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Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare

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ABSTRACT

Objectives The current research project sought to map out the regulatory landscape for patient safety in the English National Health Service (NHS).

Method We used a systematic desk-based search using a variety of sources to identify the total number of organisations with regulatory influence in the NHS; we researched publicly available documents listing external inspection agencies, participated in advisory consultations with NHS regulatory compliance teams and reviewed the websites of all regulatory agencies.

Results Our mapping revealed over 126 organisations who exert some regulatory influence on NHS provider organisations in addition to 211 Clinical Commissioning Groups. The majority of these organisations set standards and collect data from provider organisations and a considerable number carry out investigations. We found a multitude of overlapping functions and activities. The variability in approach and overlapping functions suggest that there is no overall integrated regulatory approach.

Conclusion Regulation potentially provides a variety of benefits in terms of maintaining the safety and quality of care by providing an external perspective on the care being delivered. However, the variability, extent and fragmentation of the regulatory system of the NHS make it hard for regulators to act effectively and places a massive burden on NHS provider organisations. Overlapping regulatory requests may distract locally driven initiatives to improve safety and quality. Further research is needed to understand the full extent of regulatory activity and the true benefits and costs incurred.

Strengths and limitations of this study

- ► This is the first study to attempt a complete mapping of all organisations engaged in regulatory activities in the NHS.
- ► We have included all statutory regulators but also many others who may not see themselves as regulators but nevertheless carry out regulatory activities.
- ► Understanding the full regulatory landscape enables more precise assessment of the benefits and costs of regulation.
- ► Due to resource constraints, we were only able to identify regulatory activities from the websites of the relevant organisations.
- ► Although we have searched extensively, we cannot be sure that this is a complete mapping.

INTRODUCTION

Regulation is one important means of monitoring and improving the safety of healthcare with the aim of ensuring safe, reliable treatment for patients and a safe working environment for healthcare professionals. Regulation in healthcare takes a variety of different forms and is conducted by many different actors, from formal regulatory inspections to voluntary efforts to promote good practice. Regulatory processes and activities potentially provide valuable feedback to provider organisations, supporting improvement and ensuring that high standards of performance are maintained.[1] Critics argue that although regulation may have valuable effects, it is too often ineffective,[2] inflexible[3] and generates ticking box behaviour and bureaucratic compliance.[4]

A number of organisations and commentators have called for reform, proposing that the regulatory system needs to be simpler, organised around a common approach to regulation and less burdensome for providers.[5 6] However, before such broad proposals can be given, proper consideration of a fundamental question must be addressed. What is the nature and extent of the current system? In this study, we aimed to map the current regulatory system for patient safety in the NHS, including both statutory regulators and other organisations with regulatory influence. Understanding this landscape of regulation of safety is an essential preliminary to any rational reform of the regulatory system but has, to our knowledge, never been previously attempted.

Regulation, regulators and patient safety

The term 'regulation' can be viewed negatively and narrowly by those who are subject to regulatory oversight.[7] In healthcare settings in particular, regulation can often be seen as intrusive and inefficient interference

by external authorities that distracts from the important tasks of clinical care.[8] However, activities of regulation are typically much broader and more constructive than this.[9 10] Regulation represents a wide range of different activities that seek to shape motives and attitudes within organisations, as well as policies and protocols.[11] In healthcare, regulatory activities can encompass everything from formal regulatory inspections, attempts to promote good practice, to efforts to support and initiate culture improvement.[12 13] Moreover, regulatory activities are commonly engaged in by a diverse range of different actors and institutions across healthcare, from statutory regulators to national agencies to professional bodies and charitable organisations.

The regulatory landscape of healthcare is therefore complex and multifacetted. To begin mapping the current regulatory system around patient safety, it is necessary to define the scope of our enquiries. In this study, we define patient safety regulation as *the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their care.* This definition aims to focus attention on the specific activities that are engaged in by 'external' actors to influence 'internal' processes of patient safety in healthcare organisations. It also aims to encompass the breadth of diverse institutional actors that engage in these processes of regulation, even when some of those actors may not define themselves as formal 'regulators'.

Evolution of regulation in the NHS

Before continuing to the mapping process, it is important to provide a brief historical perspective on regulation across the NHS. The 1944 National Health Service White Paper recognised that regular inspections of hospitals would be valuable but the first true external oversight body was not established until 1969, following a series of healthcare scandals.[14] Until the late 1970s, the Department of Health fulfilled most of the regulatory functions, but between 1979 and 1997, the conservative administration created a number of regulatory bodies (such as the NHS Litigation Authority, now NHS Resolution). However, broad sectors of the NHS remained free of statutory external oversight or regulation throughout this period.[15]

Several high-profile failures of care in the 1990s (including the problems at the Bristol Royal Infirmary, Royal Liverpool Children's Hospital) eroded public trust in the NHS. The labour government adopted a more interventionist approach to regulation, increasing the depth, detail and complexity of inspection processes.[5] The National Institute for Health and Care Excellence (NICE) was established in 1999 and the Commission for Health Improvement, the ancestor of the Care Quality Commission (CQC), was founded in 2001 to oversee and inspect the clinical quality of all NHS services. The 2013 Francis report on the Mid Staffordshire failings of care was a defining moment for the whole regulatory regime which had failed to detect and respond to early signs of organisational failure.[16] The governmental response generated more structural changes to the system, with an increased focus on devolution of central oversight.

The evolution of regulation in the NHS needs to be seen in the context of continual widespread reform and restructuring of the wider NHS. In 2002, the National Health Service Reform and Healthcare Professionals Act merged 95 health authorities into 28 strategic health authorities (SHAs).[17] In 2006, the number of SHAs reduced to 10 and later transformed into four clusters (North, South, Midlands and East of England) before finally been abolished in April 2013.[18] During this time, health services commissioning was undertaken by 481 Primary Care Groups, later reduced to 152 Primary Care Trusts (PCTs) in 2002, solely responsible for all NHS commissioning.[17] Finally, under the Health and Social Care Act in 2012, PCTs were replaced by statutory, commissioning 'consortia', the Clinical Commissioning Groups (CCGs).[19]

The 5-year forward review[20] brought the planning and regulation of primary, secondary and social care together with local authority influence under seven models of care each covering a core set of related services (for instance, urgent and emergency care networks). Local leaders in 44 geographical areas have been asked to design sustainability and transformation plans (STPs) to demonstrate how they intend to transform services in their local areas.[21] Ten integrated care systems (ICSs) have evolved from STPs, responsible for planning and commissioning care for their populations.[22]

The need to map the regulatory landscape of the NHS

This short overview of regulation history in the UK demonstrates a stream of structural reforms over the last 25+ years, which have gradually increased the extent and complexity of the regulatory structures.[16 23] In 2002, Walshe argued that: 'Current regulators vary widely in their statutory authority, powers, scope of action, and approach. The resulting mosaic of regulatory arrangements is highly fragmented and some roles are duplicated'.[24] Since then, the complexity of the system has increased considerably. A report from the NHS confederation argued that this complexity places an unnecessary burden on healthcare organisations when, for example, different regulators request evidence for similar safety standards.[25] The Professional Standards Authority has pointed out that all the nine bodies they oversee have a common set of functions yet there are differences in legislation, standards, approach and efficiency, among others.[6]

In this study, we attempted to map the complete landscape of all organisations with patient safety regulatory effect on NHS providers and consider the impact of this system on NHS provider organisations. This means identifying all organisations which exert regulatory influence, not just those designated as statutory regulators. In our preliminary inquiries, it appeared that no one, not even