Risk-based regulation and reforms to Fitness to Practise Tribunals in the United Kingdom: Serving the Public Interest?

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Abstract

In this paper I outline recent policy reforms to the General Medical Council and how these are designed to promote greater public confidence in its management of the patient complaint and fitness to practise tribunal process. I explore how in spite of a decade of reform, potential for bias remains in relation to how issues of race and ethnicity, disability, age, class, gender and English language proficiency, intersect with complaint making and case progression. I draw on reviews of and data from the General Medical Council to examine the key issues surrounding the representativeness of the medical tribunal process, in terms of members age, gender and race and ethnicity. I note that, as in other high-income countries, there is a tendency within the UK for the risk-focused regulatory system to focus its reforming agenda on the more effective performance management of cost and risk, rather than on inculcating a more diverse patient presence and biographical profile within the day-to-day operation of regulatory regimes. I argue that this might unintentionally lead to the promotion of an optimism bias within risk-focused regulatory systems, potentially leading to a failure to communicate realistic perceptions of medical risk to patients and their families, and in doing so perhaps serving to further exacerbate the situation when instances of medical error and negligence occur. I conclude that current regulatory reforms in the UK are unlikely as a result to as fully promote the public interest and patient safety as they intend.

Key words: risk, risk regulation, medical profession, optimism bias, General Medical Council

Introduction

Within medical regulation literature internationally, there is now wide recognition that efforts to improve patient safety are partly contingent on the establishment of effective and appropriate mechanisms for responding to complaints from members of the public about the doctors who treat them (Beaupert et al 2014). Equally, however, it is acknowledged that public understanding and awareness of the processes in place to protect them from unsafe or poorly-performing doctors is all too often highly limited, and for those unfortunate enough to require recourse to them, fraught with uncertainty and the potential for emotional trauma (Reader et al 2014). The United Kingdom (UK) is no different in this regard (Ehrich 2006).

In 2013 the UK government published the report of the Francis inquiry into serious failings in care at Mid-Staffordshire National Health Service (NHS) Foundation Trust. The Francis inquiry was concerned with 1,200 preventable deaths which occurred over a three year period at the Trust's hospital. In its findings, the report of the inquiry noted that although patient complaints had identified problems of neglect and poor care at the trust, deficiencies in complaint handling resulted in critical warning signs being missed (Francis 2013). Furthermore, the report described a culture of fear, secrecy and defensiveness in which whistle-blowers were silenced and relatives ignored (Simpson and Morris 2014).

The Francis report is the latest in a long-line of high profile medical scandals in the UK over the last two decades, which includes Bristol Royal Infirmary in 1997, Alder Hey Children's Hospital in 1999, and more lately, Morecombe Bay NHS Foundation Trust in 2015 (Dyer 2015). All of which have highlighted concerns surrounding the ability and willingness of NHS systems and medical leaders, to identify and

satisfactorily deal with underperformance and medical mistakes. The proposed creation of a statutory duty of candour to ensure openness and transparency amongst NHS staff through establishing a legal obligation to report treatment or care they believe has caused death or serious injury, is the latest governmental attempt to address this issue (GMC 2015a).

In this article I examine recent reforms to the General Medical Council (GMC) which have been implemented to improve how it responds to complaints and instigates disciplinary proceedings against doctors via a fitness to practise panel (GMC 2013a). These changes are designed to address the criticism that rather than pursing its statutory duty to secure the public interest, its processes have first and foremost acted to protect doctors (Brazier and Ost 2013). In addition to NHS complaint procedures operating at a local level in hospitals and general practice surgeries, a number of national-level bodies respond to complaints against medical practitioners (Clwyd and Hart 2013). The National Clinical Assessment Service, the Care Quality Commission, as well as the Parliamentary and Health Service Ombudsman, are all important points of contact for responding to patient complaints (Chamberlain 2015). However, the General Medical Council, that operates using powers provided legislation (the Medical Act 1983), is the only body with the authority to remove a doctor from the medical register of approved practitioners and as a result, prevent them from practising medicine in the UK. The General Medical Council remains the principal formal legal mechanism for medical regulation and responding to complaints about the fitness to practise of doctors (Williams et al 2014). As a consequence, any changes made to the General Medical Council, possess the potential to promote far reaching change in the patient experience of complaining about a doctor (Gallagher and Mazor 2015). But

before exploring this further, it is necessary to first situate my analysis of the current system within current academic debate surrounding the emergence of risk-based regulation within the medical and healthcare sphere, in order to highlight its contribution to this literature.

Risk-based medical regulation

The regulation of medical work in the UK has undergone a period of far reaching reform over the last decade as a result of external pressures broadly similar to those noted internationally in the US, European, Chinese, Indian and Australasian contexts (Bismark et al 2015, Pan et al 2015, Saks 2015, Toth 2015 and Walton-Roberts 2015). Against the background of the fluxing conditions of the post-recession global political-economy, a growing tension between rising running costs and the advocacy of greater patient choice and rights of access, has led to state intervention to promote non-medical involvement in the delivery of health care services and their quality assurance (Giarelli, et al 2014 Brown et al 2015). Although significant national variation exists in how this state of affairs both presents itself and plays out, the key result, particularly in the US and Europe, has been an intensification and expansion of managerial discourses and practices shaping the activity of the health care system and monitoring the performance of medical work (de Vries et al 2009, Risso-Gill 2014).

Healthcare managerialism utilises a mixture of 'hard' and 'soft' forms of administrative bureaucratic power which operate on institutional structures and human subjectivities via performance monitoring and appraisal mechanisms - such as standard and target setting, audit and appraisal - while simultaneous seeking to retain the appearance of devolved discretion and control over decision making

processes at a local level, primarily due to the highly specialised nature of professional forms of expertise (Courpasson 2000, Sheaff et al 2003, Checkland et al 2007, Checkland and Harrison 2010, Exworthy 2015). In this article, I argue that such managerial discourses have proliferated throughout the health and social care sphere in the UK in the last two decades, and have become increasingly inculcated within professional regulatory systems, as the state has acted legislatively under a modernising agenda to minimise costs and risks by supporting greater managerial involvement in the governance of public services (Baldwin 2004, Saks 2014).

Hood and Millier (2010:1) argue that we live in 'the age of risk-based regulation'. This is marked by professional self-regulation - where elite groups within a profession possess control over the regulatory institutions that set and maintain training, practice and disciplinary standards - giving way to regulated self-regulation - where the state legislates to subject the activity of professional groups and their regulatory institutions to independent oversight (Chamberlain 2015). For example, in the UK, the Medical Act 1858 established de facto medical control over the General Medical Council as its board members were primarily drawn from representatives of institutions controlled by doctors, medical schools and the royal colleges, supplemented by a small number of elected members drawn from the rank and file of the profession. Yet the Health and Social Care Act 2008 not only required equal non-medical lay involvement in the running of the General Medical Council, it also subjected it to independent scrutiny via the Professional Standards Authority. This body reports directly to parliament and is tasked with reviewing decisions made by UK regulators about practitioners' fitness to practise. Importantly, it possesses the power to appeal decisions to the High Court (Court of Session in Scotland) if it considers them to be insufficient for the

protection of the public This approach allows the state to subject the operation of the General Medical Council to risk-based managerial performance imperatives, such as institutional audit and target-driven outcome-based performance appraisal, while also allowing it to retain a necessary degree of discretion over professional decision-making in relation to the training and discipline of rank and file members.

A key outcome, therefore, of this shift toward regulated self-regulation for the UK medical profession has been that doctors and their professional institutions now possess a much more externally managed and risk-adverse form of professional autonomy than has historically been the case (Saks 2015). Certainly, over the last three decades the day-to-day practices of doctors have become increasingly subject to surveillance and risk-management by NHS management, the General Medical Council and elite professional medical bodies, most notably the royal colleges. The introduction of medical revalidation by the Health and Social Care Act 2008 is the latest example of this trend (Dent et al 2016). Revalidation requires the periodic (every five years) recertification of a doctor's fitness to practise, in order for them to remain on the medical register and practice medicine in the UK. The logistics involved in ensuring that all medical practitioners are revalidated has meant that its introduction nationally has taken several years and indeed, it was not fully rolled out until 2016.

The implementation of revalidation is indicative of a regulatory process undergoing a transformative period of reform from being a reactive, incident-led regime preoccupied with ensuring medical privilege, to a proactive risk-adverse overseer of professional standards designed to secure public safety (Waring and Dixon-

Woods 2010). However, whatever the value of revalidation as a tool for supporting regulatory reform towards forms of regulated self-regulation which are focused on ensuring public safety through a risk-focused lens, there undoubtedly has been a perceptible increase within the medical profession of the view that the primary purpose of the new regulatory regime is to be more discipline-oriented and punitive (Brennan 2014). Researchers have found that not only do rank-and-file doctors tend to have a cynical attitude about the substantive capacity of revalidation to identify underperforming doctors, but also, for many its introduction symbolises a discernible orientation towards more publicly 'naming and shaming' individual doctors, even when doubt exits over the cause of a clinical error (Bridges et al 2014, Entwistle and Matthews 2015). I will explore this issue in more detail in the next section when I discuss the impact of reforms to the complaint and medical tribunal process.

Lloyd-Bostock and Hutter (2008) suggest that risk-based regulation is an elusive and slippery term, which is perhaps best conceived 'as a cluster of tools and characteristics rather than a clearly defined and coherent method' (2008:70). Day et al (2016) echo these sentiments in their pilot study of the growing role of risk management tools in the domain of applied health research. Revalidation, with its focus on the anticipation and manageability of risk via periodic performance appraisal focused on individual competence, is one example of such a tool (Chamberlain 2015). In this article I explore another risk-focused regulatory tool which has not been paid as much attention as revalidation: the patient complaint and tribunal process. There has been a tendency within the academic literature to focus conceptually and empirically on exploring the impact of regulatory reforms in medicine by examining the introduction of managerialist tools designed to

support risk-identification and analysis methods, such as medical audit or contractual annual appraisal, for example (see Dent et al 2016). Yet the complaint and tribunal process must also be examined if we are to obtain as rounded a picture as possible of the impact of contemporary regulatory reforms on both the medical profession and the public experience of health care delivery (Chamberlain 2012).

By focusing on the complaint and tribunal process, I aim to supplement and extend the existing academic corpus concerned with contemporary developments in the professions and shift towards risk-based regulation in the medical and healthcare spheres. In particular, I critically investigate an important feature of contemporary developments in the modernisation of medical regulation. Namely that, in pushing through regulatory reform, the UK state rhetorically advocates greater public involvement in healthcare governance and medical regulatory processes. But in reality, as Dent et al (2016) note, calls for greater non-medical involvement in healthcare and medical regulation, no matter how well intentioned, have all too often ended up as being a tokenistic smokescreen for greater administrative and managerial control, rather than being a progressive platform for promoting closer public/professional co-operation and collaborative partnership.

Hence, by focusing on the diversity of patient involvement within the complaint and tribunal process, I aim to place under the microscope a hitherto relatively under-examined problem space from which pertinent questions and new areas for investigation may emerge, which furthermore, serve to challenge the entrenched medical and managerial interests that surround the contemporary regulation of doctors (Short 2015). For example, it may well be that only by promoting greater

diversity in user participation in regulatory processes, with the goal of embedding within health care managerial and professional systems a working culture which prioritises the patient experience and need, rather than cost minimisation and mutual protectionism, that the possible negative excesses of risk-based regulatory approaches can be more fully accounted for and the public interest protected.

I have two main objectives in this article. Firstly, to contribute to current academic discourses surrounding the shift toward risk-based models of professional regulation in the United Kingdom (UK), and secondly, to do so by outlining reforms in the UK complaint and medical tribunal process. To achieve these objectives I bring together empirical data from a variety of already published official and academic sources concerning the patient and practitioner experience of the complaint and medical tribunal process. I supplement this with empirical data obtained from the General Medical Council, through a freedom of information request, regarding the make-up of the medical tribunal panel members in terms of their gender, age and race and ethnicity.

This is an emerging area of research as it is only in the last decade that it has been possible for non-medical members to gain the necessary access to the previously closed-shop regulatory 'medical club' needed to develop a more conceptually fine-grained critical analysis of this aspect of the practice of medicine in the UK (Chamberlain 2015). Thus, in this article I use a mixture of sources to develop my analysis. However, I see this article as developing arguments and key points that will require further empirical validation, and furthermore, that this will only be achievable through sustained independent investigation of the operation of the medical tribunal process over time. Indeed, it may well be another decade (or

more) before the impact of the emergence of risk-based approaches in the field of medical regulation is fully knowable, particularly given that medical revalidation was not fully implemented in the UK until 2016, and that reforms to the medical complaint and tribunal process are currently ongoing.

Nonetheless, I will show in this article that the existing data does indicate important limitations of the current governmental-driven regulatory reform focus on more effective cost and risk management within healthcare. In particular, that there has been a failure to broaden the diversity of public involvement in regulatory processes, and as such an element of cautionary doubt must remain over their ability to secure the public interest.

Complaints and medical tribunal reform: A more punishment-focused regime?

The salience of media driven narratives in contemporary society, which substantively shape and inform public opinion, as well as serve to further politicise health care reforming agendas, means that there is an ever present need for publicly accountable bodies, such as the General Medical Council, to demonstrate institutional effectiveness in the face of growing independent evaluation of their activities (Baldwin 2004). As a result, perhaps unsurprisingly, there is a growing perception within the medical profession that the General Medical Council has become far less tolerant of infractions (Bridges et al 2014).

Therefore, it is interesting to consider whether the General Medical Council has, in reality, become a more punitive institution. It is certainly the case that legislative changes have been made to the case management and pre-tribunal process to allow the General Medical Council to be more proactive in managing caseloads via

interim order panels, which restrict a doctor's practice while allegations about their conduct are being resolved (MPTS 2015). At the same time, there has been a move to separate the General Medical Council's investigatory and adjudicatory functions in order to secure greater institutional transparency and allay concerns that its complaint system is biased toward doctors. Finally, and related to this latter point, the level of proof required to secure a tribunal conviction has been reduced. Traditionally, the evidentiary burden to be met was that of the criminal standard of proof – beyond reasonable doubt – it is now the lower civil standard of proof- on the balance of probabilities (Quirk 2013). This reform was justified on the grounds that historically the General Medical Council had often been unable to remove a doctor from the medical register, even when doubt existed over their clinical performance, because the standard of proof required was unduly high, and this has impacted significantly upon the number of successful prosecutions (William et al 2015).

There has been much criticism within the profession regarding the reduction in the standard of proof required to secure a fitness to practise conviction and strike a doctor off the medical register, with many viewing it as signifying that the General Medical Council is adopting a more punitive stance towards doctors when it receives complaints (Chamberlain 2015). Evidence exists to suggest that the General Medical Council is more proactively seeking to restrict a doctor's practice, in addition to issuing more warnings and providing individual doctors (and their employers) with informal advice and guidance, with this trebling from little over 400 in 2010 to over 1,200 in 2015 (Gallagher and Foster 2015). There is also a developing body of research to indicate that pre-hearing investigative measures are traumatising for doctors who suffer from health-related problems in particular,

and in some instances this is leading them to agree to high impact sanctions, namely suspension or erasure from the medical register, *before* they attend a tribunal hearing, with the hearing subsequently becoming a 'rubber stamp' exercise (Horsfall 2015).

This in itself raises profound concerns over the procedural fairness of the changes made to the General Medical Council processes. Researchers reporting on the experiences of nearly 8,000 doctors found that those who had recently been the subject of a complaint were twice as likely as other doctors to report moderate or severe anxiety, and twice as likely to have thoughts of self-harm (see Bourne 2015). Further evidence suggests that doctors referred to the General Medical Council have especially high rates of psychological illness, with 26% reporting moderate to severe depression and 22% cent reporting moderate to severe anxiety (Moberly 2014). Moreover, since 2004 96 doctors have died while facing a fitness to practise investigation, which suggests that there are legitimate reasons to be seriously concerned about the nature of the institutional transformation underway (Chamberlain 2015).

Protecting patients first and foremost?

As the preceding section outlined, a growing body of practitioner-focused research evidence exists to suggest that the General Medical Council is indeed changing and taking a more robust stance toward complaints. However, while recognising that the evidence discussed so far is indicative that changes introduced by the Health and Social Care Act 2008 are indeed transforming the General Medical Council, it is equally important to highlight that significant countervailing evidence exists to suggest that the impact of this transformation on the public experience of the

complaint system appears to have been negligible. The latest General Medical Council figures show that in 2014 it received 9,624 complaints, yet 7,180 (75%) were not subject to formal investigation, and of the 2,444 investigated, only 228 (10%) were later subject to a tribunal hearing, resulting in only 71 doctors (3%) having their names removed from the medical register (GMC 2015e). This seems a rather small proportion, even when it is acknowledged that not all complaints received by the General Medical Council fall within its remit. The number of complaints has increased over time from 1,003 in 1995 to 9,624 in 2014 but the numbers reaching the tribunal stage and subsequently being stuck off has remained small throughout this period. For example, 71 doctors were removed from the medical register in 2014, compared to 56 in 2001 (Archer 2014).

Williams et al in their review of the General Medical Council published by Institute for the Study of Civil Society noted that there had been an increase in the level of complaints about doctors: in 1992 less than 1% of the doctors on the register were the subject of complaints, in 2012 this had risen to 4% (Williams et al 2014). However, in spite of an increase in the number of complaints, the proportion taken forward for formal investigation each year remained relatively static at between 75% and 80%. Furthermore, although analysis of General Medical Council activity has shown that it is investigating a greater proportion of doctors, issuing more warnings and requiring a larger number of doctors to undertake rehabilitative forms of action (such as undertaking clinical skills training), and in spite of what the majority of practitioners may believe, the lowering of the standard of evidence required to remove a practitioner from the medical register has *not* resulted in a significant rise in the number of doctors being struck off. Research by Chamberlain (2015) shows that since the level of evidence required to remove a

doctor from the medical register was lowered in 2006 the number of doctors being struck off has increased slightly, but this has not been statistically significant (from 57 in 2006 to 71 in 2014).

These figures suggest that the role of the General Medical Council in investigating complaints and (when necessary) acting to remove a doctor from the medical register, remains heavily problematic. Cause for concern remains over just how it decides which complaints it should investigate, as well as within this, the role played in its decision-making processes of finite financial and workforce resources. This is a particularly pertinent point given that the General Medical Council is self-funded via an annual subscription fee that all doctors on the medical register must pay. Indeed, the little independent research which exists into the General Medical Council management of complaints reveals the apparent presence of judgmental bias in favour of protecting doctors (Smith 2005, McGivern and Fischer 2010) alongside persistently high levels of patient dissatisfaction with the complaint process (Williams et al 2014). Worryingly, small-scale independent reviews of a sample of General Medical Council complaints have found that articulate individuals who present their complaints clearly and in detail are more likely to have their cases taken up (Allen 2000, Hughes 2007, Chamberlain 2012). Furthermore, the General Medical Council has been criticised on the basis that it has not routinely collected data on how issues of race and ethnicity, disability, age, class, gender and English language proficiency, intersect with complaint making and case progression (Archer et al 2015).

In reflecting upon these developments, it is possible to conclude that although the General Medical Council is undergoing a period of transformation, significant

evidence exists to raise doubt about its ability to prioritise the public interest. The presence of a possible operational bias towards more articulate complainants, along with an apparently limited organisational understanding of the diverse nature of complainants' biographical profiles and needs, becomes an even more pressing matter for concern when plans for the future development of tribunal hearings are considered. Particularly as at their core sits the issue of how best to organise the investigatory and adjudicatory functions of the complaint process.

The Law Commission review and the future of the Medical Practitioner Tribunal Service

Between 1858 and 2008 the General Medical Council was responsible for both setting the standards governing the practice of medicine in the UK as well as investigating complaints and punishing doctors when infractions occurred (Saks 2015). It is difficult to erase 150 years of tradition overnight. However, the fact that General Medical Council remains responsible for both the investigation and the adjudication of allegations of impaired fitness to practice remained a highly contentious issue. Although not directly concerned with the General Medical Council, the Francis report raised questions over the nature of complaint processes within the NHS more generally (Abbasi 2013). For example it has been observed that over half the doctors involved in the Mid-Staffordshire scandal faced no action from the General Medical Council raising questions over whether the complaint and tribunal hearing process as it currently stands can retain the confidence of the public and profession (Dyer 2013).

It was no coincidence that at this time the Law Commission (which is an independent body set up by Parliament to review and recommend reform of the law in England and Wales) began a two-year consultation exercise in 2012 to establish areas for further regulatory reform, particularly in relation to the General Medical Council role (Law Commission 2014a, Law Commission 2014b, Law Commission 2014c). At the same time, the General Medical Council acted preemptively to reform its internal organisation to enhance the ways in which it undertook its legal duties. In doing so it established the Medical Practitioner Tribunal Service to assume responsibility for the adjudication of fitness to practice cases from June 2012 onwards (GMC 2011). The intention behind the introduction of the Medical Practitioner Tribunal Service acting as an autonomous body within the organisational structure of the General Medical Council was to provide a workable solution to the potential conflict of interest and regulatory problem resulting from a single body being responsible for both investigating and judging allegations of impaired fitness to practise (Williams et al 2014).

The creation of a quasi-independent Medical Practitioner Tribunal Service was seen by the General Medical Council, NHS management and the medical royal colleges to be a cost-effective solution which allowed for the fact that the highly specialised nature of modern medical expertise means peer review remains a vital quality control mechanism (GMC 2013a, Department of Health 2015). The Law Commission review was equally pragmatic in this regard. However, it did suggest greater separation between the Medical Practitioner Tribunal Service and the General Medical Council, albeit while still retaining them as a conjoined single legal entity. It also argued that the General Medical Council and its investigatory

arm should have the right to appeal against a judgement made by the Medical Practitioner Tribunal Service, noting that:

> The General Medical Council's proposed right of appeal is both a consequence of, and reinforces, the independence of the new Medical Practitioners Tribunal Service (Law Commission 2014a: 12).

In March 2015 parliament approved this recommendation, which came into force on the 1st January 2016. Both the Professional Standards Authority (the statutory body responsible for regulating the General Medical Council) and the General Medical Council now possess the power to appeal to the High Court to obtain a judicial review of a Medical Practitioner Tribunal Service decision. Thus, there is now a 'double layer' of regulatory oversight to tribunal hearing outcomes. A state of affairs which arguably reflects the emphasis placed by risk-averse regulatory models on minimising the possibility of harm (Chamberlain 2015).

Yet it is important to note that although the Professional Standards Authority already reviews all tribunal decisions, this has not as yet resulted in any changes in judgement about competence to practice. Between 2005 to 2013 the Professional Standards Authority asked the High Court to reconsider some 15 judgements but in all but 2 cases the Tribunal's initial judgement was upheld (Council for Healthcare Regulatory Excellence 2005, Council for Healthcare Regulatory Excellence 2006, Council for Healthcare Regulatory Excellence 2007, Council for Healthcare Regulatory Excellence 2008, Council for Healthcare Regulatory Excellence 2009, Council for Healthcare Regulatory Excellence 2010, Council for Healthcare Regulatory Excellence 2011, Professional Standards Authority 2013, Professional Standards Authority 2014). This small number of referrals might suggest an

increasingly rigorous stance on behalf of the General Medical Council towards fitness to practise cases, at least since it became subject to regulatory oversight by the Professional Standards Authority. However, it could also reinforce doubts which exist in some quarters about the ability of Professional Standards Authority risk-based audit processes to secure the public interest given the problems with the complaint and medical tribunal process previously outlined in this article and elsewhere (for example, see Wakeford 2015).

For some observers, it is not clear why giving the General Medical Council the power to appeal against the decisions of the Medical Practitioner Tribunal Service should result in a major change in the current system and its outcomes. It is also not clear why the interested parties resist the creation of a fully independent and free standing entity to judge fitness to practice cases. Such an independent entity, with specialist input from health non-government organisations and patient-interest groups alongside professional medical and legal bodies, might well be better suited to the task (Clwyd and Hart 2013). Indeed, as Gallagher and Mazor (2015) note, the current solution arguably fails to address current patient dissatisfaction with the General Medical Council, and indeed the NHS complaint systems in general. Such dissatisfaction reflects important changes in the health care environment, including the decline of deference towards doctors and the greater visibility of regulators (Archer 2014). This trend, as Alaszewski and Brown (2007) discuss, has been proactively supported by the UK news media, which over the last two decades has sought to advance discussion and action for further regulatory reform in light of repeated high profile medical negligence cases.

Diversity matters

Time and time again, research has shown that reforms of the General Medical Council and the system of investigating and judging fitness to practice has failed to acknowledge and respond to the diverse nature of complainants' backgrounds and needs (for example, see Allen 2000, Hughes 2007, Chamberlain 2012). Furthermore, a key criticism of the current regulatory reform agenda is that when the patient experience and voice is included, it tends to centre on what the eminent medical sociologist and former independent General Medical Council member, Margret Stacey, referred to as an elitist 'the great and good' conception of public involvement in medical regulation (Stacey 2000). Stacey noted that for most of the twentieth century the role of the public in regulatory processes, which is designed to act as a balance to professional and managerial interests, has been restricted to white male middle-class citizens from largely professional occupations, such as academia, law, the senior civil service and the police. The danger, Stacey argued, is that as a consequence, even when underpinned by good intentions, regulatory reforms run the risk of serving to further reinforce just how out of touch medical and socio-political elites can be with the increasingly diverse needs of the societies they profess to serve (Stacey 2000). A point echoed by other contemporary regulatory commentators (for example, see Archer 2014 and Chamberlain 2015).

Since Stacey's commentary on General Medical Council membership, there have been some important changes, especially in the lay membership of the Medical Practitioner Tribunal Service panel. In my analysis of data provided by the General Medical Council in response to a Freedom of Information request, I found that In

terms of gender and ethnicity the composition lay membership of the panel tended to reflect that of the general population, for example 46% of the 125 lay panelist are women (compared to 47% in general working age population) and 17% defined themselves as coming from ethnic minority backgrounds (compared to 14% in the general population) (ONS 2014). However, I found that in other respects, especially socio-economic status and age, panelist did not reflect the general population. 99% of the panelists possessed a higher education qualification (compared to 34% of working age population); 98% came from middle to upper class occupational groups (compared to 25% of the working age population); and 99% came from managerial, senior public official or professional occupational backgrounds (compared to 25% of working age population) (ONS 2014). Their occupation backgrounds included the law (solicitor, barrister, magistrate, 26%); senior public service occupations (24%); health (19%); education (15%); business management (14%). Finally, the panelists also tended to be older than the general working population with an average age of 55 (compared to 40) (ONS 2014).

Thus, panelists are drawn from a relatively narrow section of the UK population (Savage et al 2013). Such an unrepresentativeness of lay 'representation' is a familiar feature of public-sector regulation in Britain more generally (Gibbs 2015). Elliott and Williams (2008) argue this biased representation is a barrier to ensuring regulatory regimes are truly representative of the societies whose interests they serve. This is certainly a worrying state of affairs given that small-scale research into how the GMC handles cases has revealed that individuals from working class and ethnic monitory groups appear less likely to get their cases taken forward to tribunal(for example, see Allen 2000, Hughes 2007, Council for Health Care Regulatory Excellence 2010, Chamberlain 2012). Yet, before we can draw any firm

conclusions, I would argue that that at this point in time, when the impact of reforms to the UK regulatory field are still unfolding, before any firm conclusions can be drawn, we need to first gather empirical evidence, which explores with both the public and practitioners, the impact of possible tribunal member bias on the patient and doctor experience of the reformed complaint process. To assist in this, in the next section of this article, I consider the broader risk implications of the current reform agenda for public perceptions concerning regulatory reform and patient safety.

The risk of optimism bias

In this context of minimalist reform and underrepresentation, I would argue that the current regulatory system is vulnerable to and undermined by, 'optimism bias' (Anderson and Galinsky 2006). The current reforms of medical regulation in the UK represent a significant shift from professional self-regulation to regulated self-regulation using risk-based policy instruments, but as Beaussier and colleagues have pointed out these reforms have:

> failed to improve the proportionality, effectiveness, and legitimacy of healthcare quality regulation in the NHS (Beaussier et al 2016:1).

In the new system of medical and health care regulation, risk is no longer solely the focus of regulatory control, but rather also the means by which professional groupings have become subject to third-party probabilistic surveillance and control in order to help legitimise broader societal-level governing regimes (Power 2007).The introduction of medical revalidation, alongside reforms to the complaint and medical tribunal process, epitomise this trend within the medical and health-care spheres. Every medical practitioner working in the UK is 'tagged and tracked',

carrying with them every day to work their own personalised ‘risk portfolio’ (Chamberlain 2015). These are especially constructed for medical regulatory and revalidation purposes and contain within their bindings all the information necessary for the reader to formulate a perception about the nature and extent of a doctor’s clinical competence, as well as the depth of their professionalism, including perhaps most importantly, how adept they are at minimising injury to patients should a negative event occur (Chamberlain 2012).

However, these changes could be undermined by what Shepperd et al (2015) refer to as ‘optimism bias’. This concept refers to situations where the high probability of positive outcomes is given more weight than the relatively low probability of harmful outcomes, even though such outcomes may have devastating consequences. Indeed, instead of reassuring members of the public, ongoing regulatory reforms, such as the introduction of medical revalidation, arguably run the risk of unrealistically increasing the ‘risk optimism’ of members of public so that they develop the view that negative events are so unlikely to occur that it is unnecessary to worry about them and that current protection measure will ensure no harm occurs (Rudisill 2013). Given the claims that recent reforms of medical regulation in the UK will enhance patient safety, it is certainly likely that if and when individuals experience harm, they will blame those involved in the system for failing to protect them and creating a false sense of security even when harm involved was essentially unpreventable, an ‘accident’. After all, within today’s risk-adverse socio-political climate, it is possible to argue that there is a human factor in every event so ‘accidents’ in the sense of random natural unpreventable events no longer exist. This means that any chance of clinical underperformance should be identified and addressed via the revalidation process overseen by the

royal colleges and the GMC and more punitive measures against practitioners are required justified when harmful events occur.

There is already some evidence of this type of reaction in the public response to high profile medical malpractice and negligence cases, such as mid-Staffordshire NHS Foundation Trust. The initial media reporting of events in the Trust, as well as the subsequent Francis inquiry (Francis 2013) documented the sense of shock and betrayal of the patients and their families. There was a very palpable public sense that the suffering of the patients experienced as the result of poor care could and should have been prevented by those in authority, including those responsible for identifying and managing potentially 'risky doctors', such as the General Medical Council. Given the relatively recent introduction of medical revalidation and reforms to the complaint and tribunal process, it not possible at this stage to ascertain if recent developments in medical regulation in the UK will in time lead to patients further overestimating the effectiveness of the protective systems designed to promote public safety. But it is possible to argue that the failure of the reforming agenda to expand the diversity of public involvement in regulatory processes, could well exacerbate the situation. Particularly in the context of ongoing reforms to the complaint and medical tribunal process. In no small part due to the highly charged and emotional nature of the cases the complaint and tribunal system deals with.

There is the possibility that, instead of making the public more confident in medical regulatory reform when negative events occur, recent regulatory developments might instead lead to patients and their families possessing an unrealistic 'optimism bias' expectation that their complaints will automatically

lead to disciplinary action being taken against a doctor through a medical tribunal. Therefore, if reformers want the regulatory system to be more 'legitimate', that is enhance public support for and confidence in the health care system, then those responsible for the institutions which manage risk, for example the General Medical Council, need to create a more realistic public expectation of what is possible, and to demonstrate that swift and effective action is taken if and when the individual or groups of practitioners do not have the skills and competence to prevent harm to their patients. Such legitimacy would be enhanced if there were broader and more representative public participation in regulatory processes (Chamberlain 2015). At the very least, as I discuss in the next section of this paper, attempts to recalibrate public perceptions of medical risk and communicate more effectively what can be realistically done to minimise it, alongside what can and should be done to punish individuals who fail to effectively manage the risk of harm to others, requires the broadening of current conceptions surrounding public involvement within public service regulatory regimes, of which healthcare is one example.

Discussion: challenging the regulatory logic

The recent Law Commission review of the General Medical Council argued that the complaint and medical tribunal process is a vitally important legal mechanism for ensuring patient safety and public trust in medical regulation (Law Commission 2014a, Law Commission 2014b, Law Commission 2014c). In the past, failings in the UK regulatory system were blamed on the medical profession and its apparent refusal to modernise (see Saks 2014). Some commentators have even gone so far as to suggest there was a need to replace the General Medical Council with a new

regulatory body (for example, see Gladstone 2000, McCartney 2014). Although I have argued in this article that there are continuing grounds to be concerned about the ways in which the General Medical Council operates, it is nonetheless important to remain analytical, not overly normative, and to critically scrutinise the assumptions which underlie regulatory reform and their implications for wider society. In this regard, I have focused on how state-initiated reform to the General Medical Council and the complaint process over the last decade has led to a growing perception within the medical profession that it is far less tolerant of infractions than previously.

I have provided evidence that the General Medical Council is adopting a more hard-line approach and that this has implications for the physical and mental health of doctors under investigation (see Moberly 2014, Bourne 2015). I noted that the death of 96 doctors facing a fitness to practice investigation between 2004 and 2015 is a serious cause for concern (Chamberlain 2012). I have also argued, however, that there is evidence that the General Medical Council's gatekeeper role in investigating complaints remains highly contentious. For example, in spite of an increase in the number of complaints and two decades of reform to the General Medical Council, the proportion taken forward for investigation remained relatively static at between 75% and 80% per annum, nor has there been a statistically significant rise in the number of doctors struck off the medical register (Chamberlain 2015). This is significant as it appears, therefore, that legislative reforms designed to increase the ability of the General Medical Council to take action against incompetent doctors, have not achieved their intended goals, and indeed, run the risk of endangering already vulnerable patients further (Archer 2014). As a result, current moves to strengthen further

the investigatory and adjudication process, by legislating to ensure that the Medical Practitioner Tribunal Service is a more autonomous entity within the General Medical Council, appear problematic. I have argued that the current reforms, no matter how well intentioned, do not address the central concern that rather than reflecting the nature of the society whose interests they are charged to protect, both the General Medical Council and the Medical Practitioner Tribunal Service currently appear to fail in their institutional processes to fully account for the diverse nature of the complainant profile and to reflect the broader demographic composition of contemporary British society.

I have noted that there limits to the analysis in this article. In particular, there is limited information on this topic given historical access problems. While the still unfolding nature of the regulatory reform agenda means that considerable further empirical data must be collected over time before any firm conclusions can be drawn. It does not necessarily follow that improving the diversity of patient involvement in healthcare quality assurance and regulatory processes will lead to an increased level of public satisfaction (Dent and Pahor 2015). This is particularly true when dealing with tribunal processes which frequently deal with highly complex and emotionally charged cases (Chamberlain 2015). Nonetheless, greater diversity of patient involvement in regulatory and tribunal processes is arguably a necessity given the need for accountable and representative forms of public sector governance within democratic societies (Gibbs 2015). Furthermore, as discussed earlier in this paper, managerialism plays a key role within contemporary risk-based regulatory processes for expert and professional groups, where there is strong central control is strongly exerted (Dent 2015). The danger here is that adopting such administrative approaches to NHS service delivery without adequate

representative public involvement to counteract practices involving collusion between doctors and NHS management, could undermine or subvert the focus of the regulatory reform agenda on promoting service quality and safety, in a manner not too dissimilar to what has happened in repeated high profile medical malpractice cases reported in the media since the early 1980s (Saks 2015). Furthermore, confidence in these systems may be undermined by risk optimism biases, so that evidence of failure creates shock and anger. To avoid such reactions those involved need to develop more inclusive risk management approaches if medical regulatory systems are to communicate more realistic perceptions of medical risk to service users (Chapin and Coleman 2009).

Ferlie et al (2012) discuss how the increasing role of risk-based managerialist forms of governance in the field of cancer service management in the UK bring with them the possibly that medical systems and quality assurance processes may increasingly pay lip service to the notion of greater user involvement, but in reality concern themselves primarily with matters of economic efficiency and cost containment. Lloyd-Bostock and Hutter (2008) suggest that under contemporary neoliberal mentalities of rule, risk-based regulatory approaches to health service delivery possess the potential to conflate the aim of risk identification and management with more effective cost management, rather than the promotion of an operational culture which first and foremost acts to protect service-users from harm. In this article, I have contributed to this discussion by highlighting the ways in which the current regulatory reform agenda is operating with a restricted conception of the patient experience and participation in relation to complaint and tribunal processes when a doctor's fitness to practise is called into question. A similar conclusion was drawn by the recent Francis inquiry. It argued for the need

to include more non-medical members within complaint management processes, in an effort to ensure greater transparency and accountability within professional and administrative dominated NHS operational systems, as these have in the past acted to subvert employment processes designed to support whistleblowing when problems occur (Francis 2013).

Conclusion

A key implication of my analysis is its potential relevance to international jurisdictions, in terms of the need to increase the diversity of user-involvement in regulatory processes. Significant variation exists in how health care systems and the performance of medical work are regulated in Europe, the US and Australasia. Nonetheless, as in the UK, these countries are undergoing an intensive period of health care reform, and furthermore, they arguably share the same underpinning regulatory logic, at least in terms of rhetorically emphasising the value of the participation of non-medical groups and patients for ensuring the more effective management of health care costs and risks (for example, see de Vries et al 2009, Giarelli 2014, and Risso-Gill 2014). Yet in the pan-European, US and Australasian contexts, McDonald (2012), Chadderton et al (2013), Beaupert et al (2014), Bismark et al 2015 and Saks (2015), have all suggested that patient involvement in regulatory regimes tends to be limited to particular elite interest groups, rather than reflecting the broad social strata of these diverse societies. This point was echoed by Bouwman et al (2015), who concluded after reviewing the Dutch regulatory system that enhanced practitioner accountability and improvement in the detection of problems in health care will only emerge when a long-term learning commitment is made, on behalf of government and professional groups, to

promote more expansive and inclusive public participation mechanisms. The developments I have outlined and examined in this article tend to support this conclusion. We must begin to collectively act to challenge misconceptions surrounding what the diverse backgrounds and needs of health service users really are. If only so the all too often restrictive and exclusory neoliberal regulatory logic that tends to dominate the design of contemporary forms of risk-governance can be transformed for the greater benefit of all.

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