

A scoping study on the effects of health professional regulation on those regulated.

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1. Terms of Reference:

“To commission a scoping study of the academic literature on the subject of *the behavioural effects of regulatory activity and interventions on those regulated*. For example, this might include any literature on the behavioural impact of regulators’ codes of conduct and other guidance associated with promoting safe practice, or any other activity associated with regulators’ statutory functions. We would like the study to look at literature in English in the last 20 years, with regard to statutory regulation, and with a particular focus on health professionals.

We intend this to be a broad scoping study along the lines set out in Levac *et al*: Scoping Studies: advancing the methodology. *Implementation Science* 2010 5:69. The purpose would be to identify key pieces of research that have been conducted which will help us to understand the state of knowledge on this question. The results of the scoping study will contribute to the evidence base for our policy work on regulatory improvement and development, and will identify gaps in knowledge which might benefit from further research. This in turn will contribute to our work to identify what constitutes effective practice in professional regulation, and to fulfil our statutory functions referred to above.”

2. Executive summary:

The most notable finding to emerge from this review is thus the shortage of systematic knowledge on the main research question. Few studies have *directly* addressed the question under review: how does professional regulation affect the behaviour of those subject to regulation? The thin state of knowledge likely reflects the difficulties involved in seeking to single out the impact that professional regulation has on professional behaviour, given the myriad other sources of influence. Whilst some studies make reference to the *positive* consequences that regulatory intervention has on professional conduct, frustratingly, they do not provide much by way of detail to illustrate this point. A number of reviews have noted a positive connection between specialist certification and the quality of care. Beyond this, there is little by way of hard evidence around how professional regulation impacts on behaviour. This review thus also considers the evidence of how other sources of influence appear to impact on professional behaviour. In summary, the main themes to emerge were: (i) the under use of behavioural theory, (ii) that a combination of factors works best, and (iii) the dominance of clinical judgment over clinical governance. The clear message to emerge from a number of studies is that regulation (however well intentioned) is far more likely to be complied with when accepted as legitimate by practitioners. This review closes by considering some feasible options for advancing the state of knowledge in this area.

3. Defining the research question:

This scoping study starts by defining the research question and clarifying its key terms. Regulation has become an important concept within the social sciences. Although originally explored with reference to the economy, it is increasingly applied to social arenas in the form of health and safety, environmental and consumer protection regulations. Regulation is not a 'term of art' and has acquired a number of different meanings, but has been described broadly as any form of behavioural control (**Ogus**, 1994: 1). Julia **Black** offers a more detailed, and even broader, definition of regulation as the '*sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification*' (2002: 20). Similarly, health professional regulation may be interpreted narrowly or broadly. On a narrower reading, it essentially refers to the activity of key state sponsored professional regulators such as the General Medical Council (GMC), Nursing Midwifery Council (NMC) etcetera, and also to regulators of healthcare (Care Quality Commission - CQC) and super-regulators such as the Council for Healthcare Regulatory Excellence (CHRE). The CHRE is committed to the principles of better regulation and to what it calls 'right touch regulation' which should be: proportionate, consistent, targeted, transparent, accountable and agile.

The GMC proposes a 'four layer' model of professional regulation as follows:

1. Personal
2. Team based
3. Workplace
4. Professional (GMC regulation)

A broader vision of regulation would encompass the work of numerous organisations operating at local, national and international levels, including: the Royal Colleges, medical defence unions (e.g. MDU/MPS), trade unions (e.g. BMA, RCN), local regulations/protocols adopted within particular hospitals, peer group norms and pressure, general monitoring agencies such as the National Audit Office, and the World Health Organisation. Indeed, the last decade or so has witnessed the growth of a 'pluralistic regulatory landscape' (**Trubek et al**, 2008: 6) where numerous organisations with overlapping responsibilities attempt to implement rules and encourage certain behaviour. Whilst the terms of reference for this review would seem to envisage professional regulation in its narrower sense, in line with point 4 from the GMC model set out above, most of the selected studies here refer to regulation in a broader sense.

What do we mean by regulatory activity? Broadly conceived, regulatory activity encompasses all the key tasks performed by regulators. **Salter** has divided these activities into standard setting, monitoring, and evaluating and intervention, which in the context of medicine, are used to manage research, education and performance (1999: 149). This can be further divided into the tasks of approving medical education and training, maintaining the register, updating codes of conduct, ensuring fitness to practise, and dealing with disciplinary matters. In terms of how this might affect professional behaviour, there are two

possible research populations: all registered practitioners exposed to some form of professional regulation, and individuals who have been subject to specific interventions such as investigation about their fitness to practise. We might predict that the latter are more likely to have been strongly affected by such intervention and offer an interesting research population for assessing the impact of regulatory intervention on their medical practice.

Whilst there are interesting related research questions, this scoping study seeks to examine the evidence about whether, and if so in what ways, statutory regulation (and the rules there under) effects the behaviour of health professionals? Equally as important, what *don't* we know about the effect of statutory regulation on the behaviour of health professionals? What are the gaps in the current state of knowledge? Understandably, regulators would prefer to see a positive correlation between their interventions and the safety and quality of care. Yet it would be naïve to expect total compliance with regulations. It is here that the concept of 'relational regulation' is useful, in other words, the pragmatic realisation that regulators should abandon the pursuit of perfection in favour of keeping behaviour within a 'band of variation', and focus on 'governing rather than erasing' the gap between expectations and performance (**Huising and Silbey, 2011**).

Measuring the *impact* of regulation is difficult. Understanding how *one* type of regulation affects behaviour is sufficiently challenging given the lack of research evidence. When we factor in the messy interaction of different types of regulatory influences (guidelines, law, employment contracts, peer support/pressure) we encounter a far more complex problem. Regulation in healthcare is increasingly multi-layered and complex (**Field, 2007**), and no matter how the literature defines professional regulation, the perception of professionals may be somewhat different given the tendency to associate it with discipline and sanction. Also, many recognised sources of influence are connected to professional regulation, for example, medical education (including continuing professional education) and codes of conduct, practice guidelines, protocols and checklists. The purpose of this scoping study is not to interrogate the research question itself, but rather to review the relevant literature which may shed light on what we know / don't know about the question. Although **Levac et al (2010)** note that scoping studies (unlike systematic reviews) tend not to comment on the quality of the included studies, occasional reference is made to what appear as obvious strengths and weaknesses.

4. Methodological issues:

A wide variety of disciplines have engaged with the concept of regulation, including: criminology, economics, law, politics, psychology, philosophy, sociology and medicine/health. Decisions were therefore required in terms of which subject combinations and databases to search within. Given the focus on healthcare, the major medical and social science databases were searched between the dates of 21-28 March 2011. Care was taken to ensure that appropriate and alternative search terms were used, in various combinations,

to locate as many relevant studies as possible. The main search terms used were: “regulation/regulated”, “medical/medicine”, “behaviour/compliance”, “conduct” and “professional”. The following databases were searched for relevant material published in English between the dates of 1991-2011:

Medline, Sociological Abstracts, Web of Science and Westlaw. In addition, the following key journals were identified as likely to contain relevant material and were searched separately:

British Medical Journal, Clinical Risk, Health and Psychology, International Journal of Psychology, Journal of the American Medical Association, Journal of Healthcare Organisation and Management, Journal of Healthcare Compliance, Journal of Empirical Legal Studies, Law and Human behaviour, Quality and Safety in Health Care, Regulation and Governance, Social Science and Medicine. The discussion papers available from the **Centre for the Analysis of Risk and Regulation (CARR)** at the London School of Economics were also browsed for relevant recent research and discussion papers (see <http://www2.lse.ac.uk/researchAndExpertise/units/CARR/home.aspx>). Key publications were followed up by looking at subsequent papers citing that study.

Given the well developed literature on regulatory compliance (see **Morgan and Yeung**, 2007, Chapter 7), it was unsurprising that the searches generated numerous ‘hits’. Abstracts were examined and these were distilled down to those most relevant for the purposes of this scoping study. Empirical studies were generally selected over non-empirical studies. They were saved into two separate folders for healthcare and non-healthcare related studies. This amounted to 61 publications, which upon examination of the abstracts and conclusions were further filtered down to 32 for more careful consideration.

There are a number of issues to note before considering the summary of the material:

- The different meaning given to professional regulation in different countries where studies have been undertaken (e.g. the UK and the USA). This is connected to a wider point about the different healthcare systems and cultural attitudes within different countries, and to the different factors which might shape behaviour (e.g. a greater emphasis on financial incentives in the USA).
- Health professions also capture a number of different professions with different cultures and systems of regulation. Given this increasing specialisation, we must guard against the dangers of generalisations. The remit of this review does not allow space for careful consideration of this.
- Most studies of regulatory compliance have tended to focus on firms or organisations rather than individuals. Whilst this does not render the conclusions from such studies as irrelevant, nevertheless, the question of how various highly autonomous professionals, working within different sub-cultures, react to regulation is different.
- Given the under developed state of the literature in relation to the research question, this scoping study has deliberately strayed beyond the terms of reference to include (i) studies exploring other sources of influence on the behaviour of health

professionals, and (ii) studies from other contexts. Brief reference is also made to some relevant studies from outside the suggested study period (i.e. before 1991).

This study has also incorporated four 'elite interviews' in order to obtain responses to the emerging findings and gather further insights into the research question. The rationale for doing this was to get specific viewpoints from interviewees on issues that may have been missed by reviewing the literature. This is considered an 'optional' consultation stage of the methodological process, but one which (whilst in this case very small scale) is nevertheless important in offering further sources of information. I am grateful to the health care professionals who generously gave of their time to be interviewed. The interviews were conducted in line with the Socio Legal Studies Association's statement of principles of ethical research practice (2009), and respondents were given assurances about their anonymity and the confidentiality of discussions.

5. Descriptive summary of the selected studies:

In a useful (and recent) summary of the literature **Etienne** 'identifies the main variables and mechanisms through which regulatory policy may influence individual choices' (2010: 1) He links the under developed theory around regulatory compliance to the complex combination of factors which explain various responses to regulation. As an alternative to the dominant rational choice theory for explaining behaviour (**Ayres and Braithwaite**, 1992), he prefers the 'goal framing theory' proposed by Siegwart Lindenberg. This focuses on hedonic, gain and normative goals. According to Etienne, this captures the context and combination of numerous factors which motivate individual behaviour (2010: 3). Hedonic goals focus on preventing uncompensated loss, in the sense of avoiding emotions of guilt and shame, gain goals focus on utility maximisation, whereas normative goals prioritise 'doing the right thing'. According to Etienne, 'no matter how dehumanised, regulation almost always generates signals' (p.14). Hedonic signals play on feelings of guilt, perhaps through information campaigns. Gain signals may be notices about hand hygiene, or notices on regulator websites about successful disciplinary action against registrants, or even financial incentives. Normative signals are expressed internalised professional norms, breach of which will lead to a sanction. Etienne notes that there is no 'deterministic rule to link together a type of regulation, a goal, and a mode of response' (p.16). And as Etienne concludes 'the relevant parameters have not been specified, because by and large they are contingent on particular situations or types of situation. Only detailed empirical studies could make these parameters explicit' (p.17).

Unfortunately, few empirical studies have directly addressed the question under review here. The most notable finding to emerge from this review is thus the shortage of systematic knowledge on the main research question. Few (if any) studies have *directly* addressed the question under review: how does professional regulation affect the behaviour of those subject to regulation? Perhaps the closest sustained studies (although with a different focus and now somewhat outdated) are those by **Margaret Stacey** (1992)

and **Marilynn Rosenthal** (1995). Stacey evaluated the structure and work of the GMC and questioned its fitness for regulatory purposes, whilst Rosenthal interviewed 100 practitioners (in the UK and Sweden) to examine the range of mechanisms for dealing with incompetent colleagues. Perhaps this dearth of material reflects the reality that *clinical practice* (as opposed to non-clinical misconduct) is still relatively young as a focus for regulation and governance? After all, only during the last decade has professional regulation begun to move away from its ineffective past (Stacey, 1992) with attempts to foster a new style of professionalism (**Irvine**, 2003; **Kennedy**, 2006; **Royal College of Physicians**, 2005, 2010). The other main factor is likely to be the difficult task of measuring the impact of professional regulation from amidst the array of different influences on professional behaviour.

There are plenty of informed opinions about possible positive and negative affects of regulation, such as those presented in the Report of a Seminar on Professionalism and Regulation in Healthcare organised by the CHRE in August 2008. Such views draw on practical experience and are thus not to be dismissed lightly. They likely represent the main responses to the question of how professionals perceive regulation. However, this is not the same as rigorously conducted research which has the potential for offering richer (and more reliable) insights into the linkages between professional regulation and professional behaviour. This gap in the literature is surprising given the consensus that the main goal of regulation is to encourage or discourage certain behaviour. Whilst the literature has included detailed discussion about principles of good regulation (e.g. **Prosser**, 2010), there is far less by way of evaluating the *practical impact* of regulation on the regulated. Furthermore, most ethnographic studies about regulation have focused on regulators rather than the regulated, or assessed its impact on firms or organisations rather than individuals.

This major gap in our state of knowledge has long been noted. **Horder et al** (1986, 521) remarked that ‘Given the interest in reaching and convincing the widely dispersed and varied body of general practitioners, it is surprising that so little work has been done in this area. Considerable time and money is spent in attempting to bring about change and some effort in evaluating which approaches are successful would seem to be a wise investment.’ And in his magisterial study of the professional conduct jurisdiction of the GMC from 1858-1990, **Smith** observed that “it would be instructive to conduct a follow-up survey of practitioners dealt with by the GMC to determine whether they continue to practise medicine during the period of their erasure, and also after their names have been restored to the Register, *and, if so, what changes take place with respect to their professional conduct*” (my emphasis) (1994:202). Yet, few seem to have taken up the challenge. Given the dearth of evidence on the impact of professional regulation on the behaviour of professionals, this review makes reference to evidence about the impact of other forms of regulation (clinical guidelines, and hard law mechanisms) as well as considering other sources of influence on the behaviour of health professionals. The studies have thus been categorised according to their specific focus as follows: (a) professional regulation, (b) sources of influence, (c) clinical guidelines, and (d) legal regulation.

(a) Studies referring to professional regulation:

The following studies explore aspects of the relationship between professional regulation and professional behaviour. **Brennan et al's** (2004) review of the published studies found that despite a lack of empirical evidence at the time, that certification is associated with higher levels of safety. They concluded that:

'Error prevention depends on recognizing that different behaviors are necessary to prevent mistakes or oversights arising from these respective types of problem-solving. Certification and maintenance of certification evaluate a physician's evidence of possessing the requisite habits of practice (practice performance assessment) and robust knowledge base (cognitive examination) needed to prevent both types of errors. Common sense suggests that the physician with a broad and readily manipulated knowledge base will be more likely to arrive at the correct answer to a clinical question, although no empirical studies are available on this point.'

This connection between certification and safety has been affirmed in subsequent studies. **Chen et al** (2006) found that board certified physicians (working in family practice, internal medicine or cardiology) provided better quality of care, despite finding no significant differences in terms of 30 day mortality rates. A comprehensive review of the evidence in relation to regulation and quality improvement, on behalf of the Health Foundation, was carried out by **Sutherland and Leatherman** in 2006. This looked at the main mechanisms of professional regulation and examined the available evidence for any linkages with the quality of care. They concluded that:

"There is little evidence about the impact licensure has on quality. However, there is a substantial body of evidence that indicates a positive association between specialist certification and better patient outcomes. Research also suggests that professionally-led and publicly-reported regulation is more effective than employer-driven regulation. Furthermore, the revalidation of professionals works best when it is based on clear and objective standards, with participation from the relevant professional bodies."

This is consistent with a reasonable foreground assumption in favour of a positive connection between specialist certification (i.e. evidence of specialist training) and quality of care. It is worth noting that the reviewed studies largely measured outcomes, and say less about *behavioural* change. Whilst the two are likely to be connected (i.e. behavioural change affecting outcomes), nevertheless, it is possible that regulation may prompt lots of subtle behavioural changes which may only be revealed through differently designed studies. It is also difficult to separate the influence of professional regulation from other sources of influence, given the likelihood that they often work in combination with each other.

LaDuke's survey (2000) examined the perceptions and experiences of 33 nurses in New York State disciplined for professional misconduct in 1998. This is one of the few studies on

precisely the question under consideration in this scoping study. Respondents answered 50 Likert scale questions, which included coverage of the 'personal and professional effects of the disciplinary process' and allowed room for narrative comments. It found that discipline impacted beyond the penalties imposed. Interestingly, 42% felt that disciplinary action had a positive impact on the conduct of their clinical practice (but somewhat frustratingly we are not told in what ways). This (small) study is limited in numerous respects: 81% of disciplines nurses did not respond to the survey, therefore, only a small sample (19%) of the potential population responded. The survey was not tested for reliability or validity. And as a survey, it is unable to probe for explanations and further details. For example, whilst it notes the impact of discipline, it is unable to offer insights into the ways that it affected 'physical or mental health' or 'personal or professional growth.' The most it offers through the narrative comments is reference to the loss of self-esteem and loss of trust in others felt by nurses.

McGivern and Fischer's (2010) study draws on interviews with eight GPs and four psychiatrists, who were randomly selected, and three medical regulators, a patient organisation representative, a professional representative, and a psychologist rehabilitating problem doctors, who were purposely sampled. A narrative analysis of the interviews explored respondents' perceptions and experiences of what the authors call "transparent medical regulation." They conclude that regulation provides "spectacular transparency" which is fuelled by a "blame business" with professionals feeling guilty until proven innocent. This is seen as being perverse for patient care, though again, we are not given concrete examples to illustrate this point. The main strength of this study is that it explores experiences of both those implementing regulatory processes and those subject to them, which (by chance) included a high proportion of practitioners subject to disciplinary sanction. As the authors note, 'narratives provide clues about how and why doctors perceive, socially construct and respond to transparent forms of regulation.' They conclude that 'regulation may occur as a social defence for professionals, regulators and politicians who understandably are unable to prevent all malpractice but must be seen to do so.' (2010: 605). Yet the study suffers from several limitations: it is a small scale study (18 interviews), and in referring to regulation in an umbrella sense to include complaints it is unclear whether responses have professional regulatory intervention in mind. As with other studies reviewed here, they do not specify what is meant by 'perverse effects upon practice' but would appear to be alluding to defensive medicine. The obvious danger here is of over analysing the responses from a small sample of practitioners, from a study which does not permit confident conclusions to be drawn.

The notion of 'social defence' is developed by **Mulcahy** (2003) who draws on her extensive experience investigating the nature of complaints, including the emotional impact on doctors in terms of stress and feelings of anger and betrayal. Although not explicitly specified, this presumably extends to complaints which result in regulatory intervention. Her work is of interest as it explores how regulation may affect changes in attitude. Largely relying on unpublished data from her study of consultants' reaction to complaints (Mulcahy 2000), she argues that doctors respond to regulation and complaints with social defences. Complaints strengthen group identity and are amenable to being interpreted within a bio-medical model (i.e. part of illness/related to condition etc), and as a strategy for recapturing control.

The theme of professional control, and the tension between clinical judgment and clinical governance emerges elsewhere. **Currie et al** (2009) set out to examine the narrow question of how anaesthetists deal with attempts to regulate the use of single use devices (SUDs). Although the paper title references professional regulation, this is not used in the traditional sense of the concept, but rather in terms of compliance with one specific guideline on SUDs by the Medicines, Healthcare Products Regulatory Agency. Both survey and interview data were collected between June 2004 and February 2006 (after the introduction of the guidelines.) Informed by the survey they collected data via semi-structured interviews with anaesthetists, nurses and theatre managers, and found that medical devices *were* subject to re-use, and that this was rationalised with reference to clinical judgment rather than regulation. According to the authors of this study:

‘the narratives authored by dominant professions have the power, in the medium and long term, to challenge policy-makers’ and managerial attempts to regulate them. Regulatory and surveillance mechanisms will only be effective where their intent converges with the behaviours of healthcare professionals as they exercise clinical judgement.’ (p.132-3)

They concluded that:

“Within our study, in rationalising compliance with regulation, Anaesthetists refer less to regulatory requirements, and more to the best interest informed by clinical judgement based on experience when making the decision to re-use or not...While a plethora of regulatory and associated surveillance mechanisms appear to surround healthcare professionals, we argue that the effect is ultimately rather limited... [and that] contemporary regimes for medical regulation may be unstable.”

This tension between the managerial imposition of regulation, and the practice of professional autonomy, is one of the most important themes to emerge from this review. In order to find an acceptable balance between design and discretion, **Yeung and Dixon-Woods** (2010) set out the safety benefits of what they term ‘design based regulation’, that is, action forcing technological design as an effective way of preventing or changing behaviour. The authors explain that unlike traditional regulation, which works *after* the event, that design based regulation is specifically intended to work *before* the event, and thus offering greater promise for preventing non-compliance. Drawing on work from Science and Technology Studies, they explore how technology has the potential for enforcing versions of morality on their users. The example given is of single use devices which are designed to become auto-disabling and thus unable to be used again. They note the challenge involved in communicating to professionals that design based regulation *is* based on values, and of striking the right balance between design and discretion. The following conclusions are especially important in the context of this review:

‘where there is widespread agreement about the kind of norms and values required by good medical practice in specific clinical contexts, action-forcing technology clearly can promote patient safety and good medical practice. Technical solutions that could prevent unintentional actions with serious adverse consequences are likely to be uncontested. But when technology is used to force an action in a situation where a practitioner wants to make an intentional and principled deviation from a formal rule, and there is legitimate

disagreement about that rule, there is need to be sensitive to the range of values and motives that appropriately inform good clinical practice, and the operational conditions and dynamics that shape the environment in which professionals work' (p.507).

'The practical and research challenge is to identify where design-based approaches have a productive role to play in preventing inadvertent and unintended lapses in clinical judgement or attention, where design has a role in sharpening rather than blunting professional discretion, and where and at what point technology interferes with the exercise of professional agency necessary to deliver on commitments to patient safety' (p.508).

Benson et al's (2006) research, commissioned by the Commission for Health Improvement (CHI), examined the impact of the clinical governance reviews on NHS trusts in England. A stratified random sample of 30 NHS trusts was taken from a set of 75 trusts reviewed by CHI during a period from 2001 to 2003. Documents from these trusts' reviews were analysed which showed that trusts were generally willing to accept and then enact CHI review recommendations. There was evidence to suggest that this kind of regulatory intervention can have largely positive impacts on the organisational performance of NHS trusts, although it was hard to establish that this translated into benefitting patient care. The authors conclude that any future review or inspection processes should place a greater focus upon patient outcomes if such reviews are to demonstrate their value in making a contribution to improving health (and also to increasing public confidence in the value of such reviews).

Lombarts et al (2009) investigated the impact of quality improvement strategies on hospital care in various countries of the European Union (EU), in relation to specific needs of cross-border patients. A web-based questionnaire was used to survey acute care hospitals in eight EU countries. The reported findings were later validated via on-site survey and site visits in a sample of the participating hospitals. Data collection took place from April to August 2006. The conclusions were that external pressure from regulation and accreditation is linked to more developed/mature QI systems at organisational level, thus linked to better quality care at the clinical level.

Open Disclosure: the impact of regulation?

Open disclosure of adverse events to patients offers an interesting example for considering how regulation, in the form of professional codes of conduct, may affect the behaviour of practitioners. This has become an important topic in terms of regulating trust and safety in healthcare, with numerous studies seeking to measure compliance with ethical duties of transparency and honesty in the aftermath of adverse events. The ethical case for disclosure is unarguable: it is about truth telling and respect for persons (see **Berlinger** (2005)). The GMC's Good Medical Practice (2006), in line with guidance from the National Patient Safety Agency (2009) is clear in its call for honesty:

30. If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects.

31. Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology. You must not allow a patient's complaint to affect adversely the care or treatment you provide or arrange.

To what extent do professionals comply with guidance about open disclosure? The available evidence suggests that disclosure remains something of a minority sport. A **National Audit Office report in 2005** revealed that only 24% of English hospital trusts routinely informed patients who had been victims of adverse incidents. Research from the USA has suggested a disclosure rate of between 30% (**Blendon 2002**) and 40% (**Lopez et al 2009**). Even in the safest hospitals relatively few staff (under 10%) are trained in the skills of open disclosure (**Dr Foster 2009**). And it appears that doctors are less likely to disclose when errors are less obvious to patients, or when there are serious adverse events.

Although informing patients about adverse events is clearly 'the right thing to do' and thus a normative goal, a complex range of factors conspire to explain this disclosure gap. Doctors harbour doubts about the 'safety' of disclosing in terms of complaints and litigation, consistent with a more general suspicion of external accountability (**Mulchay 2003**). Proponents of disclosure cannot therefore ignore the medico-legal context which, although driven more by perception than empirical evidence, militates against disclosure, what **Heimer** calls the 'new legalism of medicine' (2008: 33). Doctors may also lack the necessary communication skills to be comfortable and effective at disclosing (see **Leape 2010**). Given the high number of adverse events there are also resource implications for doctors spending more time explaining, accounting and apologising at the bed side. Other likely explanations include misplaced paternalism and the fear that disclosure may alter the dynamics of power and trust within patient-professional relationships. Disclosure is crucial to a patient centred health system yet the face to face accountability it demands challenges the professional dominance norm. Sadly, given the credibility problem facing the science of patient safety (**Gawande, 2007**), the 'soft' skills required for successful disclosure are unlikely to be viewed as essential medical work.

Yet various national patient safety organisations have attempted to address the disclosure gap. In the UK, the NPSA has implemented a policy of being open (**NPSA 2009**). Whilst there is little empirical evidence to date, progress is likely to be patchy given the different degrees of commitment within different hospitals and professions. Differences between the rates and effectiveness of disclosure between professions makes the need for training and guidelines all the more pressing (**Gallagher et al 2006**). Australia published an Open Disclosure standard in 2003 and early (small scale) research suggests that the practice of disclosure is not satisfying patients and that it remains an aspiration rather than the norm (**Iedema et al 2008**). Perhaps one of the most instructive findings from the 2008 study was that only 21 of the 40 pilot sites agreed to participate, yielding a small sample of only 23 consumer interviewees, probably indicating a slight professional unease with opening up about open disclosure. Over 50% judged it to be unsatisfactory, which is particularly telling as the sample were chosen by the hospitals and thus likely to be patients' they perceived as having positive experiences. A larger study by **Sorensen et al (2010)** involving 154 respondents (health professionals, managers and patients) found that the emotional side of disclosure appears to be neglected and that there is much scope for improving the 'social

outcomes' of care in terms of emotional satisfaction. Yet most of the research is somewhat limited by being based on simulated rather than actual situations.

There are a number of unfortunate ironies here: health professionals struggle to disclose despite evidence that disclosure assists the learning central to improving safety culture. And there is some research suggesting that not only do patients want disclosure, but that it may also increase their perception of the quality of care, and so debunking the broken trust hypothesis that partly encourages secrecy. Counter intuitively, **Lopez et al** (2009) found that disclosure of adverse events doubled the odds of patients giving high ratings to the quality of care – even amongst patients suffering harm as a result. Yet research from Australia looking at patients' experience of disclosure suggests that there is much to learn in terms of effective disclosure (**Iedema et al** 2008). Overall, the evidence suggests that it is unlikely (as yet) that regulation has substantially altered behaviour around disclosure.

(b) Sources of influence on health professional behaviour:

Whilst there is little work which directly examines the impact of professional regulation, much more has been written about the broader question of identifying the sources of influence on medical work:

Horder et al (1986) reviewed the evidence for the success or failure of methods for influencing the behaviour of General Practitioners. They concluded that a *combination* of different methods were most successful. The review focused on five factors: financial incentives; personal contact; review of performance and unsolicited feedback; literature on prescribing; and vocational and continuing postgraduate education. Whilst professional regulation is absent from this list, it is clearly relevant to continuing professional education.

In order to ascertain whether professional regulation is generally absent from the range of influences commonly examined, the 32 articles on the Medline database which cited this study were searched. Surprisingly, none directly address the connection between professional regulation and professional behaviour. Professional regulation is also absent as a source of influence in a Spanish review by **Lopez Fernandez et al** (2000). 723 General Practitioners assigned to Primary Care Teams (PCTs) in two Spanish regions were randomly selected to complete a self administered questionnaire. This collected GPs' opinions rather than "observing" or "measuring" concrete behaviours or practices. They identified the main sources of influence on practice as 'the professional system setting' (training courses, scientific articles and reports, colleagues, professional associations (it is unclear whether the latter includes professional regulators). In line with the findings of **Currie et al** (2009) it found that 'managerial strategies', for example, compulsory implementation of protocols, financial incentives, reviews and audits, were less important and legitimate. Doubts about the legitimacy of managers "policing" and "interfering" are also expressed by **Storey and Buchanan** (2008). Based on research commissioned by the National Institute for Health Research (NIHR) Service Delivery and Organisation (SDO) Programme they attempt to make sense of recent empirical research about adverse events. Unfortunately, the analysis in this paper is fairly superficial and does not inspire much confidence in the conclusions.

Much attention has been given to fostering a safety culture in healthcare. **Wakefield et al** (2010) developed an understanding of the factors influencing patient safety-related behaviours by nurses, doctors and allied health staff employed in Queensland, Australia. Claiming that behavioural theory is underused in terms of patient safety, the authors conducted a survey with 5294 clinical and managerial staff (claiming to be the first study to develop predictive models for patient safety behaviours of Health Care Workers - HCWs). This survey is clearly valuable in attempting to understand why healthcare professionals engage in behaviour associated with safety. Despite a relatively low response rate, the sample population still represents around 10% of the total health workforce. They concluded that their study: 'clearly demonstrates that two key factors influence the safety behaviours of all HCWs: observed behaviour of professional peers (Professional Peer Behaviour) and a genuine belief in the safety outcomes of the behaviours (Preventive Action Beliefs). Despite this, much of the focus of current national and international safety reform strategy appears to be based on a flawed assumption that change will occur as a result of educating individual HCWs to improve knowledge of safety.' The claim that this is 'flawed' is presumably based on the idea that training individuals will yield limited success and that systems also need to be targeted for reform. The authors conclude that the key to behaviour change strategies to improve patient safety is the influence of credible, clinical leaders that believe and practice patient safety behaviours in the workplace.

Roland et al (2011) have also conducted a recent survey of professional attitudes and behaviours. A random sample of 1891 US and 1078 UK doctors completed the survey (64.4% and 40.3% response rate respectively). In the US, the doctors were certified to practise in three primary care specialties (internal medicine, family practice and paediatrics) and four non-primary care specialties (cardiology, general surgery, psychiatry and anaesthesia), whilst in the UK, there was a stratified random samples of trained general practitioners (GPs) and cardiologists, general surgeons and psychiatrists working in England and Scotland. Almost all doctors reported that they had changed their practice in the previous 3 years as a result of familiarising themselves with a practice guideline (95.5% UK, 93.1% USA). Doctors were less positive in their support for quality improvement activities. UK doctors were more likely to agree that they should participate in peer review of care provided by their colleagues (completely agree: 68.4% UK vs 54.9% US) but only just over half had taken part in reviewing another doctor's records for the purpose of quality improvement (54.5% UK vs 55.0% US). The commonest action taken by US doctors with knowledge of an impaired or incompetent colleague was to stop referring patients to that doctor an action much less commonly reported by UK doctors (17.2% UK, 72.4% US). 34% of UK doctors did not report their colleague because they were afraid of retribution, possibly reflecting unsympathetic treatment of 'whistleblowers'.

(c) Clinical guidelines and behaviour:

Robertson et al (1996) focused on the failure to follow clinical guidelines (including NICE type recommendations) or to change following audit findings. They examine possible

psychological theories and strategies for change at personal, group and organisational levels. They also note that a combination of strategies is most likely to succeed (and thus that single strategies are unlikely to succeed). **Parker and Lawton** (2000) collected data on the judgments of 310 hospital healthcare professionals (doctors, nurses and midwives) from three specialties (obstetrics, surgery and anaesthetics) about behaviour which complies or violates protocols. Respondents were required to evaluate the appropriateness of the behaviour of a fellow professional in hypothetical scenarios. This is useful as an empirical investigation of the judgements of various healthcare professionals with respect to rule-related behaviour, and is perhaps unusual for asking colleagues to comment on the behaviour of others (rather than themselves). Midwives were more strongly disapproving of violations than either nurses or doctors. Doctors were the most tolerant of violations.

(d) Law as a secondary form of regulation:

Law, like regulation, is potentially extremely broad, but for present is understood to mean civil and criminal law mechanisms for impacting behaviour. In terms of civil law, this is reflected in the tort law action for medical negligence, and for criminal law, the far less frequent instance of prosecution for gross negligence manslaughter following fatal medical error. The most promising rationale for tort law is that the *threat* of litigation deters dangerous practice. This has commonly been explained in terms of the defensive medicine thesis. Deterrence theory has intuitive appeal in the sense of hoping that rational actors and systems will want to minimize harms and thus implement learning and prevention strategies around error. It is also inspired by an optimistic belief in the ability to train individuals and design systems in a way which discourages unsafe practices.

Nevertheless, there is no clear evidence supporting a connection between the threat of civil action and safer healthcare. Whilst respected commentators have long noted that litigation is a threat to clinical autonomy (**Dingwall** 1994), there is little research which has interrogated its linkages to safety directly, and any indirect evidence remains inconclusive. A study of fifth year medical students' perceptions by **Annandale** (1996) found that 54.8% thought that rising litigation would affect practice 'a lot', and 45.5% felt it would 'a little'. In a study of general practitioners, **Summerton** (1995) found that 98% made some practice change as a result of a complaint. This survey of GPs found the following changes to practice to avoid complaints: increased testing, referral rate and follow up, detailed explanations to patients and detailed note taking. This led to the classification of 'positive' and 'negative' defensive medicine. **Mulcahy's** doctoral thesis (2000) similarly found that better note keeping and more detailed consultations were common reactions to the fear of litigation. She found that 'One hundred and fifty seven (64%) consultants' specified 371 ways in which their medical practice had changed'. This suggests that complaints have a big impact on practice (and in lots of ways). Interestingly, Mulcahy also cites a correlation between stronger emotional responses and changes to clinical practice, suggesting that strong emotional reactions may have positive consequences.

Mello and Brennan's (2002) review of US empirical studies found no firm evidence supporting deterrence theory. In the UK, a literature review by **Fenn et al** (2002) found fairly

thin evidence of deterrence. They tentatively conclude that fault based systems generate more care than no-fault systems. It is true that attention to the litigation system also sheds light on the issue of medical harm which has in turn been a springboard for the study of patient safety, but without sufficient empirical evidence, it is difficult to draw any firm conclusions on the linkages between litigation and patient safety. **Vincent** (2003) is probably closest to the truth in concluding that the idea of effective deterrence is 'bankrupt'. However, a review of the evidence by **Kessler et al** (2006) claimed to find systematic evidence of defensive medicine. Yet their review mainly comments on the economic benefits of reforming the tort system, for example, by placing caps on damages, or on the increased supply of doctors allowing greater productivity. More recently, **Linsley and Mannion** (2009) have argued that changes in the NHS are resulting in the imposition of an individualistic culture on the community of psychiatrists with the effect that behaviours are being adopted as measures to avoid potential blame. Semi-structured interviews were conducted with psychiatrists based in the North of England. The focus was on culture more than regulation. The authors express concern about the shift from an egalitarian to an individual culture. Unfortunately, the study is of limited use given that it provides little detail about the methodology.

Deterrence theory is arguably more promising when applied to systems as opposed to individuals. It is widely accepted that systems are better placed than individuals to prevent the recurrence of errors; individuals will always forget, or make incorrect judgment calls, but systems can be designed to minimize the risks, and will rationally want to avoid the financial costs of safety lapses. Litigation thus focuses institutional action to take patient safety seriously. This is partly based on the realist belief that financial penalties and shame are the only strategies that work. For example, **Annas** (2006) cites the progress made by anaesthetists in responding to litigation rates as an exemplar of what litigation can do for patient safety. He argues for the recognition of a legal right to safety. Tom **Baker**, in his book *The Medical Malpractice Myth* (2005) is another to fly the flag for litigation. However, tort law will always be limited in this respect. Safety goes beyond concern with errors and harmful outcomes, and extends to near misses and the cultural and communication problems which conspire to deliver unsafe healthcare. On balance, the narrow legalistic focus of tort law, beset by the professionally threatening term negligence, is likely to impede rather than improve safety.

Occasionally, fatal medical mistakes interest the criminal justice system. In the UK, such cases are prosecuted with reference to the controversial and catch all concept of gross negligence. This is a circular concept which is incapable of objective measurement and potentially unfair to those prosecuted (**Quick**, 2006). But leaving these criticisms of this offence category to one side, what does criminal law offer from a safety standpoint? In what ways may it impact the behaviour of health professionals? Although such prosecutions have increased since the mid 1980s they remain sufficiently rare to render any possible evidence of deterrence hard to find. Whilst criminal cases essentially focus on individual fault, they nevertheless allow (through defence argument) attention to be given to the context of fatal errors: in short, system flaws. In this sense, the publicity draws attention to problems with, for example, the design of devices, systems for storing drugs, and English language competency. Whether such opportunities for learning are always heeded is perhaps difficult to prove. Perhaps the individual in question is less likely to repeat the same mistake again, but to what extent does such learning filter out to others? On balance, criminal law is likely

to be unhelpful in terms of further fuelling a culture of secrecy and shame about errors. Whilst we lack direct evidence, manslaughter prosecutions are likely to be harmful rather than helpful to safe healthcare (**Brazier and Alghrani** 2009). The findings of a forthcoming report into 'The Impact of the Criminal Process on Healthcare Ethics and Practice' funded by the AHRC and based at the University of Manchester will hopefully be of interest here. I believe that the final report is due in the second half of 2011. This report is of considerable interest here, especially in terms of the way it approaches the task of assessing the impact of criminal law on healthcare practice. If revalidation is implemented for health professions, similar research projects might seek to examine how it appears to impact on their behaviour.

6. Consultation with practitioners: 'elite interviews'

A small number (4) of elite interviews were conducted in March 2011 to explore the perception of health professionals into the way professional regulation affects their behaviour. Most struggled to describe examples where their behaviour was affected by professional regulation. The general consensus was that that professional regulation was not very relevant in terms of impacting their clinical work. Most tended to perceive professional regulation negatively, often solely associating it with the requirement to pay their registration fees. Some noted the usefulness of checking the guidance in relation to thorny medico-legal questions about confidentiality and capacity to consent. Others suggested that regulation (and guidelines) offered more to junior colleagues, perhaps given their greater need for certainty and confidence in decision making. Experienced professionals were less inclined to need to seek out codes of conduct and guidelines. The impression was given by some that this was almost an affront to their professionalism. Most gave examples where it seemed that emotions such as pride, self-respect, and self-confidence seemed to influence their behaviour. The responses suggest that professional regulation suffers from an image problem – most practitioners tend to view it negatively, only associating it with the disciplinary function, and are thus (understandably) fearful of association with regulators. This is unfortunate given that regulation is about much more than this and the likelihood that it does – perhaps in concert with other factors – influence behaviour. Perhaps we might (optimistically) think of ways to make regulators more relevant and helpful for practitioners, as a source of guidance and inspiration rather than a last resort for complying with resented regulations? There is an important question here about how regulators can win over newly qualified practitioners and capture and sustain their attention.

7. Conclusion: summary of main findings and research options

A recent article by two leading scholars neatly sums up the knowledge gap here: ‘while we have increasingly sophisticated hypotheses for *why* some organizations [or, we might add, individuals] are committed to achieving compliance, we continue to have an impoverished sense of *how* this commitment is successfully enacted’ (**Huising and Silbey**, 2011: 14). The authors point to research which suggests that ‘factors internal to the organization, not legislative or regulatory design, influence the dynamics of compliance’, yet frustratingly, ‘we do not know how managerial commitments produce higher levels of performance’ (p. 17). Whilst we can reasonably assume that professional regulation *does* impact behaviour, we have not yet observed exactly *how* this plays out in practice. We still lack examples of empirical research which seeks to understand whether, and if so in what ways, professional regulation affects behaviour. Frustratingly, studies which do touch on the relationship between regulation and behaviour often lack detailed analysis. For example, whilst hinting at positive or negative impacts of regulation they largely do not explore what is meant by this. We cannot assume that there will be widespread agreement on what constitutes a positive or negative impact

A respondent regulator in **McGivern and Fischer’s** study, when asked how regulation affects practice, sums up the problem in researching the main research question here: ‘To be truthful, we don’t know ... it might not be knowable and would be highly expensive and complex to work out . . . and what are we going to do with that information practically, when we have a statutory responsibility to regulate?’ Perhaps the somewhat flippant (but nevertheless accurate response) is to design better regulation! This is clearly demanding research with numerous obstacles in terms of finding a suitable study population, and designing appropriate studies for offering meaningful data. Some feasible options are explored below.

(a) The under use of behaviour theory in this context:

A number of studies note that behaviour theory is underused in this context. Psychological theories about what motivates people to behave in particular ways and how this may inform the task of regulating, is clearly of great importance here. A study by **Kaine et al** (2010) from the context of food policy may provide a useful framework for analysis. Their case study explored compliance with regulations about movement of host materials (soil, grapes) which carry a grapevine pest, to reduce the risk of disease spreading. They attempt to develop an analysis that helps predict the motivation of individuals to change their behaviour in relation to policy goals underpinning regulation. They claim that there are essentially two options for increasing compliance: strategies that change behaviour by changing involvement or strategies that work with the existing level of involvement. They conclude as follows:

“We have hypothesised that the propensity of individuals to change their behaviour and comply with regulation depends first, on the intensity of their involvement with the regulation and second, on their attitude towards the regulation. This is because cognitive effort is required to form a strongly-held attitude and such effort is only invested when the matter at hand is sufficiently important to the individual. We have also hypothesised that the propensity of individuals to comply with regulation depends on the interaction between their involvement with the policy issue that the regulation addresses, and their involvement and possible attitude towards the regulation itself. Issue involvement signals the degree to which the policy objective itself is a source of motivation for the individual, irrespective of the regulation. Involvement with the intervention represents the level of personal relevance created by the regulation.”

The claim that the framework developed offers a “systematic basis for regulatory agencies to develop a mix of strategies that target relevant differences in the propensity of individuals to change their behaviour in response to the regulations. Future research will involve further testing of the framework and the development of scales for quantifying issue and intervention involvement intensity and source and their relationship to individual attitude and behaviour.”

Of course, it is true that behaviours may be shaped by *external* factors that influence whether doctors attempt or are able to behave consistently with their professional values.

(b) Combination of factors works best:

A number of studies suggest that behavioural change is much more likely when a *combination* of factors conspire to convince practitioners to alter their practice. For example, if a number of sources of influence all nudge practitioners in the same direction (e.g. terms of employment contracts, clinical guidelines, professional regulation, professional leadership, law and financial incentives), regulatory goals stand a greater chance of being realised. Perhaps this suggests that there is, as **Field** argues, some ‘method in the madness’ of seemingly overly complex and duplicate regulation (2007). Yet, assessing the effect of one aspect in isolation, for example professional regulation, is likely to be a difficult task. The review by **Horder et al** (1986) makes brief reference to the behavioural impact of ‘government regulations’ and to the reality of creative compliance:

‘One method of changing behaviour which was not investigated was change by fiat, through government regulations, for example the recent restrictions on the drugs which doctors are able to prescribe on the NHS. There is no doubt that regulations must change behaviour, but the problem is that ways around the regulations are found so that the intentions are subverted even if the letter of the law is followed.’

Heimer (2009) offers an interesting analysis of the problem of ‘paying attention’ in a world of regulatory pluralism (and possibly overload). She suggests that “If the core problem for decision making is the limited capacity of people and organizations to collect and process information, it is their limited capacity to pay attention that poses the challenge for regulation.” Drawing on a study of how rules are used in five HIV clinics she argues “that

rules, standard operating procedures, regulations, guidelines, and the like do in fact have some effect, but it is neither exactly the instrumental effect their writers intended nor the symbolic or political effect that we might expect if rules were fully decoupled from practice. To understand the effect of rules, we need to look not just at what they do to people's actions but what they do to people's attention. My contention is that rules often work through the mechanism of shifting people's attention, and that these shifts of attention sometimes lead to the (alleged) intended result and sometimes have quite different effects."

(c) Clinical judgment and clinical governance:

Finally, the question of regulatory legitimacy was a strong theme to emerge, especially the tension between clinical judgment and clinical governance. Perhaps unsurprisingly, a number of reviews demonstrate that professionals prioritise their own judgments and those of colleagues, over regulation and governance imposed by 'outsiders'. Regulation thus appears to face something of a struggle to gain acceptance by professionals, who prefer to trust professional judgment. The paper by **Yeung and Morgan** (2010) into the potential of 'design based regulation' is especially interesting in this context. They persuasively suggest that professional norms and legal regulation have been ineffective in addressing the problem of patient safety, and thus demand different solutions. The idea of pursuing technology as a 'regulatory modality' is interesting, as is the challenge of not completely designing out discretion from the equation. This is surely linked to another strong finding about the importance of inspirational medical leadership. Regulation, whether through codes of conduct, guidelines or checklists, appear to stand much greater chances of success with the commitment and skills of effective clinical leaders. The recent success of inspirational physicians such as Atul **Gawande** (2009) and Peter **Pronovost** (2010) in the USA about the value of checklists offer excellent examples of this.

(d) Next steps? Future research possibilities

Given the relatively thin state of knowledge on the question under consideration, this last section suggests some feasible options for possible future research projects. The lack of systematic knowledge is likely to be related, at least in part, to the complexities involved in seeking to assess the impact of professional regulation, given that it operates alongside a myriad of other influences on professional behaviour. Three feasible options, in order of complexity of research design, are as follows:

- (i) Conduct more interviews with health care professionals to collect data on the main research question. Whilst this would no doubt be interesting, it is unclear that the responses would yield anything substantially different to the responses from those interviewed as part of this scoping study. It was notable that these practitioners did not perceive professional regulation as impacting greatly on their behaviour, and thus it is reasonably likely that others would share this same initial response.
- (ii) Conduct a survey or focus group with practitioners who have been subject to disciplinary proceedings. This represents the most feasible option.
- (iii) Conduct a case study at a hospital unit which has been subject to recent or ongoing regulatory intervention.

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