Improving patient safety through responsive regulation

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The core role of regulation in improving patient safety

Patient safety has emerged as a focus of international efforts to improve healthcare quality, since unnecessary deaths among patients are a more compelling argument for reform than less than optimal treatment. A regulatory revolution is underway in the 21st century as governments around the world are strengthening the regulation of professionals and organisations in order to ensure better and safer health care for patients. The public expects a high standard from healthcare services, but confidence has been shaken by reports of unsafe practice and varying quality, while medical scandals reveal that providers cannot always be trusted to put the interests of patients first. While most people in developed countries enjoy good health care, an alarming and preventable number of adverse events occur that are caused by health care itself, even in the best of hospitals with the best of professionals. That errors occur is not surprising. An acute care hospital, for example, is a complex organisation where a patient’s treatment involves many technical procedures carried out by staff working in a high pressure environment.

The central purpose of regulation, its core role, according to Malcolm Sparrow is the abatement or control of risks to society, while the essence of the regulatory craft is to “pick important problems and fix them.” Health care can certainly be risky for patients and much more can be done to limit these risks. What gives the state or other bodies the right to regulate others? The scope and scale of risks to patients indicate that the state and other bodies are justified in taking regulatory action.

The first principle of good regulation is that it should build on a foundation of strengths and not weaknesses. Pick the strengths and expand on them. The strengths of a health system lie essentially in its people. Firstly, health professionals generally have internalised a strong ethical code and aim to provide a social service. Secondly, the health professions are built on a learning culture and good professionals continue to reflect upon their practice over their working life. Thirdly, the health professions value their clinical leaders, so reforms should engage champions for change as a key strategy.

Use multiple tools and techniques

Making health care safer for patients involves everyone: politicians, administrators, doctors, nurses, allied health professionals, and support staff, as well as patients and families. The regulation of patient safety must involve multiple regulators and also multiple strategies. One single regulatory actor alone cannot expect to have all the knowledge and to have full command over all the influence and actions necessary to implement change in a complex healthcare system. Smart regulation calls for networked governance where a regulator, such as the state, mobilises other actors in order to get things done. One mechanism (tool or technique) is seldom sufficient, and since each has its strengths and weaknesses, the weaknesses of one mechanism should be complemented by the strengths of another. Also, a regulator should be flexible enough to try a different approach if the first does not work.

Regulation has many meanings, but is used here in its broad sense, meaning much the same as governance conceived in its most
general sense: both meaning steering the flow of events. The “responsive regulation” model, based on studies of regulation in many sectors of the economy (for example, by Braithwaite and Drahos in 2000), argues that regulators are more likely to succeed when they respond to the context, conduct, and culture of those being regulated. Responsive regulation is an appropriate model for the healthcare sector given its many regulatory actors, tradition of self regulation, and strong ethical norms among health professionals.4

These concepts are depicted in a responsive regulation pyramid that encompasses voluntarism at its softer base and “command and control” at the apex (fig 1). The large base of the pyramid indicates that most regulatory activity takes place voluntarily in response to persuasion. The model argues that regulators should begin with softer mechanisms, rather than opting immediately for hard enforcement, in order to give more respectful (and cheaper) options a chance to work first.

Fig 1: Regulatory pyramid and safety and quality mechanisms

Examples of potential mechanisms

- Criminal or civil penalty
- License revocation or suspension
- Physician revalidation
- Enforced self-regulation
- Mandated continuous improvement
- External clinical audit
- Mandated adverse incident reporting
- Mandated root cause analysis
- Protection for whistleblowers
- Published performance indicators
- Consumer complaints commissioner
- Funding agreements
- Clinical governance
- Triple loop learning
- Accreditation – voluntary
- Performance targets
- Benchmarking
- Peer review
- Open disclosure
- Competition
- Performance payments
- Performance contracts
- Consumer information
- Clinical protocols and guidance
- Personal monitoring
- Continuing education
- New technology

Source: Healy 2011
A responsive regulation pyramid offers a conceptual framework for mapping the multiple regulatory actors and multiple regulatory strategies, for explaining and predicting behaviour, and for suggesting when to persuade and when to punish. A regulatory pyramid that aims to improve patient safety ranges from a voluntarist strategy at the base that includes information mechanisms, a market strategy that may include incentive payments, a self regulatory strategy that includes peer review, and a co-regulation strategy that involves agreement between several parties on a code of standards, while a government using a meta-regulation strategy may require hospitals to publicly report all adverse events. Failure to remedy problems despite formal requests to do so provokes enforcement from a regulator as a last resort (for example, revoking a license).

An essential element of responsive regulation is that a regulator must have the capacity to escalate upwards, if necessary, from soft words to hard deeds. Those being regulated must believe in the inexorable nature of sanctions, as polite requests followed by threats only work when everyone knows that sanctions will follow non-compliance. The threat of stern sanctions must loom in order to ensure that people comply with softer and more conciliatory approaches.

Regulation is often perceived as being only about punishment, but strategies that seek to influence behaviour should use both supports as well as sanctions; that is, praise as well as punishment. Regulators should seek to build upon the strengths of those they regulate and not just dwell upon the weaknesses. This can be illustrated in the case of hospital accreditation where a regulatory pyramid of supports seeks to reward the high performers, while a regulatory pyramid of sanctions can escalate in strength in the case of poor performers (fig 2).

Fig 2: Regulatory pyramids of sanctions and supports in hospital licensing and accreditation

Source: Healy 2011
Beware of unintended consequences

Consequences always flow, however, from changing one aspect of a healthcare system when every part connects to another. As each strategy has its strengths and weaknesses, regulators must consider carefully the consequences of each. The complexity of health care points to the wisdom of engaging a range of actors in designing interventions intended to improve quality and safety. For example, often what happens in a top down approach is that a regulator targets some salient and measurable performance indicator, such as emergency department waiting times, and punishes a hospital financially if it does not meet the target. But health professionals are clever people and good at “gaming the numbers,” as a legion of stories attest. Another problem with a performance indicators strategy for improving quality and safety is that the measurable drives out the important. Will the result of a top down edict be to pull health professionals away from other important tasks and will that produce better overall outcomes for patients?

Another example of an unintended consequence is the rise of “regulatory ritualism,” such as in an inspectorial approach, when the process becomes an end in itself. Managers and clinicians can be very creative in massaging apparent performance to outflank the regulators. Firstly, the criteria by which a regulatory authority usually judges its success is throughputs (number of inspections) and outputs (number of certified organisations), rather than outcomes (improved performance). Secondly, “gaming” can become an endemic problem. For example, when US nursing homes were rewarded financially for increasing the number of residents participating in an activity, the researchers observed sleeping residents in wheelchairs being wheeled into the room where a craft or game was going on so that they could be recorded in the head count. This is not to deny that inspection is a crucial regulatory tool, but rather to point out the possible pitfalls of a rules based stance.

Respectful regulation: engaging organisations and professionals

The responsive regulation model stresses the importance of co-regulation and other strategies towards the middle and base of a regulatory pyramid. One problem with a reliance on top down regulation is that it risks killing off cultural strengths within healthcare systems by squashing local innovation and individual commitment. Health professionals are experts in the arcane workings of health services and, when encouraged, are quite capable of finding solutions to pressing patient safety problems. Health professionals are important regulatory actors, not just objects of regulatory action. John Braithwaite has developed the idea of networked escalation in the hypothetical tale of Nurse Response, who progressively enrolls more powerful allies throughout the hospital in order to achieve safer patient care.
Hospital leaders in Australian public hospitals proved to be responsive regulators in applying multiple supports and sanctions that improved compliance with the health minister’s directive on a safe surgery protocol; the “correct patient, correct site, correct procedure protocol.” These hospital leaders typically began with softer interventions: persuade, enlist leaders, train, remind, relax protocol requirements, redesign hospital systems, and reward compliance. But in response to low and slow compliance, many hospital leaders switched to a pyramid of escalating sanctions: direct, delegate, monitor, publicly report, reprimand, and penalise. This experience with the safe surgery protocol illustrates the multifaceted challenge of health sector regulation. Informants commented that they would apply these lessons in implementing future patient safety solutions: “We have learned a lot from this experience on how to go about putting a procedure in place in the hospital, and we will definitely do better next time.”
References


Notes on the author

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