulation must address the diverse objectives and regulatory needs of firms and industry associations, as well as the individuals within them (Braithwaite 1985: x). The consistent application of predefined sanctions is clearly not possible under these circumstances. So having discussed what responsive regulation is not, how might we characterise what it is?

Walshe (2003: 41-48) identifies six main concepts, explained below, that underpin responsive regulation:

- contingency;
- an enforcement hierarchy;
- flexibility;
- tripartism;
- parsimony; and,
- empowerment.

Responsive regulation is “contingent” because it is determined by the behaviour of individuals and organisations. The universality of rigid regulation comes at a price. For example, “using the same regulatory methods with every organisation is rather like giving everyone in the population exactly the same health care services regardless of their health status or health needs” (Walshe 2003: 41). Instead, responsive regulation encourages regulators to draw upon a range of regulatory tools and strategies, in order to match design to circumstances (in other words, the response/punishment should fit the offence/crime). These tools can be applied in an “enforcement hierarchy”, whereby the regulator commences the “regulatory conversation” (Black 1998) with the least interventionist approach, and escalates to more severe sanctions when softer ones prove unhelpful or ineffective. “Flexibility”, so central to responsive regulation, conflicts with two common regulatory imperatives - consistency and transparency - a matter of particular relevance to public sector regulators. An obsessive search for greater consistency is ultimately self-defeating because it creates as many measurement problems and difficulties as it solves (Braithwaite and Braithwaite 1995). “Tripartism” encourages the engagement of a third party, often the public, and in doing so brings additional resources to bear on regulatory problems, thereby balancing the dichotomous positions of the regulator and the regulatee (the person/organisation being regulated) (Sparrow 2000: 41-43). “Parsimony” refers not only to the judicious application of sanctions, but also to the costs of regulation which can be extraordinarily high where rigid formalism is pursued. Finally, the “empowerment” of all parties is needed to maximise the regulatory outcome. The likely benefit of regulatory interventions, as well as the potential harm, affects all the parties, and through empowerment, the regulatory strategy most suitable to the circumstances can be constructed.

Responsive regulation (and the principles that underpin it) does have its shortcomings (see Walshe 2003: 39-42). Most notable is the difficulty in achieving the necessary versatility in detection, deterrence, and enforcement (Sparrow 2000:39). Nevertheless, it is a pragmatic attempt to escape the long-established preference for command and control with an approach to regulation that is highly flexible, situationally specific, and adaptable. Additionally, responsive regulation is not only something governments can do – private actors in civil society can also regulate responsively; indeed, even regulate governments responsively (Gunningham and Grabosky 1998).

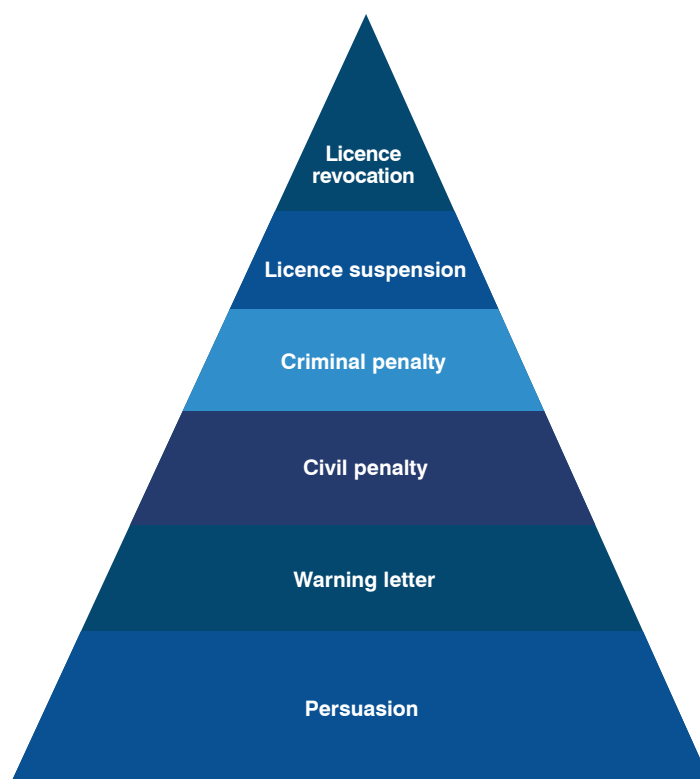
### The regulatory pyramid

The most distinctive element of responsive regulation is the *regulatory pyramid*, which is an attempt to solve the puzzle of when to punish and when to persuade. At the base of the pyramid is the most restorative, dialogue-based approach we can craft for securing compliance with a just rule or standard. Rewards rather than sanctions are a feature of this level; for instance, the regulator might grant greater autonomy and relax the regulatory regime. If the rule is of doubtful justice, we can expect the dialogue to be mainly about the justice of the rule and such discussion should be welcomed and fostered. Consequently, dialogue at the base of the pyramid is not only about repairing any harm that might have been done via restorative justice; it can entail discussion about how to prevent future harm (for a training program example, see Box 13).

As we move up the pyramid, more demanding and punitive strategies are enlisted. We stress that strategies should be commensurate with the response of the person/organisation being regulated; thus, the presumption is to start at the base of the pyramid. The idea is that informal interventions to address problems or limited follow-up inspection, as well as positive feedback on achievements and strengths, may be all that is required to persuade a regulatee to remain within agreed regulatory boundaries. Persistent infractions will eventually elicit a formal request to remedy problems, and possibly entail repeat inspections and disclosure of failure to meet standards. But even at this level, referral to support services and/or mentoring should be offered. Continued and serious breaches of the regulatory guidelines may incur financial penalties and result in the regulatee's activities being curtailed. For example, a hospital or nursing home might be refused public funding for new admissions until a problem is fixed. License removal or closure are last resorts, and signal the failure of both regulator and regulatee to ensure the public is well served.

Figure 5 is an example of a responsive business regulatory pyramid from Ayres and Braithwaite (1992: 35). When dealing with a recalcitrant organisation, the regulator can escalate from persuasion to a warning, to civil penalties, to criminal penalties, and ultimately, to corporate capital punishment – permanently revoking the company's licence to operate.

**Figure 5. A regulatory pyramid of sanctions (Source: Ayres and Braithwaite 1992: 35).**



Movement up the pyramid results from a failure to elicit reform and repair, and theoretically reaches a point where reform and repair is finally forthcoming. At this point, responsive regulation encourages us to descend the pyramid, increasingly loosening the regulatory demands in response to responsible action by those regulated. The pyramid is firm yet forgiving in its demands for compliance. Reform must be rewarded, just as recalcitrant refusal to reform will ultimately be punished.

While Figure 5 is a pyramid of sanctions, we can also craft a pyramid of regulatory incentives, with substantial incentives at the base and relatively few incentives at the apex.

### Box 13. The regulatory pyramid: GP training

The regulatory pyramid is a useful heuristic for exposing and explaining problems with the previous system of training Australian general practitioners. Initially, training and education was under the sole control of the medical profession. While government directly funded the Royal Australian College of General Practitioners (RACGP) to provide that training, it made few demands in return. Self-regulation was the order of the day. From the late 1980s, however, government became concerned about the lack of quality in the training program, but attempts to encourage the RACGP to address perceived shortcomings were met with resistance. Mutual respect and trust, the markers of virtuous actors, were demonstrably absent from interactions between government and the profession. The regulatory pyramid would suggest that the most appropriate response by government might have been to enforce the existing sanctions in the contract, but this strategy failed, arguably because of a combination of poor contract specification and a lack of political will. One could assume, therefore, that the RACGP was indeed responding rationally to the poor regulatory environment, while government proved itself to be an incompetent regulator.

Consequently, the government invoked the ultimate sanction and replaced self-regulation by the profession with an independent board of studies, General Practice Education and Training (GPET), under a tight contractual arrangement. GPET was given fund-holding responsibilities and was charged with the strategic oversight of general practice training. The path to this change was paved by the 1997-98 Review of General Practice Training, by government dissatisfaction with the RACGP, and by effective political lobbying by rural doctors. A new contract and new organisational arrangements offer a couple of alternatives. The first is to return to the bottom of the regulatory pyramid and re-engage as virtuous actors; the second is to continue to view the relationship as being located at the top of the pyramid, and for government to exert downwards pressure.

Source: Dwan 2004

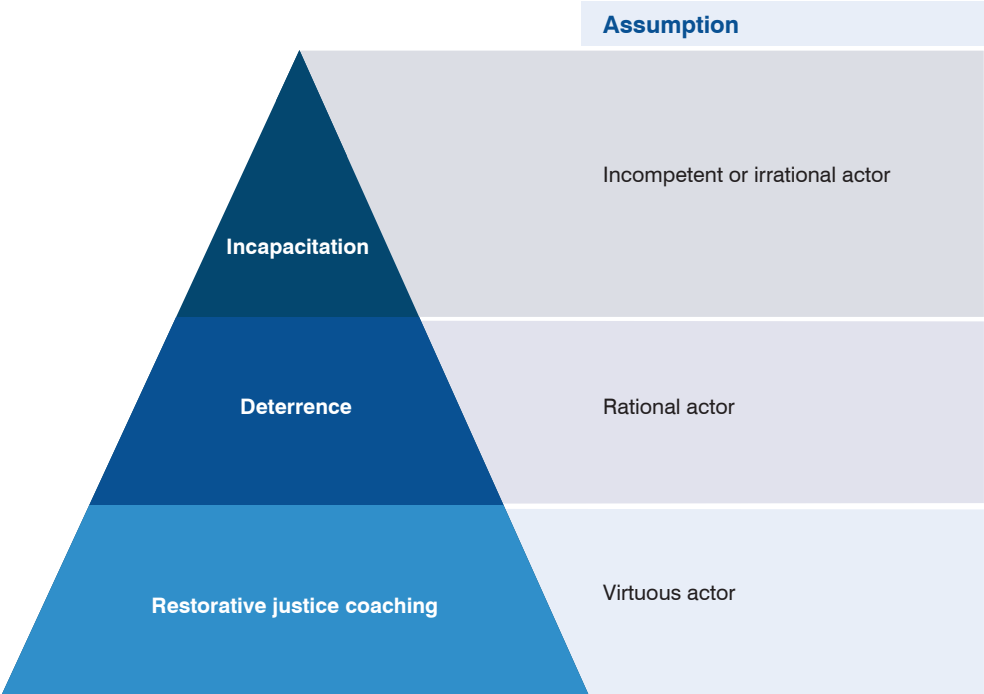
#### Why the pyramid works with business regulation

Business regulatory agencies all over the world are today deploying the idea of the regulatory pyramid. It is an influential policy idea because it reconciles the empirical evidence that sometimes punishment works, and sometimes it backfires – similarly with persuasion (Braithwaite 1985; Ayres and Braithwaite 1992). The pyramidal presumption of persuasion gives the cheaper and more respectful option a chance to work first. The empirical experience in some areas of business regulation is that persuasion does work in most cases. The more costly punitive attempts at control are thus held in reserve for the minority of cases where persuasion fails. When it fails, the most common reason is that a business actor rationally calculates the likely costs of law enforcement compared with the gains from breaking the law.

Escalation through progressive penalties that acts as deterrents will often take the non-complier up to the point where it will become rational to comply. The business regulator may begin with restorative justice as a persuasion-based approach and, if it fails, may try escalating up through more punitive options that may all fail to deter. This happens for a number of reasons. Perhaps the most common reason in business regulation for successive failures is that non-compliance is not about a lack of goodwill to comply, nor about rational calculation to cheat; it is about management not having the competence to comply. Thus, the issue is not necessarily about “bad” people or about *malpractice*, but rather, about lack of knowledge and expertise which might be remedied by training, or by bringing in other people to do the job.

A hospital administrator, for example, might simply not have the managerial or medical know-how to take on a level of responsibility this demanding, and thus should be removed from the job. It is important to identify the contributory system issues, however, and to avoid “scapegoating” when taking such drastic action. If the entire management system of a hospital is not up to the task, the hospital should lose its accreditation and be shut down (a very serious sanction - corporate capital punishment), or else a new managerial team put in place. Hospital closure would only be considered when all other approaches had failed, and would represent a last ditch effort to protect the public. So when deterrence fails, the idea of the pyramid is that incapacitation is the last port of call (see Figure 6).

**Figure 6: Toward an integration of restorative, deterrent and incapacitative justice**



A pyramid design responds to the fact that restorative justice, deterrence and incapacitation are all limited and flawed theories of compliance. What the pyramid does is cover the weaknesses of one theory with the strengths of another. Thus the ordering of strategies in the pyramid is not just about putting the less costly, less coercive, more respectful options lower down in order to save money and to preserve freedom as non-domination. Only by resorting to more dominating, less respectful forms of social control, after dialogue has been tried, does coercive control come to be seen as legitimate. There is now considerable evidence that when regulation is seen as more legitimate and more procedurally fair, compliance with the law is more likely. Astute business regulators often set up this legitimacy explicitly (Tyler 1990; Tyler and Dawes 1993; Tyler and Blader 2000; Tyler and Huo 2001). During a restorative justice dialogue over an offence, a government health inspector might say there will be no penalty this time, but that she hopes the manager understands that when she returns and, if she finds the company has slipped out of compliance again, under the rules she will have no choice but to refer it to the prosecutions unit. When the manager responds that this is understood, a future prosecution will likely be viewed as fair. Under this theory, therefore, privileging restorative justice at the base of the pyramid builds legitimacy and compliance.

There is also a rational choice account of why the pyramid works, both with organisations and with individuals. System capacity overload (Pontell 1978) results in pretence at consistent law enforcement, where in practice, enforcement is spread around thinly and weakly. Unfortunately, this problem will be worst where non-compliance is worst. Hardened offenders learn that the odds of serious enforcement are low for any particular infraction. Tools like tax audits, which are supposed to be about deterrence, are frequently exercises that backfire by teaching hardened tax cheats just how much they can get away with (Kinsey 1986: 416). The reluctance to escalate under the responsive pyramid model means that enforcement has the virtue of being highly selective in a principled way. Moreover, the display of the pyramid itself channels the rational actor down to the base of the pyramid. Non-compliance comes to be seen (accurately) as a slippery slope that will inexorably lead to a sticky end. In effect, what the pyramid does is solve the system capacity problem by making enforcement cheap. The pyramid suggests that unless you punish yourself for rule-breaking through an agreed action plan near the base of the pyramid, we will punish you much more severely higher up the pyramid (and we stand ready to go as high as necessary). So it is cheaper for the rational health providers to punish themselves (eg. by agreeing to payouts to victims, community service, paying for new corporate compliance systems, etc). Once the pyramid accomplishes a world where most deterrence is self-deterrence, there is no longer a crisis of the government's capacity to deter where it is needed. One of the implicit messages the pyramid gives is that "if you keep breaking the law, it is going to be cheap for us to hurt you because you are going to help us hurt you" (Ayres and Braithwaite 1992, Chapter 2).

Paternoster and Simpson's (1996) research on the views of MBA students regarding four types of corporate crime reveals the inefficiency of going straight to a deterrence strategy. Paternoster and Simpson found that where the students held personal moral codes, these were more important than rational calculations of sanction threats in predicting compliance (though the latter were important too). It follows that for the majority of these future business leaders, appeals to business ethics (such as confronting them with the consequences for the victims of a corporate crime) will work better than sanction threats. The same reasoning could be applied in the training of health professionals. So it is best to try ethical appeals first, and then escalate to deterrence for that minority for whom deterrence works better than ethical appeals.

### Inexorable regulatory escalation

According to responsive regulatory theory, what we want is a compliance system in which health professionals learn that responsiveness is the way our regulatory institutions work. Once they see the system as a responsive regulatory system, they know that there will be a chance to argue about unjust rules. But they will also see that game playing to avoid legal obligations, and failure to listen to persuasive arguments about the harm their actions are doing and what must be done to repair it, will inexorably lead to regulatory escalation. The forces of law then will be seen as fair and legitimate, and also somewhat invincible.

A paradox of the pyramid is that, to the extent that we can guarantee a commitment to escalate if steps are not taken to prevent the recurrence of health and safety breaches, escalation beyond the lower levels of the pyramid will rarely occur. This image of invincibility makes self-regulation inevitable. In contrast, when it is seen as usual that no escalatory consequences follow when obligations agreed through a restorative justice process are flouted, people will often flout them. The fundamental resource of responsive regulation is the belief of regulated actors in inexorability.

This inexorability is the reverse of the reality of current Western regulatory systems. Certainly, a belief in the inexorability of sanctions is lacking in the health sector for various complex reasons. As a result of overload, and also adherence to the doctrine of professional autonomy in these regulatory systems, it is the non-compliers who wear the system down rather than the reverse. The enforcement response is to hang back on confronting non-compliance in a credible way early on, wait until really serious cases land in your lap, and then impose through the courts the harsh punishments that the media and a frustrated public demand in egregious cases. When the nursing home proprietor finally has her facility shut down, for example, she is often genuinely shocked – after years of getting away with all manner of infractions, all of a sudden the evening television news strikes like a bolt from the blue. The whole approach seems arbitrary and illegitimate in the industry.

Many wrongly see inexorability as a responsive regulatory objective that requires participants in restorative justice processes to issue threats: the health inspector who says, "Next time, I'll be taking you to court and you'll probably be fined and lose your licence". What is required is quite the reverse. It is for conference participants to identify with the non-complier as someone they are working with to prevent inexorable outside forces from taking over the case and putting it on a more punitive track. Inexorability is a societal accomplishment of the legal system – under a responsive regulatory regime everyone can see that it works inexorably. The issuance of threats in individual cases will only amount to bluff if there is, in fact, no inexorability in the system.

Threat is also counterproductive because it increases a psychological process called *reactance* (Brehm and Brehm 1981), which undermines compliance. What is needed to achieve deterrence without reactance is the acceptance of the societal inexorability of escalation (supporting deterrence) combined with offers of help without threat to avert that escalation - offered by others with whom one identifies (knocking out reactance). This is the way to improve compliance in a world where the impact of sanctions on compliance is the sum of a deterrence effect and a reactance effect.

Put another way, restorative justice works best against a spectre of punishment: threatening in the background but never threatened in the foreground. Where punishment is thrust into the foreground even by implied threats, other-regarding deliberation is made difficult because the non-complier is invited to deliberate in a self-regarding way – out of concern to protect the self from punishment. This is not the way to engender empathy with the victim, or to internalise the values of improving health safety and quality. The job of regulators and other participants in restorative justice processes is to treat offenders as worthy of trust. Our study of Australian nursing home regulation suggests that compliance improves when offenders are treated as worthy of trust (Braithwaite and Makkai 1994). Even though it might be trust in the shadow of the axe, there is nothing baffling about people actually feeling trusted in these circumstances. It is in the nature of human beings to want to be trusted, and to want to trust those that they have to deal with to survive.

Even the toughest nuts are capable of being surprised by someone treating them with respect and who shows that they care about them, as well as the health and safety effects of regulatory compliance on others. As Ayres and Braithwaite (1992: 30-5) report, regulatory ethnographies show regulated actors to have contradictory multiple selves. Even the worst of us have a caring, socially responsible self as well as an exploitative self. The idea of starting at the bottom of the pyramid with the most ruthless of business people is to surprise them with a show of trust and respect, and to give them a chance to put their best self forward:

**Inspector to US nursing home administrator:**

What you want and what we want more than anything else is to improve the quality of care your residents are getting...

**(Later) Inspector to Braithwaite:**

When you say to them that we all agree that the care of the resident is what we are all concerned about, you know that's not true, that they're concerned about making money. But what are they going to say? They can't turn around and say, "Hell no, I don't care about the residents; all I care about is profits..."

Training health and safety regulators in restorative justice and responsive regulatory techniques that build trust and legitimacy, at the same time as they build enforcement credibility, would be one kind of democratic experimentalism to improve health outcomes.



### When does command and control still work?

As we explore innovative strategies for improving the governance of health safety and quality, we should not assume that command and control is only a strategy for Luddites. Occupational health and safety is the subject of a more sophisticated body of research evidence than we have for regulatory strategies in health service delivery. This reveals that old fashioned command and control inspections actually work much of the time in reducing fatalities and injuries (Braithwaite 1985; Gunningham and Johnstone 1999: Chapter 1; see also Gunningham and Grabosky 1998: 42-3). Gray and Scholz's (1990) research in the United States also shows that inspections work even when the expected punishment cost of a Occupational Health and Safety Administration citation is minor. Seemingly, they work less through deterrence, and more through simply tapping people on their shoulder and reminding them to meet their ethical obligations. For most of us most of the time, a tap on the shoulder is enough for us to put our socially responsible self forward and suppress our less motivated, self interested selves.

The overarching analysis of this paper is that what makes for effectiveness in governance has changed as a result of our becoming a networked information economy, but we must not forget that the old economy is still with us (see generally Haines 1997). Gunningham has concluded that old-fashioned, public inspectorial enforcement of simple rules still produces good results, especially with small workshops and factories that are not sophisticated enough to respond to meta-regulatory strategies (Gunningham and Johnstone 1999: Chapter 1; see also Gunningham and Grabosky 1998: 42-3). These workplaces want to be told by government what rules and standards to follow, and educated by the government in how to follow them. Why would we expect an analysis grounded in a movement to a sophisticated knowledge economy of post-industrialism to apply to remnants of the old industrial economy? In Australia, we also should not forget that the pre-industrial agricultural economy is still with us. So, for example, we know that meta-regulatory strategies to induce farmers to adopt new safety technologies are not the way to go. Farmers are often too busy with their struggle for survival to think about safety innovations, although we know that roll-over bars on tractors save their lives. The evidence is that it is best that we be paternalistic and require farmers to install them, just as it makes sense to be paternalistic and mandate the wearing of seat belts in motor vehicles. Can the same thinking be applied to small general practices which one commentator has described as still bearing the hallmarks of a cottage industry (Malcolm 2000)?

Evidence-based health and safety governance has barely begun to specify the contexts where command and control is the most cost-effective strategy, and the contexts where less coercive strategies are effective, such as meta-regulation, restorative justice and responsive regulation. On the basis of the regulatory literature, there is every reason for optimism that when we do seriously take on the challenge of evidence-based health governance, we will learn how to prevent much death and suffering and help many citizens to live healthier lives. And we will learn that we need a mix of strategies to accomplish that.

## Complementary and incompatible mixes of regulatory strategies

Responding to most health safety and quality problems will require a mix of regulatory strategies. There remain challenging questions in this field. In what circumstances does one strategy complement another? Are there circumstances in which combining two strategies is counterproductive (ie. the effects of one undermine the effects of the other)? Gunningham and Grabosky's (1998: 428-432) *Smart Regulation* provides the most sophisticated and systematic analysis of complementary and counterproductive regulatory mixes. For example, they argue that open disclosure (see earlier Box 12) is inherently complementary with all other major regulatory strategies. This is because asymmetries of information (such as consumers having less information than providers) are a threat to the effectiveness of all strategies. Open disclosure of information alone, however, is most unlikely to be an effective regulatory instrument. The provision of information is only likely to be effective in combination with other strategies. The pyramid of responsive regulation implies that self-regulation and command and control are complementary strategies so long as they are temporally ordered, with self-regulation at the base of the regulatory pyramid, followed by escalation to command and control strategies.

An example of inherently incompatible strategies, according to Gunningham and Grabosky, is a regime of economic incentives and tort liability (ie. suing doctors). Tort rules can change the optimal incentive structure in a regime of economic rewards. So if you seek to regulate workplace accidents by a national compensation scheme which discounts employers' insurance premiums according to their success in getting accident rates down, then it is necessary to have a statute to pre-empt tort actions. Unfortunately tort law does not always distinguish between a one-off lapse and negligence caused by endemic underperformance (Wellington 2004b). This creates incompatibility between tort law and systems approaches to improving performance. The research agenda of understanding empirically the nature of complementarity and counter-productivity in combinations of regulatory instruments is extremely challenging. It will take decades rather than years to make substantial inroads into it.

## Conclusion

We argue that health safety and quality research must be jolted out of its overwhelmingly internal preoccupation with behavioural change within health service organisations, and among individual health professionals. By complementing this literature with research on external regulatory reforms, new evidence-based approaches can improve health safety and quality. Equally, we have argued that external regulatory reforms that are oblivious to the cultures of different organisations and professions are counterproductive. We have made a case for an holistic approach to monitoring the complementarities and incompatibilities between different kinds of external and internal levers for change. We have explored the possibilities for getting things done through networked governance rather than government planning that stands aloof from partnership. Meta-regulatory strategies for externally regulating internal self-regulation are seen as especially fertile for research, especially when they can move the game from double-loop to triple-loop learning.

No-blame approaches to near-misses might advance learning on how to improve the design of safety and quality systems. But we have also argued that apology and restorative justice may be promising strategies where tragedy strikes and there are victims with emotional scars to be healed, or where compensation is due. Responsive regulation provides a promising overarching framework for rethinking health safety and quality (Brennan and Berwick 1996; Walshe 2003), and seeks to discover how to overcome the weaknesses of one approach with the strengths of others. As Trubeck (2004) argues, a new set of actors, retooled health professionals, and active consumers capable of co-production of safety and quality, are emerging with the confidence to take advantage of these new governance options.

These are very preliminary ideas. What the RegHealth Project will now seek to tackle, in partnership with ACT Health and the Australian Council for Safety and Quality in Health Care, is a more concrete program of regulatory research that seeks responsive regulatory approaches to major areas of patient harm in Australia. We will seek to conceptualise how to tackle these issues through regulatory strategies simultaneously at the policy level, the managerial level, and the clinical level. And we will seek to do so in disparate contexts that include general practice, hospitals, and aged care facilities.

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## Glossary

*The entries in this glossary are adapted from the website of the Australian Council for Safety and Quality in Health Care, the Institute of Medicine (2004:327-335), the Australian Institute of Health and Welfare (2004), and the Medline Plus and Medical Dictionary Online websites.*

### Accreditation:

An evaluation by an independent body of the degree of compliance by an organisation with previously determined standards and, if adequate, the award of a certificate.

### Adverse event:

An event that results in unintended harm to a patient by an act of commission or omission rather than by the underlying disease condition of the patient.

### Benchmark:

A standard or point of reference for measuring quality or performance.

### Benchmarking:

A continuous process of measuring quality or performance against the highest standards.

### Clinical audit:

The retrospective review of the patient's complete medical record by an expert for the purpose of a specific analysis. In relation to patient safety, this means identifying possible adverse events by reviewing the physician and nursing progress notes, and by careful examination of certain indicators.

### Casemix:

The range and types of patients treated by a hospital or other health facility. This provides a way of describing and comparing hospitals and other facilities for planning and managing health care. Casemix classifications group patients with similar conditions who use similar health care resources, so that the activity and cost-efficiency of different hospitals can be compared.

### Clinical governance:

A framework through which health facilities are made accountable for putting into place systems for continuously improving the quality of their services.

### Clinical protocols:

Also termed care pathways, or anticipated recovery paths, a clinical protocol for the treatment of a specific condition is drawn up from evidence on what should be done, how, and when to achieve the best outcome for patients. The aim is to develop a protocol that underpins the use of an individual care plan for each patient.

#### Command and control:

This approach involves direct top-down enforcement by government or its agents (eg. when inspectors enforce compliance with rules or when they license professionals and facilities).

#### Continuous improvement:

An internally or externally imposed requirement that a health outcome be better every year than it was the previous year, and that this progress be monitored and reported.

#### Critical incident analysis:

Critical incidents are events that represent a significant failure in design or performance that might relate to equipment, procedures, or people. Critical incident analysis is usually a multiple case study technique. A set of observed critical incidents are documented and analysed to determine the source of the failure (though sometimes critical successes might also be examined). This can highlight the importance of improving an infrequent but important task that otherwise might get ignored by a standard task analysis.

#### Economic instruments:

Involve supply-side funding sanctions or incentives for health care providers, but also demand-side measures that give more power to consumers, such as information and funds, so that they can make informed choices.

#### Enforced self-regulation:

A specific form of meta-regulation, of regulated self-regulation. Under enforced self-regulation standards are privately written and publicly ratified. They are enforced both publicly and privately by internal compliance groups with reporting responsibilities to a public regulator.

#### Error reporting systems:

Procedures for reporting and communicating failures of planned actions to be completed as intended (execution error), use of a wrong plan to achieve an aim (planning error), and failure to develop a plan to complete something (error of omission).

#### Governance:

Conceived in its most general way, the term means much the same as regulation conceived in its most general way. Both mean steering the flow of events. Governance is a more general term than government (which only governments do). When corporations govern their own affairs, we speak of corporate governance. When hospitals do so, we speak of clinical governance.

#### Iatrogenic injury:

Injury originating from, or caused by a doctor (*iatros*, Greek for doctor) including unintended or unnecessary harm or suffering arising from any aspect of health care management, including problems arising from acts of commission or omission.

#### League tables:

The public disclosure of rankings based on performance indicators (colloquially known as league tables) includes processes (eg. waiting times), and clinical outcomes (eg. 30-day post-surgical mortality) achieved by hospitals or physicians.

#### Malpractice:

The result of negligence, reprehensible ignorance, or criminal intent. This is differentiated from medical error (see below) which is regarded as an honest mistake or accident.

#### Medical error:

Errors or mistakes committed by health professionals that result in harm to patients. These include errors in diagnosis, in the administration of medication, in the performance of surgical procedures, in the use of other types of therapy, in the use of equipment, and in the interpretation of laboratory findings.

#### Meta-regulation:

Most generally, meta-regulation means the regulation of regulation. In most cases it means regulated self-regulation – an external regulator checks that a self-regulator is regulating internally to externally acceptable standards.

#### Near-miss:

An event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

#### Networked governance:

This occurs when events are steered not by a government hierarchy, but as a result of a web of often horizontally linked actors across a range of private and public organisations. Professional networks are confined to members of a profession scattered across different public and private organisations. Some networks are trans-governmental – consisting of health officials from many different national governments. Others are NGO networks. But the most influential networked governance tends to include actors from governments, professions, business, NGOs, and citizen groups. Networks govern through partnering with network partners, rather than through command and control.

#### New regulatory state:

A term used to describe the parallel development of privatisation with its increased reliance on markets and market principles, alongside increased investment in state regulation of markets. Under the new regulatory state, governments do less rowing but more steering.

#### Node of governance:

A node is a place where resources, ideas, deliberative capability, and leadership are available to make networked governance buzz.

#### Nosocomial infection:

A hospital-acquired infection, originating or taking place in a hospital.

#### Patient safety:

Prevention of harm caused by errors of commission and omission.

#### Peer review:

An organised procedure carried out by a select committee of professionals in evaluating the performance of other professionals in meeting the standards of their specialty, or in evaluating the quality of health care provided to patients.

#### Performance indicators:

Measures of the effectiveness and efficiency of health providers (professionals and facilities) in providing health care.

#### Reactance:

Threat can be counterproductive because it increases a psychological process called reactance (Brehm and Brehm 1981) – defiance – which undermines compliance. What is needed to achieve deterrence without defiance is the acceptance of the societal inexorability of escalation (supporting deterrence) combined with offers of help without threat to avert that escalation - offered by others with whom one identifies (thereby obviating defiance). This is the way to improve compliance in a world where the impact of sanctions on compliance is the sum of a deterrence effect and a defiance effect.

#### Regulation:

Conceived in its most general way, regulation means much the same as governance conceived in its most general way. Both mean steering the flow of events. Regulation is often defined more narrowly, either as something only government agencies do in steering the economy, or as governance through rules. Regulation is not used in these narrower ways in this report.

#### Regulatory pyramid:

Organising sanctions or regulatory strategies in a pyramid is an approach characteristic of responsive regulation. The least interventionist, least costly, strategies are at the base of the pyramid. The normal presumption is that they should be tried first. When these strategies fail, the regulator escalates up the pyramid. At the peak of the pyramid are the most interventionist, most costly, strategies that are the last resort.

#### Responsive regulation:

Maintains that regulators are more likely to succeed by using mechanisms that are responsive to the context, conduct, and culture of those being regulated. Escalating sanctions can be invoked. Since a single regulatory mechanism is seldom sufficient, the weaknesses of one mechanism can be complemented by the strengths of another.

#### Restorative justice:

A process that provides an opportunity for all of the stakeholders affected by an injustice to decide how to repair the harm and meet their needs.



#### Root cause analysis:

A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence of adverse events. Typically, the analysis focuses on systems and processes, and not just individual performance.

#### Self-regulation:

A situation where an organised group regulates the behaviour of its members (eg. through setting an industry-level code of practice).

#### Sentinel events:

Sentinel events are a type of adverse event. Sentinel events are unexpected occurrences involving death or serious physical or psychological injury, or risk thereof. Their occurrence signals the need for immediate investigation and response.

#### Triple-loop learning:

The first loop occurs when an innovator monitors his/her own successful efforts to improve an outcome. The second loop is when a senior manager changes the whole organisation's procedures or practices in line with the innovator's reform. The third loop is when government evaluates these experiences, revises its regulatory goals and strategies, and disseminates information on this successful innovation across the industry.

#### Voluntarism:

Based on an individual professional or an organisation undertaking to do the right thing without any coercion.

