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RAND EUROPE

# Regulatory cultures and research governance

Catriona Manville, Petal Jean Hackett, Salil Gunashekar, Molly Morgan Jones

Prepared for the English Department of Health

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1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138
1200 South Hayes Street, Arlington, VA 22202-5050
4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213-2665
Westbrook Centre, Milton Road, Cambridge CB4 1YG, United Kingdom
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# Summary

Health research governance in the UK has been the subject of much debate and discussion, particularly over the past few years, as existing regulatory approaches and processes have been consolidated and reconsidered. This has been done in response to a growing concern about overly bureaucratic and duplicative review processes for the approval of research in the UK health system, including the approval of clinical trials. This raises questions about why the regulated sector, including the applicants, sponsors, research institutions and local NHS Trusts, are responding to the regulation in ways that lead to duplication. This research was done in order to improve our understanding of the impact of regulation on health research governance, specifically in relation to the behaviour of the regulated sector. When framed in this way, the question can be extended beyond the health research sector and we can look comparatively at the behaviour of regulated sectors in different areas and countries.

Therefore, this study is centred on the key research question:

> What can be learned from a comparative study of the practice of those who are subject to regulatory requirements across sectors and countries?

This study is informed by a review of a small subset of the literature around regulation and regulatory governance in four sectors: health research, medical drug approval, environmental risk regulation and financial services. Once the review of each sector was completed, a comparative analysis drew out lessons which might be applied in the context of health research governance in the UK. Thus, this review is not intended, neither does it claim, to be an exhaustive study of regulation and related literature within each of the sectors. Rather, the sectors and literature within them were selected in the interest of identifying areas which would lend themselves to comparative analysis in the context of health research governance.

This review of health research systems in Australia, Brazil, Canada, China, India, Russia and the USA found that countries use different models to regulate and review research, although most systems have dual components of both decentralised (local) and centralised (national) processes. A further focus on the responses and changes introduced in Australia, Canada and the USA to cope with multi-site trials found that the following mechanisms were used or suggested as ways to affect the way that the regulatory system is received and responded to by stakeholders:

- use accreditation systems to instil trust into review boards which receive decisions from other review boards

- provide certification of staff to provide the required mutual trust in others' decision making – this can be particularly effective when introduced through a national training programme
- encourage reciprocal agreements to accept others' decisions
- increase the transparency of the decision making process to build trust between parties, building on shared approval systems or making use of standard operating procedures
- increase interaction and communication between committees to establish relationships and trust between the individuals involved
- provide education and encourage the use of evidence to understand the relative risk compared to the hypothetical
- evaluate or audit the current system to determine overall success – thus producing more confidence in the system.

This review of the medical drug industry in the UK and the USA focuses on selected key events over the postwar period. Specifically, we consider the Thalidomide and Acquired Immune Deficiency Syndrome (AIDS) crises, the introduction of European directives and the establishment of the European Medicines Agency. These events provide good natural experiments for understanding the effect of policy changes on the regulated sector, as the immediate changes in the regulatory stance provide a benchmark against which changes in behaviour can be examined. Based on this review, the authors suggest that the ways in which changes to the regulatory system for medical drugs are received and responded to by stakeholders offer lessons for the regulation of health research. These include the following.

- Managing seemingly inconsistent regulatory objectives carefully so that they are complementary and not contradictory. Failing to properly balance objectives may result in a cycle of increasing and relaxing standards, eroding confidence in the regulator. Further, if the guidelines resulting from this balancing exercise are not fed through a regulatory body to the relevant executing units, they may experience delays in conducting reviews.
- Developing clear, consistent guidelines on what constitutes a poor outcome (such as unnecessary risk to human lives) and how it will be handled, including setting out, where relevant, criminal and civil liabilities for non-compliance.
- Leveraging public pressure to enhance industry compliance with regulations.
- Considering regulatory actions in the context of the overall landscape in which firms operate: for example, return on investment in drug development is affected heavily by developments in the intellectual property rights landscape. Regulators must consider the likely impact of new regulatory actions on firms' ability to extract profit under intellectual property rights, in order to understand and/or predict compliance behaviours better.

The review of the environmental regulation literature showed that there has been a broader move towards a more dispersed model of environmental governance, as opposed to top-down regulation. This has meant that a range of different mechanisms are used to ensure that environmental risks are minimised, including the following.

- Harness the role of public trust and confidence. Demand from the public for environmental accountability was not only an early driver of regulatory action, but also is a current driver of proactive corporate environmental management.
- Equally, harness consumer demand, particularly where the government has less direct control over the behaviour of the regulated sector.
- Ensure there that is no misalignment of regulatory and actor philosophies, which can pose a threat to implementation of regulation and hence present challenges for effective and efficient governance responses.
- Use education, training and capacity-building to encourage actors to engage with each other, and to foster understanding of the views of different stakeholders in order to create a system that is seen by all as more legitimate and effective.
- Use incentives as the actors become more dispersed and behaviours more difficult to control. Here it is necessary to take into account the motivations of different actors and shape incentives accordingly.

Finally, this analysis of regulatory developments in the financial services industry in the UK and the USA includes the Savings and Loan crisis in the USA, the formation and dissolution of the Financial Services Authority in the UK and the global financial crisis. It examines how immediate changes in the regulatory stance have affected the behaviour of the regulated sector. It is suggested that the lessons to be learned include the following.

- Focus less on the form of the regulator and more on consistent application of the rules, along with closure of regulatory gaps. Much has been written about the pros and cons of functional regulation in the USA versus the umbrella regulator in the UK, but both have failed to treat the contributing factors to the global crisis.
- Pay careful attention to potential asymmetry in regulatory effects. Increasing the burden on one segment versus another (such as banks relative to non-banks, in the US case) or one location versus another, might lead to inter-segment competition and makes the entire system more fragile.
- Pace changes to regulation and allow adequate time for adjustment. The true impact of changes in regulation are observed fully only with a lag, and this effect is greater, the more complex the regulation. Comprehensive changes should be given longer to mature than simple changes.
- Recognise the trade-off between targeted and comprehensive regulations. Complex regulations (for example, the Financial Services and Markets Act 2000 in the UK and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 in the USA) may produce the required shifts in firm compliance and risk

behaviour, but also may result in overlapping and potentially contradictory rules, making it easier for firms to undertake risky behaviour.

- Carefully consider whether contradictory policy objectives can be executed by a single body or whether balancing among the objectives should be carried out at a higher level.

Finally, this cross-cutting comparative analysis identified five common elements or initiatives across the sectors which could be considered further, in relation to health research governance in the UK:

- increased provision of **educational initiatives** to improve awareness and training among actors
- **transparency** and promotion of a culture of openness between researchers, sponsors, trusts, institutions and the public as to the decision making and approval processes which are followed
- together with education and transparency, development of additional mechanisms to **foster trust** within the system. Formal (accreditation schemes or memoranda of understanding) and informal (networking, relationship-building) mechanisms should be considered
- consideration of the **regulatory structure**, including where trade-offs may need to be made to align regulatory philosophies and objectives
- use of **incentives**, in particular the role of the public in creating a demand for research, should be explored – this includes determination of different indicators and metrics that actors can be evaluated against, such as research publications, trials hosted or number of new participants recruited.