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Regulating Patient Safety

The End of Professional Dominance?

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REGULATING PATIENT SAFETY

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Introduction

There is nothing new about efforts to ensure the safety of patients. After all, the most famous principle of medicine is the Hippocratic instruction to 'first, do no harm'. Yet, whilst healthcare aims to heal patients it also causes harm. Although this should be no surprise given the many risks associated with providing healthcare, the problem of medical harm has not been well described. The history of medicine has tended to focus on success stories rather than failures (Wootton 2006). It is only during the last half century that serious attention has been devoted to identifying and understanding medical harm. The headline figure from various studies across the globe is that around 8–12 per cent of hospitalised patients will experience an adverse event in relation to their treatment in advanced healthcare systems (Vincent 2010: 54). This translates into a high number of preventable deaths, estimated at 180,000 each year in the United States, and the striking claim that this would equate to three jumbo jet crashes every two days (Leape 1994). There is now sufficient data to suggest that such claims, far from exaggerating the scale of the problem, are likely to underestimate it. Recent analysis suggests that medical error is the third leading cause of death in the United States (Makary and Daniel 2016). This clearly represents a major public health problem, but one which has been slow to capture the attention of the public, medical professionals and policy makers.

However, the problem of medical harm is no longer a professional secret. Two landmark reports published at the turn of the twentieth century marked its arrival as a major public issue. In the United States, the Institute of Medicine report 'To Err is Human' (1999) noted that deaths caused by medication and surgical errors were the tip of the iceberg. The report famously claimed that medical errors accounted for more deaths than road traffic incidents, workplace injuries and breast cancer. Beyond the human cost of lives lost or damaged, there are also financial costs and the potential for damaging trust, so important in the therapeutic context. In the United Kingdom, a Department of Health

publication called 'An Organisation with a Memory' (2000) had the same effect of putting medical error on the political agenda. This has been accelerated somewhat by the revelation of a number of episodes of poor care leading to preventable deaths and injuries. Amongst the many examples that attracted significant media attention were those involving paediatric heart surgery at the Bristol Royal Infirmary and the large scale neglect of patients at the Mid Staffordshire NHS (National Health Service) Foundation Trust, both of which are described in Chapter 1.

The study of error and harm has evolved into the more ambitious task of improving the safety of patient care. Whereas the study of error tended to look back and measure harmful events, concern with safety looks forward and attempts to avoid and ameliorate such events (Vincent 2010: 31). The scope of patient safety is potentially vast; most of the decisions, policies, treatments and communications that take place within healthcare have implications for the safety of patients. It thus extends beyond drugs, devices and doctors, to include issues of a multidisciplinary workplace culture, the relationship between patients and professionals, the design and funding of health systems, cleaning and portering services within hospitals, the effectiveness of healthcare administrative staff and the infrastructure within which care takes place. I experienced an example of the latter shortly before the writing of this introduction; it also illustrates the difference between focusing on patient safety rather than medical error. On the 25th March 2016, my wife was in labour for the birth of Roseanna, our second daughter. She requested an epidural for pain relief, and as the anaesthetist prepared to insert the needle into the 'epidural space' of my wife's spinal cord, the hospital power supply failed, as did the backup generator. This left us in complete darkness without the reassuring sight and sound of the foetal heart rate monitor, causing panic for all in the room. Thankfully, no harm was done as a result of this failure in the power supply. Despite the apology from the blameless anaesthetist, there was no medical error to speak of or any real harm. But the safety of care was compromised during those long five minutes in the dark. We certainly didn't *feel* safe during this short time.

This increased tendency to frame a range of issues, from infection control, the language competency of staff, to the use of telemedicine services such as NHS 111 as issues of patient safety is a positive development. However, such is the obvious attraction of the 'patient safety argument' that it can also be used to mask ulterior motives. In April 2016, the dispute over a new employment contract for junior doctors in the English National Health Service was a prime example.

The Secretary of State for Health, Jeremy Hunt, sought to negotiate new terms which no longer regarded working on Saturdays as justifying 'out of hours' pay. According to the Government, this was part of its aim of creating a seven-day NHS and was justified by concerns about the safety of care in hospitals over the weekend. This was vigorously contested by the British Medical Association, who also cited safety concerns about doctors working longer rotas as part of its position in rejecting the contract. Numerous studies were cited on both sides of the debate, although none were able to arrive at clear explanations for the so-called 'weekend effect' whereby more patients die in hospitals over the weekend (Wise 2016). However, there was little doubt about the potency of framing the debate as one about patient safety, even though this conflict raised important issues about the funding of medical services, including the remuneration of medical staff, and the quality of evidence relied on to support health service reforms. This dispute also raised doubts about the dominance of the medical profession, something which this book is centrally concerned with.

Objectives, Structure and Scope of this Book

The theoretical context for this book stems from the sociology of the medical profession. In particular, it takes as its starting point the main theoretical contribution about the status of the medical profession during the last 50 years – the professional dominance thesis associated with the work of Eliot Freidson. This regarded professionalism as the preferred model of managing medical work, as opposed to market and bureaucratic alternatives, and celebrated a high degree of medical autonomy and trust. It defended professional dominance of the clinical, economic and political aspects of medical work, and left little space for external evaluation or lay scrutiny. The sensitive issue of medical harm was kept in house so that there was limited public knowledge about the many costs of medical error. As discussed in the opening chapter of the book, whilst the idea of dominance has long been challenged, and alternative models of the relationship between the profession and the state posited, Freidson's model has remained an accurate conceptualisation. However, this book will argue that professional dominance is ill-suited to the challenging task of improving the safety of care. This task requires a different form of professionalism that embraces patient safety as its priority. This is a significant challenge involving issues of education, training and culture.

It also requires an evaluation of the role of regulation and law, and in particular a consideration of which regulatory approaches and legal duties are best suited to improving patient safety. This book will also argue that patients (and their carers) should play a more prominent role in securing their own safety. Patient safety is an issue of public health, and it is legitimate and necessary to fully involve patients in the pursuit of safer care.

Chapter 2 begins by tracing the history of attempts to measure and understand medical errors and the more recent shift towards understanding risk and safety. Despite the work of some early patient safety pioneers such as Ernest Codman, the systematic study of errors and safety in medicine has been slow to emerge. Indeed, one leading commentator was moved to describe the lack of serious interest in the safety of care as negligent (Vincent 1989). Happily, the problem of medical harm has now attracted interest from a number of different disciplines, including medical sociology, health services research, psychology, policy and medico-legal studies. Greater interest in patient safety is highly significant from a professional dominance perspective. The shift from medical error being a private professional problem to an issue of public health challenges traditional notions of professional autonomy and responsibility. However, despite this interest and the emergence of what has been called the science of improvement and implementation (Marshall et al. 2013), there remains a dearth of data on whether or not care is safer, and if it is, a lack of understanding about the possible reasons for this.

The concepts of regulation and trust, and the relationship between them, are examined in Chapter 3. Regulation is an important concept within the social sciences and has given rise to a vast literature. In terms of healthcare, interest has tended to focus on the regulation of the medical profession, mainly through institutional self-regulation, and more recently of healthcare systems. There has been much less attention given to regulating the *safety* of care. However, this is now a busy area with the creation and constant reinvention of regulatory agencies that monitor the quality and safety of care. This chapter adopts a positive view of regulation as a collaborative enterprise between the state, the profession and the public to prioritise the safety of patients. However, this positive view of regulation is not shared by professionals who have tended to associate it with discipline and sanction. Professional regulation thus faces a challenge in terms of its legitimacy and relevance for practitioners.

The concept of trust has long been central to caring relationships and to the privileged position of professional dominance reflected in self-regulation. However, discussions about trust have tended to be simplistic and one dimensional – for example, exploring whether or not patients trust or distrust their doctors, or whether trust has increased or decreased. Chapter 3 presents a more detailed understanding of trust and considers its different dimensions within the healthcare setting. It might be thought that greater public knowledge about safety failings might lead to decreased trust in medics and medicine. However, there have been few investigations into the relationship between trust and patient safety. A nuanced and positive conception of trust is proposed which is better able to protect patients and enable more productive patient–professional relationships to evolve. In particular, it is argued that trusting patients may nevertheless be vigilant about the safety of the care they receive.

Chapter 4 examines the increasingly complex relationship between regulation and patient safety. Until relatively recently, this was confined to the work of individual regulators such as the General Medical Council, which was established in 1858. For the bulk of its existence, the GMC has focused on dealing with cases of professional misconduct involving alcohol addiction or inappropriate sexual relations with patients (Smith 1994). Whilst such cases are clearly significant in terms of protecting patients, the Council has historically avoided investigating the errors or poor performance of practitioners. However, a crisis of trust, partly connected to the high profile regulatory failures exposed by the events at Bristol and Mid Staffordshire discussed in Chapter 1, has led to significant changes to the structure, remit and ethos of professional regulators, introduced following damning public inquiry reports (Kennedy 2001, Smith 2004). Changes to the landscape of professional regulation have extended beyond the GMC. Reflecting a loss of trust in the ability of self-regulation, new regulators in the form of the Professional Standards Authority for Health and Social Care and the Care Quality Commission have been created to oversee the work of individual regulators and to monitor the quality and safety of healthcare organisations. The crucial questions of how regulation might impact the behaviour of healthcare professionals and which approaches appear best suited to improving safety are also explored in this Chapter.

Chapters 5–7 consider the role of law in seeking to protect patient safety. The meaning of law is potentially very broad here given that most laws about the design and delivery of medical care will have implications for the safety of patients. However, these chapters examine established

mechanisms within civil and criminal law for responding to medical harm. In terms of civil law, this largely means clinical negligence litigation and examining whether tort law and the civil justice system helps or hinders patient safety. Literature reviews and studies from both the United Kingdom and the United States have been unable to conclude that the tort system helps produce safer care. However, this has not prevented commentators strongly defending the so-called deterrent effect of tort law and others being equally forceful in condemning it as counterproductive. Chapter 5 considers the evidence about the relationship between different liability systems and the safety of patients. It considers the experience of systems in New Zealand and Scandinavia (which have abandoned fault liability) as well as initiatives within the tort system that appear better aligned to the pursuit of safer care.

Criminal law has generally been regarded as something of a last resort for dealing with grossly negligent medical care. Historically, this has involved occasional manslaughter prosecutions following fatal medical errors, although there has been concern about a possible increased propensity to prosecute cases over the past twenty years (McDowell and Ferner 2013). Chapter 6 explains that the prosecution of a small number of individual practitioners is driven by notions of blame and justice rather than concern about improving safety. However, the expansion of criminal law during the past decade has created other mechanisms that are more consistent with attempts to regulate patient safety. Prosecutions of healthcare organisations for corporate manslaughter or for regulatory offences enforced by the Health and Safety Executive and the Care Quality Commission are not only more appropriate, given that medical harm is more often caused by organisational rather than individual failings, but are also more likely to encourage policies, protocols and practices for safer care.

Relatively few deaths associated with medical error end up as criminal cases. Far more result in investigation by coroners. Chapter 7 argues that coroners have an important public health role in trying to ensure that lessons are learned from tragedies and that safety is improved for the future. This includes commenting not only on failures at local level, for example at a particular hospital, but also on failures of regulation and of delivering safe care within the NHS. The work of coroners in this context can also be understood as part of the challenge to professional dominance as it represents a further opportunity for external, and often adverse comment on the quality of medical care. Whilst coroners are primarily interested in pursuing facts rather than fault, those called to give evidence

at inquests experience similar cross examination, scrutiny and the possibility for public shame which is central to criminal trials; they are essentially accounting for their conduct and are aware that coroners may refer cases to regulators or prosecutors.

Whilst law and formal regulation are important, they are somewhat distant from the daily business of doing medical work. Chapter 8 therefore considers the more relevant role that professionals can play in terms of raising concerns about patient safety and apologising when things go wrong. This chapter will consider the important day-to-day role of professionals in monitoring safety, whether through raising concerns about clinical competence, or unsafe working environments caused by staff shortages or inadequate equipment. It describes the negative experiences of several well-known healthcare whistle-blowers who have raised safety concerns. The culture of the medical profession, and indeed the health service, is central to this, particularly as it applies to the sensitive subject of safety. Creating a culture of safety is complex but openness and honesty are critical to it. This chapter focuses on two aspects of openness most significant for this book. First is the need for professionals to raise safety concerns, whether about individual incompetence or organisational failings that cause or risk avoidable harm to patients. This has traditionally been labelled as whistle-blowing, but has also been described in more neutral terms as the freedom to 'speak up' about safety. Secondly, and closely connected to this, is the need for professionals openly to disclose harmful adverse events to their patients through a legal duty of candour.

Finally, Chapter 9 considers the role which patients and their carers can play in terms of helping secure the safety of care. Efforts to improve safety have tended to focus exclusively on the education, training and regulation of professionals, and more recently on the regulation of healthcare organisations. However, this chapter will argue that it is legitimate and necessary to involve patients and their carers in this task. Patients are uniquely placed to comment about and question safety, given their involvement in all aspects of care, unlike the wide range and number of healthcare professionals treating them at different times. Successfully engaging patients with the safety of their care challenges the prevailing culture of medicine where doctors have traditionally dominated and left insufficient space for the input of patients and their carers. This chapter will examine how patients and carers can make valuable contributions to the study and delivery of safer healthcare,

with reference to some powerful examples of failures to involve them sufficiently.

Patient safety is an issue of global public health and the same issues are relevant to different types of health systems. However, countries take different approaches to the design and funding of health systems, and have different regulatory and legal environments in relation to patient safety. This book focuses on developments in the United Kingdom, and in particular in England. Since the devolution of powers in 1998, the United Kingdom has had four different health systems, with Northern Ireland, Scotland and Wales making their own health policies with the UK government responsible for the National Health Service in England. Whilst these systems still share much in common, the powers and approaches of national sector regulators such as England's Care Quality Commission, the Regulation and Quality Improvement Authority in Northern Ireland, Healthcare Improvement Scotland and the Healthcare Inspectorate Wales are different. Professional regulatory bodies, such as the General Medical Council, have a UK-wide jurisdiction. Whilst this book predominantly focuses on the position of the United Kingdom, and within this on England, reference is made to material and initiatives from Australia, New Zealand and the United States. Despite the focus on developments within the United Kingdom, the arguments made and conclusions drawn in this book are also likely to be relevant to the provision of safer care in other jurisdictions. The pursuit of patient safety requires a multi-disciplinary approach, and this book brings together material from various disciplines including medicine, law, sociology, psychology and health services research. In line with Charles Vincent's plea to social scientists (2009), it aims to make a positive contribution towards understanding and improving patient safety rather than being unduly critical.

1

The Rise and Fall of Professional Dominance

This chapter provides some context to the discussion that follows by offering a brief history of the modern medical profession and its regulation. It engages with the literature on the sociology of the professions in order to understand how they have been theorised. The notion of professional dominance, which originated during the so-called golden age for the professions in the 1960s, is examined. This theory, advanced by Eliot Freidson, observed how the medical profession controlled the clinical aspects of medical work, including the exclusive right to evaluate the quality of such work. Whilst alternative theories have been advanced to describe the relationship between the profession, the state and society, the dominance thesis has been dominant. However, several societal shifts, in particular the rise of consumerism and managerialism, make it timely to question whether the idea of dominance remains apposite, or indeed appropriate. The merits of professional dominance have been further doubted following evidence about the scale of safety problems within healthcare, and especially after the fallout from high profile medical disasters. This chapter will argue that a new style of professionalism is required that prioritises safety and allows space for patients to make a contribution to ensuring their own safety.

Theorising Professions

The growth of professions has been described as a 'defining characteristic' of industrial societies (Johnson 1972: 9) and has inspired a vast literature exploring the process of professionalisation and the idea of professionalism. The term profession is widely used and its meaning assumed, but considerable academic debate has surrounded its definition. Eliot Freidson, perhaps the foremost sociologist in this area, stressed the difference between two usages: a 'broad stratum' of occupations linked by some form of higher education, and a limited number of occupations that generally share 'particular institutional and ideological traits' (1994: 16). Universal consensus

over defining professional traits has proved a difficult task, not least because, as Wilensky explains: 'Many occupations engage in heroic struggles for professional identification; few make the grade' (1964: 137). The most commonly cited traits include specialised education and training, knowledge monopoly, service-orientation, work autonomy, self-regulation, and a high degree of trust between the professional and client. According to Wilensky:

> Any occupation wishing to exercise professional authority must find a technical basis for it, assert an exclusive jurisdiction, link both skill and jurisdiction to standards of training, and convince the public that its services are uniquely trustworthy (1964: 138).

Despite disagreement surrounding the definition of professions, there is no doubt that medicine is a profession; as Freidson explains, 'if anything "is" a profession, it is contemporary medicine' (1970a): 4). It has always been, and continues to be the model for other health care professions. Yet just as there is no one definition of 'profession', it would be misleading to characterise the medical profession as a single unified entity. Historically, physicians, surgeons and apothecaries were legally distinct groups under the authority of three different bodies: the Royal College of Physicians, the Company of Surgeons (the Royal College of Surgeons from 1800), and the Worshipful Society of Apothecaries (Waddington 1984: 1). Relations between elite institutions such as the General Medical Council, British Medical Association and the Royal Colleges have been marked by tension and rivalry, and such historic divisions have not made for an 'effective fighting force' when the profession is on the offensive (Salter 1998: 101). This lack of unity and overall leadership also characterises the modern medical profession (RCP 2005: 25). Within the profession there is the obvious distinction between those working in primary and secondary healthcare settings, with the latter split into several specialities, each with a different subculture. Whilst this book draws on material and discusses issues of relevance to all health professions, it focuses on the medical profession as the dominant force within healthcare, setting the tone for the organisation and regulation of other health professions.

Most theorising about professions has focused on two central aspects: the moral value of professions and a sceptical monopolisation critique. The moral dimension stems from the structural functionalist approach of Emile Durkheim (1964), which values professions as providing a means of ensuring social order. This normative view was developed by Talcott

Parsons (1947) who saw professions as acting in the public interest and providing a stabilising effect to counterbalance the crude excesses of the capitalist state. An alternative theory, rooted in the Chicago school of sociology of Everett C. Hughes and Howard S. Becker, focused on professional monopoly and social closure. For Hughes (1958: 78)

> An occupation consists, in part, of a successful claim of some people to licence to carry out certain activities which others may not, and to do so in exchange for money, goods or services. Those who have such licence will, if they have any sense of self-consciousness and solidarity, also claim a mandate to define what is proper conduct of others toward the matters concerned with their work.

This 'power' approach can be traced to the work of Max Weber. According to Weber (1968: Chapter 11), society is made up of self-interested individuals who, in order to gain monopolies and privileges, seek to exclude others from their group. This approach is primarily concerned with the question of *how* occupations become professions. Occupations first need to construct a marketable commodity, for example expert medical or legal services. However, becoming a profession demands social and market closure. A number of scholars have focused on this aspect of professionalisation (Berlant 1975; Larson 1977; Abbott 1988). Eliot Freidson blends these theoretical backgrounds in making the most significant contribution to our understanding of professions and professionalism. In his last major work, Freidson defends professions as the best form of occupational control and as legitimate monopolisation. For Freidson, professionalism exists 'when an organized occupation gains the power to determine who is qualified to perform a defined set of tasks, to prevent all others from performing that work, and to *control the criteria by which to evaluate performance*' (2001: 12, my emphasis), where neither consumers or managers can control what professionals do. It is superior to market or bureaucratic control in having a 'logic and integrity of its own' (2001: 11) and allowing for judgment and discretion. Crucially, it depends on a high level of public trust in order to flourish. Before discussing the contemporary challenges to this ideal type of professionalism, and preparing the ground for an alternative vision, the key concept of autonomy will be unpacked.

Medical Professional Autonomy

The trait theory for distinguishing professions from occupations is inevitably limited, prompting theorists such as Everett Hughes (1958) and

Eliot Freidson (2001: 13) to focus on wider questions about the sociology of work. But amongst the traits traditionally associated with professions, trust and autonomy are arguably the most important and are also interrelated. High autonomy is generally only conferred on groups who are trusted. The concept of trust, and in particular, the significance of changing trust relationships between patients and doctors, is fully explored in Chapter 3. Autonomy is generally understood to mean control over one's own actions, but in this context has two distinct meanings. First is the autonomy of individual practitioners at the micro level to decide how they conduct themselves and practise medicine. Second is the autonomy of the profession as a whole at the macro level, reflected in the control exercised by the institutions of self-regulation. Individual professional autonomy may be further distinguished into three distinct yet interrelated areas: economic, political, and clinical or technical autonomy. For Freidson, technical autonomy, that is, control over diagnosis, treatment, education, training, evaluation and discipline is at the very core of professional dominance. Unsurprisingly, the profession has been protective of its autonomy, particularly in relation to clinical work and the *evaluation* of this work. The exclusivity of professional judgment in terms of defining and dealing with error is the most jealously guarded aspect of autonomy. As the Merrison inquiry into the regulation of the profession noted (1975: 3), it is the 'essence of professional skill that it deals with matters unfamiliar to the layman, and it follows that only those in the profession are in a position to judge many of the matters of standards of professional conduct'. This aspect of technical autonomy, which incorporates defining and dealing with medical errors, and more broadly the management of the safety of patients, is the main focus of this book.

Whilst the modern medical profession is characterised by a high degree of autonomy and trust, this has not always been true. In the latter part of the seventeenth century, the family and community, rather than medical practitioners were responsible for taking care of the sick. As Freidson explained 'Official medicine, however, had only a loose, variable connection with the general cultural beliefs of the population and was more a learned than a practicing profession' (1970a: 12). Poor economic status, preference for alternative methods, and the use of unqualified practitioners meant that demand for official conventional medicine was small (Waddington 1984: 182). Indeed, much medical work was part-time and supplemented by other incomes. This low demand for a national market in healthcare was reflected in the reliance