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Adaptive regulation or governmentality: patient safety and the changing regulation of medicine

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[Pre-publication Version]

Introduction

Studies from across the world have shown that clinical mistakes are a major threat to the safety of patient care (World Health Organisation 2004). For the National Health Service (NHS) of England and Wales it is estimated that one in ten hospital patients experience some form of error, and each year these cost the service over £2 billion in remedial care (Department of Health 2000). Unsurprisingly, 'patient safety' is now a major international health policy priority, questioning the efficacy of existing regulatory practices and proposing a new ethos of learning. Within England and Wales, the National Patient Safety Agency (NPSA) has been created to lead policy development and champion service-wide learning, whilst throughout the NHS the National Reporting and Learning System (NRLS) has been introduced to enable this learning (NPSA 2003). This paper investigates the extent to which, in seeking to better manage the threats to patient safety, this policy agenda represents a transition in medical regulation.

The medical profession is often described in terms of its clinical autonomy and capacity to self-regulate; and although the business of regulation remains more complex than the term 'self-regulation' suggests (Allsop and Mulcahy 1996), it remains the case that at the micro levels of medical practice, the evaluation of performance remains largely in the hands of the profession. By highlighting the shortcomings of these regulatory practices and proposing a new approach to organisational learning, the 'patient safety' agenda challenges the technical and esoteric domains of medical practice, which have typically remained outside the scope of political and managerial reform in health care. In this paper I suggest the emerging 'patient safety' agenda outwardly signifies a new frontier in medical/managerial relations and offers to re-regulate medicine. At the outset I elaborate this argument by suggesting the prevailing discourse of safety, rooted in 'safety science', represents a non-medical discourse, knowledge-base and expertise on which to regulate medical performance. This potential is made real through the introduction of new bureaucratic and managerial systems of scrutiny embodied in the NRLS. Drawing on Foucauldian theory, I suggest that this turns the tables on medicine by providing managers with an expertise and 'gaze' on which to engage in medical regulation through a bureaucratic panopticon of surveillance. I investigate this potential drawing on an ethnographic study of one hospital's experiences of implementing the 'patient safety' reforms. As with previous studies in this area, my findings highlight the potential for doctors to resist, subvert and capture managerial prerogatives in order to maintain professional authority. I elaborate this argument, with Foucault's (1991) concept of governmentality, to suggest that in seeking to 'adapt' their regulatory practice doctors are

engaging in new forms of self-surveillance that broadly corresponds with the ambitions of policy and ultimately serves to negate the need for more or better management. As such, the future of medical regulation and also medical/managerial relations may not be characterised by expanding the domains of management over medicine, but rather expanding the domains of management within medicine.

Medical regulation and the prospect of patient safety

Together with the concept of 'autonomy', 'self-regulation' has become a conceptual hallmark of professionalism (Freidson 1970). Despite the centrality of this concept to our understanding of medicine, the wider literature on regulation has had limited influence in medical sociology. In general terms, regulation involves an intervention that seeks to monitor and control activities, exchanges or markets that are of public or social value (Selznick 1985). Regulation is multifaceted, including the control of market entry, the ordering of exchange, the control of practices, and the regulation of payment (Moran and Wood 1993). The justification for regulation can be varied; from limiting monopoly interests to compensating for the asymmetries of knowledge (Breyer 1998), and accordingly the nature of regulation varies between external/internal and formal/informal controls (Moran and Wood 1993). Internal or 'self' regulatory practices can have both public and private justifications, for example where the costs of regulation are too high or legal frameworks are ineffective (public), or to avoid external controls and maximise occupational monopoly (private) (Ogus 1998). For professional groups the exclusive access to esoteric knowledge provides the social and political rationale for self-regulation, whilst enabling these groups to 'capture' regulation to suit their own ends contributing the process of professionalization (Ashworth et al 2002; Freidson 1970; Larson 1978; Levine and Forrence 1990).

The realities of medical regulation are more complex and multidimensional than the term self-regulation suggests, being made up of a network of formal/informal and external/internal procedures at the macro, meso and micro levels of professional practice. The General Medical Council (GMC) represents the main formal mechanism for medical regulation within the UK: maintaining a register of accredited and licensed doctors, establishing the standards of practice and investigating suspected 'dysfunctional' doctors (Allsop and Mulcahy 1996). Traditionally it has been concerned with market 'entry' (licensure) and 'exit' (removing the bad apples), but more recently it has sought to 'modernise' and revalidate the quality of professional members. Furthermore, despite being described as self-regulatory the GMC operates under licence from the State and represents a form of 'state-sanction self-regulation' (Salter 2000). At the micro levels of professional practice, regulation is characterised by a range of informal, collegial and cultural practices (Rosenthal 1995). Here it is generally assumed that individual practitioners or peer groups have responsibility for maintaining their own standards. Many studies have described the collegial rituals and customs that contribute towards the internal regulation of medical work and serve to maintain professional authority, including case conferences, ward rounds, clinical audit and complaints handling (Allsop and Mulcahy 1998; Arluke 1977; Bosk 1979; Freidson 1975; Rosenthal 1995).

Over the last 20 years much has been written about the impact of New Public Management (NPM) on the ordering and regulation of public sector professionalism (Ferlie et al 1996; Hoggett 1996). Since the mid-1980s a progression of managerial and market reforms within NHS have, according to some commentators, ‘cut a swathe’ across established lines of authority in the NHS (Elston 1991) and attempted to shift the balance of power from doctors to managers (Hunter 1996). Despite proclamations about the decline of medicine, even ‘de-professionalization’, the impact of reform on medical practice and regulation remains questionable (Harrison and Ahmad 2000). More broadly, it has been shown how change is often limited by the robust nature of professionals to resist and subvert policies (Kirkpatrick et al 2005). In health care it has been shown how reforms have failed to tackle the tribalism, customs and networks of clinical practice, with doctors able to block and capture managerial prerogatives to maintain their monopoly in the delivery and regulation of medical services (Dent 1995; Harrison and Pollitt 1995). The significant issue facing such policies and reforms has been how to legitimately and effectively engage in the technical and esoteric domains of medical practice.

Taking forward these debates, the current public sector ‘modernisation’ agenda represents a more dynamic form of ‘progressive governance’ or ‘New-NPM’ (Dent 2005; Newman 2001; Rhodes 1997). In terms of medical regulation this can be seen, for example, with the creation of supra-regulatory agencies to foster better self-regulation, such as the Council for Healthcare Regulatory Excellence, and the introduction of ‘clinical governance’ to raise clinical standards through continuously assuring the quality of services. Harrison (2002, 2004) has described this modernisation agenda as signalling a shift from ‘reflective clinical practice’ to ‘scientific-bureaucratic medicine’ as medical knowledge, practice and regulation is increasingly rationalised through the rigors of Evidence-Based Medicine, subject to formulaic protocols, and routinely evaluated by external agencies. Countering claims the NPM represents a shift towards post-bureaucracy, Harrison (2002) asserts that medical practice is becoming increasingly bureaucratic in nature as the profession must seek to legitimize its role within the context of radical consumerism, enhanced perceptions of risk and declining public trust. It is within this context that the ‘patient safety’ agenda has emerged for tackling the problem of clinical error. Of interest, is the extent to which this offers to transform the regulation of medicine, and represent a new frontier in medical/managerial relations, through providing managers with the expertise and mechanisms for surveying the exclusive and illusive technical domains of medical work.

With the compelling evidence of patient harm and clinical error, together with the failures of existing regulatory procedures, health policies have looked to other industries and High Reliability Organisations for inspiration, such as aviation and petrochemicals. The zeitgeists of ‘safety science’ and Human Factors have come to shape ‘patient safety’ policies showing that the inevitability of human error is actually conditioned by the wider environment of behaviour. A distinction is made between ‘active errors’ at the ‘sharp-end’ of performance and ‘latent factors’ located upstream within the work setting that enable or exacerbate the potential for error, such as poor communications,

mismanagement of resources, or insufficient warning systems (Reason 1997). Accordingly, in seeking to better manage organisational safety we should look beyond the realm of individual responsibility to consider the interface between cognition, behaviour and the wider work context; with safety improvements focussed on making the environment less error-producing, such as re-designing work processes or introducing safety checks.

The Human Factors approach has become the prevailing safety discourse or orthodoxy within health policy, highlighting a range of technical and socio-organisational factors that condition the potential for clinical error and patient harm (Department of Health, 2000; Vincent, et al. 1998; Vincent and Reason, 1999). This safety discourse is manifest in the creation of the National Reporting and Learning System (NRLS). Like previous forms of risk management, this comprises an incident reporting system with the aim of “identifying, gathering information on, recording and reporting adverse events and near misses” (Department of Health 2001: 34). It is expected that clinicians and their co-workers will openly share information about the threats to patient safety experienced in their work, initially to local service leaders and nationally to the NPSA. Risk managers can then use this information to identify the underlying sources of unsafe patient care based on the principles of ‘root cause analysis’, which is described as “a structured investigation that aims to identify the causes of a problem, and the actions necessary to eliminate it” (Department of Health 2001: 37). From this deeper understanding of safety service leaders will then be able to instigate safety improvements through making organisational and occupational changes.

I conceive the ‘patient safety’ agenda as offering two inter-related challenges to medical regulation. The first is the emergence of a knowledge-base and expertise, namely Human Factors that enables managers to legitimately engage in the evaluation of clinical performance. The second is the introduction of new organisational procedures, based on this knowledge-base, that enable managers to survey and scrutinize clinical performance. I elaborate this interpretation with reference to Foucault’s (1980) discussion of knowledge/power, especially the idea that discourses, encompassing bodies of knowledge, thought and language, together with their manifestation in social practice, constitute complex expressions of social power. An important feature of his work has been to understand the relationship between disciplinary discourses and their articulation as forms of social control. For Foucault (1970) the discourse of ‘anatomo-clinical method’ provides the language and metaphors to define the social reality of illness, manifest through what he called the ‘gaze’ of clinical practice. Significantly, this ‘gaze’ enables the surveillance and control of the ‘subject’ or patient. This shows that power is not just held in sovereign institutions but is dispersed throughout social practice. Based on this theoretical perspective I suggest that the new discourse of patient safety, based upon the Human Factors approach, provides NHS managers with a coherent expertise and knowledge on which to legitimately engage in medical work, through re-defining social knowledge about error and safety. Furthermore the manifestation of this discourse within the bureaucratic systems of the NRLS illustrates an organisational ‘panopticon’ that enables managers to actively survey and scrutinize medical work at a distance. A managerial ‘gaze’ is therefore turned upon medical practice to identify those factors that

make medical care unsafe. It can be argued that the patient safety agenda therefore represents a shift in medical regulation and a new frontier in medical/managerial relations (Waring, 2005a), whilst it is also important to consider the ways in which doctors are resistant to this discourse or even striving to capture it for their own ends. In the remainder of this paper I want to empirically explore how doctors are responding to the patient safety reforms, to investigate and theorise about the future of medical regulation.

The study

The findings are taken from an ethnographic study of one medium-sized NHS District General Hospital's experience of implementing patient safety policies between 2000 and 2003. Observations were conducted at the managerial (corporate) and the departmental (local) levels of the hospital. Those carried out with managers were participatory in nature, as I took the role of an outside 'advisor', invited into the hospital to analyse ongoing organisational changes, enabling me to witness and engage in many of the corporate activities related to risk management and patient safety. This included long periods researching alongside those working within the Risk Management Department: recording how administrators sought to implement new procedures, analyse incidents and deal with safety issues. Time was also spent within hospital committees, especially the Risk Management committee, to understand how these groups were responding to policy and seeking to make safety improvements. Within the clinical departments, my observations were non-participatory and I was particularly careful to portray myself as an independent university-based researcher, not affiliated with hospital management, as I believed this would strongly influence the actions of doctors. These observations focussed on how these new procedures were received by doctors and the extent of medical participation in the NRLS.

I also interviewed 43 members of hospital staff. Initially, 14 participants were selected based on their involvement in the management of quality, risks and safety at the corporate levels of the hospital. This included 9 managers with duties in finance, human resources, risk management, litigation and patient safety; and 5 senior doctors with leadership roles in issues of quality and risk, including the Medical Director and the clinical lead for Medical Audit. The second phase of interviews involved a representative sample of 25 specialist (consultant-grade) doctors working in the five medical departments used for observations. This included five physicians from the departments of Acute Medicine, Anaesthesia, Obstetrics, Rehabilitation and Surgery, inclusive of each Clinical Director. In addition, four departmental 'risk administrators' were sampled from these departments. The interviews followed a broad thematic guide that aimed to gather occupational narratives, understand pre-existing regulatory practice, and to explore the introduction of new 'patient safety' systems. Ethical approval for the research was acquired from the hospital's Research Governance committee, Trust Board, and Risk Management committee, including formal documentation of my research activities and responsibilities with regards to the confidential and anonymous handling of data. When interacting directly with individuals or groups I described the research aims and methods,

the ethical approval for the study, and reassured potential participants of the confidential handling of data before acquiring their consent.

All of the electronically recorded interviews were transcribed verbatim and, together with the observational records, were imported into the computer package *Atlas ti* for analysis. This broadly followed the procedures of grounded theory (Charmaz 2000) whereby prominent and emergent issues and themes informed subsequent sampling and research activities, whilst also providing a framework for the coding, interpretation, analysis of data (Glaser and Strauss 1967). Through the coding process detailed descriptions, beliefs and shared assumptions were identified, which were further analysed and cross-referenced for their empirical relevance, internal consistency and thematic relationships. I was firstly concerned to draw out information relating to how managers were responding to policy recommendations and seeking to implement new hospital procedures, and secondly how these engaged with medical work and regulation. Through this analytical process conceptual and theoretical statements were developed about the changing nature of medical regulation.

Findings

Surveillance and scrutiny

My first aim was to ascertain the extent to which the ‘patient safety’ agenda was indeed providing hospital managers with an expertise and legitimacy in matters of safety, and to determine the extent to which organisational changes were re-regulating medicine. Following the publication of *An Organisation with a Memory* (Department of Health 2000) or “OWAM” as managers often called it; ‘patient safety’ had become a priority for organisational change within the hospital. Those working at the ‘corporate’ centre of the hospital, for example in finance, human resources and corporate management, saw the agenda as an opportunity for improving patient care. For those directly involved in the management of risk and quality, there was greater enthusiasm given its relevance to their core duties, and the Human Factors approach was regarded as a new ethos and rationale for managing safety in the hospital. The logic of ‘patient safety’ seemed to represent inventiveness and originality, providing managers with a new way of thinking about safety and in turn a new way of improving the quality of patient care. The popularity of this knowledge was manifest in the way managers used the terminology of policy and, as further demonstrated below, in the strong support for ‘root cause analysis. More significantly the principles of Human Factors provided managers with an expertise and legitimacy for seeking to improve the safety of patient care that was endorsed by policy and proven within other industries.

“It’s like the Swiss Cheese model, things sometimes slip through when the system doesn’t work well!” (Manager 3) (see Department of Health 2000).

“With OWAM and the Patient Safety Agency we’re meant to do root cause analysis...it means we can start to learn about what’s really going” (Manager 6)

“We need to be looking differently at the risks and the accidents in the hospital, we need to be learning from the airlines that have been managing safety for years...and that’s what we are now supposed to be doing” (Manager 1)

The enthusiasm for this new approach primarily focussed on the procedures associated with the NRLS. It was interesting to find that the hospital already had in place risk management processes, including an ‘untoward event’ reporting system that was introduced in the mid-1990s as a condition of the hospital’s participation in the Clinical Negligence Scheme for Trust (CNST) (a scheme established to insure against the growing costs of litigation). Despite the outward similarities with the NRLS, the hospital managers were critical of these existing systems, claiming they had limited coverage across the hospital and lacked a unifying purpose or ethos. This comparison further demonstrated the apparent originality and utility of the Human Factors approach.

“The existing systems of risk management were put in place with our involvement in CNST, which is good but it really doesn’t do enough or provide a thorough framework from which we are supposed to take action.” (Manager 1)

“We’ve had some things in place for a few years now, critical incident reporting, some departments have other approaches for ‘untoward events’ but with the new system we all get to be involved and doing the same thing.” (Manager 8)

The enthusiasm for Human Factors and the support for the NRLS as a model of safety management led to a number of significant changes within the hospital. First, a new centralised, hospital-wide incident reporting system was introduced. This involved the distribution of an incident reporting pack to all hospital departments, designed to reflect the information needs of the NPSA. According to hospital documentation it was expected that all staff would complete a form upon witnessing any event that represented an actual or potential threat to patient safety, with the form returned to the centralised Risk Management Department for analysis. In design, this provided managers with the mechanisms for routinely gathering information on clinical safety and as speculated above, represented a level of clinical surveillance previously unseen within the NHS.

The second series of changes occurred within the Risk Management Department itself, with the appointment of two new ‘risk officers’ and the acquisition of IT resources. One of the ‘risk officers’ (with a clinical background) examined incident forms to check for data quality and entered the information into a specialised computer package. The second (with a background in IT and risk management) used this package to analyse incidents. Initially, this involved producing *incident trends*, or statistical summaries of incidents analysed in terms of location, time, staff, and incident-type. These incidents would then be *stratified*, through cross-referencing their ‘severity’ and ‘frequency’, to produce scores of high (red), medium (amber) or low (green) risk. For those incidents graded ‘amber’ or ‘red’ the departmental Risk Manager would make an initial *causal analysis* with the aim of identifying possible latent factors. The systematic procedures for incident analysis demonstrate a shift in the management and scrutiny of medical performance as non-

medical groups took a more active and routine role in assessing and evaluating clinical safety, identifying, for example, 'suspect performers' and 'high-risk' departments.

The third set of changes occurred at the hospital committee level, specifically within the Risk Management Committee, where new procedures were implemented for overseeing the management of safety and carrying out 'root cause analysis'. This monthly committee, with representation from across the clinical, technical and managerial domains of the hospital, received regular statistical updates from the Risk Management Department, in the form of incident trends and initial causal analysis. The committee would then scrutinise this data to better understand the risks across the clinical departments, making recommendations for change. Where incidents were graded 'red' the committee would initiate a more thorough investigation. These were typically led by the Risk Manager and one other member of the committee, selected according to their occupational relevance, who would visit the site of the incident and interview staff and patients. Following the principles of 'root cause analysis' the investigators would attempt to identify the range of causal factors that led to the incident. This information would then be reported back at the following committee meeting where decisions would be made about service improvement both locally and across the hospital. Common examples included changes in shift patterns, rearranged communication procedures, the procurement of new equipment, and extra training for staff. Again this indicated the new powers and opportunities for hospital managers and service leaders to more thoroughly engage in the regulation and modification of day-to-day clinical care.

In summary, the hospital managers firmly endorsed the principles of 'patient safety', welcoming and utilising it as a new rationale or logic for tackling clinical errors. In operational terms this led to the creation of new hospital systems to pool information about safety and to enable the managerial analysis of safety events with the intention of making occupational and organisational changes. Drawing on my earlier interpretation, this certainly appears to represent a transition in the management and regulation of clinical quality. The prevailing orthodoxy of Human Factors represents a disciplinary discourse that serves to establish and legitimise a managerial gaze in areas of clinical practice that had previously been beyond the vision of management, which is made real through the introduction of systematic procedures to survey and scrutinize professional work. The question to be answered is what impact did these changes have on medical practice and regulation?

Marginalizing error management

Although there were variations in how the five medical departments dealt with issues of risk and safety, there was a common lack of support for the hospital's new safety systems. The clearest example of this was the unwillingness of doctors to participate in incident reporting. It is well documented that there are significant barriers to medical reporting, including resource constraints, the taboos of medical culture, and the fear of blame (Lawton and Parker 2002; Vincent et al. 1999; Waring 2004, 2005b). Such issues were also identified in this study, but of relevance here were doctors' views regarding the

appropriateness and legitimacy of management-led incident reporting, which serve to justify non-participation. Although the doctors supported efforts to improve patient safety, they were sceptical of the ability of managers to adequately and meaningfully take the lead in this area because of their remoteness from the “coal-face” and, more fundamentally, because of their lack of clinical expertise and experience. A prominent theme was the need for greater clinical involvement and ownership of any process for dealing with patient safety.

“I think it has to be a professional thing because if it is a managerial thing I think it is going to lack reality.” (Doctor 12)

“If we look at where problems arise I can see that the management could not really comment on the doctors medical assessment, the details of the history, the details of the examination, they couldn’t really... be best placed to judge that event.” (Doctor 2)

Although the principle behind the patient safety movement is to examine the ‘latent’ factors that influence clinical practice, the majority of doctors believed that first hand clinical experience remains important for understanding and interpreting the information contained within incident reports. For the few doctors more familiar with the content of policy, mainly clinical directors, it was still evident that Human Factors was no substitute for clinical experience. Although a number of these senior doctors appreciated the need for managerial input into making safety improvements this reinforced a demarcation between the appropriate ‘medical’ and ‘managerial’ realms of expertise and activity.

“[A manager] will see the throughput, the waiting, the parking. I’m not saying doctors are blind to that... but doctors are primarily concerned with the medical product because that is what they have an influence on. As a doctor we are trained in biological science so we think in terms of biological systems, which is maybe different to an engineer who is dealing with physics and mathematical formulas, or a manager who is dealing with systems.” (Doctor 14).

Through criticising the appropriateness and legitimacy of this new managerial knowledge, doctors questioned the purpose and underlying motives of the new hospital procedures. In general, medical talk about hospital ‘management’ illustrated an underlying hostility and distrust. When this was further explored in the context of patient safety such feelings were expressed by a common belief that managers would use these procedures to expand their authority within the hospital and over doctors. A number of doctors alluded to George Orwell’s ‘Big Brother’ (Orwell 1991) indicating that they felt incident reporting was an explicit form of surveillance. Despite the idea of ‘no blame culture’ doctors were disinclined to complete incident reports because it was assumed managers would use the information unfairly or for ulterior purposes, because they lacked the technical knowledge to use the information for the positive of clinical care.

“I think we are all aware of it, in that the information is useful for us as clinicians but if somebody else gets hold of it, it’s whether it’s going to be a big brother thing looking down upon you.” (Doctor 17)

“I think there is a potential problem of a ‘them and us’ situation, with the people working hard in the clinical situation and some manager sitting in an office somewhere is going to look at the incident form and come down on us in a judgemental way.” (Doctor 3)

Such feelings encouraged doctors to reject and marginalize the new hospital-wide systems on the grounds that they were ‘un-medical’ and represented a form of unwanted managerial control. By not reporting incidents the doctors effectively disabled the new system, marginalizing the capacity of managers to engage in the analysis of medical work. The extent to which ‘patient safety’ procedures challenged and encroached upon medical regulation therefore becomes questionable. Without incident data, managers are denied the insight into clinical care, illustrating a fundamental weakness of the policy in that its capacity to make improvements is dependant upon staff compliance through self-reporting, which in turn requires trust within the wider regulatory system. Given the divergent and often competing cultural and ideological perspectives of managers and doctors in the NHS it is unsurprising to find that this trust is not forthcoming. Unsurprisingly the common view of doctors was that these initiatives should be undertaken from *within* the profession where the appropriate expertise and experience exists.

“If you are assessing clinical competence type risk issues then I think it can only be reviewed by your colleagues with an expertise in it.” (Doctor 18)

“I think classifying them at a corporate level is impossible, I think a doctor needs to do it, to sort of itemise what happened at each step and recognise what it was that doctors can learn because the work is extremely complex.” (Doctor 1).

Internalising error management

In general the doctors remained highly committed to their existing informal and formal routines and rituals for ‘self’ regulating medical practice. I often observed the subtle and close-knits ways of dealing with performance issues, what Rosenthal (1995) calls ‘small chats’. These took many forms, from discussions in the clinical setting to conversations over lunch and what I term ‘corridor committees’, where small groups of colleagues would discuss work related issues away from their normal work environment. Observing these settings was difficult as membership appeared to be based upon collegiality, trust and professional membership; with ‘outsiders’ excluded, including other staff groups, junior doctors, and myself. Whilst I was aware of these meeting I was unable to access them as naturally occurring events and instead relied upon follow-up conversations with individual members with whom I had developed trust and familiarity. Such informal and localised activities reveal the problems of penetrating and changing the day-to-day

regulation of medicine, which remains committed to the expectations of 'reflective practice' and 'collegiality'.

Researcher: ...but do you talk about things related to your work or maybe things that concern you that you wouldn't raise elsewhere

Doctors: Well yes. There is a bit of that. If such and such has done something amiss we will talk about it or if the clinical director has introduced a change we don't necessarily agree with or if we have a problem with some of the nursing staff" (Doctor 18)

I also found that each department had more formal regulatory practices, involving variations of case review, Morbidity and Mortality (M&M) Conferences, 'significant event audits', and clinical audit. In general these served as opportunities for reviewing and benchmarking past performance or research through peer-review, whereby doctors of similar expertise and experience would systematically analyse individual, firm and departmental performance; a prominent feature being the exclusivity of medical knowledge and the status of the lead consultant (Freidson 1975).

"They are something we traditionally use... we have a duty to look at our morbidity and mortality, and you know we review interesting cases and we can normally find something in a case that should have been done differently and I think the sign of a mature and competent clinician is somebody who can hold his hand up and say 'I think I made a mistake'." (Anaesthetist 18)

"We address most things within the firm through case review. We also have a departmental significant event audit that I lead where we look over case notes" (General Physician 3).

In addition to these collegial forms of peer-review I was surprised to find that four of the five departments (all but surgery) had attempted to enhance their techniques of quality improvement by applying what could be described as more 'managerial' forms of risk management. Significantly, these initiatives had been initiated, modified or justified by the recent hospital-wide developments in patient safety. Moreover, they revealed the flexible nature of professional regulation to change incrementally and strategically in the face of wider policy and organisational reforms.

Most notably the department of Obstetrics had a well-established system of risk management that operated alongside their other systems of peer review. It was claimed that these practices pre-dated recent hospital changes, even those associated with CNST, and were largely a response to the growing pressures of litigation in maternal care. It was claimed that since the early 1990s a system of incident reporting had been in operation within the department recording information about unsafe care. These reports were collected internally by an experienced midwife and were analysed by a lead obstetrician. The information was then used to compliment and contribute to other forms of peer review and departmental planning. These doctors appeared to be supportive of the wider

patient safety agenda, especially the idea of ‘root cause analysis’, but remained reluctant to switch to the new hospital procedures. It appeared that the new policy agenda served to further justified the use of their own systems.

“The two ways of addressing risk, from my perspective at least, is on the one hand have a risk management group, on the other we have audit and peer review... that is a very well oiled system and very tight when things go wrong.” (Obstetrician 1)

“We have been reporting for years... I think certainly when you look at the latest report our maternal care seems to have improved... [incident] reporting has enabled us to make these targeted improvements” (Obstetrician 2)

Similarly, the Anaesthetists had sought to enhance their systems of peer review and audit through establishing a Critical Incident Reporting system. This also pre-dated the recent hospital developments, being introduced nationally by the Royal College of Anaesthetist to improve professional education and quality improvement. This system operated exclusively within this department and was co-ordinated by a consultant anaesthetist, who collected and analysed reports anonymously. The information was then circulated to all staff members in the form of a summary and utilised within existing departmental and professional regulatory procedures before being returned to the Royal College for national professional learning.

“Anaesthesia has independently done this for many years before the Trust [hospital]... we have done it for years and years.” (Anaesthetist 1)

“One of the consultant’s jobs is to analyse incidents regularly, and for anybody to report to this particular consultant if anything has gone wrong. Any incidents that occur are reported and then we have a regular Morbidity and Mortality meeting every month, looking at a series of incidents that have occurred, plus we have regular departmental meetings where we can feedback.” (Anaesthetist 5)

For the obstetricians and anaesthetists, these localised systems not only complemented and improved upon existing forms of regulation and service improvement, but also reflected the norms of collegiality and self-regulation, being developed locally by colleagues in whom there is common experience, understanding and, importantly, trust. Through bringing within or internalising the techniques and practice of risk management and, more recently patient safety, these doctors secured a strategic advantage and legitimacy in this area of service improvement ahead of the ongoing managerial initiatives. Furthermore, the popularity and effectiveness of these systems provided doctors with the justification for not participating in the new hospital-wide systems on the ground that these were comparatively ineffective, not tied to local service improvements and managerial in nature.

Unlike these two specialities, the departments of Acute Medicine and Rehabilitation had only recently introduced ‘shared’ procedures of risk management. It was apparent that

these changes had been made in reaction to recent managerial developments as an attempt to enhance pre-existing forms of peer review and justify non-participation in the new hospital-wide procedures. Although it was expected that nursing staff should use the hospital system, it was believed that doctors should continue to rely on existing collegial procedures for case review and complaints handling, but these should be appropriately brought 'up-to-date' through introducing more formal procedures for risk management. The approach taken replicated and modified the hospital system. For example, the hospital-wide incident form was redesigned to better reflect the information needs of physicians and to encourage participation, whilst reports were collected and analysed by a physician prominent in issues of clinical audit. This information then contributed to case reviews, clinical audit and service planning, and as shown above, served to justify non-participation in the hospital-wide system. The experience of these two departments further highlights the capacity for doctors to strategically adapt to reform and, in doing so, to maintain a sense of occupational control and limit managerial encroachment

"I think there is a lot of concern that actually we don't particularly learn from our mistakes, as clinical director I think that is one of the main challenges as a director." (Physician 1)

. "We asked every physician to carry a chart in their pocket and just record every event.... It was a little thing, that size [A5] and it had four boxes: patient's ID, date, description of the event." [Rehabilitation 1]

The only department not to have introduced additional forms of risk or safety management was Surgery. In this department the established regulatory procedures of peer review and 'M and M' remained the main formal mechanisms of local performance assessment and service improvement in regard to patient safety. Moreover, there was also no evidence that surgeons were actively participating in the hospital incident reporting system. This raises an additional and perhaps alternative account of how doctors are responding to the patient safety reforms. Unlike the other departments where efforts had been made to take up the managerial procedures locally, these doctors appeared to be wholly rejecting the reform agenda through refusing to participate in the managerial hospital-wide system and also modify their existing regulatory practices. Despite the clinical director's enthusiasm for the introduction of new departmental procedures and the appointment of a local risk manager, it appeared that these doctors were not internalising the patient safety discourse whilst still marginalizing and resisting managerial prerogatives.

Either through national or local initiatives, the majority of the doctors in this study had sought to modify and adapt their pre-existing forms of regulation to better address clinical risks. For some, this occurred in advance of recent hospital changes, with the 'patient safety' agenda merely serving to justify the procedures used within these departments. For others, change occurred in direct response to the new hospital-wide system and in many ways mimicked these procedures. This typically involved *adapting* the emerging managerial practices, such as incident reporting, making complement the cultural and regulatory norms of medicine, and then *adopting* these within or alongside

these existing collegial practices. Significantly, this reveals the capacity for medical regulation to strategically adapt to the changing political and managerial landscape. Of significance, for risk and safety management to be effective and appropriate it needed to be operated *by doctors, for doctors*, with learning based within the department and collegial setting not across the hospital. This illustrates the capacity for medical professionals to resist, subvert and ‘capture’ this policy initiatives, making it serve their own ends and reinforcing occupational monopoly. Specifically, by internalising the patient safety procedure these doctors were able to more effectively marginalise managerial engagement in medical regulation and to maintain a sense of self-control.

Discussion

At the outset I speculated that the current ‘patient safety’ policy agenda could bring about a change in the regulation of medicine. Drawing on Foucauldian theory I suggested that it could represent a new frontier in medical/managerial relations through providing hospital managers with the expertise, legitimacy and panopticon-like procedures for scrutinizing medical work. The study shows that a new managerial logic or disciplinary discourse had indeed emerged within the hospital, forged from the language and recommendations of policy, and that this was informing the implementation of hospital-wide procedures for incident reporting and ‘root cause analysis’. At the departmental-level, however, I found that doctors were actively marginalizing these new managerial prerogatives, primarily through non-participation in incident reporting, which effectively disabled the capacity for managers to gather information on medical errors. Simultaneously, in several departments doctors were drawing on the emerging safety discourse to either justify the existence and exclusive use of their internal risk management procedures, or alternatively, to strategically modify and expand their pre-existing regulatory practices in order to better address the issues of risk and safety. In both scenarios doctors typically refrained from participating in the new hospital-wide systems. In these locations, the principles and procedures of ‘patient safety’ were internalised within medical regulation, suggesting that, in this one hospital at least, regulatory change is highly strategic, motivated to protect the ideals of ‘professionalism’ and limit ‘managerialism’. It also raises questions about the ambitions of policy, as doctors appear to be prioritising ‘professional learning’ over ‘organisational learning’ thereby undermining the implementation of the NRLS.

This tendency towards regulatory modification and capture demonstrates a form of what I term *adaptive regulation*. Given that any form of regulation is rarely static or fixed but contested and negotiated in the context of social change, professional groups must be able to adapt their regulatory practices to meet changing social expectations, new forms of knowledge and also the cultural needs of the profession. Salter (2000) has characterised medical regulation throughout the twentieth century as a *bargain* between the ‘State’ (to provide health care), the ‘public’ (in need of health care), and ‘medicine’ (requiring monopoly in care provision). Not only does this highlight the fact that professional status is a legacy of State approval, but it also suggests that changes in any part of this relationship implicitly requires a re-negotiation of this bargain. This has necessitated that

the profession be in some sense adaptive: to be able to respond, even resist, and ‘move with the times’, whilst maintaining or not excessively fracturing the enduring norms of professionalism. Over the last 20 years, developments in health service management have seemingly challenged medical autonomy and self-regulation, yet the eventual impact has often been small or incremental as managers have lacked the capacity to engage in the technical areas of medicine and doctors have been able to reinforce their monopoly through blocking or ‘capturing’ managerial initiatives. This highlights the adaptive qualities of medicine and this case study research goes some way to further illustrating the capacity for doctors to adapt to new situations and reforms.

It is possible to tentatively extend this analysis and theoretically speculate whether the process of adaptive regulation actually constitutes a new trajectory for the future of medical regulation in areas where management capacity is known to be lacking and professional resistance strong. This interpretation again draws on the work of Foucault (1991) and the theoretical lens of ‘governmentality’. This extends his notion of knowledge/power to account for how disciplinary discourses become internalised, rather than imposed, shaping how we see ourselves and govern our actions, and in doing so negating the need for external surveillance or authority (Dean 1999). As suggested by Dean (1999) governmentality can be defined as the ‘conduct of conduct’ where forms of self-surveillance ensure that our actions conform to the expectations of prevailing social discourses, following in the theoretical traditions of ‘hegemony’ (Gramsci 1971), ‘normative compliance’ (Etzioni, 1970) and ‘culture management’ (Wilmott, 1993). Such an analysis has already been applied to wider developments in clinical governance revealing the ways in which doctors are re-ordering their practices in accordance with policy and managerial discourses (Flynn, 2004). Through adapting their regulatory practices in the light of the patient safety agenda it could equally be argued that doctors are not only defending the norms of medicine, but in doing so engaging in new forms of self-surveillance and self-control as the discourse of ‘patient safety’ together with the bureaucratic procedures of the NRLS are internalised within medical practice, culture and regulation. In being adaptive and seeking to limit managerial involvement, doctors are seemingly re-articulating what it means to self-regulate, absorbing managerial assumptions and recreating themselves as the managers.

It remains important, however, to consider the limitations of this interpretation and to recognise that the extent of self-surveillance and governmentality maybe overstated or partial in nature. It may well be the case that rather than internalising this discourse, doctors are in fact ‘going through the motions’ of taking up these new procedures in an effort to resist regulatory change. The clearest example of this resistance was with the surgeons who were seemingly marginalizing the hospital-wide systems and also declining to take up new departmental procedures. It is also worth reiterating that this research is only based on a single case study and therefore the experiences of other hospitals could well be different.

Notwithstanding such reservations, the findings indicate that the future of medical professionalism could be seen as a retreat from ‘traditional’ notions of autonomy and self-regulation to more ‘managerial’ or ‘bureaucratic’ forms (Harrison, 2004). This is not

occurring through the introduction of bureaucratic structures or rules over medicine simply through state-level reform or the renegotiation of State-Medical relations, but rather through doctors strategically and perhaps voluntarily bringing these rules and procedures within medicine at the levels of practice, culture and discourse. This is comparable to what Heimer et al (2005) characterise as a new era of 'legalization' within medicine as indigenous and internalised legal and rule-based systems emerge to accommodate the risks and uncertainties of medicine, such as clinical protocols. As such the processes of adaptive regulation have the potential not only to maintain notions of professionalism and collegiality but also to introduce new forms of self-control that potential reflect the changing ambitions, values and discourses of society. Locating this analysis within the wider policy context and returning to the wider literature on regulation, the concept of adaptive regulation bears some similarity with the idea of 'responsive regulation': the notion that it is not always appropriate to adopt a single regulative strategy, rather the mode of control should be responsive to the conduct and context of those being regulated (Braithwaite, 2002). Braithwaite (2002) suggests regulation and justice is often more successful and efficient when forms of persuasion, rather than punishment, are used to evoke change or secure control. In recognition of the prevailing context of medical regulation and practice, it may be more effective therefore to persuade doctors to better utilise or modify their existing regulatory practices, rather than seeking to re-regulate or further manage medical practice. The process of adaptive regulation may therefore be the key to enhancing the safety of patient care if policy-makers and doctors alike appropriately harness it. The future success of the NRLS and the work of the NPSA may therefore be to work more effectively with the medical profession and to promote greater sharing of information between professions and external groups.

It is because of the limits of management to engage in the technical domains of medical practice and the potential for professionals to block, capture or adapt to reform that the future of public sector modernisation may involve less external management and more internal management, i.e. the managerialisation of professionalism: transforming the essence of what it means to be a professional into something more managerial. Rather than analysing the outward changes in management or accounting for the overt methods by which professionals resist management, we need to look more deeply at the changes within professional practice and culture to understand how resistance or adaptation leads to new forms of governmentality and a convergence between professionalism and managerialism. Where the future of being 'professional' implies being more 'managerial', in much the same way that other writers have shown how the logic of being 'professional' has been fostered amongst managers and other occupations as a form of discipline (Evetts, 2005; Fournier, 1999).

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