



NIHR King's Patient Safety and Service Quality Centre
(PSSQ)

Organisational Governance Programme

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GOVERNING FOR PATIENT SAFETY

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Introduction

Although most work on patient safety has focused on individual (micro) level factors and interventions, increasingly the role of organisational factors (meso level) in providing high quality and safe health care is being acknowledged (Waring, 2007). However, the effect of organisational governance on patient safety is an area that has received little attention so far in the growing patient safety literature. Instead, to date, the vast majority of research into patient safety has focused on the clinical aspects of safe care. This is at odds with the recognised importance of systems in ensuring safe and high quality care (Institute of Medicine, 2000, 2001). This paper aims to develop the organisational perspective on patient safety by looking at governance for patient safety. The focus is on *organisational* governance rather than governance at the macro level. We are concerned with the organisational structures, cultures and instruments that are used to organise and manage behaviour. We do not investigate which forms of governance work best at the macro level (i.e. markets, hierarchies and networks), as an in-depth review of this has already been completed (Davies, 2005). Rather, we are concerned with the origins of ‘organisational governance’ and how it can be linked to patient safety at the meso (organisational) level. We include a discussion of the definitions of organisational governance in order that we can adopt a working definition for our research.

The purpose of the paper is to provide a conceptual context for the organisational governance research programme within the NIHR King’s Patient Safety and Service Quality Research Centre, based on a broader social science literature than is usually applied to the concept of ‘patient safety’.

In order to do this, we first describe the context within which discussions of organisational governance and patient safety have developed. We identify three inter-related, society-level explanations that have been used to explain the increased preoccupation with controlling risk through governance at the meso level that has occurred. First, the notion of the ‘risk society’, which suggests that

the risks facing society have objectively changed or are perceived differently in ways that make them harder to measure and govern than previously. Secondly, the emergence of the 'regulatory state', whereby the state's retreat from direct control has been associated with the development of governance solutions to risk 'problems', resulting in an increased number of regulatory bodies 'looking' for risks to regulate. Finally, the concept of the 'audit society', which describes how it is to live in this 'regulatory state' in which organisations have to account for what they do and how they do it. The process of audit has developed in order to govern and regulate risks.

Next we discuss different perspectives on the concept of governance broadly; and, in particular, governance in healthcare. We look at two specific areas of governance, corporate governance and clinical governance, and how they have developed and been applied in health care. Finally, we adopt a working definition of organisational governance for use in our research programme.

'Risk Society'

Beck (1992) proposes that we are living in a 'risk society'. He argues that the type of risk that populations are exposed to has changed, both in the nature of the threats posed and in their causes. He identifies contemporary risks as those of modernisation, a product of industrialisation. As such, they have systematically intensified as industrialisation has spread and grown (Beck, 1992). Beck believes that risk can be defined "as a systematic way of dealing with hazards and insecurities induced and introduced by modernisation itself." (Beck, 1992: 21).

The 'risks of modernisation", for example those from scientific and technological developments such as genetically modified crops or mobile phone masts, can be viewed as being characterised by invisibility and immateriality, and as such are highly dependent on interpretation (Adam & van Loon, 2000). Indeed, according to Douglas (1992), the concept of 'risk' itself is hypothetical and metaphorical; a way of thinking. Conventional probabilistic measures of risk used and accepted

as 'objective measures', challenge this notion that risk is artificial. For example, epidemiological and laboratory evidence have been used to address the question 'How dangerous are mobile phones, transmission masts, and electricity pylons?' (Wood, 2006). Nevertheless, any such measurement depends on the risk in question having first been accepted and defined as a risk. In this sense, risks *are* constituted through social processes of authorisation and legitimation by relevant actors.

Designation of something as a risk can occur in the absence of any empirical evidence about the nature and extent of the dangers involved, and social actors can be mobilised to address a risk that does not, according to empirical evidence, actually pose much danger (Castaneda, 2000). Conversely, some 'real' potential hazards never attain the status of defined risks. Thus there is no simple correspondence between risk perception and 'real risk' (Adam & van Loon, 2000). Beck-Gernsheim (1996) highlights the social and political dimensions of the construction of risk, particularly the debate and contestation between different groups that is an important factor in determining what constitutes a risk.

It has been argued that organisations are the most important unit of analysis within risk society because it is in these environments that perceived dangers undergo measurement and control (Short in Hutter & Power, 2005). Hutter and Power argue that organisational responses to risk are influenced by their environments, and that "this organising process is itself a source of risk for individuals, for other organisations and for wider environments." (Hutter & Power, 2005:3). Therefore, the management of risk is a core feature of an organisation, not an accidental one. However, they also note that this does not mean that organisations always fully understand their risks or invest in the best possible management systems (Hutter & Power, 2005).

The idea of a “risk society” reflects the view that contemporary societies are so profoundly affected by technologically-induced risk that this is their defining feature (Beck, 1992; Castaneda, 2000). Although to start with these risks can be legitimated as ‘latent side effects’ of a modern, technological society, as they spread and grow they become subject to public criticism and scientific investigation, and thereby acquire a central importance in social and political debates (Beck, 1992). Consequently, risks have become a considerable force of political mobilisation. Indeed Adam and van Loon (2000: 4) suggest that risk has become “the object of one of the most effective discursive strategies for changing the political horizon of modern industrialised society”.

The ‘Regulatory State’

The rise of governance is linked with a different societal change: the move away from the traditional ‘welfare state’ and towards a ‘regulatory state’ (Majone, 1997). This is the emergence of a new institutional and policy style, in which the government’s role as regulator advances as its direct control functions decline (Hood, Rothstein & Baldwin, 2001). Of particular relevance is the state’s retreat from some particular direct forms of intervention, like public ownership; and the advance of new forms of control, especially the growth of regulation over a wide range of potential risks to health and safety (Moran, 2001). This new and expanded regulation, rule-setting, monitoring and enforcement is carried out increasingly through delegation of these functions to a growing number of relatively autonomous regulatory bodies (King, 2007).

Some authors have disagreed with labelling this new way of governing the ‘regulatory state’, because they argue that previous forms of government were also regulatory states (Moran, 2002; Braithwaite, 2000). For example, Braithwaite believes that “the Keynesian state was the original regulatory state based on a law-sanctioning, hierarchical and command form” (Braithwaite, 2000: 7). Given that regulation can be traced back centuries, what is so different or special about this contemporary regulatory state? King points to the increasing emphasis on

regulation as an instrument of state control “in comparison with the state’s other functions, such as taxation, expenditure, redistribution, industrial planning, public ownership and macro-economic stabilisation” (King, 2007: 14). Moran (2001) highlights several novel features of the new regulatory state, including its scale, the creation of distinctive, specialised groups of regulators, the elaboration and pervasiveness of new regulatory codes and the range and ambitions of regulation in this context.

Hood et al. (2001) propose that ‘risk society’ and the ‘regulatory state’ are linked, insofar as contemporary regulatory growth is often held to be driven by ideas of risk and safety (2001:4). Rothstein, Huber & Gaskell (2006: 94) suggest, likewise, that the growth of risk regulation could be viewed as a response to newly created and discovered risks in modern society, and so a “risk society is inherently a regulatory society”. Regulation can also be seen as a way for governments to distance themselves from organisational risks. For example, Salter (2007) explains that the benefits for a state of moving from a welfare to a regulatory role with regard to medicine are that it creates a distance between the state and its citizens that allows it to deflect responsibility for maintaining standards to the medical profession.

Rothstein et al (2006) offer two further perspectives on the relationship between the regulatory state and risk society. They argue that “the regulatory society is a risk (generating) society” (Rothstein et al., 2006: 96), in that the changing scope and character of state and non-state regulatory frameworks has led to the growing centrality of risk to regulation; and they suggest that in contemporary society risk is also used as an organising idea for decision-making and the management of uncertainty. Thus risk is not just an object of regulation, but also a method for organising regulatory activity in a wide range of policy domains and organisational settings (Rothstein et al., 2006).

The ‘Audit Society’

The conjunction of ‘risk society’ and ‘regulatory state’ is associated with demands for increased and new forms of trust and assurance at both institutional and organisational level. Webster comments that in complex, differentiated social systems, trust depends on the mobilisation of more reflexive, more codified forms, providing reassurance and accountability from the state to manage risks (Webster, 2007). In a range of arenas where there were previously high levels of trust, and governance was handled through professional self-regulation, the state has increasingly moved towards formal audit mechanisms (Moran, 2002).

However, attempts to meet greater demands for assurance can have perverse effects. Increased regulation creates risk as well as responding to it and thereby generates an ever increasing need for risk management and regulation. Consequently, trust becomes defined in terms of governance processes and measures such as audit and performance indicators (Webster, 2007; Power, 2007). A vicious circle is created whereby organisations become safer via their risk management processes, “at the expense of citizens”, so that, in turn, trust in institutions declines (Hutter and Powell, 2007). A gap appears between macro-level policy aspirations for trusting and trusted public services and the micro-level practical practices that could engender those (Dibben and Lean, 2003). It is not clear that reactively created certification and disclosure regimes are an effective means of creating public trust (Power, 1997).

Power (1997) draws attention to the ‘audit explosion’, incorporating a variety of related monitoring, evaluating and assessment practices, which in the UK occurred in the 1980s and early 1990s. Auditing in the UK became a key instrument of attack on the closed systems of professional self-regulation that, for a variety of reasons, had lost public confidence (Power, 2005; King, 2007). The ‘audit explosion’ in the UK was part of the wider move to new modes of government steering via regulatory agencies, such as auditing and inspection bodies (Power, 2005). Power (2005) proposes that the audit explosion also represents a rise in “control of control”. To this end, state inspectorates require

organisations in the UK to install effective control systems, which are then used to 'audit' the organisation (Power, 1997). Such frameworks for internal control are increasingly described in terms of organisational governance (Power, 2005).

Audit, however, faces problems in meeting the expectations placed upon it, since there is a large gap between the programmatic demands on audit and its operational capabilities (Power, 1997). For this reason, Power calls audit and other monitoring practices 'rituals of verification'. But if this is all they are, why have such rituals spread so rapidly and deeply throughout society? Moran (2002) suggests they are spreading because such demands for assurance are prompted by a lack of trust, and that audit is not needed, nor is it much practiced, where social actors can trust each other.

It is in this context that there has been a dramatic increase and formalisation in the use of "governance", first in the private and then the public sector, as a way of meeting the demands for increased assurance that the conjunction of increased exposure to 'manufactured risks' and increased regulation produces. In the regulatory state, new forms of monitoring are stimulated and hitherto private practices, like internal control, are governmentalised and formalised (Power, 1997). Furthermore, once such assurance measures are introduced, mitigation of any loss of trust, for example, through high-profile failure, is attempted by introducing further more elaborate and formal 'assurance' demands on organisations. This has been the pattern in the financial world and is now developing in other domains too (Hood et al., 2001).

What does governance mean?

Having briefly discussed three inter-related, society-level explanations for the increased control of risk through governance at the meso level, we now turn to organisational governance itself. Broadly, organisational governance refers to the systems within an organisation which ensure it is effectively managed. Following a number of corporate scandals in the UK in the 1980s (Barings, etc) and in the

USA in the 1990s and later (Enron and WorldCom), there has been a strong focus on improving corporate governance. A number of reports in the UK since 1992 set new standards for corporate governance in the private sector (Cadbury, 1992; Turnbull, 1999; Higgs, 2003). Subsequently, the public and NGO sector also began to focus on governance issues. In the NHS this followed a number of inquiries into serious failings of clinical care (Bristol, Alder Hey and others). More recently in the NHS, policies intended to devolve responsibilities and increase autonomy to local organisations (e.g. Foundation Trusts) have given particular importance to governance.

The term 'governance' has become ubiquitous in both the public and private sectors, characterising both global and local arrangements, and referring to both formal and informal norms and understandings (Lynn, Heinrich & Hill, 2000). Frederickson (2007) lists some of the many widespread applications and interpretations of governance at both the macro and meso level (shown in Box 1).

Box 1

- the structure of political institutions
- the shift from the bureaucratic state to the hollow state or to third-party government
- market-based approaches to government
- the development of social capital, civil society, and high levels of citizen participation
- the work of empowered, muscular, risk-taking public entrepreneurs
- a political packaging of the latest ideas in new public management, expanded forms of political participation, and attempts to renew civil society
- the new public management or managerialism

- public sector performance
- interjurisdictional cooperation and network management
- globalisation and rationalisation
- corporate oversight, transparency and accounting standards

In particular, there is a current fashion for governance to be defined as networks of power and management (Gray, 2004). However, it has been argued that it is important not to depend on any narrow definition, since each one represents a particular form of governance rather than capturing its essence (Gray, 2004). To define governance by any one usage may weaken analytical capabilities and consequent understanding (Gray, 2004).

As shown by the multitude of uses and definitions, notions of governance both in functional usage and in the literature are somewhat confused. This is partly because the concept of governance is applied so broadly that virtually any meaning can be attached to it (Frederickson, 2007). Like the concept of audit (Power, 1997), it may be that the vagueness and imprecision of governance as a term contributes to its survival and resilience as a concept, because these features allow its migration to and application in a wide variety of contexts.

Lynn et al. suggest that despite the ambiguity of definitions, governance generally refers to “the means for achieving direction, control, and coordination of wholly or partially autonomous individuals or organisations on behalf of interests to which they jointly contribute” (Lynn et al., 2000:235). Gray identifies the common elements of governance as “the arrangements by which authority and function are allocated and rights and obligations established and regulated and through which policies and practices are affected” (Gray, 2004: 4). Finally, Webster views governance as forms of social accountability and responsibility that are procedural, codified and subject to scrutiny, making it “a highly reflexive set of procedures and expectations that mark out contemporary society, and its subsystems, such as health.” (Webster, 2007: 133). The difference between

these authors in their conceptualisation of the ‘common elements’ of governance highlights the need to distinguish between governance and governance regimes. Broadly, governance is about the exercise of control and governance regimes are the manifestation of this.

Governance in healthcare

In addition to the definitional difficulties already noted, Lynn et al (2001) argue that the concept of governance is more complex in the public sector than in the private sector because the objectives and outcomes of transactions are less transparent, the power of direction and control is widely dispersed and the goals of actors are multifarious and often in conflict. Given all of this is not surprising that there is no universal definition of or approach to governance within healthcare.

There are multiple inter-linked strands of governance in the NHS, including not only clinical governance, but also corporate and financial governance; and numerous governance instruments, such as risk management and controls assurance. Many organisations are now bringing separate governance domains and activities together within the concept of ‘integrated governance’. This acknowledges both the existence of different governance regimes within the health service and “their vital importance and their inter-dependence and inter-connectivity” (Department of Health, 2006: 3). The *Integrated Governance Handbook* defines integrated governance as, “systems, processes and behaviours by which trusts lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organisations” (Department of Health, 2006: 10). This definition indicates that as well as ‘formal’ governance mechanisms such as systems and processes, governance regimes include ‘informal’ mechanisms such as culture and behaviour. As *Governing the NHS* outlines, “control systems are the procedures and processes that ensure necessary actions are taken to achieve the organisation’s objectives. Controls

can be 'hard' such as policy, rules, standards and prescribed processes or 'soft' which include the organisational culture, ethics, commitment and leadership of the Board, effective communication, appropriate incentives and adequate training." (Department of Health, 2003: 10). The *Integrated Governance Handbook* and other NHS governance documents do not specify the areas of governance within NHS organisations that should be integrated.

There are three main governance areas within an NHS organisation: financial, corporate and clinical governance. These three areas have specific official policy documents dedicated to them and have the largest impact on the organisation. There are a few other discrete areas of governance in the NHS, such as IT governance and research governance. However, these are more specific than the wider, generic areas of governance we wish to investigate. For this document and in our programme of work on healthcare we have decided to focus on the concepts of corporate and clinical governance since these have the main implications for patient safety. Besides these two areas of governance, we will explore the important mediating factor of organisational culture in relation to governance.

Corporate governance

The concept of 'corporate governance' first came to prominence in the private sector in 1992 with the publication of the Cadbury Report (Cadbury, 1992). Several notable corporate collapses led to the publication of the Cadbury report, which gave recommendations on how to strengthen corporate governance arrangements in order to avert further incidents of corporate failure. In particular, the report emphasised the role of the board and non-executives in governance and initiated the "comply or explain" practice for corporate governance. Following the Cadbury report, several further reports were published that provided guidance on corporate governance. Some of these looked at specific aspects of corporate governance, such as the Turnbull report, which focused on internal control (Turnbull, 1999). From these reports the Combined Code of Corporate

Governance was developed, which British companies have to comply with or explain their reason for non-compliance. The successive collapse of Barings, Enron and Arthur Anderson has ensured that corporate governance remains high on the agenda of governments and the financial markets.

Although corporate governance is a prominent and established sector of governance, which paved the way for the development of governance in other areas, there are still dozens of definitions and interpretations of the term. One of the first was in the Cadbury Report, where corporate governance was defined as “the system by which companies are directed and controlled.” (Cadbury, 1992: 15). Since then many and varied definitions have been proposed. Each emphasises different qualities, including:

- Direction/leading
- Control
- Accountability
- Supervision
- Compliance
- Regulation
- Change/reform
- Assurance
- Checks and balances
- Systematic approach
- Umbrella framework
- Relationships and networks/patterns of interaction

NHS documents do not help to clarify how corporate governance within healthcare is defined. *Governing the NHS* simply states that “each Board’s prime duty is to ensure good governance” (NHS, 2003: 3). It goes on to note that NHS Boards “work within a framework of national, legal, procedural, quality and outcome standards and with professional staff who themselves are subject to a range of professional standards and obligations.....The Board is ultimately responsible for the achievement of standards” (NHS, 2003: 13). *The Intelligent*

Board expands on the importance of responsibility: “The Board of every NHS organisation carries the final overall corporate accountability for its strategies, its policies and its actions as set out in the Codes of Conduct and Accountability issued by the Secretary of State” (Wells, Moyes, Fry, et al., 2006: 9). The *Integrated Governance Handbook* also states that it is the Board’s responsibility to make sense of the complex array of systems, procedures, reporting frameworks, standards and inspection frameworks that NHS organisations are subject to.

Corporate governance and patient safety

Guidelines for corporate governance in the private sector (for example: Higgs, 2003; Turnbull, 1999) were used to develop the documents which provide guidance on corporate governance in the NHS. This includes guidelines on matters such as the composition of Board, role of Board members, information the Board should receive, committees and so on. These have important implications for the quality and safety of the care provided within the organisation. The Healthcare Commission investigations into *Clostridium difficile* (*C. diff*) outbreaks at Maidstone and Tunbridge Wells NHS Trust and Stoke Mandeville Hospital found many failures at Board level that contributed to the outbreaks (Healthcare Commission, 2006). The overall culture and attitude of the board is also important in governing for safety. For example, the unwillingness of the Board of Maidstone and Tunbridge Wells NHS Trust to hear bad news was identified as a factor in the outbreaks of *C. diff* that occurred there (Healthcare Commission, 2007). The importance of leadership by the Board and specifically the Chair and Chief Executive is frequently emphasised. For example: “the role of the Chair is pivotal to the success of the Board” (NHS 2003: 16) and “leadership by the chief executive is probably the most critical element of controlling clinical governance” (Hackett, Lilford & Jordan., 1999: 101). Following the corporate governance issues in the private sector, the role of non-executive directors (NEDs) on the boards of NHS trusts has been clarified. It is argued that the NEDs’ role is to challenge and contribute to the development of strategy and

to provide independent views and scrutiny, particularly of the performance of management (Higgs, 2003). It is argued that it is important that all Board members feel able to (and actually do) challenge within the Board environment (NHS, 2003).

Another important aspect of corporate governance for patient safety is the enthusiasm and priority the Board gives to the quality and safety of care. Walshe and Offen (2001) report that a major lesson from the Bristol enquiry is that organisations need a strong corporate focus on quality. Stanton also emphasises that “a Board’s scrutiny and strategic leadership of the safety and quality of care demands more than a superficial or rhetorical commitment to clinical governance” (Stanton, 2006: 43). The Board’s commitment and enthusiasm is needed to overcome obstacles and resistance to change needed to improve the quality of care (Stanton, 2006). The events at Stoke Mandeville Hospital and Maidstone and Tunbridge Wells NHS Trust both show the importance of a board’s focus and priorities. In both these cases the Board gave the highest priority to waiting time targets, which, in conjunction with other factors, compromised infection control and resulted in major outbreaks of *C. diff*. It is an important part of the Board’s role to give strategic direction; however boards also need to ensure they have an operational focus in order to govern for safety. This is a complicated challenge, where boards are expected to “not get into the detail” but also to know that their decisions have been translated successfully into action by those who are close to patients. (NHS, 2003: 7).

Clinical governance

Definitions of clinical governance range from simple and focused to complex and all-encompassing. Clinical governance has been defined succinctly as “corporate accountability for clinical performance” (Scotland, 2000) and “the accountable principles of clinical practice”. The description in the 1998 consultation document *A First Class Service: Quality in the New NHS* was more elaborate. Clinical governance is, “a framework through which NHS organisations are accountable

for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.” (Department of Health, 1998). This definition incorporates two distinct elements of governance – mechanisms for ensuring systems are in place and the more philosophical aspect of producing a culture in which clinical quality can flourish (Haslock, 1999).

Elsewhere, clinical governance has been described as a whole system cultural change, “which provides the means of developing the organisational capability to deliver sustainable, accountable, patient focused, quality assured healthcare” (Nicholls et al., 2000: 174). Gray’s examination of defining clinical governance takes a broader perspective, seeing clinical governance “less as a formal arrangement of structures and processes for quality assurance (expressed perhaps in ‘upper case’ Clinical Governance) than a relationship of authority and function through which clinical policies and practices are effected and rights and obligations regulated (perhaps expressed as ‘lower case’ clinical governance) or, more strictly, the governance of clinical practice.” (Gray, 2004: 5). This last approach demonstrates the formal and informal aspects of governance discussed previously.

Development of clinical governance in the NHS

Before the 1980s in the NHS there were a few pioneering quality initiatives in particular specialties or organisations (Walshe & Offen, 2001), but nothing systematic or organisation or nationwide. Self-regulation was the dominant paradigm, reflecting trust in the altruism of the caring professions (Bevan & Cornwell, 2006). It was assumed that quality was inherent within the system (Cullen, Nicholls & Halligan, 2000). Walshe and Offen note that many clinicians and professional organisations “had a record of being disinterested, sceptical, or even actively hostile towards the idea that systematic or formal quality improvement activities had much to offer health care.” (Walshe & Offen, 2001: 251). However, in the 1980s this started to change. Key developments included

the Griffiths report (1983), which identified a lack of clarity in accountability at local level and led to the introduction of general managers in the NHS. During the same period, medical audit was taken up by some enthusiasts and was introduced as an expectation for all doctors in the 1990 NHS reform (Department of Health, 1989), but its application and use remained inconsistent (National Audit Office, 1995).

During the 1990s, it is argued, the perception of quality in healthcare fell below 'actual performance' for the first time (Nicholls et al, 2000). In response, there was a raft of national and local quality initiatives, accompanied by £250 million investment over five years in quality improvement (Walshe & Offen, 2001). Many quality initiatives were introduced in the 1990s, such as continuous quality improvement, reform of professional regulation and the Patient's Charter. By 1995, clinical audit or quality improvement systems and structures were established in most healthcare organisations (Walshe & Offen, 2001). The concept of clinical governance was first mentioned in 1997 in Labour's first white paper on the NHS, *The New NHS Modern, Dependable*. Clinical governance became a central plank in the government's modernisation strategy for the NHS. The white paper and *A First Class Service* aimed to make "quality of care the driving force for the development of health service in England" (NHS, 1999: 4).

An important factor in the ascendance of clinical governance was the introduction of a statutory duty of quality upon NHS organisations in the 1999 Health Act. This states that, "it is the duty of each Health Authority, Primary Care Trust and NHS trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals." (Health Act, Section 8, 1999). It made NHS chief executives responsible for the quality of the clinical care provided by their organisations. This requirement has been called the "second bottom line" attempting to make the management of healthcare clinical activities as 'disciplined' as financial management (Flynn, 2004).

The report of the Bristol Inquiry (Kennedy, 2001), was a key driver for increasing the priority given in the NHS to addressing poor performance and quality and standards of care (Walshe & Offen, 2001). More recently, enquiries into failings of infection control at Stoke-Mandeville and Tunbridge Wells and Maidstone NHS trusts (Healthcare Commission, 2006, 2007), have ensured a continuing high profile for concerns about quality and safety and a continuing need to build public confidence. Indeed, McSherry and Pearce (2001) have suggested that clinical governance was promoted because it was viewed as a panacea for the perceived failing NHS as reported in media coverage. The NHS Clinical Governance Support website acknowledges that “clinical governance was born out of the need for real accountability for the safe delivery of health services. This was due partly to the public’s and professionals’ perception of systemic failings within the NHS.” (Clinical Governance Support Team website). As in the private sector, high profile failings have often resulted in new governance guidelines or requirements; and events of this sort also provide the sense of urgency that is arguably key to achieving successful change in organisations (Halligan and Donaldson, 2001). The rise of clinical governance must also be seen in the general context, discussed previously, of a society that is more pre-occupied than previously with scandal and risk and sees the solution to this framing of the world as lying with monitoring, inspection and regulation.

A number of critiques have been made of the concept of clinical governance, including the ambiguity of its definition (Maynard, 2004; Flynn, 2004). This ambiguity may help its acceptance, but can also lead to misunderstanding and disagreement (Flynn, 2004). It has been pointed out that the elements of clinical governance are not new; that health care professionals have always undertaken, for example, audit and clinical review (Scott, 1998); and the introduction of clinical governance in the NHS also raised concerns that it was simply another quality initiative that would fail to live up to its promises. But, despite such concerns, the advocates of clinical governance argue that it has much to offer. Scally and Donaldson, for example, proposed that “clinical governance is to be

the main vehicle for continuously improving the quality of patient care and developing the capacity of the NHS in England to maintain high standards” (Scally & Donaldson, 1998: 61). Heard (2000) argues that clinical governance is different due to its inclusion and prominence of education and professional development and leadership.

Finally, one of the most common themes in the literature on clinical governance is the fact that its purpose is to bring together quality initiatives in a systematic way and to make quality the responsibility of all. Previously, different quality initiatives were owned by different staff groups and were not coordinated, whereas the overarching framework for quality improvement and assurance that clinical governance provides changes this (NHS Executive, 1999; Dewar 1999: 8) Some of the activities (also called ‘pillars’) in the integrated approach to quality provided by the clinical governance framework include: coordinated quality drives; evidence-based practice; clinical risk management; clinical audit; and continuing professional development (Firth-Cozens, 1999).

However, just bringing these activities together is not enough to improve the quality and safety of care. Clinical governance is also about using the outputs from these activities to recognise good and poor care and to bring about the necessary cultural and practice changes to address this (Scally and Donaldson, 1998). Finally, clinical governance attempts to ensure that there is accountability up to board level for ensuring safe and high quality care and has added the emphasis on continuous improvement in quality of care to the quality agenda.

As discussed above, more recently there have been moves towards integrating clinical governance with other areas of governance. This recognises the fact that clinical and corporate risks are interrelated and that, to improve the quality of healthcare provision, both need to be addressed. It also acknowledges the tensions within a healthcare organisation: “Integrated governance recognises the dynamic tension of competing elements: national v local, quality v cost,

information sharing v individual rights, lessons from the past v demands of the future, and encourages Trust Board members to be the arbiters of these balancing acts.” (Clinical Governance Support Team website).

NHS organisations have been provided with guidelines and principles for developing integrated governance systems, for example: *The Intelligent Board*, *Integrated Governance Handbook*.

Organisational Culture

There has been an increasing interest in the concept of organisational culture both within and beyond healthcare settings. Two main debates surround this. First, whether organisational culture can be defined; and second, if it can be defined, how this is to be done and how it can be measured (Davies, Nuttley & Mannion, 2000). Our purpose here is not to summarise the large body of literature on these issues and other aspects of organisational culture, but rather to demonstrate how culture is an important factor in governing for patient safety. Organisational culture can act in three different ways in conjunction with governance:

- 1) culture may affect the governance that is designed;
- 2) culture change is needed to implement governance, and governance will lead to culture change; and
- 3) culture acts as an informal governance mechanism.

Each of these interactions will be looked at in turn. While most of the relevant literature refers to clinical governance, the points made are applicable more widely to healthcare governance.

First, research suggests that healthcare quality improvement or clinical audit programmes reflect the organisational culture and context in which they are established (Walshe & Offen, 2001). Therefore, organisations that have a positive and receptive culture are more successful at making governance work. In essence, quality improvement instruments are a reflection of the organisation

that they work within, both positive and negative (Walshe & Offen, 2001: 255). The way an organisation is led, the extent to which staff are involved in planning its development, its willingness to embrace constructive criticism and new ideas and its determination to break down barriers between professional groups all affect the quality of its governance arrangements (NHS, 1999). Gray (2004) identifies both formal (structural) and informal (behavioural) aspects of clinical governance. He too believes that clinical governance is shaped by the culture of an organisation, reflecting the fact that staff are not passive but active users of and participants in leaders' visions and policies (Scott, Mannion, Davies & Marshall, 2003b).

Secondly, if culture affects the implementation of governance then many organisations will need cultural change to achieve successful governance. Scott et al (2003a) emphasise that NHS organisations will have to develop strong cultures and structures that both monitor and support to establish a positive governance regime. The Department of Health has also stressed the need to move away from a 'blame culture' if governance is to achieve its aims (DoH 1999, in Heard, 2000). At the same time, it has been argued that introducing and implementing governance can itself to produce culture change. Halligan observes that clinical governance is "a transforming initiative, which designs-in the necessary cultural levers to make safe, high quality service not just achievable but inevitable" (Halligan, 2006: 6). A middle ground between these two views could be that "the implementation of clinical governance provides the opportunity to begin the cultural shift necessary to underpin quality in the modern NHS" (Cullen et al., 2000: 233).

Thirdly, within the context of governance regimes, culture acts as a mechanism of governance. The *Integrated Governance Handbook* provides the following useful example demonstrating the importance of culture and behaviour as an informal sphere of governance:

“sound structure and systems are not, on their own, enough to secure good governance. A complaints system is of no value unless those who are intended to use it (customers, clients, patients etc.) know of its existence and unless staff within the organisation are trained to operate it effectively. A whistle-blowing policy will not be used unless staff are made aware of it and are confident that, if they voice their concerns, those concerns will be taken seriously and the organisation will deal with them fairly.” (NHS, 2006: 10)

There is an ever-growing body of literature looking at the cultures and behavioural characteristics needed to ensure good governance, in particular for patient safety, such as: a ‘no blame’ or ‘low blame’ culture; ‘safety culture’; and a ‘learning organisation’ (e.g. Halligan and Donaldson, 2001; Walton, 2004; Waring, 2005; Carroll and Edmondson, 2002). For example, the Health Service Circular on Clinical Governance states that, for clinical governance to be successful, organisations need to have an open and transparent culture and value professional development (NHS Executive, 1999: 7).

Leadership is a critically important cultural governance mechanism and may even be the chief prerequisite for successful quality improvement in a health care organisation (Walshe & Offen, 2001: 253). Halligan (2006) asserts that good clinical governance is a result of effective leadership and the essence of such leadership is to demonstrate that positive change is achievable. Leadership is often linked solely to corporate governance, but leadership at corporate level is likely to mirror the wider organisational approach to leadership and culture. For example, Walshe and Offen (2001) believe the limited vision or strategic direction and poor attempts at planning or management at Bristol Royal Infirmary reflected the wider culture of the organisation, and that progress was slowed and limited by this approach to leadership.

Conclusions: adopting a working definition of organisational governance

Despite the apparent difficulties in defining governance, we believe it is important to adopt a working definition of organisational governance for our research programme. This may, of course, change over time as our research gives us a greater understanding of the concept and its elements.

Given the discussion above of perspectives on governance and the importance of factors such as organisational culture, we are basing our definition on that used in the NHS *Integrated Governance Handbook* (Department of Health, 2006:10), but adding the concept of ‘cultures’. In our working definition, organisational governance within health care comprises “the systems, processes, behaviours *and cultures* by which health care organisations lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organisations” (adapted from NHS, 2006: 10).

However, there are two important points to bear in mind. The first is that the context for our definition is that set out at the beginning of this paper, i.e. the three inter-related, society-level explanations that have been used to explain the increased control of risk through governance at the meso (organisational) level (‘the risk society’, ‘the regulatory state’, and ‘the audit society’). Secondly, while the organisation is our central analytic focus, we are mindful of the crucial importance of the wider environment within which organisations “lead, direct, and control” their functions, particularly in a centralised system such as the current NHS. The influence of this wider context is, therefore, an important consideration in any study of organisational governance.

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