

Appendix 2:

A Review of Literature on Professions, Health Professional Regulation, Revalidation and Continuing Fitness to Practise

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Introduction

This review provides a brief overview of the history of health professional regulation and the background and context regarding the inception of 'Revalidation' and 'Continuing Fitness to Practise' to in the United Kingdom (UK). This review is written in three parts. Part one provides an insight into the historical narrative of defining professions, professionalisation and the expansion of health professional regulation. Part two provides background and context to the modernisation of health professional regulation within the National Health Service (NHS) and the inception of revalidation as health professional regulatory reform. Part three explores the concept of health professional regulation in defining regulation, theoretical perspectives regarding regulation in practice and the impact of regulation upon those being regulated.

Part One – Historical framing of the health professions and regulation

Historical theoretical framing of the Professions

The sociology of professional groups has its own history, where its focus has shifted over time between different interpretations and concepts of professionalism (Evetts 2006b). The concepts of 'profession' and 'professionalism' are increasingly applied to work and workers in modern societies, yet the concept of 'profession' dates back to pre-modernity, when the term 'profession' held religious connotations of 'professing' a vow (Harrison and McDonald 2008). Physicians, along with the clergy and lawyers were three original Europe-spawned 'learned professions' (Freidson 1983), who were viewed as seeing their occupation 'not only as a way of making a living, but as a vocation from God to be cheerfully and diligently fulfilled' (O'Day 2000 p11).

The professional institutions of medicine are the oldest in the health field and from the sixteenth century medicine was divided into three branches, physicians, surgeons and apothecaries (Harrison and McDonald 2008). Within the early modern period bodily health became an obsession for many who were concerned over their living conditions and life expectancy, and the organisation of professional medicine arguably satisfied this obsession (O'Day 2000 p185). Medicine, as one of the learned professions, grew out of the philosophy of life of the sixteenth century which viewed the well-educated men who entered the profession as seekers of a vocation, service and commitment rather than seeking a way of earning a living. This enabled professionals to declare a professional ethic and claim authority as well as expertise (O'Day 2000 p5).

'Professions' were not accepted uncritically however. Criticisms of professions date back to the seventeenth century and have centered around the creation of monopolies and professional experts failing to meet the ideals of their vocation (O'Day 2000 p15), the mystifying of their knowledge (Johnson 1972), being viewed as insular and mismatched in their vision of the public good (Laski 1931), and claims that professions were 'conspiracies against the laity' (Shaw 1932 p106).

Freidson (1986) discusses how the word 'profession', as early as the sixteenth century, could be used to mean an exclusive set of occupations or the exact opposite, meaning any

occupation at all. The word profession was also utilised in conversation to ascertain occupational status, therefore one would enquire about a 'persons' profession', not assuming that the answer would be limited to a prestigious occupation.

Historical documented debates and theorising regarding the professions have focused upon how professions should be defined, which occupations should be called professionals and by what institutional criteria (Freidson 1983), with a number of prominent sociologists such as Spencer (1914), Flexner (1915), Carr-Saunders and Wilson (1933) and Parsons (1954) contributing to such debate. Whilst most definitions in early analyses overlapped in the elements, traits or attributes they described, a persistent lack of consensus about which traits to be emphasised in theorising was demonstrated (Millerson 1964 p5).

Until the late 1960's, the functionalist theory appeared to flourish within the sociology of the professions literature, arguable due to the interpretation of Durkheim (1957), in that professions were viewed as moral occupational communities. The traits utilised to define occupations as professions were generally uncritical, somewhat socially desirable, and in some way functional for society (Harrison and McDonald 2008). The trait approach however proved inadequate in theorising. Due to its atheoretical character the trait approach all too easily accepted the professionals' definition of themselves (Johnson 1972), and failed to assist in the understanding of occupational power or of the appeal of being a professional (Evetts 2006a).

By the 1970's sociologists had begun to demonstrate skepticism regarding the functionalist perspective of professionalism. This change in direction may be traced back to the work of Hughes (1963), who argued that rather than concentrating upon what constitutes a profession, the more fundamental question was under what circumstances do workers

within occupations attempt to turn into a profession and themselves into professional people. A more critical approach to the analysis of the professions and professionalism was adopted and focus had turned from attempting to define the traits or attributes of a profession to an interactionist perspective of a profession.

The title of 'profession' was noted to be utilised as a status of successful occupations and gaining recognition of such was noted as important to occupations because not only was it associated with 'traditional gentry status', but also 'disinterested dedication and learning legitimated the effort to gain protection from competition in the labour market' (Freidson 1983 p24).

Jamous and Peloille (1970) introduced their concept of the 'indetermination/technicality (I/T) ratio' to the analysis of the professions (Jamous and Peloille 1970). This served to explain how professions are occupations which display a high I/T ratio, in that the individuals of a profession have a heavier weighting on the utilisation of judgment within their work than upon a structured set of actions. The variance in the level of indeterminacy was noted to have consequences for the relative autonomy of occupational groups (Johnson 1972) and herein provided the potential for professions, with a high I/T ratio to claim dominance over other occupational groups (Jamous and Peloille 1970).

The analysis of the professions within this era focused upon the theorising of professional power, autonomy, knowledge and control, and Freidson was one of the first scholars to focus on the political influence of the professions. Freidson (1970a, 1970b) used the concept of 'profession' to highlight how occupational groups, with significant focus upon medicine, gain professional dominance. By gaining social closure over their work through the implementation of a complex set of occupational strategies, including the establishment of

a professional ethic and corresponding professionalism, such social closure emerges as almost total occupational control (Pescosolido et al 2011 p205). Freidson (1970a) notes however that the gaining and sustaining of such professional status and dominant position is dependent upon the persuasiveness of the occupational group in convincing the state of its legitimacy, thus requiring political support and acceptance. With successful acceptance therefore, comes a set of institutions as hallmarks of professionalism, granted by the state, by virtue of winning the support of the political, economic or social elite to protect it from competition (Freidson 1970b). Autonomy and self-regulation, as hallmarks of professionalism, were theorised as central attributes of professionalization. Autonomy, being 'control over the content and terms of work' and being 'self-directing' (Freidson 1970b p134), was granted as the state and outsiders of such professional groups could not judge the performance of their professional work (Light 1988). Autonomy was granted in return for quality of care and altruism (Light 1995).

Johnson (1972) acknowledged the work of Freidson in his account of professionalisation but placed greater emphasis on market conditions. Johnson argued that a profession is not an occupation, but a means of controlling an occupation in that professionalism becomes redefined as a form of occupational control rather than an expression of the nature of occupational groups (p45). Johnson (1972) suggests that the development of specialised skills in society creates a potential asymmetry between producer and consumer and the success of an occupation to impose its own definitions of how services are provided is dependent upon a large, heterogeneous, fragmented source of demand. The successful imposition if its knowledge base provides autonomy for the individuals within the occupational group as well as the associations which regulate the profession (Harrison and McDonald 2008). Harrison and Macdonald (2008 p30), summarising Johnson's argument

about successful professionalisation, suggest professionalisation is firstly about the development of specialised skills in society, which create a potential asymmetry between producer and consumer. The higher the social class of clients served, the easier official recognition is gained and the mystifying of its specialist knowledge serves as a potential manipulative tool. Secondly, the success of an occupation to impose its own definitions of how services are provided is dependent upon a large, heterogeneous, fragmented source of demand. Thirdly, the successful imposition if its knowledge base provides autonomy for the individuals within the occupational group as well as the associations which regulate the profession.

In seeking to answer the question of Hughes (1963), regarding the circumstances in which occupations attempt to turn into professions, it can be seen how Freidson (1970a, 1970b) and Johnson (1972) served to provide answers. Such critical theorists sought to demonstrate how professional groups, by seeking market closure, achieve monopoly control in order to promote their own occupational self-interests such as salary, power and status returns (Evetts 2006a). Within the analysis of market closure and monopoly, Larson (1977) presented a conceptualisation of 'the professional project'. The professional project, drawing on the work of Freidson (1970a, 1970b), Johnson (1972) and Hughes (1963, 1958), presented a working theory of the professions by which monopoly in the market, upward social mobility and ultimate social closure were achieved. With roots in the Chicago School of Sociology and its successors such as Freidson and Johnson, and incorporating the insights of Marx and Weber, Larson provided a new insight into the sociological analysis of the professions (MacDonald 1995). Within the 'professional project' occupational groups are seen as entities that have to work and keep up a continued effort to maintain and enhance

the position of their occupational group. The occupational quest is for monopoly in the market, and status and upward mobility in the social order (MacDonald 1995).

Shifting focus from the dominant status of professions, Abbott (1988) developed an alternative viewpoint on a 'professional project' by examining the carving out and maintenance of professional jurisdiction. Abbott views inter-professional competition and disputes between jurisdictional boundaries as a perpetual dispute resulting in the potential decline and disappearance of professional groups as well as the emergence and amalgamation of others where jurisdictions become vacant (1988 p3, 18). Abbott defines a profession as an occupational group that has secured jurisdictional control over the theoretical basis and practical skill of its work and the ability to control abstract knowledge generated from such practical skill (1988 p3, 8). Therefore any threat to such abstract knowledge and practical skill arguably presents a challenge to jurisdiction. This resonates with Freidson's early caution that autonomy is not absolute in that 'the profession's privileged position is given by, and not seized from society, and it may be allowed to lapse or even be taken away' (Freidson 1970a p73).

This historical framing of professionalisation portrays the thoughts of Halliday (1985) in that professions are in fact social constructions, based upon epistemological foundations, conveyed to the public through rhetoric and manipulation of knowledge to which it exclusively claims. By establishing ideologies of self-description, professions seek to advance their self-interests (Gieryn 1983). Professionalism in itself is therefore not a status, but arguably a discursive claim, which is more or less successful in differing social contexts (Abbott 1988). The discourse of professionalism organises relationships and is a site of struggle and change as such relationships are adapted, resisted and transformed (Shirley

and Padgett 2006). Within professions sources of power are socially constructed (Larkin 1983) and the professional project is a useful tool in conceptualising the discourse of professionalism and the social construction of power. This is particularly useful in interpreting the actions of the medical professions as well as aspiring occupations seeking professionalisation within the historical framing of health professional regulation.

Historical Framing of Health Professional Regulation

Historically, physicians and other healthcare professionals would take the 'Hippocratic Oath' and swear to uphold a number of professional ethical standards and practice medicine honestly (O'Day 2000), establishing an informal 'social contract' with the state. This was the case up to the inception of formal health professional regulation of the medical profession which formalised this 'social contract' between the professions and the state. The formal basis of regulation, defined as 'the activity by which the rules governing the exchange of goods and services are made and implemented' (Moran and Wood 1993 p. 17), began in 1858. This was born out of the 1858 Medical Act, which established the General Council of Medical Education and Registration, abbreviated to the General Medical Council (GMC) in 1951, as the regulatory body for the medical profession. This act allowed formal recognition of medicine as a profession and the GMC to control entry into the medical profession by means of a register of recognised professionals. The 1858 Medical Act and the establishment of the GMC formalised the 'social contract' between the professions and the state, granting the profession the privileges of autonomy and self-regulation once licensure to practice was recognised. Self-regulation enabled and obliged the medical professional to

set their own professional standards, ensure compliance with those standards and take action against non-compliance.

Theoretically known as the 'regulative bargain' (Cooper et al 1988), professional groups such as the medical profession seeking to standardise and control the dissemination of their specialist knowledge base established 'a legal monopoly over the provision of services through licensure by the state' (Parkin 1979 p. 57). Such licensure provided 'an occupation with a legal monopoly over the performance of some strategic aspect of its work and effectively prevented free competition from other occupations' (Freidson 1970b p. 134). This legal and political position of privilege was granted in recognition that such professional knowledge based services were required by the state, establishing a 'regulative bargain' (Cooper et al 1988 p. 8) allowing the professional groups to 'restrict access to their knowledge', to 'control their market' and to 'supervise the production of producers' (MacDonald 1995 p. 11, Larson 1977 p. 71). Professional groups had authority and trust vested directly in them by the public's homage to professional claims to monopolies of knowledge and the certification and licensure of such knowledge (Simpson 1979). Intangible professional services could not be verified, therefore professional groups were dependent upon the state being persuaded to trust in the knowledge based services being provided and in the members of the professional group themselves. With successful acceptance came the privileges of autonomy and self-regulation as hallmarks of professionalism, granted by the state (Freidson 1970b).

The historical evolvement of the system of health professional regulation in the United Kingdom is marked by the distinctive imprint of the country's historical development with industrialisation creating both opportunities and challenges in the markets for health care

(Moran 2002). Opportunities arose with the opening of profitable markets for health care, leading to the expansion of professional regulation with other occupations seeking state licensure.

The first was the Pharmacy Act of 1852 which established licensure for qualified practitioners, however failed to ban unqualified practice. The act was later modified in 1868 to prohibit unqualified dispensing (Donnison 1988 p.70, 94). The challenges it created centered on the threat to existing professional groups, particularly specialties of medicine, in the markets creating the opportunities for other occupations to seek professionalisation (Moran 2002). The process of obtaining state licensure for other health care professionals was rather protracted. This was due to the resistance of the medical profession fearing threat of upstarting occupations and seeking to create an ordered hierarchy within the world of health care providers (Moran 2002).

The Midwives Act of 1902 established a Central Midwives Board to register qualified practitioners and ban unqualified practice if midwifery. The Nurses Registration Act of 1919 similarly established to General Nursing Council (GNC). Following the successful licensure of Midwifery and Nursing other healthcare occupations including Physiotherapists, Opticians, Dentists and Chiropodists also sought licensure. Despite dentists being awarded monopoly over the repair and removal of teeth in 1921, their registration body, the Dental Board, remained under the supervision of the GMC until 1957 (Thorogood 2002 p. 109). The medical profession, operating through the GMC and the British Medical Association, were able to persuade government to refuse licensure to other occupations, even where such occupations sought to meet the medical demands of the state (Larkin 1983; Harrison and McDonald 2008).

By the mid 1930's the medical profession had become to realise that opposition to the licensure of other occupations could be viewed as crude protectionism by aspiring occupations and the state, and its efforts shifted to controlling the terms upon which such occupations could be licensed (Harrison and McDonald 2008). The GMC instigated its own licensing arrangements with the establishment of the Board of Registration of Medical Auxiliaries (BRMA) in 1936. This board controlled the training requirements of such professions and deemed that the work undertaken by such professions must be under medical direction (Larkin 1983). Occupations such as chiropodists, dieticians, opticians, physiotherapists, radiographers and speech therapists were party to this voluntary agreement (Armstrong, 1976; Larkin, 1983; Harrison and McDonald 2008).

The founding of the NHS in 1948 provided the opportunity for many aspiring occupations to re-visit their claim to professionalism and from 1957-1960 many occupations were successful in gaining licensure by the state. In 1957 the General Dental Council was established removing dentists from the control of the GMC and 1958 saw the licensure of opticians with establishment of the General Optical Council (Harrison and McDonald 2008). In 1960, despite resistance from the medical profession, the government established a Council for the Professions Supplementary to Medicine (CPSM). This was created, replacing the function of the BRMA, to oversee the licensure of chiropodists, dieticians, orthoptists, occupational therapists, medical laboratory technicians, physiotherapists, radiographers and speech therapists (Armstrong, 1976; Larkin, 1983; Harrison and McDonald 2008). From the 1980s there were many more occupational achievements in obtaining state licensure and changes to the existing councils responsible for the regulation of licensed health professionals in the UK.

In 1983 change occurred with the amalgamation of the CMB and the GNC to form the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) and national boards were established for the four countries of the UK (Davies and Beach, 2000). In 2002 the UKCC and national boards ceased to exist and the regulatory function of the UKCC was taken over by the Nursing and Midwifery Council, continuing to regulate midwives, nurses and health visitors. In 1993 the General Osteopathic Council was established by the passing of the Osteopaths Act 1993, and similarly in 1994 The General Chiropractic Council was established as a regulatory body for chiropractors, established by the Chiropractors Act 1994 (General Chiropractic Council 2014).

In 2002 the Council for the Professions Supplementary became the Medicine Health Professions Council, and subsequently the Health and Care Professions Council in 2012. The Health and Care Professions Council currently regulates 16 health and care professions. Arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dietitians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists/orthotists, radiographers, social workers in England, speech and language therapists (Health Care and Professions Council 2014).

Following the Pharmacy Order 2010, the General Pharmaceutical Council (GPhC) was established as the body responsible for the independent regulation of the pharmacy profession within England, Scotland and Wales, responsible for the regulation of pharmacists, pharmacy technicians and pharmacy premises. It was created, along with the Royal Pharmaceutical Society, when the previous Royal Pharmaceutical Society of Great Britain was split so that representative and regulatory functions of the pharmacy profession

could be separated. The Pharmaceutical Society of Northern Ireland (PSNI) was thereby established as a professional body for pharmacy in Northern Ireland (General Pharmaceutical Council 2014). History has therefore witnessed the expansion of health professional regulation, with many occupations seeking and achieving state licensure. Despite licensure however, many of these occupations have failed to obtain the degree of self-regulation enjoyed by the medical profession (Davies, 2002; Dingwall et al, 1988; Larkin 1983; Harrison and McDonald 2008), and all professionalising projects have been shaped by the efforts to emulate the early institutional pattern of medical regulation (Moran 2002).

Part Two – Modernising Health Professional Regulation within the NHS and Revalidation as Health Professional Regulatory Reform.

Modernising Health Professional Regulation and Policy within the NHS

Since the inception of the NHS in 1948 medical practice has altered dramatically. Historically, medicine was simple, often ineffective but relatively safe. Modern medicine is complex, predominantly effective but sometimes potentially dangerous (Chantler 1999). The pace of change in medical practice is argued to have outstripped the development of health professionalism (Irvine 1999). Health professions have been criticised in their lack of willingness and ability to communicate effectively, to act promptly to protect patients from poor practice and to admit to the errors that are an everyday occurrence in judgment-based clinical decision-making (Horton 1998, Treasure 1998, Irvine 1999, Rosenthal 1999). In the late 1990's, amidst the undertaking of major official public enquiries into health care scandals (The Shipman case, The Ayling case, The Kerr and Haslam case, The Green case,

The Bristol Royal Infirmary case, Richard Van Velzen, The Neale case and The Ledward case), 'The New NHS: Modern and Dependable' (Department of Health 1997) was published. This White Paper set out the foundations of 'clinical governance', a process to assure and improve clinical standards throughout the NHS based upon safety and quality assurance processes. Subsequently, clinical governance was defined as "a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence can flourish" (Department of Health 1998, paragraph 3.2). In 1998 it was announced that, for the first time in the history of the NHS, hospital Trusts were to be held legally accountable for the quality of the service they provided and this was subsequently made a statutory requirement by the Health Act 1999 (Salter 2007).

Rather than quality being a desirable accessory, which it was assumed would prevail when the NHS was founded without a quality agenda (Nicholls et al 2000), it was to become a prevailing purpose (Leatherman and Sunderland 1998). Quality assurance had become high priority and clinical governance emerged as an instrument of the government's wider agenda to modernise health policy and management (Gray 2004). Clinical governance, by means of a whole system cultural change, was intended to provide a framework to deliver sustainable, accountable, patient focused, quality assured healthcare (Nicholls et al 2000). Under the umbrella of clinical governance, numerous practices were introduced including the increase in guidelines within National Service Frameworks (NSF). Bodies were also established such as the National Institute for Health and Clinical Excellence (NICE) to issue guidance on the organisation, efficiency, efficacy and cost-effectiveness of services and treatments, and the Commission for Health Improvement and Inspection (CHI) to advise on

clinical governance, inspect and monitor NHS organizations' and review the implementation of NSFs (Harrison and McDonald 2008, Nettleton et al 2008, Gray and Harrison 2004).

Clinical governance displays clear examples of placing responsibility upon clinicians and including them as active participants in their own surveillance, whilst distancing this process from traditional forms of managerial control (Flynn 2004, Swage 2000). Whilst clinical governance was presented with the primary aim of 'modernising' welfare provision, providing transparency of practices and procedures (Department of Health 1997) and continuous improvement in the quality of patient care (Scally and Donaldson 1998) , the scrutiny of professionals was apparent in the discourse of reform such as 'governance', 'accountability' and 'performance' (Nettleton et al 2000). A secondary aim of clinical governance was evident in linking quality to stronger mechanisms for professional self-regulation, in order to manage quality proactively and minimise risk (Department of Health 1998). With an overriding concern for economy, efficiency and effectiveness (Rhodes 1994), and under the guise of improving patient involvement and satisfaction, the state-enforced regulation of health professionals spiraled within the NHS modernisation and quality improvement agenda.

Revalidation as Health Professional Regulatory Reform

Traditionally clinicians have regulated themselves informally 'behind closed doors' (Rosenthal, 1995). New and more experienced doctors informally discussed complex clinical practices in which the boundary between inevitable failures of clinical practice and clinical errors was often blurred and errors ultimately unavoidable (also see Bosk, 1979). It was assumed that, with collective professional support in place, clinicians would be more likely

to openly discuss and learn from mistakes and that clinical colleagues would 'forgive and remember' medical failure that was unavoidable (Bosk, 1979) but that the profession collectively would act, often informally through diplomatic chats, to prevent incompetent doctors (Rosenthal, 1995).

However, to the present day, a succession of major, high-profile scandals about the quality and safety of healthcare services have led to sustained public and political calls for the reregulation of healthcare professionals. These included the failure of regulatory systems to detect that GP Dr Harold Shipman had been murdering hundreds of his patients; the failure of colleagues of paediatric cardiac surgeons at Bristol Royal Infirmary to report concerns about their poor performance; and, more recently, poor care at Mid-Staffordshire Hospitals Trust, (The Kennedy Report 2001, Smith 2004, World Health Organisation 2004, Francis 2013, Keogh 2013, Berwick 2013). Health care professions have been scrutinised and criticised for the lack of robust systems which assure on-going competence and fitness to practise post qualification. In the UK self-regulation has been traditionally favoured over more formalised systems of regulation (Baggott 1989), however scrutiny and criticism have led to recommendations for health professional regulatory reform to safeguard the public in the future. The traditional model of self-regulation was deemed to have failed in the past and viewed inadequate for the future (Department of Health 2006a).

Following initial calls for reform of UK self-regulation, the GMC published 'Good Medical Practice' (General Medical Council 1998), which was followed closely by the publication of 'Supporting Doctors, Protecting Patients (Department of Health 1999). These documents set out the generic medical standards underpinning quality assured practice, with emphasis upon personal accountability of professionals to patients and colleagues, and set out

proposals for the reform of professional self-regulation in light of the government quality improvement agenda for the NHS (Department of Health 1997, Department of Health 1998). Extensive consultation began regarding the future vision of UK health professional regulation.

In 2007 the Government published the White Paper, 'Trust, Assurance and Safety-The Regulation of Health Professionals in the 21st Century' (Department of Health 2007a). This paper endorsed the findings of the Foster Review (2006b) The Regulation of the Non-Medical Healthcare Professions, that revalidation was necessary for all health professionals. This white paper led to the passing of legislation in The Health and Social Care Act 2008. This legislation granted the powers to ensure that all statutorily regulated professionals, medical and non-medical, have systems in place to demonstrate their continued fitness to practise in the form of 'revalidation'. Seven working groups were established to take forward the recommendations in the 2007 white paper. These included the working group for medical revalidation and the working group for non-medical revalidation.

Despite its contemporary high profile, revalidation is not a new phenomenon. It was first discussed as a concept in the 1970s during the Merrison inquiry into the regulation of the medical profession (Merrison Committee, 1975). This inquiry, commissioned to explore the existing regulatory framework and highlight areas for improvement, was the first of its kind to review medical regulation since the passing of the 1858 Medical Act. Despite the committee noting an interest in 'tying continued registration to periodic tests of competence' (Merrison Committee, 1975 p. 47) the committee at this time deemed the methods available for measuring competence inadequate and the concept of periodic competence testing was never developed. Amidst the succession of major, high profile

scandals (as previously discussed) the regulation of all health professionals once again became of major political interest and the reform of health professional regulation became statutory in the form of revalidation.

Revalidation is described as 'a mechanism that allows health professionals to demonstrate that they remain up-to-date and can demonstrate that they continue to meet the requirements of their professional regulator. Revalidation confirms that the registrant is practising in accordance with their regulators' professional standards and will identify for further investigation, and remediation, poor practice where local systems are not robust enough to do this or do not exist' (Department of health 2008a p5). Following the passing of legislation in 2008 all 9 regulatory bodies within the UK were tasked with the responsibility of reviewing regulatory processes and the planning and implementation of revalidation for their registrants. Emphasis was placed on the urgent reform of medical regulation and in 2008 'Medical Revalidation – Principles and Next Steps' (Department of Health 2008b) was published by the chief medical officer to inform this process. This report asserted that medical revalidation had three main aims:

- to confirm that licensed doctors practise in accordance with the GMC's generic standards (relicensing)
- 2) for doctors on the specialist register and GP register to confirm that they meet the standards appropriate for their specialty (recertification)
- to identify those who require further investigation and remediation, poor practice where local systems are not robust enough to do this or do not exist

Secondary aims were evident in improving quality and safety of patient care through continuous professional development and reflective practice (Department of Health 2008b).

In 2008 the working group for non-medical revalidation published 'Revalidation Principles' (Department of Health 2008). This report outlined the principles that the 8 regulatory bodies responsible for regulation of non-medical professionals should consider when preparing proposals for revalidation.

Principle	Theme	Summary Description
Principle 1	Consistency	Models should be consistent with the Better Regulation Executive's five principles of good regulation.
Principle 2	Professional Standards	The regulatory body for each profession should set out the contemporary professional standards, which registrants will have to meet in order to maintain registration.
Principle 3	Remediation	Where revalidation processes highlight performance concerns there should be scope for remediation of the professional but measures to secure public safety must remain paramount.
Principle 4	Patient and public involvement	A successful revalidation process must have the confidence of the public that it is appropriate, relevant and fit for purpose
Principle 5	Continuing Professional Development (CPD)	This is the process by which individual registrants keep themselves up-to-date in order to maintain the highest standards of professional practice.
Principle 6	Quality Assurance	Quality assurance mechanisms must be built into revalidation processes.
Principle 7	Equality	Equality and diversity

		considerations must be evident in the development of systems and processes for revalidation.
Principle 8	Integration	Clinical governance frameworks yield information on professionals' performance and practice. Where appropriate, effective connections need to be made between them and the system of revalidation.
Principle 9	UK-wide	Revalidation arrangements should be consistent in outcome across the United Kingdom.
Principle 10	Demonstrating Benefits	The structures and processes of revalidation should be effective in confirming fitness to practise.
Principle 11	Information	The nature of the information required by each regulatory body will be based on their risk profiling of their registrant groups.
Principle 12	Incremental Introduction	The introduction of revalidation should be incremental

These principles were meant to underpin revalidation across regulatory bodies. However it was recognised that the intensity and frequency of the revalidation processes implemented by each regulatory body should be proportionate to the risks inherent to the work of each practitioner involved (Department of Health 2007a).

In 2011 the command paper 'Enabling Excellence, Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers (Department of Health 2011) was published. This paper detailed the continued commitment to the proportionate introduction of revalidation, recommending the further piloting of medical revalidation before official roll-out across the profession. The paper also questioned whether a 'one size fits all model' was appropriate and urged each regulator to develop an evidence base to inform individual revalidation proposals (Department of Health 2011).

Revalidation Progress to Date

The GMC was the first professional regulatory body to initiate the formal rollout of revalidation through a series of legislative and non-legislative initiatives on 3rd December 2012. All 9 regulatory bodies have declared their commitment to developing and implementing an effective system of revalidation for their registrants and are at varying levels of the policy development stage. It is envisaged that through local systems of clinical governance, effective appraisal and revalidation, the profession, employers and regulatory bodies will be able to provide further assurance to patients and the public that all health care professionals working within the UK are fit to practise (Spendlove 2013). Medical revalidation combines re-licensure by the GMC and recertification by the specialist Royal Colleges, aiming to ensure doctors' ongoing competency in their chosen specialty and that they remain fit to practise. Medical revalidation involves a formal assessment of a doctor's fitness to practise every five years by an appointed responsible officer within their employing organisation. This assessment is based upon the review of satisfactory yearly appraisals, a cycle of multi-source feedback and the satisfactory attainment of the minimum standards of continuing professional development stipulated by their professional and regulatory bodies. There are also additional elements, such as significant events analysis, complaints and clinical audit and patient feedback (see gmc-uk.org). The responsible officer has the responsibility for the decision making process as to whether each and every doctor

within their employing organisation is recommended to the GMC for revalidation of their license to practise.

In 2011 the Health Professions Council published a scoping study of the current approaches to revalidation amongst all UK health professional regulators. This study, along with providing a detailed account of individual regulator revalidation processes and progress, highlighted discussion points relating to the regulatory body's approach to revalidation. These discussion points were:-

1) Concept and outcome of revalidation, in terms of how revalidation is defined and whether the desired outcome of revalidation is viewed as quality control, quality improvement or both.

2) Conceptualisation of risk.

3) Proportionality.

4) Role of continuing professional development (CPD).

5) Standards of revalidation and use of existing regulatory processes.

6) Sources of evidence for revalidation.

The scoping study within these discussion points highlighted many differences as well as similarities between each regulator's approach to revalidation, based upon individual conceptualisation of revalidation and the links between revalidation and CPD. (Health Professions Council 2011). All regulatory bodies were noted to have commissioned research into the risks posed by their registrants' practice.

Research by the NMC, GPhC and PSNI identifies risk factors posed by the individual, such as individuals inexperienced in their particular area of work, and risks caused by the particular

situation in which the registrant is working, such as lone working (Health Professions Council 2011). The risk factors identified by the NMC and GPhC were noted to be similar to those identified by the Extending Professional and Occupational Regulation working group (Health Professions Council 2011). This group was founded to make initial decisions about extending professional regulation. They proposed that decisions regarding regulation should be based upon the risks posed by practice in a particular area and identified key factors when assessing such risks, thereby underpinned by risk based regulation. These included the type of intervention, where the intervention takes place, the level of supervision, the quality of education, training and appraisal of individuals and the level of experience of the individual carrying out the intervention (Department of Health 2009).

The research commissioned by the GCC adopted an economic model, which outlined in monetary terms the effect that adverse and sub-optimal outcomes might have if revalidation was not introduced for chiropractors. The research the GCC commissioned suggested that the risk of harm posed by chiropractic practice was low. As a result, its proposed revalidation scheme focused on using revalidation to address 'sub-optimal outcomes', in other words, situations where the outcome for the service user is not the best outcome. For example, whilst the GCC research focused on the likelihood of adverse incidents or sub-optimal care and the impact on the patient. By contrast, the research commissioned by PSNI involved a literature review as well as a survey of registrants to measure risk factors. The different approaches taken to research into risk were acknowledged to have resulted in different research outcomes. PSNI research has identified factors which could be used to make decisions about the potential risks posed by individual practitioners (Health Professions Council 2011).

The regulators have taken different approaches to quantifying the risks posed by their registrants' practice. The methodologies used have included literature reviews, surveys, interviews, workshops and analysis of data about complaints or concerns. Using these different methodologies allows the researchers to try to establish risk that is not captured through fitness to practise data. However, these approaches are only effective where data exists to support a broader approach to risk. The research commissioned by the NMC for example, makes clear that it is difficult to carry out an in depth analysis of the risks of practice because there is insufficient information about the areas in which nurses practice. As a result, the regulators have conceptualised risk in different ways. Many of the regulators have focused on the risks posed by the individual or the context in which they are working such as lone working, sometimes in their or their patient's own home, or by contrast the risk of harm to the individual patient (Health Professions Council 2011).

From Revalidation to Continuing Fitness to Practise

Revalidation is a broad term used to refer to a policy of proactively ensuring that practitioners who are registered to practice remain safe and competent to do so (Health Select Committee, 2011). Revalidation has come to mean a point in time assessment and may be associated with the medical model put forward by the General Medical Council (Professional Standards Authority, 2012), rather than a continuous process in which professionals maintain a minimum level of practice and professionalism in line with standards for best practice in their relevant profession.

Rather than revalidation, other regulatory bodies, including the Professional Standards Authority (PSA; See Professional Standards Authority, 2012), Health and Care Professions Council¹ and General Osteopathic Council and, have more recently started to use the broader term 'Continuing Fitness to Practise', placing more emphasis on the formative rather than summative nature of the process . By Continuing Fitness to Practise the General Osteopathic Council, for example, means 'that osteopaths should have the necessary knowledge and skills to perform their job effectively, they should have the health and character to practise safely and competently, and they can be trusted to act legally and responsibly'².

A report published by the Professional Standards Authority Report (2012) entitled 'An approach to assuring continuing fitness to practise based upon right-touch regulation principles', building on an earlier PSA report (2010/2014) discussing a risk-based form of 'right-touch regulation' and the principle that regulators should only apply the force necessary to achieve desired results, suggested that regulation and 'Continuing Fitness to Practise' should be proportionate, consistent, targeted, transparent, accountable and agile. The report highlights the importance of regulation being 'reliable' in terms of identifying those who 'pass' or 'fail' to meet minimum standards but also notes that regulation should be understood in relation to 'contextual factors', that risks relating to different professionals' practice vary and could be quantified. For high risk professions (e.g. medicine) revalidation was more appropriate, whereas for lower risk professions (such as osteopathy) audit, based upon self-audit and continuing professional development, was more appropriate. The PSA report suggests that regulation and Continuing Fitness to Practise

¹ https://www.hpc-uk.org/assets/documents/10002AAEContinuingfitnesstopractise-

 $[\]underline{Towards an evidence-based approach to revalidation.pdf}$

² <u>http://www.osteopathy.org.uk/information/complaints/fitness-to-practise/</u>

processes should aim to reduce the regulatory burden by building on existing local or national mechanisms, where possible, while at the same time providing transparency and accountability to the public and ensuring professionals maintained standards of practice and professionalism. The PSA report (2012) therefore provided justification for regulators, such as the General Osteopathic Council (GOsC), who regulate what are seen to be a low risk profession, to adopt a lighter touch form of regulation, more based on self-reported audit and CPD.

Revalidation in Context

Revalidation marks the largest and most significant development in the history of health professional regulation within the United Kingdom since its inception. Revalidation is part of a movement from state-sanctioned, collegial, self-regulation to a form of state-directed bureaucratic regulation (Waring, Dixon-Woods and Yeung 2010). For the state, clinical governance forms the lynchpin of its drive to increase managerial control over doctors and, for the profession, revalidation is seen as the means for ensuring the quality of medical performance whilst preserving medicine's historic autonomy. Both policies aim at addressing the central political issue of the protection of the patient and the decline in the public's trust in doctors (Salter 2007). Revalidation is embroiled within a wider political NHS modernisation agenda (Department of Health 1998) and embeds professional regulation firmly within NHS clinical governance (Chamberlain 2009).

As a consequence revalidation has been viewed as a state-enforced bureaucratic way of attempting to control professionals (Flynn 2004). Since inception, revalidation has been met with reluctance and skepticism. The British Medical Association and the NMC, up to the

passing of legislation, refused to acknowledge the requirement for change (Chamberlain 2009, McLellan 2008), and general concerns arose over resource implications (Health Committee 2011). Policy on the governance of UK medical performance has also generated a lengthy battle for control of the policy process, with an unresolved competition for dominance between the state and medical profession (Salter 2007), arguably won by those arguing in favour of revalidation, with revalidation being passed as a statutory requirement (Department of Health 2008). Once a statutory requirement, the GMC and Royal Colleges were the first regulatory body to initiate revalidation pilot schemes, implemented through a series of legislative and non-legislative initiatives (General Medical Council 2010). An independent evaluation of the active revalidation pilot schemes in July 2011 however suggested that optimism towards revalidation was low with less than half of the rank and file respondents expecting revalidation to improve the quality of patient care (Frontline 2011).

Professional self-regulation is described as health professionals taking ownership of their own standards of practice, conduct and discipline. In justification of such privilege, and in order to maintain public trust and autonomy claims however, professionals are expected to be openly accountable for the setting and enforcement of such standards (Flynn 2002, Department of Health 1998). Whilst the primary purpose of professional regulation is directed at impacting upon patient safety, regulation undoubtedly has an impact upon professionals in the controlling of their behaviour. Due to the numerous aspects of regulation which influence professional behaviour, measuring the practical impact of such regulation upon professionals is complex with a dearth of research evidence. Quick (2011) provides a scoping study of the effects of health professional regulation on those regulated. There is a dearth of UK published research which mainly focuses upon the relationship

between regulation, safety, quality and behavioural compliance (Currie et al 2009, Sutherland and Leatherman 2006, Vincent 2003, Parker and Lawton 2000), however very little is known about the tension between regulation and professional autonomy and its impact upon inter-professional or intra-professional dynamics and behaviours, which may depend on the context in which individuals work and are regulated.

The medical and non-medical revalidation working groups have referenced six main areas that could challenge implementation.

Logistic:	Large numbers of healthcare professionals need to be covered by the revalidation schemes, which need to encompass a great diversity of groups, roles and practice settings. The numbers involved in non- medical revalidation will be greater than one million and the scope of practice varies significantly even within discrete professional groups.
Methodological	Valid, reliable, proportionate and fair systems still need to be designed in all areas to set standards and to assess practice against them. Proportionality is essential and a one-size fits all approach should be avoided.
Connections	Many systems and organisations examine the quality of healthcare in the NHS and throw light on professionals' performance and practice. Where appropriate, effective connections need to be made between them and the system of revalidation.
Information	High quality data is vital to effective assessment of practice and although these may have been lacking in the past in some areas they must be developed. This might be outcome data or other measures could be used.

Cultural	Revalidation should be seen primarily as supportive, focused on raising standards, not a disciplinary mechanism to deal with the small proportion of health professionals who may cause concern. The involvement of patients and the public at all stages will greatly enhance the quality of the process of revalidation and help promote public confidence in the profession itself. Careful consideration needs to be given to how patients and the public can be involved meaningfully.
Resources	Revalidation will require considerable investment to develop, including potentially advanced expertise in assessment. There may be an adverse reaction from both professional groups and employers if packages of revalidation are resource intensive. Implications for registration fees would need to be handled carefully in such circumstances.

The implementation of revalidation is set to further challenge the concept of the 'regulative bargain', and the historic and sociological foundations from which the 'professions' have emerged (Spendlove 2013), leading to changing definitions of professionalism and tensions between professionals and policy makers. With the introduction of reforms to the United Kingdom health professional regulatory framework, it is argued that professions will no longer be able to profess to be 'self-regulating' as the powers of standard setting, monitoring practice and managing defaults will be relocated to outside of the profession (Dixon-Woods et al 2011). Central to regulatory reform is also the changing shift in attitudes towards health professionals, seen as potentially dangerous through negligence or design (Hutter 2008).

There is a dearth of research regarding revalidation. Archer et al (2012) explored the perspectives of key leaders in revalidation policy examining potential implications of revalidation for change in medical culture, professionalism and culture. Key findings highlighted that the practical challenges of implementation would cause tension and conflict and the changing social contract between medicine and the public will lead to a changing definition of professionalism. It was also felt that revalidation as an explicit form of regulation may present as a threat. Leadership and political struggles were noted with an irresolvable contradiction between the need and for leadership and shared responsibility in protecting patients with no consensus over who is responsible for the patient centred agenda. Archer at el (2012) made many recommendations including the need for clarity of the purpose of revalidation, the anticipation of both intended and unintended consequences, the need for true patient focus and the need for revalidation to be meaningful to the day-to-day work of doctors rather than a bureaucratic exercise. Revalidation remains at an early stage of introduction therefore professional reactions to revalidation are yet to emerge. The King's Fund has undertaken research exploring the early experiences and views of Responsible Officers in the London area (The King's Fund 2013). Less than half of the respondents expressed positive experiences of the first few months of revalidation. Where existing robust systems of appraisal and clinical governance were present the implementation of revalidation was felt to be supported and where investment in IT systems, resources and development of individuals took place the process ran smoothly and was seen as valuable. The role of the Responsible Officer was noted to be a significant management task and support from the revalidation team, the GMC and organisational human resource departments were noted as a necessary investment in making the process of revalidation work.

Part Three - Exploring the Concept of Health Professional Regulation

Defining Regulation

Regulation is a broad term upon which traditional conceptualisations have been built in relation to government-society and intra-society relationships (Black, 2002). A further detailed definition of regulation as provided by Black (2002 p. 20) is:

'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 behaviourmodification'.

Regulation has three key characteristics, a public interest purpose such as protecting and serving the interests of the public, a regulatory agency such as the health professional regulatory bodies and formal regulatory powers and processes, statutory and non-statutory, given to the regulatory body to undertake its role (Walshe and Boyd 2007). The primary purposes of health professional regulation are to ensure patient safety and quality care (Department of Health 2007a), with further intended consequences of increased transparency and accountability. This is broadly achieved through processes which aim to

control professionals, in particular the behaviour of professionals within clinical practice and professional life.

The varieties of processes by which health professionals can be regulated are articulated by the GMC as a four-layer model of regulation (General Medical Council 2005 p3). The four layers being personal, team-based, workplace and professional. Based upon modern regulatory practices personal regulation incorporates aspects of self-regulation and professional commitment to a common set of ethics, values and principles. Team based regulation reflects the individual and collective responsibility for the performance, conduct, and identification of poor performance and misconduct. Workplace regulation reflects the responsibility that healthcare workplaces have for ensuring that professionals employed within that organisation are fit for practice such as performance management, clinical governance and disciplinary procedures. Professional regulation covers the breadth of responsibility of regulatory and professional bodies and Royal Colleges. Professional regulation is based upon standards, education, and registration and licensing, including the introduction of revalidation and fitness to practise procedures. Professional regulation also reflects the role of healthcare regulators where regulations and actions have direct impact upon the workplace, indirectly affecting the individual practice of employed professionals (Health Professional Council 2008, General Medical Council 2005). The regulation of the medical professions spans these four layers of regulation. However the 'layers' of regulation required for other UK health professional regulatory bodies to adequately regulate their registrants will vary according to the risks they pose and the nature of their professional role.

Self-Regulation

In the UK self-regulation has been traditionally favoured over more formalised systems of regulation (Baggott 1989) and The National Consumer Council (2000) identify eight main types of self-regulatory arrangement that fall broadly along a spectrum:

Unilateral Codes of Conduct

 implement specific policies which amount to some form of self-restraint on its conduct towards its customers e.g. codes of ethically or socially responsible business conduct in relation to employees or the environment

Customer Charters

 a formal exercise covering all key aspects of its dealings with customers e.g. a company's formal public commitment to combine compliance with its legal obligations with customer service initiatives

Unilateral Sectoral Codes

 entirely voluntary, self-imposed, collective – code of practice or similar set of rules unilaterally adopted by a trade or profession, without any consultation or discussion with the outside world e.g. the start of a longer process of developing self-regulation such as the beginnings of complementary and alternative health therapies

Negotiated Codes

 codes of self-regulation which have been negotiated, or at least discussed (either formally or informally) between an industry body on the one hand, and government and consumer organisations on the other e.g. the code of practice adopted by the Association of Energy Suppliers to restrain unacceptable methods of marketing gas and electricity

Trade Association Codes

 This category is a variant of negotiated codes and covers the 49 codes that have been drawn up by trade associations in consultation with the Office Of Fair Trading (OFT) and formally approved by the Director General of Fair Trading

Recognised codes

 Codes which have some form of statutory foundation or recognition. It includes the professional 'codes' of lawyers and doctors. The Solicitors Act empowers the Law Society to make 'practice rules' for solicitors and the General Medical Council has a corresponding power for doctors.

Official codes and guidance

 Government department or regulatory agency issuing a code or guidance (often elaborating on statutory provision), which has had self-regulatory input and is intended to be followed within the business sector in question. The 'enforcement' of such codes is left to traditional methods – in other words, civil or criminal action in the courts.

Legal codes

• codes imposed by government or by a public authority under the authority of statute, but which lack the full force of conventional law

Despite the many differences between the eight types of self-regulation, three elements were identified, common to most forms of regulation, both statutory and self-regulatory:

- 1. Rules which set out how conduct is to be judged.
- 2. Monitoring and enforcement of the rules.

3. A redress system for consumers who have suffered loss, through breach of the rules³.

The three elements may not always be provided for in one system but, unless all three are covered somehow, the regulation is unlikely to be effective (The National Consumer council 2000). Effective, credible self-regulatory processes are suggested to have all of the following elements:

1. Must be able to command public confidence.

2. There must be strong **external consultation and involvement** with all relevant stakeholders in the design and operation of the scheme.

3. As far as practicable, the operation and control of the scheme should be **separate** from the institutions of the industry.

4. Consumer, public interest and other **independent representatives must be fully represented.**

5. The scheme must be based on clear and intelligible statements of principle and measurable standards – usually in a Code – which address real consumer concerns. The objectives must be rooted in the reasons for intervention.

6. The rules should identify the intended outcomes.

7. There must be clear, accessible and **well-publicised complaints procedures** where breach of the code is alleged.

8. There must be adequate, meaningful and commercially significant **sanctions** for non-observance.

9. Compliance must be monitored.

10. Performance indicators must be developed, implemented and published to measure the scheme's effectiveness.

11. There must be a degree of **public accountability**, such as an Annual Report.

³ Revalidation or Continuing Fitness to Practise is exclusively about demonstrating professionals' ongoing Fitness to practice and accordingly protecting the public; it is explicitly not a system for redress.

12. The scheme must be **well publicised**, with maximum education and information directed at consumers and traders.

13. The scheme must have **adequate resources** and be funded in such a way that the objectives are not compromised.

14. Independence is vital in any redress scheme which includes the resolution of disputes between traders and consumers

15. The scheme must be regularly reviewed and updated in the light of changing circumstances and expectations (National Consumer Council 2000).

Risk-based regulation

The Better Regulation Task Force report (2005) 'Regulation – Less is More Reducing Burdens, Improving outcomes' outlined 5 principles for good regulation. The Legislative and Regulatory Reform Act (2006), which came into force in January 2007, underpinned these

principles.

Transparent	Regulators should be open and keep regulation simple and user-friendly.
Accountable	Regulators must be able to justify decisions and be subject to public scrutiny.
Proportionate	Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised.
Consistent	Government rules and standards must be joined up and implemented fairly.
Targeted	Regulation should be focused on the problem and minimise side effects.

Such principles are embodied by the concept of risk-based regulation. Risk-based regulation brings together and focuses upon risk management and regulatory practices (Hutter 2008)

bringing together a broad range of approaches (Hutter 2005). As discussed above, the Professional Standards Authority (PSA) promotes the concept of right-touch regulation (Council for Healthcare Regulatory Excellence (CHRE) 2010), a process underpinned by riskbased regulation. Right-touch regulation means always assessing the risk being regulated, being proportionate and targeted in regulating that risk or finding ways other than regulation to promote good practice and high quality healthcare. It promotes the minimum regulatory force required to achieve the desired result. Right touch regulation builds upon the principles of good regulation as identified by the Better Regulation Executive: proportionate, consistent, targeted, transparent, and accountable. The PSA add a sixth principle of agility (CHRE 2010).

Agility	Regulators should look forward to anticipate change rather than looking
	back to prevent the last crisis from happening again.

In addition to, and in support of the 6 principles of good regulation as previously described, the PSA identify eight elements that sits at the heart of right-touch regulation (CHRE 2010): identify the problem before the solution, quantify the risks, get as close to the problem as possible, focus on the outcome, use regulation only when necessary, keep it simple, check for unintended consequences and review and respond to change. The PSA profess that the benefits of right touch regulation are that it ensures the most efficient impact on the problem being tackled. It also enables all parts of the system to play a full role in providing a more appropriate response to a problem. In healthcare, this includes the contribution of employers, educators, professionals and patients. The PSA also propose that the consequences of this approach may lead to the requirement for more, or even less regulation, but will ultimately result in improved regulation of health care professionals. Right-touch regulation supports a nuanced approach to health professional regulation allowing individual regulators to identify the risks posed by their registrants and base regulatory processes upon those identified risks (PSA 2014).

Within the UK, many regulators have developed risk-based frameworks of regulation (Black 2008), as a framework for the management of their resources and their reputations amidst the UK government regulation modernisation agenda (Rothstein et al. 2006; Black 2005; Hampton 2005). There is a growing literature based on the concept of risk-based regulation and Black and Baldwin (2010) add to the commentary proposing a "really responsive" approach to risk-based regulation delivering two central messages. The first is that it is best to regulate in a way that is responsive to regulated firms' behavior, attitude, and culture; institutional environments; interactions of controls; regulatory performance; and change. The second is that the challenges of regulation to which regulators have to respond vary across the different regulatory tasks of detection, response development, enforcement, assessment, and modification. There is a need to think in a more structured manner about the ways in which risk-based regulation can come to terms with the many hurdles to be overcome if it is to succeed on the ground. Black and Baldwin (2010) propose that the 'really responsive' framework offers a basis for such structured thinking for astute regulators to deal with the variety of those challenges.

Lloyd-Bostock and Hutter (2008) argue however that the concept of risk based regulation poses dilemmas, carries unintended consequences and needs to be considered critically. Difficulties are acknowledged with true objectivity in evaluating and managing risk (Hutter 2005), and with the role of blame, questioning whether regulation can ever be blame free. Risk based approaches are only as good as the information which goes into them and the

decisions made upon such information are inescapably normative (Lloyd-Bostock and Hutter 2008).

Theoretical Perspectives regarding Regulation in Practice

There is extensive literature which brings wider theoretical perspectives from other disciplines with key ideas shaping the thinking about the nature, form and purpose of regulation (Walshe and Boyd 2007, McCraw 1984, Croley 1998, Uche 2001). Walshe and Boyd (2007) provide a review of the theories which underlie the common ideas about regulation in practice.

Theoretical perspectives and lessons for regulation (Walshe and Boyd 2007)

Theory	Some lessons or implications for regulation
Public choice theory	Regulate sparingly and as a last resort, and prefer alternative strategies to regulation. When it is needed, aim for minimally intrusive regulation which can be withdrawn once normal market mechanisms come into play. Be aware of and guard against the risks of regulatory capture.
Interest group theory	Pay more attention to the governance of regulation, the accountability of regulators, and the relationships between stakeholders in regulation than to the specifics of the regulatory

	regime. Design regulatory regime to achieve intended shifts in the influence of key interest groups, and where necessary to empower some groups.
Institutional theory	Recognise the importance of organisations' awareness and understanding of the purpose and process of regulation and their response to it. Explore likely organisational responses to regulatory interventions and consider potential adverse effects. Analyse the wider external environment for organisations and see the regulatory regime as working alongside other external influences and competitive pressures.
Principal agent theory	Consider the imbalance in resources, information and attention between the regulator and regulated organisations, and design the regulatory regime to make performance measurement objective and transparent and to achieve maximal impact with limited regulatory resources.
Game theory	Understand both the regulatory regime and the behaviours it elicits from regulated organisations more fully, and design it to allow for a "win-win" equilibrium in which positive and desired behaviours on the part of regulated organisations are recognised and rewarded by the regulator.

Such theoretical insight offers ideas about how and why regulation may work and what those responsible for designing systems of regulation should aim to do (Walshe and Boyd 2007).

Regulatory transparency is a key component in many theories of regulation and transparency and sits at the core of 'better regulation' and 'right-touch regulation' (The Better Regulation Task Force report 2005, Council for Healthcare Regulatory Excellence CHRE 2010). Transparent or explicit regulation is envisaged to facilitate compliance with regulatory processes. Lee, Aaker and Gardner (2000) also propose that regulatory focus theory can aid in distinguishing between self-regulatory processes that focus on promotion and prevention strategies for goal pursuit, and compliance with such regulatory focus. Lee, Aaker and Gardner (2000) review five studies, which provide support for the hypothesis that these strategies differ for individuals with distinct self-construals. Self-construal refers to the extent to which the self is defined independently of others or interdependently with others. Specifically, these studies proposed that individuals with an independent self-construal were predicted to place more emphasis on promotion-focused information, and those with interdependent self-construal more emphasis on prevention-focused information (Lee, Aaker and Gardner 2000; Zhang & Mittal 2007).

Research on self-regulatory strength suggests that people with high interdependent selfconstrual experience less regulatory depletion compared to people with high independent self-construal in some situations as people predisposed toward a more cooperative orientation are stronger at self-control and, accordingly, are better able to ward off the adverse impact of ego depletion on self-regulation (Seeley & Gardner, 2003). This is particularly interesting in that 'professionalism' is believed to be a 'collective' conscience (Bhugra and Malik 2010) and the presence of differing self-construals will undoubtedly have an impact upon the concept of professionalism, professional self-regulation and regulatory compliance.

The concept of 'relational regulation' (Hiusing and Silbey, 2011) is based on the premise that there is an inevitable 'gap', however minor, between regulation and regulatory compliance in practice and that practices are often 'loosely-coupled' with regulatory requirements. Hiusing and Silbey (2001) suggest that the working of front-line managers, who implement this 'gap' into practice, is often invisible to senior managers and regulators. In order to increase regulatory compliance, regulation and practice need to be aligned, both aligning practice more closely with regulation and designing regulation that reflects the

nature of practice, narrowing the gap between regulatory expectations and practice in everyday life (Huising and Silbey, 2011).

Huising and Silbey (2011) propose a model of 'pragmatic relational regulation' likely to produce regulatory compliance. They suggest for relational regulation to be effective, external regulators provide a credible threat to those they regulate, through periodic review and demands for accountability, providing a form of 'governance at a distance' (Foucault, 1991). External regulators should engage in 'macromanagement', which can be seen as a form of cultural management allowing 'temporal space' for those implementing regulation to discuss what is required and how it can best be achieved, while also shaping this 'behavioral space' for self-directed action.

Actors subject to regulation often have heterogeneous motivations and simultaneously pursue different goals affecting compliance and non-compliance with regulation, which may be both automatic and/or planned (Etienne, 2011). Etienne (2011) outlines a model explaining compliance and non-compliance, based upon three goals; *hedonic, gain* and *normative*. *Hedonic* goals are motivated by trying to "feel good", to experience positive emotions (e.g. pride; comfort; joy) and avoid negative emotions (e.g. guilt; shame; discomfort). *Gain* goals relate to motivations to increase one's resources (e.g. money, power, influence, free time) and may be linked to creative compliance and regulatory avoidance. *Normative* goals relate to the motivations, to "do the right thing", and behave in ways that are appropriate and comply with social norms, including, where relevant, those of professional communities, and relate to self-categorisation and a feeling of duty.

Etienne (2011) suggests that actors may simultaneously pursue different compatible and incompatible goals in the 'foreground' and 'background' and that compliance is affected by

the 'relative prices' of these goals and the regulatory 'signals' sent by both peers and regulators about them, associated with events, behaviours and messages. Hedonic signals may induce a sense of pride and self-esteem linked to regulatory compliance, or fear or shame associated with non-compliance. Gain signals are linked to the perceived selfinterested costs and benefits associated with regulatory compliance. Normative signals signal what is appropriate and thus induce normative compliance. Etienne argues that regulators need to attend to all three (hegemonic, gain and normative) goals and associated signals to ensure that their 'relative prices' support regulatory compliance (Etienne, 2011). However 'signals in the regulator-regulatee relationship' are often interpreted by both regulator and regulatee in ambiguous ways, so close attention needs to be paid to understanding the ways signal are experienced and interpreted (Etienne, 2013).

McGivern and Ferlie (2007) and McGivern and Fischer (2010; 2012) draw attention to the ways in which clinicians experienced and interpreted transparency and regulation, which in a regulatory climate they do not trust or feel safe in, were seen as a threat. Clinicians make sense of regulatory processes using (often extreme and atypical) narratives circulating in professional communities, rather than the more rational accounts of the purpose of regulation as espoused by regulators (McGivern and Fischer, 2012). This had the unintended consequence of producing defensive practice and an unwillingness among many professionals to openly discuss the problems they may be facing in practice in regulatory spaces. So perversely, regulatory transparency in a threatening wider climate, could lead to professionals being more likely to cover up issues that might make their practice unsafe (McGivern and Ferlie, 2007; McGivern and Fischer, 2012).

In other circumstances, however, clinicians may draw upon and actively use regulation and transparency to shape their identities and behaviours, as well as those of professional colleagues. For example, Ferlie et al (2011, 2012, 2013; Ferlie and McGivern 2014) describe how clinicians drew upon forms of transparency and associated evidence-based standards, which had been developed in collaboration with respected clinicians and were seen to be legitimate and useful within the wider professional community, to make sense of themselves and colleagues as 'good clinicians' and enact higher quality health care services. Consequently we can think of regulation, associated standards and forms of transparency as potentially producing both positive and negative 'reactivity' (McGivern and Fischer, 2012). Given people's limited capacity to collect and process information, and the potential for information overload in response to burgeoning sometimes trivial rules and guidelines clinicians do not understand (McCarthy et al. 2011), it is important that regulation 'structures attention' to focus on things that are the most important in terms of producing safe and effective health care (Heimer, 2008).

Impact of Regulation

Evaluating the impact of regulation is difficult as regulatory processes are generally applied universally in circumstances where there are many other influences or pressures on the behaviour of those being regulated. Walshe and Boyd (2007) in their scoping review of the literature provide a summary of the potential positive and negative impacts of regulation.

Positive and negative impacts of regulation (Walshe and Boyd 2007)

Positive effects	Negative effects
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•	Specific changes and improvements in services resulting from regulatory	• Temporary rather than sustained performance improvement, which disappears after regulatory intervention
•	attention Causing organisational reflection and comparison with regulatory standards	 Pointless conformance behaviours in which things are done solely to satisfy regulators which have little or no value for service users or the organisation
•	and with the performance of others. Giving important or longer	• Defensive or minimal compliance, in which standards effectively act as a limit on rather than a stimulus for improvement.
	term issues greater organisational priority than they would otherwise receive	 Creative compliance, in which organisations appear to comply with regulatory requirements by making superficial changes
•	Providing leverage for change for groups or individuals within	 Prevention of innovation or improvement, in which regulatory standards discourage or prevent change
	regulated organisations	Distortion of organisational priorities, as
•	Driving continuing improvement as regulatory standards are continually	organisations respond to issues raised by regulators instead of dealing with internally identified issues
	updated and improved	 Opportunity costs, as organisations invest considerable resources, particularly managerial time, in interacting with the regulator

These factors perhaps assumed that regulatory interventions take the form of a one off

intervention rather than a culture change, aiming to change the nature of professionalism

and bring it and regulatory standards more genuinely in line.

Walshe and Boyd (2007) in their scoping review of the literature also provide a summary of

the common problems associated with regulatory failure.

Common Problems in Regulation (Walshe and Boyd 2007)

Dog	ulatory	
кед	ulatory	

Characteristics

failure	
Regulatee resistance	Regulated organisations either individually or jointly develop a culture of resistance in which opposing and undermining the regulator directly or indirectly is seen as normal, acceptable or even desirable behaviour
Ritualistic compliance	Regulated organisations and the regulator develop a formalised and ritualistic style of interaction, in which compliance with the letter of regulatory direction rather than with the broader regulatory purpose becomes the primary goal
Regulatory collusion and capture	The regulator colludes with one or other stakeholder in the regulatory process – usually but not always regulated organisations – and the interests of those stakeholders come to dominate regulatory decision making
Measurement ambiguity and problems	The regulator is unable to measure the performance of regulated organisations sufficiently to differentiate between them and to adopt appropriate regulatory strategies and interventions.
Goal displacement	The regulatory purpose becomes subordinated to a range of other objectives, often linked to the performance of the regulatory process itself.
Regulatory proliferation and growth	The regulatory regime becomes more complex, wide ranging and onerous as the regulator adds new requirements and extends existing ones
Regulatory rigidity, juridification and inflexibility	The regulatory regime becomes difficult or impossible to change, often through the application of a highly legalistic approach, and cannot be adequately updated or revised in response to changes in the environment.

In relation to the last point, it should be noted that the Law Commission recently published a draft Health and Social Care Bill⁴ in order to address this issue, although the Bill was not given time in the following Parliamentary session.

In times of challenge, it is recognised that the medical profession in particular has

demonstrated the ability to retain its overall dominance and utilise strategies to maintain

monopoly in the market and resist managerial encroachment (Foucault 1991, Waring 2007).

⁴ <u>http://lawcommission.justice.gov.uk/areas/Healthcare_professions.htm</u>

The intended consequence of professional regulatory processes is to provide transparency against standards, expose poor regulation and poor performance and deliver improvements in health care (Hood and Heald 2006). Professional regulation however can produce unintended consequences which are more difficult to detect and measure (Hood 2006), such as superficial 'tick box' compliance, which neither reflects nor improves the nature of care in professional practice (Hood 2006, McGivern and Ferlie 2007, McGivern and Fisher 2012, Waring 2009).

Research by the Solicitors Regulation Authority (2011) has highlighted 11 dimensions for assessing attitudes towards regulatory compliance. Research by the General Medical Council (Scraggs et al, 2012), CHRE (Quick, 2011) and on the regulation of social work (Munro, 2011, Meyeral, 2011) has highlighted a number of other factors that may support or inhibit professional regulatory compliance. However these studies often presume professionals react to regulation in a rational way. Empirical research has also drawn attention to 'irrational' factors, like anxiety, strong emotionally-driven reactions, and professional narratives about regulatory processes and their wider contexts, which lead to professional defensive practices that undermine patient care (McGivern et al., 2009a, 2009b, McGivern and Fischer, 2012, Waring, 2009, Fischer, 2012).

Regulatory Methods

Clinical Supervision

Clinical supervision has been defined as 'An exchange between practising professional to enable the development of professional skills' (Butterworth 1992). Burton and Launer (2003) define clinical supervision as 'facilitated learning in relation to live practical issues.'

However, Clark et al. (2006) suggest a wide definition that includes a variety of one-to-one professional encounters including mentoring and coaching. The term 'clinical supervision' is sometimes used in the sense of the everyday supervision of a trainee's performance. Clinical supervision according to 'The Gold Guide' to specialty training (Department of Health 2007b) involves being available, looking over the shoulder of the trainee, teaching on the job with developmental conversations, regular feedback and the provision of a rapid response to issues as they arise.

Clinical supervision is increasingly being carried out as an aspect of personal and professional development in both primary and secondary care. It is an aspect of lifelong learning with potential benefits for both supervisor and supervisee. The expansion of supervision is arguably underpinned by the managerial and political agenda of performance management in the risk-averse cultures of contemporary health and social care (Johns, 2001).

Beddoe (2010) investigated the experience of six expert practitioners of professional supervision in order to explore the impact of the 'risk discourse' upon supervision within social work. It was recognised that supervision cannot operate in a vacuum, even in the external form, away from the front line workplace; the nagging concerns of risk, fear and accountability are inevitably present in the space between the participants. These supervisors however rejected a surveillance role for supervision and supported the maintenance of a reflective space as crucial to effective practice. This supports McGivern et al (2009a; 2009b) in highlighting the importance of 'formative spaces' in professional regulation, in which professionals are able to discuss ambiguous and difficult aspects of their practice in a way that helps them address, rather than hide, potential problems.

However, it is noted that wider rational-legalistic and media-driven regulatory climates undermine formative spaces (McGivern et al. 2009a; 2009b; McGivern and Fischer, 2012). Supervision is a statutory responsibility for every midwife practising in the United Kingdom and provides a mechanism for support and guidance. The purpose of supervision of midwives is to protect women and babies by actively promoting a safe standard of midwifery practice. Supervision is a means of promoting excellence in midwifery care, by supporting midwives to practise with confidence, therefore preventing poor practice (NMC 2009). Supervisors of midwives are experienced, practising midwives who have undergone education and training in the knowledge and skills needed to supervise midwives. They act as an impartial monitor of the safety of midwives' practice and they encourage midwives to develop their skills and knowledge. Supervisors of midwives are appointed by the Local Supervising Authority and they are accountable in their role to the Local Supervising Authority Midwifery Officer. When acting in their capacity as a supervisor of midwives, they are independent of their employers, investigating and reporting directly to the Local Supervising Authority Midwifery Officer when there are concerns about safe practice. Their role is different to a midwifery manager who is responsible to the employer for making sure that maternity services run effectively. All midwives have a named supervisor who they are required to meet with at least once a year. This annual supervision meeting essentially provides a 'formative space' (McGivern et al 2009a; 2009b; McGivern and Fischer, 2012) in which midwives are able to discuss ambiguous and difficult aspects of their practice in a way that helps them address, rather than hide, potential problems.

Appraisal and Multisource Feedback

Appraisal is a process of facilitated self-review supported by information gathered from the full scope of a professional's work. The origin of appraisal systems lies within industry, where it was introduced to evaluate the performance of individual members of staff. The actual aims of the systems and processes used have varied considerably in reviewing the past performance of employees, setting future objectives, improving performance through the identification of training and development needs and assisting with the assessment of future potential and decisions on career progression (Brown et al 2003, Hogg, 1988). Medical appraisal, introduced in 2002, can be used for four purposes:

 To enable doctors to discuss their practice and performance with their appraiser in order to demonstrate that they continue to meet the principles and values set out in Good Medical Practice and thus to inform the responsible officer's revalidation recommendation to the GMC.

2. To enable doctors to enhance the quality of their professional work by planning their professional development.

3. To enable doctors to consider their own needs in planning their professional development.

 To enable doctors to ensure that they are working productively and in line with the priorities and requirements of the organisation they practise in (Revalidation Support Team 2013).

It is recognised that there is a potential conflict of interest when the individual's ability to meet organisational priorities and requirements, which is normally part of the job planning process, is combined with the developmental elements of appraisal. For this reason the two processes of appraisal and job planning should remain separate, though the outputs from each will inform the other (Revalidation Support Team 2013).

In a study of the introduction of appraisal for NHS hospital consultants, McGivern and Ferlie found tension between the formative (developmental) and summative (assessment) aspects of appraisal, the appraised were often reluctant to openly discuss difficult issues in their appraisal which might be formally recorded and then prevent them from continuing to practise clinically. They noted the importance of the willingness of both appraisers and appraised to engage in the process in order for consultant appraisal to be an effective forum in which clinicians were able to reflect on and learn to improve their practice. If clinicians being appraised did not trust their appraiser, or the system using information generated in the process, or felt that the concerns they raise would not be acted upon, the processes was likely to become a 'tick box exercise', providing only superficial (perhaps false) assurance of clinical professional regulation (McGivern, 2005; McGivern & Ferlie, 2007).

A review of the literature, by Mugweni et al (2011), looked at what benefits GPs perceived appraisal to offer. They found that appraisal offers the chance to reflect on their personal development, and promotes educational activity and there is a strong perception that appraisal encourages changes in clinical practice and offers additional benefits such as mentorship and motivational support for the doctor. The conclusion drawn was that GPs, and the patients that they treat, should continue to benefit from outputs of medical appraisal after the introduction of medical revalidation (Mugweni et al 2011).

The relationship between appraisal and revalidation however needs to be clarified. Boylan at al. (2005) highlight apprehension about a scheme that attempts to link professional development and assessment or revalidation. Greater clarity about the precise nature of the linkage is required to avoid a process that fails to fully satisfy the requirements of either appraisal or revalidation.

Middlemass and Siriwardena (2003) suggest a better understanding of knowledge, beliefs and attitudes towards appraisal will ultimately help in setting up a successful appraisal system. Placing emphasis on appraisal as an educational tool will help to foster positive attitudes. Middlemass and Siriwardena (2003) suggest further that concerns relating to lack of time and resources for appraisal and revalidation need to be addressed.

Murphy et al (2012) explored the concept of medical revalidation and that decisions need to be reliable if they are to truly reassure on the quality and safety of professional practice. The study tested an innovative method in which GPs were assessed on their reflection and response to a set of externally specified feedback. Results suggested that face-to-face assessment proved unreliable. Anonymous global assessment by three appraisers of insightful practice was however found to be highly reliable, as were revalidation decisions using four anonymous assessors Murphy et al (2012) concluded that unlike face-to-face appraisal, anonymous assessment of insightful practice offers a valid and reliable method to decide GP revalidation, reinforcing the potential of multisource feedback.

Holmboe and Ross (2012) discuss how multisource feedback (MSF) is promoted as a useful approach for formative assessment and is increasingly becoming part of regulatory-based assessment programs, such as revalidation. They suggest that to achieve the full potential of MSF, more attention should be directed at the specific purpose and processes of the MSF

tool and the ability of the results to initiate and drive improvements in health care, stating greater awareness is also needed around how the results of MSF are interpreted, processed, and applied by physicians. Holmboe and Ross (2012) suggest 'both government and independent professional self-regulatory bodies walk a difficult tight rope in developing instruments that are psychometrically credible to both physicians and the public, yet truly drive improvements in quality and safety. Ultimately, a formative assessment approach is only as good as the quality of care it detects and improves for the benefit of patients and the public' (p1657).

Summary

This review has provided a brief overview of the history of health professional regulation and the background and context regarding the inception of revalidation in the United Kingdom (UK). This review has provided an insight into the historical narrative of defining professions, professionalisation and the expansion of health professional regulation. It has provided background and context to the modernisation of health professional regulation within the National Health Service and the movement from state-sanctioned, collegial, selfregulation to a form of state-directed bureaucratic regulation, exploring revalidation as health professional regulatory reform. This review has also explored the concept of health professional regulation in defining regulation, theoretical perspectives regarding regulation in practice and the impact of regulation upon those being regulated, providing a brief discussion of methods of professional regulation.

References

Abbott, A. (1988) The System of the Professions. London: University of Chicago Press.

Archer, J. Regan De Bere, S. Nunn, S. Clark, J. Corrigan, O. (2012) Revalidation: In Policy. Available at

http://www.rcpsych.ac.uk/pdf/REVAL2013%2012%20Revalidation%20in%20Policy.pdf as at [Accessed 8th February 2014].

Armstrong, D. (1976) Decline of the Medical Hegemony: A Review of Government Reports During the NHS. Social Science and Medicine 10 pp157-163

Baggott, R. (1989) Regulatory Reform in Britain: The Changing Face of Self-Regulation. Public Administration 67 pp 435-454

Beddoe, L. (2010) Surveillance or Reflection: Professional Supervision in 'the Risk Society'. British Journal of Social Work (2010) 40, 1279–1296

Berwick, D. (2013) A promise to learn – a commitment to act: Improving the Safety of Patients in England. National Advisory Group on the Safety of Patients in England. Available at https://www.gov.uk/government/publications/berwick-review-into-patient-safety. [Accessed 23rd February 2014]

Better Regulation Taskforce (March 2005) Regulation –Less is More – Reducing Burdens, Improving Outcomes. Available at <u>http://www.bis.gov.uk/files/file22967.pdf</u> [Accessed 30th January 2014].

Bhugra, D. Malik, A. (2010) Professionalism in Mental Healthcare: Experts, Expertise and Expectations. London: Cambridge University Press.

Black, J. (2002) Critical Reflections on Regulation. Paper No 4. Centre for Analysis or Risk and Regulation. Available at http://eprints.lse.ac.uk/35985/1/Disspaper4-1.pdf [Accessed 25th April 2013].

Black, J. (2005) The Emergence of Risk-based Regulation and the New Public Risk Management in the United Kingdom. Public Law: 512–48.

Black, J. (2008) Risk-Based Regulation: Choices, Practices and Lessons Being Learned. Paris: OECD.

Black, J. Baldwin, R. (2010) Really Responsive Risk-Based Regulation. Law and policy 32(2) pp181-213.

Bosk, C. (1979) Forgive and Remember: Managing Medical Failure. Chicago: Chicago University Press.

Boylan, O. Bradley, T. McKnight, A. (2005) GP Perceptions of Appraisal: Professional Development, Performance Management, or Both? British Journal of General Practice 55 pp544–545.

Brown, N. Parry, E. & Oyebode, F. (2003) Appraisal for consultant medical staff. Advances in Psychiatric Treatment 9, pp152–158.

Burton, J. and Launer, J. (eds) (2003) Supervision and Support in Primary Care. Radcliffe Medical Press, Oxford.

Butterworth, T. (1992) Clinical supervision as an emerging idea in nursing. In: Butterworth, T. and Faugier, J. (eds) Clinical Supervision and Mentorship in Nursing. Stanley Thornes, Cheltenham.

Carr-Saunders, A. Wilson, P. (1933) The Professions. Oxford: The Clarendon Press.

Chamberlain, J. (2009) The Changing Medical Regulatory Context: Focusing on Doctor's Educational Practices. Medical Sociology Online 4(2) pp26-34. Available at http://www.medicalsociologyonline.org/ [Accessed 14th May 2012].

Chantler, C. (1999) The role and regulation of doctors in the delivery of health care. Lancet, 353 pp. 1-2

Clark, P. Jamieson, A. Launer, J. Trompetas, A. Whiteman, J. Williamson, D. (2006) Intending to be a supervisor, mentor or coach: which, what for and why? Education for Primary Care. 17 pp109–116.

Cooper, D. Lowe, A. Puxty, A. Robson, K. Willmott, H. (1988) Regulating the UK Accountancy Profession: Episodes in the Relation Between the Profession and the State, paper presented at ESRC Conference on Corporatism at the Policy Studies Institute, London, January.

Council for Healthcare Regulatory Excellence (2010) Right Touch Regulation. Available at<u>http://www.professionalstandards.org.uk/docs/psa-library/right-touch-</u>regulation.pdf[Accessed 8th February 2014].

Croley, S. P. (1998) Theories of regulation: Incorporating the administrative process. Columbia Law Review, 98 pp 1-168.

Currie, G. Humphreys, M. Waring, J. Rowley, E. (2009) Narratives of Professional Regulation and Patient Safety: The Case of Medical Devices in Anaesthetics. Health, Risk & Society 11(2) pp117–135.

Davies, C. Beach, A. (2000) Interpreting Professional Self-Regulation. A History of The United Kingdom Central Council for Nursing, Midwifery and Health Visiting. London: Routledge.

Davies, C. (2002) Registering a Difference: Changes in the Regulation of Nursing In Allsop, J. Saks, M. (Eds) Regulating the Health Professions. London, SAGE Publications.

Department of Health (1997) The New NHS: Modern and Dependable. London: HMSO.

Department of Health (1998) A First Class Service: Quality in the New NHS. London: Department of Health.

Department of Health. (2006a) Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients. A report by the Chief Medical Officer. London: Department of Health.

Department of Health (2006b) The regulation of the non-medical

healthcare professions. London: Department of health.

Department of Health (2007a) Trust, Assurance and Safety-The Regulation of Health Professionals in the 21st Century. Available at www.officialdocuments.gov.uk/document/cm70/7013/7013.pdf [Accessed 10th October 2011]

Department of Health (2007b) A Guide to Postgraduate Specialty Training in the UK: The Gold Guide. Available at

http://www.jrcptb.org.uk/SiteCollectionDocuments/Gold%20Guide.pdf [Accessed 23rd February 2014].

Department of health (2008a) Health and Social Care Act 2008. Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSoci alCareBill/index.htm [Accessed 26th March 2012].

Department of Health (2008b) Medical Revalidation – Principles and Next Steps

Department of Health (2008c) Principles for Revalidation. Report of the Working Group for non-medical Revalidation. Professional Regulation and Patient Safety Programme. Available at

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/di gitalasset/dh_086431.pdf [Accessed 10th October 2011]

Department of Health (2009) Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation. Available at <u>http://www.nursingtimes.net/Journals/1/Files/2009/7/28/DH_102818.pdf</u> [Accessed 23rd February 2014].

Department of Health (2011) Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. London: Department of Health.

Dixon-Woods, M. Yeung, K. Bosk, C. L. (2011) Why is UK Medicine no Longer a Self-Regulating Profession?, The Role of Scandals Involving 'Bad Apple' Doctors. Social Science & Medicine73 (10): 1452–1459.

Dingwall, R. Rafferty, A. M. Webster, C. (1988) An Introduction to the Social History of Nursing. London: Routledge.

Donnison, J. (1988) Midwives and Medical Men. London: Historical Publications.

Durkheim, E. (1957) Professional Ethics and Civic Morals. London: Routledge.

Etienne, J. (2011) Compliance Theory: A Goal Framing Approach. Law and Policy, 33 (3), 305-333).

Etienne, J. (2013a) Ambiguity and relational signals in regulator-regulatee relationships. Regulation and Governance, 7 (1) 30-47. doi 10.1111/j.1748-5991.2012.01160.x.

Etienne, J. (2013b) Thoughts on how to regulate behaviours: An overview of the current debate. British Journal of Guidance and Counselling. 41 (1) 36-45.

Evetts, J. (2006a) Introduction : Trust and Professionalism : Challenges and Occupational Changes. Current Sociology 54(4) pp515-531.

Evetts, J. (2006b) Short Note: The Sociology of Professional Groups : New Directions. Current Sociology 54(1) pp133-143.

Ferlie, E., Fitzgerald, L., McGivern, G., Dopson, S. & Bennett, C. (2011) Public Policy Networks and 'Wicked Problems': A Nascent Solution?' *Public Administration*, 89, 307-324.

Ferlie, E., McGivern, G. & Fitzgerald, L. (2012) A New Mode of Organising in Health Care?: Governmentality and Networked Cancer Services in the UK. *Social Science & Medicine*, 74, 340-347.

Ferlie, E., Fitzgerald, L., McGivern, G., Dopson, S. & Bennett, C. (2013) *Making Wicked Problems Governable? The Case of Managed Health Care Networks.* Oxford. Oxford University Press.

Ferlie, E. & McGivern, G. (2014) Bringing Anglo-Governmentality into Public Management Scholarship: The Case of Evidence-based Medicine in UK Health Care. *Journal of Public Administration Research and Theory*, 24, 59-83.

Fischer, M. (2012) Organizational turbulence, trouble and trauma: Theorizing the collapse of a mental health setting Organization Studies, 33, 1153-1173.

Fischer, M. & Ferlie, E. (2013) Resisting hybridisation between modes of clinical risk management: Contradiction, contest and the production of intractable conflict. Accounting, Organizations and Society, 38 pp 30-49.

Flexner, A. (1915) Is Social Work a Profession cited In R. Dingwall & P. Lewis, (1983) The Sociology of the Professions: Lawyers, Doctors and Others. London: The Macmillan Press Ltd.

Flynn, R. (2004) 'Soft Bureaucracy', Governmentality and Clinical Governance: Theoretical Approaches to Emergent Policy In A. Gray, S. Harrison, (Eds) Governing Medicine: Theory and Practice. Berkshire: Open University Press.

Flynn, R. (2002) Clinical Governance and Governmentality. Health Risk and Society 4(2) pp155-173.

Foucault, M. (1991) Governmentality. In Burchell, G. Gordon, C. Miller, P. (Eds) the Foucault Effect: Studies in Governmentality. Hemel Hempstead: Harvester Wheatsheaf.

Francis, R. (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive summary. Available at:

www.midstaffspublicinquiry.com/sites/default/files/report/Executive%20summary.pdf [accessed 19th July 2013].

Freidson, E. (1970a) Profession of Medicine. New York: Dodd, Mead & Co.

Freidson, E. (1970b) Medical Dominance. Chicago: Aldine-Atherton.

Freidson, E. (1983) The Theory of the Professions: The State of the Art. In Dingwall, R. Lewis, P. (eds) The Sociology of the Professions. London: MacMillan Press.

Freidson, E. (1986) Professional Powers. London: The University of Chicago Press.

Frontline (2011) Independent Evaluation of the Medical Revalidation Pathfinder Pilot. Final Report. Available at http://www.revalidationsupport.nhs.uk/files/DE0270-00-DH-MedRev-Summary_Report_FINAL.pdf [Accessed 1st November 2011].

General Chiropractic Council (2014) About us. Available at<u>http://www.gcc-uk.org/</u> [Accessed 29th January 2014].

General Medical Council (1998) Good Medical Practice. Available at <u>http://www.gmc-uk.org/good medical practice july 1998.pdf 25416527</u> [Accessed 20th March 2012]

General Medical Council (2005) Exploring a Risk-Based Approach to Medical Regulation. Available at http://www.gmc-

uk.org/4d_Developing_Riskbased_Regulation_Progress_Reportannex_A.pdf_25398949.pdf [Accessed 25th April 2013].

General Medical Council (2010) Revalidation. A statement of Intent. Available at http://www.gmc.uk.org/Revalidation_A_Statement_of_Intent_October_2010__Final_versio n_web_version_.pdf_35982397.pdf [Accessed 10th October 2011].

General Pharmaceutical Council (2014) About us Available at http://www.pharmacyregulation.org/ [Accessed 29th January 2014].

Gieryn, T. (1983) Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists. American Sociological Review 48 December pp781-795.

Gray, A. (2004) Governing Medicine: An Introduction In A. Gray, S. Harrison, (Eds) Governing Medicine: Theory and Practice. Berkshire: Open University Press.

Gray, A. Harrison, S. (2004) Governing Medicine: Theory and Practice. Berkshire: Open University Press.

Halliday, T. (1985) Knowledge Mandates: Collective Influence by Scientific, Normative and Syncretic Professions. The British Journal of Sociology 36(6) pp421-447.

Harrison, S. McDonald, R. (2008) The Politics of Healthcare in Britain. London: SAGE Publications.

Hampton, P (2005) Reducing Administrative Burdens: Effective Inspection and Enforcement. Hampton Review Final Report. London: HM Treasury.

Health Care and Professions Council (2014) About us Available at http://www.hpc-uk.org/ as [Accessed 21st January 2014].

Health Committee (2011) Health Committee 4th Report: Revalidation of Doctors. Available at

http://www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1033/103304.ht m [Accessed 26th March 2012].

Health Professions Council (2011) Current Approaches to Revalidation Amongst UK Health Professional Regulators. Available at <u>http://www.hpc-</u> <u>uk.org/aboutregistration/revalidation/work/</u> [Accessed 8th February 2014].

Health Professional Council (2008) The purpose of revalidation: Executive summary and recommendations. Available at ://www.hcpc-uk.org/assets/documents/1000221D13052008-enclosure3-Thepurposeofrevalidation.pdf [Accessed 24th April 2013].

Heimer, C. (2008) Thinking about how to avoid thought: Deep norms, shallow rules, and the structure of attention. *Regulation and Governance*, 2, 30-47.

Holmboe, E. & Ross, K. (2012) Realizing the Formative Potential of Multisource Feedback in Regulatory-Based Assessment Programs Academic Medicine (87) 12 pp1657–1659

Hood, C. (2006) Gaming in Target world: The Targets Approach to Managing British Public Services Public Administration Review, 66, 515-521.

Hood, C. & Heald, D. (2006) Transparency: The Key to Better Governance? Oxford, Oxford University Press.

Horton, R. (1998) How should doctors respond to the GMC's judgments on Bristol? Lancet, 351, pp. 1900–1901.

Hughes, E. C. (1963) Professions. Daedalus 92(4) pp655-668 Available at http://www.jstor.org/stable/10.2307/20026805 [Accessed 29th March 2012].

Hughes, E. C. (1958) Men and Their Work. Illinois: The Free Press.

Huising, R. & Silbey, S. (2011) Governing the gap: Forging safe science through relational regulation. *Regulation and Governance*, 5, 14-42.

Hutter, B. (2008) Risk Regulation and Health Care. Health, Risk and Society 10(1) p. 1-7.

Hutter, B. (2005) The Attractions of Risk-Based Regulation: Accounting for the Emergence of Risk Ideas in Regulation. Available at http://www.lse.ac.uk/researchAndExpertise/units/CARR/pdf/DPs/Disspaper33.pdf [Accessed 8th February 2014].

Irvine, D. (1999) The performance of doctors: the new professionalism. The Lancet 353, (9159) pp 1174–1177.

Jamous, H. Peloille, B. (1970) Changes in the French University-Hospital System in Jackson, J.A. (Ed) Professions and Professionalisation. Cambridge: Cambridge University Press.

Johns, C. (2001) 'Depending on the intent and emphasis of the supervisor, clinical supervision can be a different experience', Journal of Nursing Management, 9(3), pp. 139–45.

Johnson, T. (1972) Professions and Power. London: Macmillan.

Keogh, B. (2013) Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report.

Available at www.nhs.uk/NHSEngland/bruce-keogh-review/Documents/outcomes/keogh-review-final-report.pdf [Accessed 19th July 2013].

Larkin, G. (1983) Occupational Monopoly and Modern medicine. London: Tavistock Publications.

Larson, M. S. (1977) The Rise of Professionalism: A Sociological Analysis. London: University of California Press.

Laski, H. J. (1931) The Limitations of the Expert. London: The Fabian Society.

Leatherman, S. Sutherland, K. (1998) Evolving Quality in the NEW NHS: Policy, Process and Pragmatic Considerations. Quality in Health Care 7(Supplement) pp54-61.

Lee, A. Aaker, J. Gardner, W. (2000) The pleasures and pains of distinct self-construals: The role of interdependence in regulatory focus. *Journal of Personality and Social Psychology* 78 *pp*1122-1134.

Light, D. W. (1988) Turf Battles and the Theory of Professional Dominance. Research in the Sociology of Health Care 7 p203-225.

Light, D. W. (1995) Countervailing Powers: A Framework For Professions in Transition In T. Johnson, G. Larkin, M. Saks, (Eds) Health Professions and the State in Europe. London: Routledge.

Lloyd-Bostock, S. & Hutter, B. (2008) Reforming Regulation of the Medical Profession: The Risks of Risk-Based Approaches. Health, Risk and Society 10(1) pp 69-83.

MacDonald, K. (1995) The Sociology of the Professions. London: SAGE Publications.

McCarthy, J., Walker, S., Deelchand, V., Vincent, C. & Griffiths, W. (2011) Breaking the rules: Understanding non-compliance with policies and guidelines. BMJ 343: d5283. Doi 10.1136/bmj.d5283.

McCraw, T. K. (1984) Prophets of regulation. Cambridge MA: Harvard University Press.

McGivern, G. (2005) The Introduction of Consultant Appraisal: Playing the Tick Box Game. PhD, Imperial College London.

McGivern, G. & Ferlie, E. (2007) Playing Tick Box Games: Interrelating Defences in Professional Appraisal. Human Relations, 60, 1361-1385.

McGivern, G., Fischer, M., Ferlie, E. & Exworthy, M. (2009a). The Visible and Invisible Performance Effects of Transparency in Medical Professional Regulation: Full Research Report. Swindon: ESRC.

McGivern, G., Fischer, M. Ferlie, E. & Exworthy, M. (2009b) Statutory Regulation and the Future of Professional Practice in Psychotherapy and Counselling: Evidence from the Field. King's College London. Available at: http://eureka.bodleian.ox.ac.uk/4328/1/StatutoryRegulation1.pdf

McGivern, G. & Fischer, M.D. (2010) Medical Regulation, Spectacular Transparency and the Blame Business. Journal and Health Organization and Management 24 (6) 597-610.

McGivern, G. & Fischer, M. D. (2012) Reactivity and reactions to regulatory transparency in medicine, psychotherapy and counselling. Social Science & Medicine, 74, 286-296.

McLellan, A. (2008) Nursing Times Speaks to Professor Tony Hazell About the Rehabilitation of the NMC. NursingTimes.net. Available at http://www.nursingtimes.net/whats-new-in-nursing/nurses-do-not-need-revalidation-to-prove-safe-practice-says-new-nmc-chair/1943739.article [Accessed 8th May 2012].

Merrison committee (1975) Report of the Committee of Inquiry into the Regulation of the Medical Profession. HM Stationery Office, London.

Meyeral, L. (2011) Reframing Conduct: A Critical Analysis of the Statutory Requirement for Registration of the Social Work Workforce. DPhil Thesis: University of Sussex.

Middlemass, J. & Siriwardena, A. (2003) General Practitioners, Revalidation and Appraisal: A Cross Sectional Survey of Attitudes, Beliefs and Concerns in Lincolnshire. Medical Education 37 pp778–785.

Millerson, G. (1964) The Qualifying Associations: A Study in Professionalism. London: Routledge and Kegan Paul.

Moran, M. Wood, B. (1993) States, Regulation and the Medical Profession. Buckingham, Open University Press.

Moran, M. (2002) The Health Professions in International Perspective In Allsop, J. Saks, M. (eds) Regulating the Health Professions. London, SAGE Publications.

Mugweni, K. Kibble, S. Conlon, M. (2011) Benefits of Appraisal as Perceived by General Practitioners. Education for Primary Care 22(6) pp393-398.

Munro, E. (2011) The Munro Review of Child Protection: Final Report: A Child-Centred System. Norwich: The Stationery Office.

Murphy, D. Guthrie, B. Sullivan, F. (2012). Insightful practice: a reliable measure for medical revalidation. British Medical Journal Qual Saf 21 pp649-656.

Nettleton, S. Burrows, R. Watt, I. (2008) Regulating Medical Bodies? The Consequences of the 'Modernisation' of the NHS and the Disembodiment of Clinical Knowledge. Sociology of Health and Illness 30(3) pp333-348.

Nicholls, S. Cullen, R. O'Neill, S. & Halligan, A. (2000) Clinical Governance: It's Origins and Its Foundations. British Journal of Clinical Governance 5(3) pp172-178.

Nursing and Midwifery Council (2009) Modern Supervision in Action: A Practical Guide for Midwives. London: NMC.

O'Day, R. (2000) The Professions in Early Modern England 1450-1800: Servants of the Commonwealth. London: Longmans.

Parker, D. Lawton, R. (2000) Judging the Use of Clinical Protocols by Fellow Professionals. Social Science & Medicine 51(5) pp669-677.

Parkin, F. (1979) Marxism and Class Theory: A Bourgeois Critique. London: Tavistock Publications.

Parsons, T. (1954) Professions and Social Structure. Essays in Sociological Theory. Illinois: The Free Press.

Professional Standards Authority Report (2012). An approach to assuring continuing fitness to practise based on right-touch regulation principles. Available at: <u>http://www.professionalstandards.org.uk/docs/psa-library/november-2012---right-touch-continuing-fitness-to-practise.pdf?sfvrsn=0</u>

Professional Standards Authority (2014) Right Touch Regulation Available at <u>http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation</u>[Accessed 30th January 2014].

Quick, O. (2011) A scoping study on the effects of health regulation on those regulated. Council for Health and Regulatory Excellence.

Revalidation Support Team (2013) Medical Appraisal Guide: A Guide to Medical Appraisal for Revalidation in England. Available at http://www.revalidationsupport.co.uk/CubeCore/.uploads/documents/pdf/rst_medical_appraisal_guide_2013.pdf [Accessed 23rd February 2014].

Rhodes, R. (1994) The Hollowing Out of the State: The Changing Nature of the Public Services in Britain. Political Quarterly Available at http://www.behave.minhal.022.co.il/BRPortalStorage/a/13/57/01-pTye36Oqn9.pdf [Accessed 2nd May 2012].

Rosenthal, M. (1995). The Incompetent Doctor: Behind Closed Doors. Buckingham: Open University Press.

Rosenthal, M. M. (1999) How doctors think about medical mishaps in MM Rosenthal, L Mulcahy, S & Lloyd-Bostock (Eds.), Medical mishaps. Pieces of the puzzle, Open University Press, Buckingham.

Rothstein, H., Irving, P., Walden, T. & Yearsley, R. (2006) The Risks of Risk-Based Regulation: Insights from the Environmental Policy Domain. Environment International 32 (8):1056–65. Salter, B. (2007) Governing UK Medical Performance: A Struggle for Policy Dominance. Health Policy 82 pp263-275.

Scally, G. Donaldson, L. (1998) Clinical Governance and the Drive for Quality Improvement in the New NHS in England. British Medical Journal 317 pp61-65 Available at http://www.bmj.com/content/317/7150/61#alternate [Accessed 1st May 2012].

Scraggs, E. Brereton, L. Newbould, J. Drabble, S. Tiefensee, C. Schweppenstedde, D. Miani, C. Ling, T. (2012) Factors that encourage or discourage doctors from acting in accordance with good practice. Report to the General Medical Council (DRR-5728-GMC).

Seeley, E. A. & Gardner, W. L. (2003). The "selfless" and self-regulation: The role of chronic other-orientation in averting self-regulatory depletion. Self and Identity, 2, 103-117.

Shirley, J. Padgett, S. (2006) An Analysis of the Discourse of Professionalism In D. Wear, J. Aultman, (Eds) Professionalism in Medicine: Critical Perspective. New York: Springer.

Simpson, I. (1979) From Student to Nurse: A Longitudinal Study of Socialisation. London: Cambridge University Press.

Shaw, G. B. (1932) The Doctor's Dilemma, Second Edition. London: Constable.

Smith, J. (2004) Safeguarding Patients: Lessons from the past - Proposals for the future. The Shipman Inquiry. London: Stationary Office.

Solicitors Regulation Authority (2011) Attitudes towards regulation and compliance in legal services. Available at <u>www.sra.org.uk</u>. [Accessed 23rd February 2014].

Spencer, H. (1914) The Principle of Sociology cited in R. Dingwall, & P. Lewis, (1983) The Sociology of the Professions: Lawyers, Doctors and Others. London: The Macmillan Press Ltd.

Spendlove, Z. (2013) Regulatory Reform: Revalidation as Professional Crisis or Critique and Change Opportunity for Midwifery? British Journal of Midwifery 21(6) pp356-360.

Sutherland, K. Leatherman, S. (2006) Regulation and Quality Improvement: A Review of the Evidence. London: Health Foundation.

Swage, T. (2000) Clinical Governance in Health Care Practice. Oxford: Butterworth-Heinemann.

The Kennedy Report (2001) The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995. Available at http://www.bristol-inquiry.org.uk/final_report/report/index.htm [Accessed 1st November 2011].

The King's Fund (2013) Revalidation: The early experiences and views of responsible officers from London. Available

at<u>http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/revalidation-early-experiences-of-responsible-officers-kingsfund-oct13.pdf</u> [Accessed 8th February 2014].

National Consumer council (2000) Models of Self-regulation; An overview of models in business and the professions. Available at<u>http://www.talkingcure.co.uk/articles/ncc_models_self_regulation.pdf</u> [Accessed 6th February 2014].

Thorogood, N. (2002) Regulating Dentistry. In Allsop, J. Saks, M. (Eds) Regulation the Health Professions. London: SAGE.

Treasure, T. (1998) Lessons from the Bristol case: more openness—on risks and an individual surgeon's performance. BMJ, 316 (1998), pp. 1685–1686.

Uche, C. U. (2001). The theory of regulation: A review article. Journal of Financial Regulation and Compliance, 9p67.

Vincent, C. (2003) Compensation as a Duty of Care: The Case for "No Fault". Quality and Safety in Health Care 12(4) pp240-241.

Walshe, K. Boyd, A. (2007) Designing Regulation: A Review. Available at<u>https://www.escholar.manchester.ac.uk/uk-ac-man-scw:118421</u> [Accessed 8th February 2014].

Waring, J. (2007) Adaptive Regulation or Governmentality: Patient Safety and the Changing Regulation of Medicine. Sociology of Health and Illness, 29(2) pp163-179.

Waring, J. (2009) Constructing and reconstructing narratives of patient safety. Social Science & Medicine, 69, 1722-1731.

Waring, J. Dixon-woods, M. & Yeung, K. (2010) Modernising medical regulation: where are we now? Journal of Health Organisation and Management, 24, 325-42.

The end of secrecy; new medical ethic needed. The Guardian, 23 November 1998.

World Health Organisation (2004) World Alliance for Patient Safety. Geneva: WHO.

Zhang, Y. & Mittal, V. (2007) The attractiveness of enriched and impoverished options: Culture, self-construal, and regulatory focus. *Personality and Social Psychology Bulletin, 33*, 588-598.