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THE REGULATION OF INNOVATION

PhD THESIS

Institute of Law and Financial Studies

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The Regulation of Innovation

Table of Contents:

1) Setting the scene	7
The doctor patient relationship	9
Defining and classifying interventions	12
Experimentation is research, innovation is therapy	
Brushwood	13
Dickens	13
A contrary view- innovation is not therapy	16
A third view: Experimentation is a separate entity, distinct from research	17
A Continuum	18
Experimentation – a part of innovation	20
Personal innovation	21
Introducing and adopting new technology	23
Staging	28
Different arrangements	33
Conclusion	36
2) Failures of regulation	38
Experimental innovation: Transplantation	39
Liver transplantation	40
Heart transplants	41
The UK's first heart transplant	44
The first artificial heart	48
Personal Innovation: The Bristol Affair	52
The GMC's findings	53
Key Issues	55
Conclusion	57
3) The Professions and self-regulation	59
Three forms of law	60
The introduction of self-regulation	61
The General Medical Council	62
The experiment of heart transplantation	64
The moratorium	66
Personal innovation: Bristol	67
Learning curves	69
Supervision	72
Openness	72
A hospital system	72
Evidence of acceptance of Recommendations	73
Supervision – revisited	73
Performance tables	75
The impact on consumer actions	77
The impact on providers	78
The reliability of league tables	79
Therapeutic Innovation and Self regulation	81
Criticism	82
Does self-regulation work?	83
SERNIP	85
Research	86
Regulating research	86
Concerns?	87
Fraud and misconduct	88
Conclusions	90

4)	Regulation by Government	93
	Government proposals	95
	National Institute for Clinical Excellence	95
	Evidence-based medicine	97
	Limitations	97
	Rationing and cost-effectiveness	102
	Limitations	104
	Variation	107
	Limitations	107
	Clinical guidelines	108
	Benefits	108
	Limitations	109
	The Commission for Health Improvement	113
	Limitations	115
	Regulating Innovation	116
5)	Legal Regulation	122
	Medical Malpractice	123
	Battery	123
	Negligence	124
	Duty of care	124
	Standard of care	124
	Causation	127
	Criminal Law	128
	Innovation	128
	Analysis of Liability	132
	Justifying the experiment	136
	'Recognised risk avoidance'	137
	Legal limitations	139
	<i>Karp v Cooley</i>	142
	The law regarding guidelines	145
	Personal Innovation	151
	<i>Nettleship v. Weston</i>	152
	Reconciling different requirements	156
	Change the law	156
	Supervision	162
	Hospital liability?	163
	Conclusion	166
6)	Consent	168
	Informed consent and autonomy	170
	The elements of consent	173
	Competence	174
	Disclosure	174
	Understanding	178
	Voluntariness	180
	The Law	181
	Battery	182
	Negligence	188
	Professional standard test	188
	Patient centred standard	189
	Causation	189
	Beyond Bolam	192
	<i>Sidaway v. Bethlem Royal</i>	
	<i>Hospital Governors</i>	192
	<i>Bolitho v. City and Hackney HA</i>	196
	<i>Pearce v. United Bristol</i>	
	<i>Healthcare NHS Trust</i>	201
	Deference	202

Consent and innovation in the UK	205
Heart transplants revisited	206
Bristol revisited	210
Two meanings of consent	212
Disclosure in the research setting	215
Foreign law - in brief	218
UK law- revisited	220
Evidence of change?	229
An ethical foundation	230
7) Summary and Conclusions	233
A new model of contact- innovation	234
A continuum	235
Examples of innovation	235
Self-regulation	236
Government regulation	237
Legal regulation	238
Failure of legal regulation of experimentation	240
Failure of legal regulation of personal	
Innovation	243
Solutions?	244
Consent	247
Consent and Innovation	250
An ethical foundation	255
Practicalities	256
Conclusion	260

Bibliography:	262
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The thing that strikes me now, looking back on it, was the relative freedom that everybody had to do it. If one was making a world-shaking advance now, one would probably have to apply to statutory bodies for permission, acquire the funds and get it approved by many committees. I imagine that it would be much more difficult today.¹

¹ Joseph S. in Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p13

THE REGULATION OF INNOVATION:

CHAPTER 1:

SETTING THE SCENE	8
The doctor patient relationship	9
Defining and classifying interventions	12
Experimentation is research, innovation is therapy	
Brushwood	13
Dickens	13
A contrary view- innovation is not therapy	16
A third view: Experimentation is a separate entity, distinct from research	17
A Continuum	18
Experimentation – a part of innovation	20
Personal innovation	21
Introducing and adopting new technology	23
Staging	28
Different arrangements	33
Conclusion	36

CHAPTER 1: SETTING THE SCENE

Britain's National Health Service [NHS] was constituted in 1948 as a universal system, funded predominantly by taxation, to provide health care without financial barriers to access. At its inception it was essentially a paternalistic service where the professionals delivering the care defined the needs of patients and set up services to meet those needs. Within this model the expectation was that high individual professional integrity and competence would lead to a high quality service.

Indeed, many books on medical law or ethics highlight the high esteem the medical profession enjoys in the eyes of the general public.² For example, the British Medical Association, in the introduction to its book *The Handbook of Medical Ethics*, states:

Because of their special knowledge and the vulnerability of their patients, members of the medical profession have traditionally been regarded as particularly trustworthy and responsible by the public. From the profession, therefore, society expects high standards, not only of scientific education and clinical skill, but also of professional and humane conduct.³

In turn Brazier⁴ states that the medical profession, the patient and the public have a common need for:

- a) the medical profession to be properly regulated and controlled,
- b) a clear definition of the rights and obligations of patients, doctors and other health professionals,
- c) an adequate and rational system for compensation for patients suffering injury,
- d) effective means of investigating medical accidents and errors and
- e) doctors and patients to be given comprehensible guidance on those areas of medical practice of moral and ethical sensitivity.

A fundamental difficulty, however, is the fact that the doctor's relationship with his patient is not equally balanced; just as the lawyer knows more about the law than does his client, the doctor knows more about medicine than does his patient. The patient, therefore, needs to trust in the learning of another at a time of great uncertainty when suffering ill health. However, the easy availability of health information, coupled with a sense of entitlement, is shifting the power in the doctor-patient relationship. Patients are now asking for greater involvement and control over what happens to them, reflected by a gradual evolution in the legal control of medical practice.⁵ This control may vary according to the form that the doctor patient relationship takes.

² Brazier M. *Medicine, Patients and the Law*. 3rd ed. Penguin 2003, p4-5.

³ British Medical Association. *The handbook of medical ethics*, BMA, 1980, p9.

⁴ Brazier M. *Medicine, Patients and the Law*. 3rd ed. Penguin 2003, p8

⁵ British Medical Association. *Rights and responsibilities of doctors*. BMA, 1992, 2nd ed, p xxi.

THE DOCTOR-PATIENT RELATIONSHIP:

A doctor may come in contact with a patient in one of three ways:

Firstly, a person may consult a doctor as part of the normal therapeutic doctor/patient relationship. The patient consults the doctor because of illness and the doctor is then responsible for that patient's treatment.

Secondly, a doctor may come into contact with patients when involved in clinical research.

Thirdly, a doctor may act as an impartial medical examiner, reporting to a third party.

In each model of contact there is a difference in the attitude of the patient, the constraints on the doctor and the relationship between patient and doctor.⁶

The fundamental difference is the objective of the contact between patient and doctor. When part of a therapeutic relationship, the doctor's main objective is the well being of the patient and improvement in that patient's health. This is the 'therapeutic' model. When involved in research the doctor's aim is the accumulation of medical knowledge. The benefits may therefore be designed to aid future patients, although there is still potential for the research subject to obtain benefit. This is the 'research' model. Finally, in the third setting, when acting as an impartial medical examiner accountable to a third party who commissions their services, as for example on behalf of an insurance company, the doctor's concerns lie with obtaining information for that third party. The normal therapeutic doctor-patient relationship therefore does not arise. In this, the 'medical examiner' model, any tests carried out on the patient are not done primarily for the purposes of the health care of that patient but rather are done on behalf of the third party and in the interests of that third party.

There are thus different objectives in the contact between doctor and patient. Thus:

[in the therapeutic setting] the physician is seen as acting wholly in the patient's interest, with pure undiluted humanistic motives whereas in the [research setting], the interests of the patient are generally assumed to have been subordinated, be it only slightly, to another objective.⁷

A Royal College of Physicians Report summarised this distinction:

The distinction between therapy and research derives from intent. In medical practice the intention is to benefit the individual patient not to gain knowledge of general benefit, though such knowledge may incidentally emerge from the clinical experience gained. In medical research the primary intention is to advance knowledge so that patients in general may benefit; the individual may or may not benefit directly.⁸

⁶ British Medical Association. The handbook of medical ethics, 1980, p11.

⁷ Edsall G. A Positive Approach to the Problem of Human Experimentation. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 276-292 at p279.

⁸ Royal College of Physicians. Research Involving Patients. Royal College of Physicians, London, 1990 at 5

It is therefore clear that, because there are different objectives in the contact between patient and doctor, ethical and legal rules and guidelines may vary according to the model of contact. For example, it would be quite improper for a doctor to examine a person purportedly on the basis of a normal therapeutic relationship when in reality the doctor is acting as a medical examiner on behalf of other third parties, such as an insurance company. Promoting the patient's own health interests and protecting their confidentiality are not the goals of this interaction.⁹ In this situation, the person may volunteer information he or she would otherwise not have divulged, had it been known that the doctor was acting on behalf of the insurance company.

Similarly, the ethics of clinical care should not be confounded with those of research.¹⁰ In a randomised clinical trial comparing two treatments, the null hypothesis, that there is no difference between the two treatments, is the starting point in the design of the study, the aim of which is the generation of knowledge. As mentioned, it may be that only future patients will benefit and not the research subject. Indeed, in a randomised placebo-controlled trial, some patients will only receive a dummy treatment and thus be denied active treatment. Further, in non-therapeutic research, there is not even an element of therapy for the research subject.

Controlled clinical trials are often defended by arguments that stress the benefits that will accrue to future patients. Modern societies have come to expect steady advances in medical care and, as a public service, controlled [clinical trials] are required so that real advances are efficiently distinguished from those that are illusory.¹¹

The main impetus for regulating medical research and formalising a set of ethical guidelines arose out of the Nazi war crimes trials at Nuremberg, resulting in the Nuremberg code.^{12 13} This later led the World Medical Association to draw up the Declaration of Helsinki.^{14 15} The ethical principle of respect for the research subject's autonomy underpins research regulation.

In later chapters it will be shown that the law has different expectations when doctors undertake research as opposed to normal therapy. Thus, ethical codes of conduct and laws of consent, confidentiality and negligence may all vary according to the role played by the doctor and the objective of the

9 British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMA, 2004, p27.

10 Horng S, Millar FG. Is placebo surgery unethical? *N Engl J Med* 2002;347:137-9.

11 Chalmers I, Silverman WA. Professional and public double standards on clinical experimentation. *Cont Clin Trials* 1987;8:388-91 at 390.

12 *Dictionary of Medical Ethics*. Duncan AS, Dunstan GR, Welbourn RB (eds). Darton, Longman and Todd, London, 1981

13 Katz J. *Experimentation with human beings*. Russell Sage Foundation, 1972, p305-6

14 The World Medical Association. *The Declaration of Helsinki. Recommendations guiding medical doctors in biomedical research involving human subjects*. 1964 (revised 1975, 1983, 1989, 1996 and 2000).

15 *Declaration of Helsinki (2000)*: World Medical Association. *Bull Med Ethics* 2000;162:8-11.

contact between patient and doctor. Evidently, therefore, misplacement into the wrong model could potentially have serious consequences.

However, this traditional division into three doctor patient relationship models has a major shortcoming. Although the three models appear clearly defined, in reality it may be difficult to place a particular mode of contact into one of the three. This is especially so when attempting to distinguish between the therapeutic model and the research model. The line between undertaking research on a patient and doing the utmost for him under the therapeutic model is blurred. Furthermore, questions arise about the boundary between research and innovation.¹⁶ Brazier uses the recent legal case of *Simms v Simms and another*¹⁷ to illustrate this point.

... if a doctor caring for patients with new variant CJD attempts a novel treatment as a last resort, knowing that there is no conventional treatment that will prolong the patient's life, has he crossed that line and made his patient a research subject?¹⁸

Similarly, the recent use of sildenafil (Viagra) in three newborn babies with pulmonary hypertension in India caused controversy over the unauthorised use of the drug. The doctor concerned was criticised by local non-governmental organisations and the national media for the unethical and illegal administration of the drug. Using the drug on three patients was held to have been a planned experiment.¹⁹ Others, however, were disappointed to hear of the criticism.²⁰ Physicians and researchers are thus still unclear about what is treatment and what is research.

Levine believes a distinction should be made.

We fail to distinguish adequately between research, on the one hand, and the accepted and routine practice of medicine on the other. Because we fail to make these distinctions, we commonly find ourselves developing ethical norms, guidelines, and regulations that do not fit the class of activities for which they are designed.²¹

Thus the introduction of regulatory codes, such as the previously mentioned Declaration of Helsinki^{22 23}, that govern medical research requires the establishment of where routine therapeutic practice ends and research begins. The need to make these distinctions therefore flows from the adoption

16 British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMA, 2004, p489.

17 *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669.

18 Brazier M. *Medicine, Patients and the Law*. 3rd ed. London: Penguin, 2003, p405.

19 Kumar S. Indian doctor in protest after using Viagra to save 'blue babies'. *BMJ* 2002;325:181

20 Oliver J, Webb DJ. Sildenafil for 'blue babies'. *BMJ* 2002;325:1174-5.

21 Levine RJ. In: *Legal and ethical issues in human research and treatment*. Ed Gallant DM, Force R. Halsted Press, New York, 1978, p86

22 Declaration of Helsinki (Doc.17.c) (1996) World Medical Association. *Bull Med Eth* 1999;Aug:16-17.

23 Declaration of Helsinki (2000): World Medical Association. *Bull Med Ethics* 2000;162:8-11.

of regulatory codes for medical research.²⁴ However, while it is possible to identify some procedures or treatments as clearly medical practice or clearly research, many lie in the grey area between, as the above examples of the use of sildenafil and the novel treatment of new variant CJD illustrate. It is also unclear how procedures, such as the development of new surgical techniques or implants, are ethically and legally regulated. Should they be considered a form of therapy or come under the auspices of research regulation or is it more appropriate for them to be considered separately?

A recent editorial stated:

Throughout the world, systems are in place to ensure that any new drug is subjected to rigorous trials, appraisal, and approval before unrestricted use on patients. Medical devices are also subject to scrutiny and approval. By contrast no system exists for interventional procedures, many of which are done by surgeons but increasingly by other specialists as well. Recent press reports of surgical scandals and heightened public concern have led to political and consumer pressure for formal systems to assess new interventions.²⁵

Thus, new surgical and other invasive procedures appear to enter clinical practice without an assessment of their safety and efficacy being undertaken.²⁶ For example, novel designs of hip prostheses can come to market with limited evaluation of their clinical performance.²⁷ There is therefore growing concern that the introduction of new interventional procedures appears to be unregulated. Before considering how to regulate them, however, better definitions are required.

It should be pointed out that the previously described third category of contact between doctor and patient, namely that of the doctor acting as an impartial medical examiner, has no relevance to this thesis and will not be considered further.

DEFINING AND CLASSIFYING INTERVENTIONS:

Classifying the various activities undertaken by doctors into different categories can be difficult because the meanings of the terms used to describe the categories are ill defined. Problems of ambiguity and lack of clarity in basic concepts pervade the area.²⁸ As mentioned, the dividing line between treatment and research appears fine and further confused by the issue of innovation. Furthermore, different authors have confusingly used different definitions. For example, some have described new surgical interventions as being innovations while others classify them as

24 Gaze E, Dawson K. Distinguishing medical practice and research: the special case of IVT. *Bioethics* 1989;3:301-319.

25 Campbell B, Maddern G. Safety and efficacy of interventional procedures. *BMJ* 2003;326:347-8.

26 Dent T, Wortley S, Campbell B. New interventional procedures. *BMJ* 2004;329:3-4.

27 Faulkner A, Kennedy LG, Baxter K, Donovan J, Wilkinson M, Bevan G. Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model. *Health Technol Assess* 1998;2:6.

28 Price P. *Legal and ethical aspects of organ transplantation*. 2000, Cambridge: Cambridge University Press, p419.

experimentation. Some use the words 'research' and 'experimentation' interchangeably while others make a clear distinction between the two. It is therefore appropriate to define what exactly is meant by the terms 'innovation', 'research' and 'experimentation' in this thesis.

Experimentation is Research, Innovation is Therapy:

Brushwood:

Commenting on a case of 'experimental' drug therapy that reached the US courts²⁹, Brushwood states that, in the strictest scientific sense, experimental drug therapy is the use of a drug in circumstances where the goals of the experiment take precedence over the goals of therapy.³⁰ Thus, in his view, an experiment is an exercise designed to test rigorously a causal hypothesis by manipulating a treatment variable and observing the effects of this manipulation on one or more dependable variables. Clearly, the purpose of such an experiment is to gain new knowledge, although an additional result may be the relief of suffering in those subjects who have been assigned to the treatment group rather than the control group.

It is therefore clear from this that Brushwood equates experimentation with research. He further claims that innovative therapy, although sometimes referred to as experimental therapy by other observers, should not be called that. He believes the purpose of innovative therapy is to relieve human suffering, although a happy additional result may be the acquisition of new knowledge. He states that in an experiment, one refers to investigators and subjects, while in innovative therapy one refers to health care providers and patients. Innovative therapy differs from standard therapy because the results are more difficult to predict. However, innovative therapy is still therapy. It is not experimentation because there is no experiment.³¹

In summary, Brushwood equates experimentation with research and considers innovation to be distinct from experimentation and be a form of therapy. While appearing clear-cut, his definition implies there is no grey area between research and therapy. A medical intervention, even if novel, is a form of therapy.

Dickens:

A somewhat more confusing picture emerges when considering the definitions used by Dickens.³² He at first appears to agree with Brushwood. By reducing procedures to their elements, he claims that therapeutic procedures are intended to yield knowledge for aiding the patient, whereas experimental procedures are intended to yield knowledge for its own sake, irrespective of the patient who in this regard is better described as the subject.

29 Henderson v. Bodine Aluminium, Inc., 70F. 3d 958 (8th Cir 1995)

30 Brushwood DB. Challenging denial of coverage for innovative therapy. Am J Health-Syst Pharm. 1997; 54: 572-4.

31 Brushwood DB. Challenging denial of coverage for innovative therapy. Am J Health-Syst Pharm. 1997; 54: 572-4.

32 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9.

He continues:

...a treating physician may be inspired in giving a patient bona fide therapy by a strong sense of novel enquiry. Therapeutic innovation in seeking to aid a patient may be acknowledged. The fact of novelty alone, however, does not make the procedure experimental.³³

Thus, he clearly also equates experimentation with research and regards innovation as being a distinct entity and a form of therapy. For example, he believes the first human heart or kidney transplant was not experimental, although by definition it was novel. Heart transplantation, to his mind, was a form of therapy.

However, the picture becomes a bit more confusing as Dickens then appears to contradict himself.

When orthodox therapy is available, and a new treatment is administered to see if it will prove more successful, use of the new treatment would be experimental, even though upon proving more successful it will become the new orthodox treatment.³⁴

Indeed, he claims that

if ... an orthodox treatment exists, any departure from it will be experimental if deliberate, and negligent if not.³⁵

This argument had previously been used in the 1871 case of *Carpenter v. Blake*.³⁶ In it the physician concerned argued that his unorthodox procedure to correct a dislocated shoulder represented innovation rather than negligence. The court, however, ruled that any deviation from standard practice that lacked the approval of respectable practitioners was not acceptable when it did not benefit the patient.³⁷ This is very similar to the Scottish case of *Hunter v. Hanley*³⁸ that will be discussed later.

To return to Dickens' argument, he now appears to define a novel treatment as being part of either therapy or experimentation by ascertaining whether there is a current orthodox treatment available. If no orthodox treatment exists a new intervention is described as innovative treatment and forms part of therapy. On the other hand, if there is an orthodox treatment the deliberate use of a novel intervention will be deemed to be experimental and thus research.

33 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9 at 635.

34 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9 at 636.

35 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9 at 636.

36 *Carpenter v. Blake*, discussed in Faden R, Beauchamp T. The History and Theory of Informed Consent. Oxford: Oxford University Press, 1986, p100.

37 *Carpenter v. Blake*, discussed in Faden R, Beauchamp T. The History and Theory of Informed Consent. Oxford: Oxford University Press, 1986, p100.

38 *Hunter v Hanley* (1955) SC 200

On this basis it should be noted that although the physician in *Carpenter* argued his novel treatment was innovative, Dickens would have defined it as experimental because an orthodox treatment already existed. Furthermore, it could be argued that Dickens would not have considered the defendant to be negligent because the attempted unorthodox procedure was undertaken deliberately. Clearly Dickens' argument does not hold because it implies that, provided the attempted novel treatment is deliberate, negligence will not be found.

Dickens' argument also implies that if no orthodox treatment is available, doctors are free to try any new treatment they wish on a patient under the guise of therapy, thus using ethical and legal codes of conduct designed for ordinary treatment. This was the argument used to allow the introduction of organ transplants. Some of the surgeons involved in the early heart transplants rejected the use of the word experiment and considered the new technique to be therapy. Regarding the first heart transplant Christiaan Barnard stated

I wouldn't like to call this operation an experiment. It was treatment of a sick patient.³⁹

Similarly another transplant surgeon, Reemtsma, believed the distinction between therapeutic and experimental procedures was merely qualitative. Experimental merely meant that the outcome was uncertain but the procedures were undertaken with therapeutic purposes in mind.⁴⁰

Shumway, who had undertaken much of the early work in developing heart transplantation, also objected to the idea that cardiac transplantation was human experimentation. In his view it was clinical investigation.⁴¹

Heart transplantation is therapeutic from the perspective of the designated recipient. Heart transplantation continues, however, to be a field of clinical investigation from the viewpoint of the medical scientists involved.⁴²

Beecher in turn claimed that transplantation was a desperate effort to save a desperate situation. It was a *therapeutic* effort that would become widely practised once the rejection problem had been overcome. The operation also 'focussed attention on a great need.'⁴³

39 Barnard CN. quoted in Time, 29/12/67.

40 Reemtsma K. in Ethics in medical progress. Wolstenholme GEW, O'Connor M eds. Boston: Little, Brown. 1966: 164-6.

41 Stinson EB, Dong E Jr, Iben AB, Shumway NE. Cardiac transplantation in man. 3. Surgical aspects. Amer J Surg 1969;118:182-7 at p187.

42 Shumway NE. Transplantation of an unpaired organ, the heart. Proc Nat Acad Sci USA 1969;63:1032-3.

43 Beecher HK. Scarce Resources and Medical Advancement. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 66-104 at 96.

A Contrary View- Innovation is not Therapy but Research:

As will be discussed in the next chapter, if innovation is classified as part of therapy, patients subjected to innovative treatments such as organ transplantation will not be afforded adequate protection. There is thus a contrary view to what has just been described and this is that new treatment, given to see if it will prove more successful in a specific patient, is by definition an innovative treatment that needs to be distinguished from ordinary treatment.

Dickens, once again, appears to contradict himself when at one point he concedes that research and experimentation are not identical. He claims that a different dilemma arises when considering randomised controlled clinical trials, in which two orthodox treatments are compared to see which gives the better progress. In so far as each treatment is orthodox therapy, he believes the situation appears non-experimental and although the patient's selection to receive one form of treatment or another is designed to produce useful knowledge, the procedure itself is no less a therapy. He states that this is human research but it does not constitute medical experimentation.⁴⁴

He further claims that it is important not just to seek the predominant motive of a treatment but also *any* signs of an investigational motive. This thereby allows protection of the patient from even minor experimentation being concealed within the interstices of orthodox therapy and exposes it to the light of peer review and ethical (including legal) assessment.

Evans and Evans agree with this. They believe that the evolution of new or revised techniques and procedures in clinical practice at the very least implies the conduct of clinical research on patients.⁴⁵ It should be noted that they use the word 'research' where Dickens would use the word 'experimentation'. As previously mentioned, the use by different authors of the same word but with different meanings or the use of different words but having the same meaning has lead to much confusion in analysing the various concepts.

Kennedy and Grubb, in turn, believe that:

Innovative therapy should properly be regarded as one of two things: either *research*, with all that flows therefrom; or *therapy*, where the sole intention is to care for the particular patient involved. Consequently, the law does not inhibit development. It says, however, that any development must be defended as research or justified as appropriate albeit innovative therapy, against the background of a possible claim in negligence.⁴⁶

⁴⁴ Dickens BM. What is a medical experiment? Can Med Assoc J 1975;113:635-9 at 636.

⁴⁵ Evans D, Evans M. A decent proposal: ethical review of clinical research. John Wiley & Sons, Chichester, 1996, p54

⁴⁶ Kennedy I, Grubb A. Medical Law. Butterworths: London. 3rd ed, 2000, p1742

However there are few doctor-patient interactions where the *sole* intention is the care of that patient. Thus, according to the above definition, therapy *per se* would virtually cease to exist and practically all interventions would need to be regarded as research. Furthermore, since by definition, innovative therapy cannot have as its *sole* intention the care of the particular patient due to its investigational aspect, it also would need to be considered research.

This would also apply when a doctor is learning how to perform a particular recognised technique. Future patients will clearly benefit by the doctor learning how to perform this technique, although the current patient on whom the technique is being learnt should also benefit, provided the attempted procedure has been successful and no unnecessary complications have arisen. This form of innovation, called *personal innovation* for the benefit of this thesis, will be considered in greater detail later.

To return to Kennedy and Grubb's statement, the first part implies that all innovation should be treated as research. This however does not sit logically with the second part of their statement where the *appropriateness* of the innovation appears to be given prominence and, in their view, makes it 'therapy'.

A Third View: Experimentation is a separate entity, distinct from Research:

Clearly there are a number of the inconsistencies in the previous arguments. A different argument is that experimentation is a separate entity from both therapy and research. Mason, McCall Smith and Laurie, for example, equate experimentation with innovation and furthermore distinct from research.⁴⁷ They believe that research implies a predetermined protocol with a clearly defined end point. Experimentation, by contrast, involves a more speculative, ad hoc, approach to an *individual* subject (my italics). The individual's response may indeed lead to the experiment being modified to allow greater benefit of the individual. A research protocol, however, will tie the researcher to a particular course of action until such time as its general effectiveness or ineffectiveness is satisfactorily demonstrated.

Price agrees with this distinction.⁴⁸ He contends that a novel treatment is by its nature experimental, although it is not necessarily also research. He believes the distinction is founded on the intention of the clinician. Similarly, Nicholson believes that innovative therapy consists of the performance of a new or non-standard intervention as part of a therapeutic activity but not as part of a formal research project.⁴⁹

Much innovative therapy is surgical in nature, since surgeons often try out modifications to existing surgical procedures and occasionally try out new operations. In general these are not subject to peer review or review by a research ethics committee and this, to reiterate, is the problem with accepting

47 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. 2002. 6th ed, London:Butterworths, p573.

48 Price D. Legal and Ethical Aspects of Organ Transplantation. Cambridge: Cambridge University Press; 2000. at 419.

49 Nicholson RH. Medical research with children: Ethics, Law, and Practice. Oxford University Press, 1986, p37

Dickens' argument, which concludes that if no orthodox treatment is available, novel innovative treatments form part of therapy and, by implication, are not subject to more analytic review. The consequences of such a point of view will be examined in the next chapter.

A more reasonable viewpoint is that taken by a Royal College of Physicians Report, which states that

when a clinician departs in a significant way from standard or accepted practice entirely for the benefit of a particular individual patient, and with consent, the innovation need not constitute research, though it may be described as an experiment in the sense that it is novel and unvalidated.⁵⁰

This statement is consistent with the previous arguments put forward by Mason and colleagues, Price and Nicholson. This is the position that this author intends to take; namely that experimentation can be seen to be distinct from both research and normal therapy.

This distinction is fundamental and thus it is appropriate to recap on the definitions and objectives of the various modes of contact between doctor and patient.

During normal *therapy* the doctor's objective is the well being of the patient and improvement in that patient's health. It implies there is a standard accepted practice which is undertaken to benefit a particular patient.

Experimentation entails a more speculative departure from routine therapy, such as a modification of an established surgical technique, where the intention is to benefit the health of the patient. By definition, such a departure is unvalidated.

In contrast, the main objective of *research* is the generation of new knowledge. Although the research subject may obtain benefit, this is only a secondary objective. Indeed, research can be further subdivided into therapeutic and non-therapeutic subsets depending on the degree of this secondary objective, a point that will be returned to later in this chapter.

A CONTINUUM:

Despite such distinct definitions, it may be difficult to clearly differentiate between the different entities. For example, there is always an element of treatment or clinical care in any experiment and furthermore a 'preoccupation with the therapy that is distinct and absent from pure research.'⁵¹ Normal everyday medical practice is by its very nature experimental to some degree.

Medical experimentation on human beings, in its broadest meaning and for the good of the individual patient, takes place continually in

⁵⁰ Royal College of Physicians. Research Involving Patients. Royal College of Physicians, London, 1990 at 5

⁵¹ Starzl TE. Experience in hepatic transplantation. Philadelphia: WB Saunders Co. 1969;144.

every doctor's office. Hence the general question of human experimentation is one of degree rather than of kind.⁵²

Thus, merely giving a patient an aspirin involves a degree of experimentation. Will the patient respond and symptoms disappear or will the patient react in an unfamiliar way? Is the dose insufficient and need to be increased? Are the reported side effects worse than any perceived benefits? A doctor cannot be absolutely certain how a patient will react. There are no guaranteed outcomes in medicine. Medical education strives to instil in every doctor a sense of inquiry, an intuition for biological variables, and an innate desire to evaluate evidence realistically. Each doctor should therefore employ some of the essential features of the scientific and experimental method in the daily treatment of every patient.⁵³

There thus appears to be a continuum ranging from routine medical treatment, through experimentation, to research and, as previously mentioned, clearly delineating where each one ends and another starts may be difficult.

In normal, routine, medical treatment the main element (and intention) is therapy for the patient. However, within this concept and at the patient level there is still a small element of experimentation since, as previously argued, patients do not all behave in the same way.

As the novelty of the proposed treatment increases we come to experimentation, although the point at which treatment becomes experimentation is ill defined. Indeed, it is probably quite difficult in certain instances to completely separate experimentation from therapy. Physicians throughout history have seized opportunities to combine therapy with the generation of knowledge. Doctors have always modified methods of investigation and treatment in the light of experience.

...medicine ...has realized how difficult it is to separate the practice of medicine from experimentation. ... there is a realization that experiment and therapy have much in common and that knowledge can only be acquired by experimentation, ultimately only by experimentation on man.⁵⁴

The purpose of experimental therapy, such as when the first organ transplants were carried out, is still partly therapeutic in that it is undertaken to relieve human suffering. However it has the additional and significant intention of the

52 Shimkin MB. The Problem of Experimentation on Human Beings: The Research Worker's Point of View. *Science* 1953;111:205-7 at p205.

53 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p359.

54 Katz J. The Education of the Physician-Investigator. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970. 293-314 at p294.

acquisition of new knowledge.⁵⁵ Here the clinician may depart from accepted practice for the benefit of a particular patient. It differs from standard therapy because the results are more difficult to predict and there is also an element of research, though this is not overwhelming. The degree of digression from usual practice will be an important consideration when analysing its acceptability.

With experimental therapy, such as the development of a new technique, generalisable knowledge may be acquired on the basis of individual cases. Such experimental therapy is undertaken not just for the benefit of individual patients but also to test its efficacy for later use in others.⁵⁶ More debatable is Leffingwell's claim that 'whether the procedure pertains to medicine or surgery, so long as the amelioration of the patient is the one purpose kept in view, it is legitimate treatment.'⁵⁷ The legitimacy of experimental treatment, such as organ transplantation, will be discussed later.

Finally, as we progress along this continuum, the therapeutic element decreases to such an extent that the motive and primary aim is the acquisition of new knowledge. This is research, although coincidentally the patient may still benefit. Indeed, research can be subdivided further into therapeutic and non-therapeutic subsets, depending on whether the patient can potentially benefit. Thus, non-therapeutic research lies at the extreme end of the continuum described because the object of such research is purely scientific, with no diagnostic or therapeutic value to the person subjected to the research.

A continuum has thus been described ranging from routine therapy, through experimentation, to therapeutic and non-therapeutic research. While it may be difficult to decide precisely where one starts and another ends, in individual cases it should be possible to ascertain the nature of a particular intervention. This depends on what the degree of the primary and secondary intentions and aims of the intervention are. The greater the intention to treat the patient as compared to generating new knowledge, the more the intervention will be seen to be at the therapeutic end of the continuum. Conversely, the greater the intention being to generate new knowledge, the more the intervention should be considered to be at the research end of the continuum.

EXPERIMENTATION – A PART OF INNOVATION:

A further question that also needs to be considered is whether experimentation is distinct from the term 'innovation.' Moore, a pioneer of early transplantation operations, used the terms interchangeably. He was

concerned with a few of the ethical questions of therapeutic innovation raised by the application of new treatments to sick people. These are initial trials, carried out in human patients, or drugs or operations that

55 Brushwood DB. Challenging denial of coverage for innovative therapy. *Am J Health-Syst Pharm.* 1997; 54: 572-4.

56 Anon. Ethical emergencies. *Lancet* 1992;339:399.

57 Leffingwell AT. *An Ethical Problem.* New York: CP Farrell, 1916, p290.

may benefit the subject. This is the largest single category of medical experimentation - if that is a suitable term for therapeutic innovation - currently practised at the clinical level.⁵⁸

However, according to the Shorter Oxford English Dictionary⁵⁹, 'innovation' means 'the introduction of novelties, a *novel practice or method*'. Experimentation, on the other hand, is 'an action or operation undertaken *in order to discover something unknown*.' They therefore have similar meanings but while they are not entirely identical, they are also not mutually exclusive terms. Indeed, it could be argued that experimentation forms part of innovation.

PERSONAL INNOVATION:

There also appears to be a further distinction within the concept of innovation. It has already been established that if a practitioner is trying something that nobody else has attempted, such as the first heart transplant, this is defined as experimentation. However, if the technique has already been established elsewhere and the practitioner himself is trying it for the first time, then it can be described as *personal* innovation.

This concept is of such fundamental importance to this thesis that it bears repeating. When a normal routine therapeutic intervention is being undertaken by an individual for the first time as part of his or her learning process, personal innovation is occurring. Although the main aim is the treatment of a particular patient, there is a substantial secondary aim, this being the acquiring of new *personal* knowledge and experience that will benefit future patients.

This distinction from normal routine therapy was fundamental and led to many of the recommendations in the Bristol Report⁶⁰, the public inquiry into children's heart surgery at Bristol Royal Infirmary. One of the defendants, Dhasmana, tried to excuse the level of mortality and morbidity in his practice as being due to his learning curve,⁶¹ blaming 'beginner's bad luck' for some of the deaths.⁶²

This concept of a learning curve for the development of operative skills has always been important in surgical training. There are two different varieties of this. One format is where doctors need to perform a certain number of procedures to maintain a particular skill, as for example learning how to use the technique of fiberoptic intubation in anaesthesia. This involves passing a fiberoptic scope into a patient's trachea while the patient is awake. This skill is

58 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p359.

59 The Shorter Oxford English Dictionary, Clarendon Press, Oxford. 3rd ed, 1973.

60 Learning From Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. HMSO 2001 (CM 5207)

61 Dyer C. Surgeon blamed beginner's bad luck for cardiac deaths. *BMJ* 1998;316:1114.

62 Dyer C. Surgeon blamed beginner's bad luck for cardiac deaths. *BMJ* 1998;316:1114.

essential in anaesthetic practice and can be life saving when needed. The problem is that it is very rarely needed and thus the skill can easily be lost. In an effort to maintain their skills, some anaesthetists have a very low threshold for employing it, thereby subjecting some patients to an uncomfortable procedure that many other anaesthetists would not deem appropriate.

Another, more common, format occurs when some doctors have already learned the new technique and others are 'playing catch-up.' It is of course in the interests of society that doctors keep up to date and learn to use the latest technology and techniques. Thus, Lord Cameron stated:

I think it is well that the search for further knowledge and experience should not be inhibited by undue apprehension of charges of negligence for the consequences to a patient of treatment or diagnosis where such may diverge from the normal.... Medicine is not an exact science and the solutions of its problems are not susceptible of mathematical calculation, while the frontiers of medical knowledge are always moving and advance may often be achieved only at the cost of what in retrospect appear to be errors and divergences from the correct path as that is ultimately mapped out.⁶³

A more extreme view was stated by one of the surgeons involved in the first heart transplants.

People must die! It's no good to speculate that somebody might have done a better job, that somebody else might have cut this or that differently ... But unless *you* do the surgery, how then are you going to become good?⁶⁴

And later:

some patients must be sacrificed to the God of Experience. Excellence comes out of experience and nothing else. A doctor can reach the supreme pinnacle of technique, but only after he has done many, many cases and perhaps participated in many, many deaths. If every patient in the world got the best possible surgery, then there would be no resident program and, consequently, no new surgeons. Some surgery must be done by those who are less than perfectly qualified. ... A surgeon who is the best is a surgeon who has gained the most experience. And some of the first few people that surgeon operated on are dead. ... I know a lot of patients who are dead today because I operated on them early in my career. If I could do them tomorrow, they'd be alive.⁶⁵

While it is understandable and desirable that doctors gain experience, this should not be accomplished at the expense of individual patients' health. It is

63 McHardy v Dundee General Hospitals' Board of Management. (1960) SLT (Notes) 19

64 Hallman G. in Thompson T. Hearts. New York: McCall 1971 at p245-6.

65 Hallman G. in Thompson T. Hearts. New York: McCall 1971 at 246.

difficult to see how the two can be reconciled. These issues will be discussed in later chapters.

Thus *innovative practice* can be further analysed by being subdivided into two. If a completely new intervention is being attempted, this is termed *experimental innovation*. If, on the other hand, the technique has already been established but the practitioner concerned has not attempted it before or is still learning how to perform it, this is termed *personal innovation*. This issue of learning on the job, leading to a 'learning curve' being established, can be particularly problematic and will be discussed later.

In summary, innovation can be analysed separately from normal therapy and research (both therapeutic and non-therapeutic), although all lie on a continuum. Innovation, in turn, can be further subdivided into two forms, experimental innovation and personal innovation.

INTRODUCING AND ADOPTING NEW TECHNOLOGY:

What is accepted as routine medical practice, innovation (whether of the experimental or personal innovation type) and research is never static. The normal process by which procedures move over time from being part of a research protocol, to experimental treatments, to becoming accepted as part of orthodox medical practice and subsequently learned by other doctors, is of considerable importance in relation to regulatory codes. Although the process may not necessarily start by subjecting the procedure to research, it is important briefly to discuss how new technology is introduced and adopted and then to examine the factors useful in deciding where a new treatment lies on the continuum described above.

Historically surgery has been largely unregulated, and there have been few obstacles, other than the obtaining of consent from the patient for the operation, to prevent surgeons from developing and introducing new practices. By contrast a scientific evaluation of a new drug almost always requires approval by a Research Ethics Committee, which may seek assurances about the inclusion of a control group, adequacy of the proposed sample size, data collection and monitoring.

It goes without saying that novel surgical interventions should have proven advantages and be demonstrably effective. Implementation should be based on evidence and the need for such assessment is widely acknowledged. However, new techniques are sometimes widely implemented and only subsequently found to have no advantage, be less effective, or worse are more harmful than those they were intended to supplant. For example the Gamma nail was introduced in the late 1980s for fixation of extra-capsular hip fractures. This nail was thought to have theoretical advantages over the established fixation device, the sliding hip screw. However, a systematic review of ten randomised controlled trials has shown the nail to be associated with an increased risk of operative fracture of the femur and with later fracture of the femur and re-operation.⁶⁶ Patients who had their broken hip fixed with

66 Parker MJ, Handoll HHG, Robinson CM. Gamma nail versus sliding hip screw for extracapsular hip fractures.

this nail could thus be considered part of an experiment where a new technique was developed and implemented. It is unclear whether such patients knew of their involvement and the question of consent and information disclosure will be analysed in later chapters.

Advances in medical knowledge and technique do not normally occur in giant steps and typically involve overlapping steps. The stage of development of a new treatment is

more accurately viewed as a process or a continuum that moves from animal [research] to clinical trials with terminally ill patients beyond the help of conventional therapies, then to the use of the treatment on less and less critically ill patients.⁶⁷

It can take many years to progress through the stages. For example, it took twenty years of kidney transplantation before it could be said that it had become a 'generally practical aspect of human biology.'⁶⁸ Furthermore, this evolution is not always continuous, unbroken or in one direction. As the investigations progress, unanticipated problems may come to light necessitating return to further animal research. In some cases there may even be a clinical moratorium where the clinical use of the innovative treatment is suspended, as happened in heart transplantation.

How long investigators maintain scientific optimism in the face of uncertainty and feel justified in continuing 'depends on where on the spectrum from experiment to therapy they believe a particular clinical innovation falls.'⁶⁹ This changes as the new treatment evolves.

The first stage in the development of any technique or procedure is to attempt it in animals.

Laboratory study puts the stamp of human and ethical acceptability on therapeutic innovation more than does any other characteristic. Preliminary laboratory trial is the only way to provide information, however incomplete or inadequate, which might lead to an acceptable informed consent.⁷⁰

There are, however, limitations to using animal research as a basis for future human experimentation. It can be difficult to create an animal model of a particular human illness and extrapolation of such research may not be applicable to humans as the human response may be very different. Animal research will not answer all the questions posed by human patients. New

Cochrane Library. Oxford: Update Software, Issue 1, 1999

67 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p64.

68 Moore F. Medical responsibility for the prolongation of life. *JAMA* 1968;206:384-6 at p385.

69 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p58.

70 Moore F. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p367.

operations are being employed which depend for their success on complicated physiological or pharmacological interactions. These can be complex and often specific to man. They are also often paradoxical or unpredictable.⁷¹

Imaginative experimentation is indispensable to the progress of medical science. Had ... transplantation never moved from the ... laboratory to the operating room, problems peculiar to human subjects would have to remain unknown and therefore unsolved, and persons living today with transplanted kidneys would surely have died. If all forms of treatment were, in fact, withheld until everything is known about them, physicians would not even be prescribing aspirin or performing appendectomies today.⁷²

Similarly, there is no quick way to reproduce in the laboratory the passage of years. The human experiment always carries a few surprises when contrasted with preliminary laboratory work.⁷³

At what stage does an investigator working on animal laboratory research decide it is time to try the new technique on human subjects? There are no guidelines defining when to move from animals to trial in humans. If this is premature then it is deemed controversial and perhaps immoral. For example, some believed this prematurity was the root cause of the controversy that accompanied the introduction of heart transplants.⁷⁴

Others, however, disagreed, claiming there appeared to be a consensus at the time that sufficient basic and developmental research in the laboratory had been conducted to warrant the extension of heart transplantation to man. For example, Shumway believed that the way was clear to try human heart transplantation. A degree of experience with heart transplantation in the laboratory had been achieved which left him confident he could take appropriate care of the patient with a cardiac transplant.⁷⁵

However, as a consequence of the many unknown and uncontrolled factors, and the severe illness of the patients involved in this early phase of clinical trial, successful outcomes are often rare and death rates high.⁷⁶ Thus the new

71 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p364.

72 DeBakey ME. Medical research and the Golden Rule. *JAMA* 1968;203:574-6 at 574..

73 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p367.

74 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p70.

75 Shumway NE, Lower RR, Doig E. A heart transplantation narrative: the earliest years. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 435-449.

76 Swazey JP, Fox RC. The Clinical Moratorium: A Case Study of Mitral Valve Surgery. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970. 315-357 at p335.

intervention cannot yet be regarded as an accepted form of therapy and has to be viewed as a scientific exploration of the unknown.

For example, there were many deaths when the use of artificial kidneys was first attempted in the early 40's. Similarly, Lawler, who undertook the first kidney transplant in June 1950, reported that this first operation was a complete failure due to tissue incompatibility.⁷⁷

Earlier, 23 percent of the first two hundred children who had a 'Blalock' shunt inserted to correct cardiac malformations died. However, all children were hopeless cases and thus saving a significant number was considered a sensational achievement.⁷⁸

Similarly, in 1948 Brock operated on a number of patients with heart conditions previously thought of as inoperable. The first died on the table but the next three survived.⁷⁹

At the same time, in Philadelphia, Bailey's first three patients died but he then was successful in repairing a stenosed mitral valve in a twenty four year old woman, who then accompanied the surgeon to medical meetings as living proof of his success.⁸⁰

Many of these early efforts were severely criticised. Early renal transplantation to treat terminal kidney failure for example was described as a 'pioneer era doomed to failure' in which the 'risk imposed' and the death rate were both 'exorbitant'.⁸¹ The experimental nature of these transplants was not acceptable to many and led to a letter to a Paris newspaper in May 1952 referring to one patient as 'a needless victim of a needless experiment. ... how many other patients, in spite of the ominous example, have since been sacrificed on the altar of surgeons' ambitions.'⁸²

The early high mortality of these transplants was however recognised by the surgeons concerned. When heart transplants were started one stated:

I think we must face the fact that in the beginning stages of a procedure as radically different as cardiac replacement, one is going to have to take patients who are far from ideal candidates ... there are really no contra-indications for cardiac transplantation at this early stage except that patients might be too well to need it.⁸³

77 Lawler RH, West JW, McNulty PH, et al. Homotransplantation of the kidney in the human. JAMA 1950;144:844.

78 Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p28.

79 Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p30.

80 Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p30.

81 Starzl TE, Marchioro T. The past and future of organ transplantation. Radiology 1965;85:369-72 at p369.

82 Anon in Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p112.

83 Lillihei CW. In Experience with human heart transplantation. Proceedings of the Cape Town Heart Transplantation Symposium, 1968. Ed Shapiro HA. New York: Appleton-Century-Crofts 1969, p17.

Similarly, in his final report on surgery for mitral valve disease, Cutler insisted that the high mortality figures (90%) should not deter further investigation since they are to be expected in the opening up of any new surgical field.⁸⁴

Innovations such as the early transplants involve doctors and patients in explorations of the medical unknown that are as perilous as they are promising.⁸⁵ On the other hand, it is essential that boundaries are extended and dogma refuted. For example it was believed that wounds of the heart were necessarily fatal and the beating heart could not withstand manipulation.

Surgery of the heart has probably reached the limit set by Nature to all surgery: no new method, and no new discovery, can overcome the natural difficulties that attend a wound of the heart.⁸⁶

This was stated in 1896. If it had been accepted, and pioneers actively discouraged from making advances, much of what is routine practice today in medicine, cardiology and cardiac surgery would not exist, to the detriment of today's patients and society. Problems of uncertainty are therefore inherent in all aspects of medical practice but these are encountered with greater frequency and acuteness in therapeutic innovation.

In transplantation surgery this uncertainty was very much greater and was especially so in the early years.

In most cases of organ transplant surgery, there is as much an element of ... continued experimentation and investigation as there is of therapy. In a real sense, organ transplant surgery remains at such an early stage of development that nearly every organ transplant patient has to make a 'critical choice' of whether or not to submit to medical experiment or to die ... The competent surgeon must strike a balance between the experimental and the therapeutic. That is, there must be a balance between what the surgeon knows will help the patient and what new procedures deserve to be tried out in the interests of medicine as well as for the benefit of the patient.⁸⁷

The attempt to compare clinical and investigative responsibilities is related to a basic problem; determining how experimental and/or therapeutic a new operation, drug or other procedure is at a given time in its development and for a given class of sick patient. This evaluation is essential in determining on whom and in what circumstances it may justifiably be used.⁸⁸

84 Cutler EC, Beck CS. Present status of Surgical Procedures in Chronic Valvular Disease of the Heart: Final Report on All Surgical Cases. Arch Surg 1929;18:403-16.

85 Fox RC, Swazey JP. The Courage to Fail. Chicago: University of Chicago Press, 2nd ed. 1978 at xiii

86 Paget S. The Surgery of the Chest. Bristol 1896, p121 quoted in Swazey JP, Fox RC. The Clinical Moratorium: A Case Study of Mitral Valve Surgery. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 315-357 at 318.

87 Leinward G. Transplants: Today's Medical Miracles. New York: Franklin Watts, 2nd ed. 1992, at p50

88 Fox RC, Swazey JP. The Courage to Fail. Chicago: University of Chicago Press, 2nd ed. 1978 at p63.

Staging:

Deciding where along the research- experiment- therapy continuum a new treatment lies depends on a number of factors.

The medical profession attaches special significance to the mortality rate as a primary indicator of where a particular form of innovation, such as heart transplantation, lies on the continuum.⁸⁹ This, in turn, leads to a number of questions. If the mortality and morbidity rates are not acceptable should the procedure only be undertaken when part of a research project? Should it be stopped until further questions can be answered? Are there other aspects of the procedure that require further understanding, as for example the problem of rejection in the early heart transplants despite the surgical technique itself being well established?

Thus a treatment that was still very experimental would be one in which the problems of uncertainty are numerous or of basic importance;

the death rate is high and the survivors do not do very well so that the only suitable human candidates are patients so totally incapacitated that their death is imminent.⁹⁰

On the other hand, the mortality associated with a particular operation would have to be compared with the mortality of the disease itself. Thus, the mortality of heart transplantation in its early development stages had to be offset against the fact that the patients were at death's door. When the mortality rate of an innovative treatment falls to a sufficiently low level it then starts to become part of accepted treatment. It is now termed successful treatment. However, it may still not be clear at what point the procedure can be applied to less than terminally ill patients.

Indeed, patient selection criteria are themselves important determinants of how experimental or therapeutic a procedure is.⁹¹ For example, in the early years of kidney transplants, the patients had no alternative as dialysis was still in the very early stages.

The standards for acceptability of operation were therefore lowered to give the patient at least some chance for recovery. In many of these early desperate attempts, experiences were gained which later made it possible to raise the standards of acceptability for other patients with less urgent situations.⁹²

Thus the use of kidney transplantation in patients who were not terminally ill suggested that a new stage had been entered. The procedure was no longer experimental and had now become part of routine treatment.⁹³ In other words,

⁸⁹ Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p340.

⁹⁰ Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p67.

⁹¹ Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p340.

⁹² Moore F. Medical responsibility for the prolongation of life. *JAMA* 1968;206:384-6.

⁹³ Merrill JP. Medical aspects of transplantation. *Transpl Proc* 1969;1(2):162-70.

the use of procedure in progressively less unwell patients moved it along the continuum from experimental towards ordinary routine therapy.

Other criteria suggested to help in assessing whether a procedure is experimental or part of ordinary medical practice are how many centres and surgeons are undertaking it, the predictability of outcome, and the amount of mass media coverage.⁹⁴

However, even if a large number of centres are undertaking a procedure this does not automatically mean that it is not experimental. For example, there was a bandwagon phenomenon involved in heart transplantation that fizzled out after a few months. Most surgeons only undertook one or two. Similarly, Starzl describes the introduction of kidney transplantation as a 'gold rush'.⁹⁵ At the beginning of 1963 there were only three centres in the United States actively undertaking kidney transplants. Within the next year more than 25 new ones sprang up. Kidney transplantation seemed to have become a clinical service overnight, despite the fact that the results were still disastrous.⁹⁶

Similarly it is also important to examine the capabilities of the institution in which the surgeon works. There are many other aspects apart from surgery which are essential if the project is to succeed, such as what equipment and personnel are available, where is the funding to come from, is it adequate, do the staff have experience in performing similar operations and so on.

Another aspect that may help define whether a procedure has become routine is by the degree of attention afforded to it by the media. Medawar stated:

the best quantitative measure of the success of clinical transplantation is the degree to which it does not receive publicity, i.e. the degree to which we take its accomplishments for granted. Kidney transplantation is no longer reported in the papers unless some particularly macabre circumstance surrounds the act of grafting. ... in other words, it has been almost completely received into the ordinary repertoire of surgical practice. We will have succeeded with liver and heart transplantations when they are no longer news...⁹⁷

A further factor defining the status of an innovation, at least in some countries, is the method of reimbursement. For example, in the United States defining the status of a procedure as experimental or therapeutic has a profound implication on how the procedure will be paid for. It is thus not merely a medical decision because there are political and economic pressures as well.

94 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p74.

95 Starzl TE. My Thirty-five year view of organ transplantation. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 145-182 at p159.

96 Starzl TE. My Thirty-five year view of organ transplantation. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 145-182 at p159.

97 Medawar P. The future of transplantation biology and medicine. *Transpl Proc* 1969;1(2):666-69 at p666-7.

For example, in the early years most health insurance agencies refused to pay for dialysis support because it was 'experimental'.⁹⁸

Clearly there are ambiguities in deciding at what stage along the continuum between therapy and research a particular innovative treatment lies. A further problem is that clinical fervour leads physicians to overestimate how far a treatment has progressed along the continuum towards the therapy end of the spectrum.⁹⁹

Also it has been noted that:

Initially investigators respond to new discoveries with enthusiasm and hope. It is not only their intellectual excitement over solving a scientific problem that accounts for their buoyant reaction, but also their expectation that the advances made will allow them to care for patients more effectively. But with every such breakthrough new uncertainties, therapeutic limitations, and negative aspects are gradually discovered. ... investigators [tend] to deal with uncertainty by focusing on the positive ... in their publications, they typically write first of 'encouraging results' and later of 'discouraging results'.¹⁰⁰

Hence, there are no clear guidelines or signposts telling the investigators that the time has arrived to move to the next stage in the development of the procedure. There is a need continually to assess the state of the art, their own capabilities, the probable risks and benefits to their patients, the possible yield in knowledge that might help other patients and the proper allocation of scarce resources, such as manpower, equipment, facilities and funds.¹⁰¹

Fox and Swazey believe that there is thus a complex, multivariate nature to the development of therapeutic innovation. There are not only biological and medical, but also psychological and social factors involved in the unfolding of such an innovation.¹⁰² Their analysis disclosed several alternative phase-movements between the early clinical trials and the established therapy points on the proposed spectrum.

The transplantation sequence has suggested that after a medical innovation has moved past early clinical experimentation into what might be termed the "pretherapeutic" stage of its development, patient selection may take one of several forms. Trials with a procedure or drug may advance directly to the stage where it is used in the treatment of progressively less critically ill patients. This is the post experimental /pretherapeutic pattern of patient selection that we

98 Starzl TE. My Thirty-five year view of organ transplantation. in: History of Transplantation: Thirty-Five Recollections. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 145-182 at p159.

99 Fox RC, Swazey JP. The Courage to Fail. Chicago: University of Chicago Press, 2nd ed. 1978 at p68.

100 Fox RC, Swazey JP. The Courage to Fail. Chicago: University of Chicago Press, 2nd ed. 1978 at 55-6.

101 Swazey JP, Fox RC. The Clinical Moratorium: A Case Study of Mitral Valve Surgery. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 315-357 at p335

102 Fox RC, Swazey JP. The Courage to Fail. Chicago: University of Chicago Press, 2nd ed. 1978 at 340, 343

originally postulated. But we have found that at least two other possibilities exist. The therapeutic innovation may be extended to terminally ill patients with a wider, more inclusive range of serious diseases and medical problems than was characteristic of those who were the subjects of earlier clinical trials. This is currently [in 1978] the case with renal transplantation and the “all risk” patients who have become its recipients. There is a third alternative patient selection trend that has become apparent. This is exemplified by the field of heart transplantation, which continues to choose recipients from among patients who are dying of end-stage cardiac disease as it did at its inception but has now gone on to select the “best risk” patients – psychologically as well as biomedically – within this otherwise “doomed” category.¹⁰³

They believe this perspective of a relatively conservative, low key, hard working, clinically focussed approach stands in marked contrast to the phases in ideology and goals that often precede it, that is:

the exuberant, aggressive, frequently hubris-ridden outlook that characteristically prevails in the very first period of early clinical trials [with] the expectation of imminent ... breakthroughs.¹⁰⁴

In turn, assessment of any new technology needs to include systematic review and synthesis of a range of evidence on the effects of the intervention.¹⁰⁵ For technology assessment to improve health care for patients there must also be institutions responsible for disseminating high quality evidence to relevant target audiences, thereby promoting the uptake of effective measures and the discontinuation of ineffective or harmful ones.

In the United Kingdom, the Centre for Reviews and Dissemination at the University of York, funded by the National Health Service Research and Development Programme, fulfils this role. A database of abstracts of reviews of effectiveness prepared by the Centre is available through the Cochrane Library.¹⁰⁶ Such reviews can contribute to the establishment of clinical guidelines, issued by the National Institute of Clinical Excellence (NICE). The role of NICE, clinical guidelines and evidence based medicine in regulating innovation will be considered in a later chapter.

However, problems can arise at each stage in the assessment of a new surgical procedure. At the very start of the process, it is difficult to know when to give a new procedure priority for evaluation. If an assessment is done too early, before surgeons have mastered the technique (i.e. early in the learning

103 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at 341-2.

104 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at 342.

105 Chalmers I, Hetherington J, Elbourne D, Keirse MJNC, Enkin M. Materials and methods used in synthesizing evidence to evaluate the effects of care during pregnancy and childbirth. In: Chalmers I, Enkin M, Keirse MJNC. eds. *Effective care in pregnancy and childbirth*. Oxford: Oxford University Press, 1989:39-65

106 The Cochrane Library. Oxford: Update software, Issue 1, 1999. Website address- <http://www.update-software.com/ccweb/cochrane/cdsr.htm>

curve), there is a risk of rejection of an effective procedure. If too late, the technique may have diffused and become established, by which time it may at first be considered unethical to withhold it, although subsequent assessments may show it to be ineffective or even harmful.

Indeed, as mentioned, what makes a surgical technique new is not always easy to define because surgical procedures generally evolve in small steps, making it difficult to decide when a procedure has changed sufficiently to justify formal evaluation.

The uptake of minimally invasive surgical techniques provides an example of some of the problems that can arise. Laparoscopic cholecystectomy was adopted in preference to mini-cholecystectomy by many surgeons without any evidence of its effectiveness and resulted in a higher rate of bile duct injuries while surgeons were still learning the technique.¹⁰⁷ Formal evaluations were hampered by widespread optimism about the effectiveness of the minimally invasive approach, which was subsequently found to be exaggerated. Furthermore, it was very difficult to perform a randomised controlled trial to compare the two techniques. Such trials are more straightforward to conduct when assessing therapies adjuvant to surgery rather than comparing alternative surgical procedures. This is because placebo controls cannot be undertaken and if two surgical techniques are to be compared, differences in wound site and size would allow bias from both patient and doctor, thereby confounding the results.

Other problems arise in other branches of medicine. For example, efficacy has not been proven for many interventional radiological procedures.¹⁰⁸ This is because interventional radiology is both consumer and technology driven and rapid and frequent modifications of equipment and devices make the methods and the results of studies obsolete before they are completed and published.¹⁰⁹

On the surgical front, the possibility that some surgeons may have better outcomes with one procedure than other surgeons with an alternative procedure - that is there is an interaction between surgeon and technique - creates a particular difficulty. If there is an interaction between surgeon and procedure, pooling the results across surgeons would give a misleading picture, and quantifying the interaction would require a very large sample size. Randomising patients to surgeons who use different procedures, while studying patients of different surgeons observationally, may represent the pragmatic alternative but addresses a different question - namely what are the effects of the alternative procedures when carried out by surgeons who prefer them?¹¹⁰

107 Richardson MC, Bell G, Fullarton GM, et al: Incidence and nature of bile duct injuries following laparoscopic cholecystectomy: An audit of 5193 cases. *Br J Surg* 1996;83:1356-60

108 Dondelinger RF. Advances in abdominal interventional radiology. *Lancet* 1999; 353 (Supplement 1): 15-18

109 Dondelinger RF. Advances in abdominal interventional radiology. *Lancet* 1999; 353 (Supplement 1): 15-18

110 Reeves, B. Health Technology Assessment in Surgery. *Lancet* 1999; 353 (Supplement 1): 3-5.

The difficulty of performing randomised control trials of new surgical procedures means that in a recent update of the Cochrane Library there are few systematic reviews of the effects of surgical procedures,¹¹¹ although there are many more reviews of adjuvant surgical therapies.

Furthermore, since the Bristol Report¹¹², the General Medical Council has been grappling with the problem of measuring and comparing surgical outcomes. This problem will be considered in a later chapter.

There can also be difficulties in weighing up the benefits and costs of new surgical techniques. Adopting a new procedure may not be straightforward since it is likely to require a surgeon to acquire new practical skills and to develop competence over a number of cases. The costs of mastering the new procedure are likely to be substantial for patients, surgeons, and health services, since surgeons who are learning a new technique typically take longer to carry out a procedure and have a higher rate of complications than do experienced ones. Thus, once a previously experimental therapy has been in use and accepted as routine therapy, the problems of personal innovation need to be considered. Furthermore the gradient of the learning curve may vary considerably between surgeons.¹¹³

The introduction of new prosthetic joints in orthopaedics illustrates another problem; that is, the need to assess long-term outcomes for some procedures. Clinically and economically important differences in the failure rate of alternative prostheses are unlikely to emerge for several years and manufacturers are understandably reluctant to invest in the long-term and expensive evaluations that are needed to show benefit.

Devising ways of encouraging surgeons to recognise uncertainty about the effects of surgical procedures and to be less susceptible to the lure of new and expensive technologies that have not been fully evaluated probably represents the greatest challenge to health technology assessment in surgery. A greater awareness of the need to assess surgical technologies should lead to more and higher quality evaluations of effectiveness, the opportunity to synthesise evidence from individual studies in systemic reviews, and the incorporation of high quality evidence into guidelines. There also needs to be wider acknowledgement of the difficulty of carrying out randomised trials in some circumstances and a greater appreciation of the potential value of assessments with non- randomised designs when randomised trials prove to be impractical.

DIFFERENT ARRANGEMENTS:

As previously mentioned, there is a striking contrast between the arrangements that exist in many countries for evaluating new forms of drug

111 The Cochrane Library. Oxford: Update software, Issue 1, 1999. Website address- <http://www.update-software.com/ccweb/cochrane/cdsr.htm>

112 Learning From Bristol: Summary and Recommendations. HMSO 2001 (CM 5207(ii))

113 Reeves, B. Health Technology Assessment in Surgery. Lancet 1999; 353 (Supplement 1): 3-5.

treatment, using formal, controlled research studies, and other forms of health care therapy of the experimental variety such as infertility treatment.¹¹⁴

For example, in the UK, licensing decisions for medicinal products are based on trials involving on average around 1500 patients.¹¹⁵ New drugs are introduced following rigorous testing in animals, followed by carefully controlled testing in humans with appropriate follow up observation. Although there are elaborate and expensive arrangements for protecting patients from the unexpected and unwanted effects of drug research and routine therapy, similar arrangements do not appear to be in place to protect patients from the adverse effects of surgical innovation. Many of these non-drug interventions can be both ineffective and dangerous. As has been said:

By default this double standard actively promotes poorly controlled clinical experimentation within a sizeable segment of the health services.¹¹⁶

Thus new surgical operations may or may not be tested in animals, may be introduced as human therapy with or without review by a research ethics committee and with or without a formal research design, and may or may not be evaluated by long term follow up observation.

Surgical technology has advanced exponentially in recent years, but attitudes towards its introduction into normal routine practice remain archaic. Whereas, as mentioned, strict licensing laws exist for the introduction of new drugs, surgical innovation is assimilated relatively unchecked.¹¹⁷ This occurred regularly in the past, as for example in the introduction of operations such as heart transplantation (discussed later), but also for relatively new techniques such as minimal access surgery.^{118 119}

Indeed Moore felt that experimentation was of greater concern than pure research.

A far more important biomedical-ethical problem arises daily in thousands of hospitals concerning the initial use of drugs, treatments, or operations (as well as) the initial employment of untrained personnel in the care of patients. Here the subject-patient stands to benefit from the 'experiment' if it is properly done; the line between experiment and therapy is never clearly drawn. Every new operation, for example, is an experiment; indeed every operation of any type contains certain

114 Gaze E, Dawson K. Distinguishing medical practice and research: the special case of IVT. *Bioethics* 1989;3(4): 301-19. (NB. Probably should read IVF but IVT used in title.)

115 Rawlins MD. Pharmacovigilance: paradise lost, regained, or postponed? The William Withering Lecture 1994. *J R Coll Phys Lond* 1995;29:41-9.

116 Chalmers I, Silverman WA. Professional and public double standards on clinical experimentation. *Cont Clin Trials* 1987;8:388-91 at 389.

117 Ridgway PF, Darzi AW. Placebos and standardising new surgical techniques. *BMJ* 2002;325:560.

118 MacIntyre IMC, Wilson RG. Laparoscopic cholecystectomy. *Br J Surg* 1993;80:552-9.

119 Ridgway PF, Darzi AW. Placebos and standardising new surgical techniques. *BMJ* 2002;325:560.

aspects of experimental work. Likewise the employment of a familiar drug on a new patient for the first time constitutes an experiment in the precise determination of the proper dose, and there is an inevitable period of uncertainty about unusual reactions that the patient may exhibit.¹²⁰

Occasionally, in an effort to bypass the requirement for formal ethical committee approval for a research project, it is claimed that a study is merely a form of therapy. In 1988 a paper was published suggesting that treatment with buserelin, an agonist of luteinising hormone releasing hormone, and human menopausal gonadotrophin was more effective than conventional treatment in stimulating oocyte production and achieving pregnancy in women undergoing in vitro fertilisation.¹²¹ The patients were not randomly assigned to the two treatment groups and the authors suggested that because all they were reporting was an extension of the drug's regular use formal ethical approval for the study was not required. Furthermore, because the study was not a randomised trial, it was suggested that no formal ethical approval was required. However, Chalmers and Silverman have argued that these double standards are inexcusable and those who suggest that 'the interests of patients involved in poorly controlled, casual experiments are less in need of formal protection [than those involved in research] must be called to account.'¹²² Indeed, it could be argued that these patients need more protection rather than less. At least something good might come out of a well-designed randomised controlled study. Poorly conducted experimental innovation, where the results may not be interpretable and therefore of no use to the medical scientific community, is unethical.

On the other hand, it was only fortuitous that the introduction of the Charnley hip replacement (a new surgical implant) into the United States came to be under the review of the Food and Drug Administration (FDA). This was due to the use of methylmethacrylate, a high-density polyethylene, in the acetabular cup inserted into the patient. A casual inquiry as to the FDA's possible interest in the use of methylmethacrylate elicited the prompt institution of the FDA's regulations as for any new investigational drug, including a requirement to submit full particulars of proposed research protocols, before orthopaedic surgeons were allowed to proceed with the new operation.¹²³ This allowed a large database to be set up from the outset, making the surveillance of these new joints relatively straightforward. In the UK, it is only recently that the

120 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p358-9.

121 Rutherford AJ, Subak-Sharpe RJ, Dawson KJ, Margara RA, Franks S, Winston RML. Improvement of in vitro fertilisation after treatment with buserelin, an agonist of luteinising hormone releasing hormone. *BMJ* 1988;296:1765-1768.

122 Chalmers I, Silverman WA. Professional and public double standards on clinical experimentation. *Control Clin Trials* 1987;8:388-91 at 391.

123 Bunker JP, Hinkley D, McDermott WV. Surgical Innovation and Its Evaluation. *Science* 1978;200:937-41.

government has announced the creation of a registry, the National Joint Registry for Hip and Knee Replacements.¹²⁴

A problem that also merits further discussion is the use of drugs outside their licensed indications. The Medicines Act 1968 regulates activities of pharmaceutical companies and others involved in the supply of medicines but under section 9 it specifically preserves the clinical freedom of the medical profession.¹²⁵ This allows doctors to prescribe as they see fit, prescribing unlicensed drugs or drugs outwith the terms of their product licence on a 'named patient basis'. For example, a quarter of all prescriptions in palliative medicine are for licensed drugs that are used for unlicensed indications or are given by an unlicensed route.¹²⁶

CONCLUSION:

The concept of innovation as a separate entity from research and therapy has been introduced. Innovation may take two forms. One form is experimental innovation, in which a completely untried new technique is attempted. The second is personal innovation in which the technique has already been developed elsewhere and the doctor is now in the process of learning it for him/her self. The predominant intent here is therapeutic as opposed to the intent of research, even of the therapeutic kind, where the primary intention is the acquisition of new knowledge.

This distinction between therapy, personal innovation, experimental innovation and research has been largely unrecognised. However, this evaluation is important because it allows analysis of the ethical and legal requirements for each and is essential in determining on whom and in what circumstances a procedure may be used. Issues of consent and negligence can be more clearly discussed.

Furthermore, a continuum has been described ranging from routine medical treatment, through innovation (encompassing both experimental and personal innovation) through to research. The primary aim of a procedure in terms of therapy or acquisition of knowledge helps to determine where along the continuum that procedure lies. In addition, mortality rates, patient selection criteria, how many centres and surgeons are undertaking it, media coverage and political and economic considerations aid in defining the status of the procedure. In addition it should be remembered that initial enthusiasm leads to doctors tending to overestimate how far along the continuum towards the therapy end of the spectrum a particular innovative procedure lies.

The development of organ transplantation is an example of experimental innovation. The early heart transplants 'attracted a degree of interest ... seldom equalled by any new development in medicine ... this interest taking the form of a continuing debate and discussion as to the medical, ethical,

124 Anon. Details of joint replacements registry. Hospital Doctor, 26/9/02 at p7.

125 Medicines Act 1968, s9.

126 Pavis H, Wilcock A. Prescribing of drugs for use outside their licence in palliative care: survey of specialists in the United Kingdom. BMJ 2001;323:484-5.

moral and legal aspects of [this innovation].'¹²⁷ They will serve as an excellent example of the issues relevant to the undertaking of a completely untried new technique. This is especially so when considering the attempted insertion of the first artificial heart into a patient. The following statement highlights these problems:

Some experiments upon human subjects must also be carried out not only in an attempt to provide therapy but to provide clues that may help other patients. The primary justification for organ transplant surgery as experiment is that new knowledge will come from the study that may benefit others.¹²⁸

It could be argued that to require virtually any innovation to undergo peer review and ethical and legal assessment would be a significant burden and seriously curtail any advances, to the detriment of current and future patients. On the other hand, there may be an argument that, when viewed from the standpoint of patient autonomy and issues of consent, a different conclusion may be reached.

The other form of innovation, personal innovation, where the doctor is himself learning how to undertake a recognised technique, is exemplified by the 'Bristol' case,¹²⁹ which concerned the higher than expected rates of mortality in children undergoing heart surgery at Bristol Royal Infirmary.

Here

the most serious charge levelled against [the] doctors [concerned] was not that individuals betrayed patients' trust but that too little was done by doctors to identify and remedy other doctors' failings.¹³⁰

Examination of what went wrong at Bristol will illustrate the role of performance tables, guidelines and regulatory bodies such as the National Institute for Clinical Excellence and the Commission for Healthcare Audit and Inspection.

A discussion of the regulation of innovation also requires a review of how doctors are currently guided and regulated through both internal and external controls. Professional ethics and self-regulation thus need to be discussed. The external controls available to regulate the medical profession, including the role of the law, will also be examined, especially in terms of consent issues and safeguarding the interests of patients. If current controls have not been successful in regulating innovation then some other model of regulation needs to be proposed and examined.

¹²⁷ American Medical Association. House of Delegate's statement on heart transplantation. JAMA 1968;206:2631.

¹²⁸ Leinward G. Transplants: Today's Medical Miracles. New York: Franklin watts, 2nd ed. 1992 at p50.

¹²⁹ Horton R. How should doctors respond to the GMC's judgements on Bristol? Lancet 1998;351:1900-1.

¹³⁰ Brazier M. Medicine, Patients and the Law. 3rd ed. London: Penguin 2003, p5.

THE REGULATION OF INNOVATION

CHAPTER 2:

FAILURES OF REGULATION	39
Experimental innovation: Transplantation	39
Liver transplantation	40
Heart transplants	41
The UK's first heart transplant	44
The first artificial heart	48
Personal Innovation: The Bristol Affair	52
The GMC's findings	53
Key Issues	55
Conclusion	57

CHAPTER 2: FAILURES OF REGULATION

In the previous chapter, Dickens was reported as arguing that if no orthodox treatment was available novel treatment, such as the first human heart or kidney transplant, was to be considered a form of therapy.¹³¹ If accepted, this implies that doctors would be free to try any new treatment they wish on a patient under the guise of therapy, using ethical and legal codes of conduct designed for ordinary treatment. This chapter will examine the consequences of such reasoning by reviewing two forms of novel or innovative treatment, the introduction of organ transplantation, an example of experimental innovation, and the circumstances surrounding the 'Bristol' affair, illustrating personal innovation.

It is important to reiterate key concepts that have been established in the previous chapter. Innovation is a separate entity from research and routine therapy. In turn, it may be divided into experimental innovation, where a completely new technique is attempted for the first time, and personal innovation, where the doctor is learning how to undertake an already proven procedure.

EXPERIMENTAL INNOVATION -TRANSPLANTATION:

Transplantation is the transfer of tissues from one individual to another and often involves therapeutic innovations.¹³² These have ranged from the first human to human and animal to human heart transplants to the implantation of temporary and permanent artificial heart devices. All generated considerable controversy and led to the charge that the patients involved were no more than human guinea pigs undergoing treatment for the benefit of society.¹³³ In other words these patients were experimented upon.

Transplantation and implant surgery such as hip and knee replacements, stand as symbols of what modern, high technology medicine can achieve. Fifty years ago, however, transplantation surgery seemed impossible. It was only in 1954 that a team of doctors in Boston successfully transplanted a kidney into a patient from his twin brother. Fifty years from now, today's standard procedures will appear primitive.¹³⁴

The early organ transplants were largely experimental and today's expertise and successful results would not have been achieved without this experimentation. Early popular accounts of liver and heart transplants accentuated the heroism of the patient, who may have had no alternative but death, and the skills and daring of the surgeons, while obscuring the experimental nature of the procedure and sometimes guarded prognosis despite so called 'successful' surgery.¹³⁵

131 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9.

132 Furrow B, Johnson S, Jost T, Schwartz R. Health Law: Cases, Materials and Problems. St Paul: West Publishing Co; 1987 at 130.

133 Price P. Legal and ethical aspects of organ transplantation. Cambridge: Cambridge University Press: 2000;418.

134 Leinwand G. Transplants: Today's Medical Miracles. New York: Franklin Watts, 2nd ed. 1992.

135 Leinwand G. Transplants: Today's Medical Miracles. New York: Franklin Watts, 2nd ed. 1992, at p11.

Liver Transplantation:

The first human liver transplant was attempted in March 1963. The patient unfortunately bled to death on the operating table. It was clear from this that surgeons at the time had little idea how to control the severe defective blood clotting that characterised severe liver disease.¹³⁶

A few more transplants were undertaken but again the patients suffered a similar fate. They, however, had little choice. For example, although it was explained to one patient dying of advanced liver cancer that no one had ever lived for more than twenty days following a liver transplant, he grabbed at a second chance of life.¹³⁷ Ten days later the patient was dead.

These first clinical liver transplants were undertaken by Starzl, one of the pioneers of liver transplantation. Despite such dismal results,¹³⁸ other surgeons, such as Calne in Cambridge, felt it was time for them also to embark on a clinical program.¹³⁹ His colleagues, however, were unanimous in advising him against liver transplantation. Only one, a visiting professor from Harvard, Dr Francis Moore, felt it should be undertaken. Although the first UK liver transplant was technically successful the patient died six weeks later.¹⁴⁰

Starzl has stated that 'between the 60s and 80s was the time for those thousands of details to be clarified which had been skipped in the rush to the finish line'¹⁴¹, implying a certain haste in commencing these experiments. More worryingly, when commenting on the early failures in liver heterotransplantation, he stated:

Although I reported them, I may have tried subconsciously to hide the experience by stashing the reports in obscure corners and funny places. ... Much to my amazement (possibly even chagrin), Auchincloss ha[s] discovered all of these cases ... There were many dumb things that were done ... We made another foolish mistake at operation when we actually heparinized the child after the liver was put in. the child bled to death.¹⁴²

136 Starzl TE. *The Puzzle People: Memoirs of a Transplant Surgeon*. Pittsburgh: University of Pittsburgh Press, 1992:100.

137 Leinward G. *Transplants: Today's Medical Miracles*. New York: Franklin Watts, 2nd ed. 1992, at 25.

138 Starzl TE, Marchioro TL, VonKaulla KN, et al. Homotransplantation of the liver in humans. *Surg Gynecol Obstet* 1963;117:659.

139 Calne R. Recollections from the laboratory to the clinic. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 227-243 at 235.

140 Calne R. Recollections from the laboratory to the clinic. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 227-243 at 235

141 Starzl TE. My Thirty-five year view of organ transplantation. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 145-182 at 169.

142 Starzl TE. Baboon renal and chimpanzee liver heterotransplantation. In *Xenograft* 25. Hardy MA (ed.) Amsterdam: Elsevier, 1989. 17-28 at 25.

In many respects these early liver transplants were futile efforts to push back the boundaries of medical knowledge, attempted by experimenting on patients. This was mirrored when heart transplantation started.

Heart transplants:

Heart transplantation started slightly later. In the late Fifties and early Sixties a number of heart surgeons, but most notably Norman Shumway in California, had been working on the technique of heart transplantation using animal models.¹⁴³ He had spent ten years perfecting the technique and by the mid sixties it was widely expected that he would perform the world's first human heart transplant. However, the course of medical history was changed when Christian Barnard, a relatively unknown South African surgeon, visited Shumway for two months in 1967. Two months later Barnard performed the first human heart transplant on Louis Washkansky at the Groote Schuur Hospital, Cape Town, South Africa, on the 3rd December 1967. In the entire history of transplantation, this was the event that most attracted the attention of the general public.

The operation was a technical success. The media elevated Barnard to the status of international superstar and hailed his achievement as one of the major medical advances.¹⁴⁴ The medical community however expressed surprise because, as already mentioned, it was expected that the first such operation would be undertaken in America. 'He jumped the gun to get ahead of the front runners in the field', it was said.¹⁴⁵

The reason the first such operation was not done in the US was not due to lack of technical expertise but because each surgeon was waiting for another to overcome the last moral scruples and attempt the operation. The most important question at the time was the legality of killing a patient by removing the heart.¹⁴⁶ A further problem was the issue of rejection. Just before the first operation, Donald Ross, one of the surgical team that undertook the first UK heart transplant, had remarked that the technical problems of transplantation had been resolved but those surrounding rejection had not and it would probably take a decade before they were.¹⁴⁷ Shumway was of the same opinion. 'Not until each of [three crucial] problems w[ere] solved could human application be suggested even for the sickest patient.'¹⁴⁸ In other words, most believed that it was not yet time to embark on human heart transplantation.

143 Shumway NE, Lower RR, Doig E. A heart transplantation narrative: the earliest years. in: History of Transplantation: Thirty-Five Recollections. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 435-449.

144 Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. BMJ 2001;323:1478-80.

145 Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. BMJ 2001;323:1478-80.

146 Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999: 22-23, 32-34.

147 Ross D. in: Thorwald J. The Patients. New York: Harcourt Brace Jovanovich, 1971 at p291.

148 Shumway NE, Stinson EB, Dong E Jr. Cardiac homotransplantation in man. Transpl Proc 1969;1:739-45 at p739.

Barnard, however, had no such scruples. Furthermore, opinion in South Africa was more permissive. Fewer questions would have been asked and there would have been less accountability had the operation failed.¹⁴⁹ Indeed, a special issue of the South African Medical Journal celebrating the event never mentioned or discussed the ethical and legal issues surrounding the removal of the heart from the donor.¹⁵⁰

Barnard needed success and he had the audacity and the determination to be the first. He was egocentric, ambitious, brash and arrogant, functioning on the principle that anything others could do he could do at least as well.¹⁵¹ He persuaded his colleagues to refer patients for transplantation by stating that there was no risk to these patients if they only had a few days or hours to live. He believed any such patient would beg for a chance to live.¹⁵²

Ross stated:

He had the courage to do it, but the background knowledge belongs to the Shumway group... We were just following like sheep in the background. We all did the operation because they showed us the way, and Barnard had the courage to do it first.¹⁵³

Although technically the operation was a success, the patient died 18 days later from a chest infection. Clearly when complications set in the doctors had no idea what to do next, illustrating that the operation was experimental in the extreme. They had no idea how to combat rejection. This picture of great uncertainty on how to treat the deteriorating patient was repeated throughout the world when other surgeons started undertaking heart transplants.

To illustrate the prevailing naivete in respect of the problem of rejection, Shumway ridiculously reasoned that the heart would be less antigenic than the kidney because

[the heart] is a far less complex tissue than either skin or kidney and perhaps therefore less antigenic. ... teleologically, perhaps the animal would be reluctant to shed such a vital foreign tissue!¹⁵⁴

However, by early 1971, assessment of the first 170 heart transplants established that the heart was not a privileged organ as regards rejection.¹⁵⁵

¹⁴⁹ Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. *BMJ* 2001;323:1478-80

¹⁵⁰ Heart transplantation. *S Afr Med J* 1967;41:1257-78.

¹⁵¹ Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. *BMJ* 2001;323:1478-80

¹⁵² Barnard C, Pepper CB. *One life*. New York: Macmillan. 1969.

¹⁵³ Ross D. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p5

¹⁵⁴ Shumway NE, Angell WW, Wuerflein RD. Heart replacement: The cardiac chimera vs. mechanical man. *Lancet* 1968;88(July):172.

In the first such operation, despite the majority opinion of the doctors involved, Barnard believed the problem was one of rejection, although clearly the cause of the deterioration was infection. When it was obvious the patient was dying Barnard, in an act of desperation, wanted to put him back onto the heart lung machine, thereby prolonging the patient's agony, because he himself could not give up.¹⁵⁶

Paradoxically, despite all the problems, the world media still believed that all was well. The reasons were that the world wanted to believe that such operations were possible.¹⁵⁷ For example, it was said that:

The early round of heart transplants should be considered a success in that they have provoked the kind of concentrated effort that ... is sure to bring valuable progress.¹⁵⁸

Indeed, the early era of transplantation was described as being a time of 'tremendous euphoria.'¹⁵⁹ Public opinion in countries around the world virtually forced doctors into attempting heart transplants. In May 1968 a team from the United Kingdom undertook the world's 10th heart transplant. By the end of the year a further 95 had been performed worldwide by 64 surgical teams in 24 countries.¹⁶⁰

One reason why so many surgeons jumped onto the bandwagon was because very few had even heard of Barnard. They reasoned that if an obscure surgeon in South Africa could undertake a heart transplant, then it could not be too difficult to undertake.¹⁶¹

Other factors that led to the explosion in heart transplants around the world were not only medical or surgical. All over the world, in various 'advanced' countries, it was felt that a transplant had to be attempted. There was 'a very nationalistic dimension to it.'¹⁶² The UK team that undertook the first such operation was photographed with a Union Jack and a poster stating 'We're backing Britain.'¹⁶³ Furthermore there was a powerful symbolism in heart transplants that contributed to the boom.

155 Thompson T. *Hearts*. New York: McCall, 1971

156 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971.

157 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971.

158 Stinson EB, Dong E Jr, Schroeder JS, Harrison DC, Shumway NE. Initial clinical experience with heart transplantation. *Amer J Cardiol* 1968;791-803 at p802.

159 Rochelle D. Thompson T. *Hearts*. New York: McCall, 1971 at p167.

160 Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. *BMJ* 2001;323:1478-80

161 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971.

162 Fox R. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p50.

163 Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. *BMJ* 2001;323:1478-80

Other doctors, however, believed that much damage was done to the image of heart transplantation by this unseemly scramble, with many operations undertaken by ill trained surgeons without proper back up and with poor matching of donor and recipient, no proper aftercare and little appreciation of the management of rejection.¹⁶⁴ One heart surgeon named Harken felt that the risks of the operation heavily outweighed any benefits.¹⁶⁵

It must be noted that while the early operations were purely experimental, these later operations also involved an element of personal innovation. As the operation became established, later surgeons were undertaking a recognised intervention for the first time. Furthermore, the results of these personal innovators were worse than those achieved by the early experimenters.¹⁶⁶ For example, despite much of the criticism being directed at Barnard, his results were very good. Three of his first five patients survived more than eighteen months, one dying twelve and a half years after surgery.¹⁶⁷ Thus although Barnard was an experimenter, after a few cases it was becoming an accepted technique in his hands. Unfortunately for many of the later surgeons the results were very poor and resulted in patients suffering harm and dying unnecessarily. This serves to highlight that patients needed as much if not more protection from personal innovators as they did from the early experimenters.

The UK's first heart transplant:

The first heart transplant in the UK was undertaken on 3 May 1968. A leading article in the British Medical Journal stated that:

On the third of May the tenth heart transplant in the world was successfully accomplished at the National Heart Hospital, London. Mr Donald Ross, Mr JK Ross and Mr Donald Longmore and their team deserve the congratulations of their colleagues on the success of their first human transplant.¹⁶⁸

The first UK donor was a man called Patrick Ryan. The top of his head had been cut off in a building accident. He had a beating heart but essentially no brain. It must be remembered that at that time there were no brain stem death criteria.¹⁶⁹ It appears that the surgeons waited for the heart to stop before taking it out. They switched the ventilator off, waited till all the various recordings were flat and then the ventilator was restarted and external cardiac massage given. A similar occurrence had occurred in South Africa where

164 Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. *BMJ* 2001;323:1478-80

165 Harken DE in Blumgart HL. The medical framework for viewing the problem of human experimentation. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller, 1970, p57.

166 Thorwald J. *The Patients*. New York: Harcourt Brace Jovanovich, 1971.

167 Barnard CN. The first human-to-human transplant. in: *History of Transplantation: Thirty-Five Recollections*. Terasaki PI (ed). Los Angeles: UCLA Tissue Typing Laboratory, 1991. 565-584 at 580.

168 Anon. First British heart transplant. *BMJ* 1968; ii:315.

169 Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999, p32-34.

Barnard first disconnected the donor's ventilator and then waited for the heart to stop beating.¹⁷⁰

The difficult medico-legal issues at the time are illustrated by the fact that some anaesthetists in the United States had been warned by the local district attorney that involvement in heart transplants could lead to them being indicted for murder.¹⁷¹

Others, however, offered helpful advice. One friendly district attorney was quoted as saying

it would appear to me that due to the uniqueness of such operational procedures and the lack of the ability of the law to anticipate problems until they arise that this entire matter requires the utmost co-operation and understanding by all concerned.¹⁷²

The heart transplantation operations thus initiated philosophical, ethical and legal inquiry about concepts of death, culminating in October 1976 when the criteria for the diagnosis of brain-stem death were published.¹⁷³ From an ethico-legal standpoint this was a great advance.

Interestingly in Japan, Juro Wada, who performed the world's 32nd heart transplant in 1968, was indicted for murder, although he was not prosecuted because of lack of evidence.¹⁷⁴ The next transplant undertaken in Japan was over 30 years later, in 1999, following the introduction of a law permitting the use of organs from brain-dead patients.¹⁷⁵

In the early days in the US some believed that the lawyers should have set guidelines to protect the surgeons and anaesthesiologists in advance. The lawyers responded that '... medicine ha[d] to establish [its] procedures and we will try to determine how to legalize them afterwards.'¹⁷⁶

A heart surgeon in Houston, Texas, called Denton Cooley, mirrored the arrogance displayed by Barnard. His competitiveness with a senior colleague, Michael DeBakey, culminated in the premature use of the first artificial heart.

170 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971.

171 Bunker J. in: *The Anesthesiologist and the Surgeon*. Boston, MA: Little Brown, 1972. Transplanting the heart at Stanford; Shumway and the anesthesiologists', 123-138.

172 District Attorney, Santa Clara County. *San Jose Mercury*, 27 August 1968, quoted in Bunker J. in: *The Anesthesiologist and the Surgeon*. Boston, MA: Little Brown, 1972. Transplanting the heart at Stanford; Shumway and the anesthesiologists', 123-138 at p131.

173 Jennett B, Hissett C. Brain death in Britain as reflected in renal donors. *BMJ* 1981;283:359-62.

174 Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p34

175 Japan: Law No 104 of 16 July 1997

176 Bunker J. in Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p23

DeBakey's view was that the assessment of the risks of heart transplants was still not complete.

Since the physician can never afford to delay medical treatment until knowledge is complete and risk is entirely removed, he must apply current knowledge cautiously and judiciously, weighing the benefits against the hazards, in his efforts to relieve suffering and cure disease. Continued clinical trials [of transplants] are therefore necessary, but only after the most sober deliberation and most prudent consideration of all present evidence of their potential usefulness and limited scope. The indications for transplantation of the human heart must therefore be carefully delineated. The competing risks must be thoroughly assessed¹⁷⁷

It is also well reported that Cooley at first was not keen on undertaking transplants.¹⁷⁸ However, at a meeting in South America, which was also attended by Barnard who had just performed the first human heart transplant, he claimed sorrowfully:

I went there as a surgeon with the largest cardiac series in the history of medicine, and nobody even knew my name.¹⁷⁹

It therefore appears that the reasons Cooley started undertaking heart transplants were purely personal, with the aim of achieving recognition through scientific ambition. Thus, in May 1968, in less than three weeks, he undertook 4 transplants.

Prior to his first transplant, Cooley had done only one practice operation, on a cadaver. Since he had undertaken more heart surgery than anyone else had he felt he was prepared. There are thus elements of both experimentation (he started undertaking the operations soon after Barnard's first attempt) and personal innovation in these first operations.

His first patient had come to hospital expecting to receive new heart valves. Cooley explained that it might not be possible to do so and if that were the case the patient would die. Only a heart transplant could save him. One surgeon present in the operating room that day said there was no doubt that the heart needed replacing. But 'it goes without saying that it would have been considerably anticlimactic to call everything off at that point and just put in three valves.'¹⁸⁰

Cooley's arrogance can be best demonstrated by his attitude to cooling the heart prior to transplantation. Surgeons believed, and still do, that it was necessary to cool the donor heart immediately once it was removed from the donor. Cooley, however, decreed this was not necessary and that a heart

177 deBakey M. in Thompson T. *Hearts*. New York: McCall, 1971 at p200.

178 Thompson T. *Hearts*. New York: McCall, 1971.

179 Cooley D. in Thompson T. *Hearts*. New York: McCall, 1971 at p149.

180 Thompson T. *Hearts*. New York: McCall, 1971 at p154.

could remain in transplantable condition for up to an hour at room temperature,¹⁸¹ despite there being no evidence to support this.

A statement he made to a visiting psychiatrist following his foray into heart transplantation epitomized his ego:

... I as a personality was vaulted into some sort of orbit where they thought I was some kind of super-surgeon. ... It was fantastic!¹⁸²

Rochelle, one of the immunologists in Houston at the time of the first transplants, believed Cooley was prepared to transplant everybody. Out of the first nine, three were almost dead before they went into surgery and never stood a chance.

Denton took (th)em on anyway – to hell with statistics! To the surgeon, it was almost akin to really being god. It was a feeling of rare ecstasy that enveloped Denton. He was given the power to grant life!¹⁸³

Not everything went according to plan. Bizarrely, when a donor heart could not be found for a dying patient, Cooley tried implanting a ram's heart. When this immediately rejected on the operating table he requested a large pig be brought down to theatre. However, it became very difficult to anaesthetise this pig and eventually the patient succumbed before the pig's heart could be implanted.¹⁸⁴

Cooley's inability to let his prize patient, Everett Thomas, die was remarkably similar to Barnard's inability to give up on Washkansky and Blaiberg (his second patient). When the transplanted heart started failing both surgeons considered the option of implanting a second new heart. Indeed Cooley did precisely that in November 1968. This heart lasted only a few hours. At the same time Shumway at Stanford, in a similar act of desperation, had also implanted a second heart into a patient whose first transplanted heart only lasted a few hours.

...Shumway immediately repeated the experiment... because a donor happened to be available.¹⁸⁵

Within a few months the euphoria surrounding heart transplants disappeared once it was realised that the majority of the operations both in the United States and around the world had failed. After three years, 166 heart transplants had been undertaken world-wide but only 23 patients were still alive, an overall mortality rate of 85 percent. Ten of the twenty three however had survived for more than two years.¹⁸⁶ Cooley's poor success rate was

181 Thompson T. *Hearts*. New York: McCall, 1971 at p155.

182 Thompson T. *Hearts*. New York: McCall, 1971 at p167.

183 Rochelle D. Thompson T. *Hearts*. New York: McCall, 1971 at p167.

184 Thompson T. *Hearts*. New York: McCall, 1971 at p185.

185 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at 317-8.

186 Thompson T. *Hearts*. New York: McCall, 1971.

described as an impressively macabre series.¹⁸⁷ Surprisingly, he still believed that heart transplants could be undertaken with very low risk, with mortality of 5 percent, and become a routine operation within a decade.¹⁸⁸

In the UK many doctors disapproved of heart transplantation and believed that those who had undertaken them should be disciplined.¹⁸⁹ There was similar disapproval in the US.¹⁹⁰ The press also took a different view from previously. At first it reported that heart transplantation was 'a wonderful operation' but this was soon followed by 'how dreadful it all was'.¹⁹¹

However, it was not only the failure rate that was coming under scrutiny but also the consent process and where on the research /experimental innovation /therapy continuum transplantation belonged. As mentioned in the previous chapter, many of the surgeons considered the operation to be therapeutic. These issues were brought into greater focus when Cooley implanted an artificial heart into Haskell Karp in April 1969, marking the first time such an event had occurred in medicine.¹⁹²

The first artificial heart:

Cooley's surgical first of using a complete mechanical substitute for the heart attracted worldwide publicity. This was undertaken in April 1969 and implanted into a patient called Haskell Karp. The patient's widow sued, raising questions of consent and the experimental nature of the procedure. The legal aspects of this case will be reviewed later.

Karp was a forty seven year old man who had been incapacitated by a series of heart attacks. When he arrived in Houston, Karp did not want a heart transplant and merely wanted his own heart repaired. Cooley attempted to persuade Karp that a heart transplant was essential. He believed Karp was 'disinclined to accept what was necessary for him...' conveniently forgetting that the vast majority of his recipients had died.¹⁹³

At first Karp had no idea that Cooley had plans to insert an artificial heart into him. Cooley explained that he would try to repair the heart but if that failed the patient would die on the table unless other steps were taken. If no donor heart were available then Cooley would have to use an artificial device¹⁹⁴ as a stop gap until a donor could be found. Karp reluctantly signed a consent form to

187 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p291

188 Cooley D. Thompson T. *Hearts*. New York: McCall, 1971 at p172.

189 Somerville J. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p27

190 Bunker J. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p28

191 Longmore D. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p27

192 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971.

193 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p397.

194 Reinhard HC Jr. in Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p402.

that effect. He was convinced, however, that Cooley would succeed in repairing his heart.

During the operation Cooley did as he had promised and for an hour tried to repair the damaged heart. It soon became obvious however that this would be unsuccessful and because no donor heart was immediately available the implantation of the artificial heart had to be attempted to allow the patient to be taken off the heart-lung machine. Cooley maintains that the intention all along was to perform heart muscle repair and only when it became obvious this would not be successful did he resort to the artificial pump in a desperate attempt to save the patient's life.¹⁹⁵

The artificial heart kept Karp alive for 64 hours. During this time it became increasingly obvious that serious complications were setting in. It was then removed and replaced by a human donor heart. Unfortunately by then the damage had been done and the patient died 32 hours later.

Following the operation the medical community was deeply divided as to its merits. One group believed that it was a brilliant scientific breakthrough. Others believed it was an act of betrayal and a severe breach of ethics. It was a reckless attempt, which was undertaken solely in the interests of ambition and would bring discredit to the whole artificial heart project.¹⁹⁶ Yet again, many members of the medical community were surprised at the news, believing firstly, that the clinical use of an artificial heart was many years away and, secondly, that Cooley was not associated with work in this area.¹⁹⁷ This situation is analogous to when Barnard unexpectedly undertook the first heart transplant.

The primary motivation and the degree to which it was premeditated warrant further examination. It is clear that Cooley had not followed carefully laid out guidelines pertaining to surgery of an experimental nature. He had not discussed it with DeBakey, the senior investigator and the man who had actually developed the artificial heart, and he had not asked for permission to perform the surgery from the Baylor Committee on Research Involving Human Beings. Cooley did not ask because he knew he would be turned down.¹⁹⁸ He also explained that 'we had to try it sometime and here was the ideal patient.'¹⁹⁹

In the background to the whole affair were the ambitions and jealousies of the two surgeons, Cooley and DeBakey.²⁰⁰ In Houston at the time there was major conflict between the two. DeBakey was the more senior and Cooley

195 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p405.

196 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p411.

197 Fox RC, Swazey JP. *The Courage to Fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984, p139

198 Thompson T. *Hearts*. New York: McCall, 1971 at p213-4.

199 Cooley D in Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p401.

200 Thompson T. *Hearts*. New York: McCall, 1971 at p211.

wanted to get out of his shadow. There was very much a conflict and competition between the two to be first. Cooley's feat of implanting the artificial heart was the very one DeBakey had been investigating and planning for years. Following the decline in heart transplantation, Cooley wanted to be the first to implant an artificial heart and forestall DeBakey. '... Cooley had an emotional vested interest in replacing Mr. Karp's heart with a cardiac prosthesis.'²⁰¹ His strong drive for achievement, success, and fame was a motive to which he unashamedly testified.²⁰²

Cooley has always claimed that his use of the artificial pump in Mr Karp had only come about because the patient was dying on the operating table and no human donor heart was available. However, it was clear that he had planned to use the artificial heart because he arranged for all the technicians and equipment to be in place in the operating theatre prior to starting Karp's operation.

It is also apparent that Cooley 'stole' the artificial heart developed by DeBakey. One of DeBakey's engineers, Liotta, who had been heavily involved in the implant's development, unknown to DeBakey, started working for Cooley because he believed DeBakey was not ready to take the next step and implant it into a human being. 'If you don't have a man who will go ahead and take the risk then my work is valueless.'²⁰³ Cooley made some very minor changes to DeBakey's design and passed it off as his own.²⁰⁴

A different stance was taken by the first engineer approached to look after the equipment that allowed the artificial heart to work. He had previously worked with DeBakey and refused to be involved as soon as he realised that an experiment on a human being was being attempted.²⁰⁵

The National Heart Institute also raised concerns and requested data on the testing and evaluation of the device in animals prior to its use in humans. Furthermore, it requested information on whether the clinical application had been reviewed by the local committee for human investigation.²⁰⁶

In the meantime DeBakey joined in the chorus of disapproval. He found it inconceivable that Cooley could use the pump in a patient knowing of its prior very poor performance in animals.

201 Fox RC, Swazey JP. *The Courage to Fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984, p153

202 Fox RC, Swazey JP. *The Courage to Fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984, p175

203 Liotta D. in Thompson T. *Hearts*. New York: McCall, 1971 at p213.

204 Thompson T. *Hearts*. New York: McCall, 1971.

205 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p403.

206 Thompson T. *Hearts*. New York: McCall, 1971 at p214.

Application of an unproved device ... into a human being for primary experimentation before its safety and effectiveness have been proved scientifically in animal experiments is a breach of scientific ethics.²⁰⁷

Cooley argued that the pump would keep a dying patient alive for long enough until a human heart donor could be found.²⁰⁸ It is not clear, however, on what evidence he based this. He had undertaken virtually no animal research in artificial heart transplants and had apparently only tested the pump in seven calves. Though all died, one lived for 44 hours. Remarkably, Cooley felt this was enough experimentation to allow him to proceed to the next stage (i.e. human trial) and was convinced it would function longer in humans.²⁰⁹ Again, there was little evidence to support this. Indeed, there appears to be little evidence that he had in fact undertaken any animal studies and those which he did quote (ie the seven calves) appear to have been undertaken by DeBakey's team, who had published their results.²¹⁰ Whatever, Cooley knew of the technical and medical problems that had occurred in these experiments but despite this, decided to proceed.

He believed that, based on his experience he was qualified to judge what was right and proper for his patients.

The permission I receive to do what I do, I receive from my patients. It is not received from a government agency or from one of my seniors.
211

However, Moore stated:

There is simply no evidence to suggest that [the artificial heart] would be helpful. It raises false hopes for the patient and his family, it calls into discredit all of biomedical science, and it gives the impression that physicians and surgeons are adventurers rather than circumspect persons seeking to help the suffering and dying by the use of hopeful measures.²¹²

Despite criticism in the US, other countries feted Cooley like a king, awarding him countless national honours. For example, Spain bestowed the Grand Cross of Alfonso X on Cooley and Liotta in honour of 'meritorious service to medicine. The implantation of the artificial heart was a moment in history.'²¹³

Thirteen years later, in December 1982, an artificial heart designed by Jarvik was transplanted into a retired dentist, Barney Clark. The patient died a few

207 DeBakey M. in Thompson T. *Hearts*. New York: McCall, 1971 at p215.

208 Cooley D. in Thompson T. *Hearts*. New York: McCall, 1971 at p215.

209 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p400.

210 DeBakey M, Hall CW, et al. Orthotopic cardiac prosthesis: preliminary experiments in animals with biventricular artificial heart. *Cardiovasc Res Cent Bull* 1969;7:127-142.

211 Cooley D in Thompson T. *Hearts*. New York: McCall, 1971 at p216.

212 Moore FD. *Transplant: The give and take of tissue transplantation*. New York: Simon and Schuster, 1972, at 275.

213 Martinez-Bordieu C in Thompson T. *Hearts*. New York: McCall, 1971 at p233.

weeks later but it was claimed that 'a great deal was learned about the potential and limitations of this procedure.'²¹⁴

Again there was great debate about whether this was acceptable. Yet again a patient was experimented upon and this was justified by the knowledge this would generate. As has been said:

One can argue that his story is grotesque, an ugly assault on a gullible, desperate, vulnerable, and ill-chosen patient. One can argue that it is a story with great dramatic appeal, and hence with substantial literary merit. Or one can argue that it is a beautiful example of a stage in the process of scientific progress.²¹⁵

These words, written when discussing the merits of implanting the Jarvik artificial heart into Barney Clark, are equally applicable to a discussion on the Karp case or even the first human heart transplant by Barnard.

There is little doubt that scientific progress did occur. However this appears to have been at the expense of patients, who were subjected to an experimental procedure in the interests of society and for the personal benefit (in terms of personal fame) of arrogant surgeons. Thus experimental innovation cannot be justified by reference to normal ethical codes of conduct applicable to therapy.

PERSONAL INNOVATION- THE BRISTOL AFFAIR^{216 217}

On May 29 1998 the Professional Conduct Committee (PCC) of the United Kingdom's General Medical Council announced that there was sufficient factual evidence to find three Bristol doctors guilty of serious professional misconduct.²¹⁸ The investigation lasted eight months and centred on charges that between 1988 and 1995, surgeons James Wisheart and Janardan Dhasmana continued to undertake paediatric cardiac procedures, despite colleagues' concerns about excess mortality. In addition, the then Chief Executive of the United Bristol Healthcare NHS Trust, John Roylance, was accused of not intervening when this was brought to his attention. Wisheart and Roylance were erased from the Medical Register. Dhasmana was banned from undertaking paediatric procedures for three years.

The PCC investigated the cases of 53 children; 29 died and four were left with some form of brain damage. Wisheart, who at the time was also the Medical Director of the Trust, was investigated over the correction of 15 atrioventricular septal defects (AVSD) performed between April 1990 and

²¹⁴ Leinward G. *Transplants: Today's Medical Miracles*. New York: Franklin Watts, 2nd ed. 1992, at p24.

²¹⁵ Gorovitz S. *The Artificial Heart: Questions to Ask, and Not to Ask*. *Hastings Center Report*, 1984;14(5):15-17 at p17.

²¹⁶ Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001

²¹⁷ Department of Health. *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*. CM 5363. London:HMSO, 2002

²¹⁸ Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

August 1994; nine children died. Evidence was taken on 38 arterial switch operations for transposition of the great arteries that Dhasmana undertook between February 1988 and January 1995; 20 of these patients died.²¹⁹

The Bristol programme of arterial switch operations for transposition of the great arteries had been started in 1988. Dhasmana started performing 'switches' on babies and toddlers in February of that year and on neonates in 1992. Between 1988 and 1990 he had operated on nine patients, of whom five died. He excused the level of mortality and morbidity as being due to his learning curve, blaming 'beginner's bad luck' for some of the deaths.²²⁰ He argued that every surgeon experiences a learning curve when he or she starts to undertake a new procedure and that he had sought advice on how to improve his technique.²²¹ Indeed, he claimed no-one had tried to dissuade him from moving on to neonatal switches.

Dhasmana therefore is a clear example of the 'personal innovator' described in the last chapter. He was trying to learn an established technique, the arterial switch operation for transposition of the great arteries. The switch had presented a particular dilemma for surgeons in balancing risk and benefit. It had replaced well-established but only palliative operations (devised by Senning and Mustard). During the 1980s more and more surgeons turned to the technically exacting, but in the long-term more satisfactory, arterial switch operation with the objective of restoring normal expectation of life and function. The transition, however, entailed the possibility of an increase in the operative mortality for this condition (of transposition) when surgeons first started performing this operation. The operation eventually became the standard of care, but precise pre-operative assessment, impeccable surgical technique and skilled peri-operative care are needed for consistently good results.²²²

The GMC's Findings:

The GMC's Conduct Committee's statement began with an affirmation that trust lay at the centre of any doctor/patient encounter. Action would be taken when it appeared that a doctor had betrayed that trust. Any inquiry into an alleged breach of trust would be governed by objectivity and fairness without recourse to emotion, the benefit of hindsight, or judgement made mercilessly according to the highest achievable performance.²²³

The PCC was satisfied that there was evidence to prove that Wisheart was made aware on several occasions, starting in 1990, of the concern of professional colleagues about the level of mortality and morbidity in paediatric cardiac surgery at the hospital. Despite this concern, and despite the fact that Wisheart's previous 12 AVSD corrections had resulted in six deaths, he operated on further patients who subsequently died. The PCC concluded that

219 Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

220 Dyer C. Surgeon blamed beginner's bad luck for cardiac deaths. *BMJ* 1998;316:1114

221 Dyer C. Compensation claims expected to follow GMC's findings. *BMJ* 1998;316:1691

222 Treasure T. Lessons from the Bristol case. *BMJ* 1998;316:1685-6

223 Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

Wisheart had undertaken operations without seeking and obtaining adequate retraining, assistance or advice; and without paying sufficient regard to the safety and best interests of the patients concerned when deciding whether to operate. There was no available reason to explain why his results were worse than those of his colleagues.

In addition, the PCC concluded that Wisheart had mislead two sets of parents when he had said that the risks of mortality were 20-25%, a figure that did not accurately reflect his own experience as a surgeon. He had denied the parents the facts they needed in order to make informed decisions about their child's treatment. Indeed, the prosecution claimed that all parents had been given an exaggerated estimate of the chance of a successful operation at the Bristol Royal Infirmary.

It also found that Wisheart, in his capacity as Dhasmana's senior colleague, had failed to heed advice in 1992 regarding the continuation of Dhasmana's arterial switch programme. Having agreed with Roylance that there should be an external review of the operations that were causing concern, Wisheart withheld this information from Dhasmana and other clinical colleagues at a critical time.

Dhasmana in turn knew that he was less successful than his peers in the UK at arterial switch procedures for transposition of the great arteries. He discussed his results with others and he visited another specialist centre to improve his surgical skills. The Committee agreed that he displayed concern but concluded that his efforts were insufficient. The PCC found that in 1993, despite undertaking 32 arterial switch procedures in which 16 neonates died, Dhasmana went on to perform two more procedures; one child subsequently died. Thus, despite being unable to find a cause for his inferior results apart from his belief that he needed more experience Dhasmana continued to operate, which was a serious departure from safe and proper practice. As with Wisheart, the PCC found that Dhasmana had failed to do sufficient self-audit, had not sought or obtained retraining and had not sufficiently considered the best interest of the patients when deciding whether to operate. The PCC was also satisfied that Dhasmana was made aware of concerns about his work at a meeting in late 1994.

The PCC found that Dhasmana proceeded with an operation on Joshua Loveday in the face of colleagues' concerns. Wisheart, as Medical Director, gave permission for the operation to go ahead despite concerns expressed by professional colleagues at meetings and in writing, and despite the fact that he ought to have known that the operation was not in the child's best interests. Joshua Loveday died. The internal self-regulatory mechanisms failed.

The PCC found proven that, in addition to receiving letters from a consultant anaesthetist, Stephen Bolsin, Roylance was alerted several times about the high mortality rate of paediatric cardiac surgery at the hospital. Despite this he failed to act, especially by not bringing in external assessment by other clinicians or the Department of Health. Roylance was found to have ignored

the concern expressed by the Professor of Adult Cardiac Surgery at the hospital and by the Department of Health that the operation was to go ahead.²²⁴ Again, although there was a possibility of some form of regulation through external assessment, it did not occur and, it could be argued, at the time, there was no requirement for it.

Interestingly the General Medical Council also warned several consultant colleagues that their conduct might also be open to question.²²⁵ Furthermore, the evidence presented showed failings in pre-operative diagnosis, such that the surgeons often went into operations with an incomplete picture of the heart defect they were meant to repair.²²⁶

Compensation claims totaling at least £10 million pounds are expected to follow. United Bristol Healthcare Trust have publicly admitted liability for injuries to a child brain damaged during heart surgery. A spokesman for the Trust said it had admitted breaching its duty to Ian Stewart in that it failed to provide accurate information to his parents.²²⁷

Key Issues:

Several key issues emerged from the GMC's judgement. First, in the case of the two surgeons James Wisheart and Janardan Dhasmana, there was a conspicuous lack both of self-audit and of willingness to seek and obtain retraining, indirectly denying the presence of learning curves. New techniques had been introduced which had not been available during their pre-consultant training period. They had never, therefore, been properly trained to undertake these procedures. Second, in the case of Chief Executive John Roylance, there was an unwillingness to use the power of his managerial position to intervene in clinical activities. Third, all three clinicians, at some point, ignored the concerns about excessive mortality expressed to them by professional colleagues. Furthermore, professional bodies outside Bristol, such as the Royal College of Surgeons and the Department of Health, were aware of the poor success rates in paediatric cardiac surgery at Bristol, yet either failed to act or did not use their position of authority to apply consistent pressure to force a change in practice. Formal action was taken only after an anaesthetist blew the whistle on his colleagues.²²⁸

The determination ended by raising a number of issues that arose during the course of the inquiry concerning the practice of surgery and of medicine generally. In the view of the Committee, these matters needed to be addressed urgently by the profession and others. Troubling deficiencies were identified in professional accountability, honesty and integrity, and the maintenance of standards of good medical practice.²²⁹

224 Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

225 Delamothe A. Who killed Cock Robin? *BMJ* 1998;316:1757

226 Dyer C. Compensation claims expected to follow GMC's findings. *BMJ* 1998;316:1691

227 Dyer C. Bristol trust admits liability in baby heart surgery case. *BMJ* 1999;319:213

228 Anon. First lessons from the "Bristol case." *Lancet* 1998;351:1669

229 Horton R. How should doctors respond to the CMC's judgments on Bristol? *Lancet* 1998;351:1900

Some of the wider issues identified by the GMC that particularly apply to this thesis are:

- A How clinical competence and technical expertise are assessed and evaluated.
- B The training of doctors in advanced procedures.
- C How to approach the so-called learning curve of doctors undertaking established procedures.
- D The reliability and validity of the data used to monitor doctors' personal performance.
- E The use of medical and clinical audit.
- F How doctors explain risks to patients.

Of perhaps greater significance, but not specifically addressed by the committee, is the question of self-regulation by the medical profession.²³⁰ Many of the above issues will be examined in later chapters.

After the GMC's decision came the recriminations, followed by the questions that won't go away. Firstly why weren't the surgeons stopped from operating on young children once their poor results became widely known? Immediate colleagues, their employer, the Royal College of Surgeons and the Department of Health all knew or had been told how badly they had been doing. The United Kingdom Cardiac Surgery Register, to whom cardiac surgeons voluntarily submit their annual figures, has been run by the Society of Cardio-thoracic Surgeons of Great Britain and Ireland since 1977.²³¹ It has provided a useful benchmark against which to discuss variations in the provision of services and for individual surgeons to monitor their own mortality figures against a national average. At the time it was set up there was an assumption that the patients and surgeons in the dataset were anonymous and would remain so. Furthermore the use of that benchmark to assess one's own practice was a matter of honour and personal reflection.²³² This register, to which Bristol contributed data, was available for comparison throughout this time. Furthermore, the surgery undertaken in Bristol, which was the subject of the General Medical Council's disciplinary case, was within the realms of routine practice, for which there were known and well established standards. Thus Bristol was not a form of 'experimental innovation' as described in the last chapter and illustrated earlier in this chapter by the introduction of organ transplantation and the first artificial heart. The Bristol case exemplifies personal innovation on the part of the surgeons concerned and, once again, points to a failure of regulation.

Following the GMC's decision, the Health Secretary announced a Public Inquiry. At the time it was felt that one likely outcome of this would be a system of performance indicators for surgeons.²³³ The inquiry also looked at the wider issues that the saga has thrown up for the Health Service as a whole, such as the determination of performance and professional and

²³⁰ Anon. First lessons from the "Bristol case." *Lancet* 1998;351:1669

²³¹ English TAH, Bailey AR, Dark JF, Williams WC. The UK cardiac surgical register 1977-82. *BMJ* 1984;289:1205-8

²³² Treasure T. Lessons from the Bristol case. *BMJ* 1998;316:1685-6

²³³ Dyer C. Compensation claims expected to follow GMC's findings. *BMJ* 1998;316:1691

managerial culture. The inquiry has now published its findings²³⁴ and the Government has issued its response.²³⁵ The report stated that in the period from 1991 to 1995, between 30 and 35 more children under the age of 1 died after open-heart surgery in the Bristol Unit than might be expected had the Unit been typical of other Paediatric Care Surgical units in England at the time. This mortality rate was probably double the rate in England at the time and was even higher for children under 30 days. Issues raised were the competence of the healthcare professionals, standards of care, monitoring of performance and the gaining of consent for surgery. Recommendations made will be reviewed when assessing how self-regulation, the use of performance tables and guidelines, learning curves and issues of consent can be used to regulate innovation.

CONCLUSION:

In cardiac surgery there are high expectations of good results for tens of thousands of patients each year. As Treasure states²³⁶, it is easy to recall the surgeons who performed the first heart operations, used cardio-pulmonary bypass while it was still in its infancy, or who first started transplantation, all of which were undertaken with a high initial mortality. They worked on in the face of doubt, scepticism and often widely publicised criticism. They are now remembered with respect, having had the courage to fail. Many others, equally determined, did fail and are not remembered.

Some of that determination in the face of possible failure is necessary in every surgeon. This, however, may be at the expense of patients. Indeed, although these innovators are, as Treasure states²³⁷, remembered with respect, few remember the early patients who suffered so that later generations may gain. Similarly patients operated upon by surgeons in the early part of their learning curve also may suffer so that later patients may gain when the surgeon becomes more accomplished.

These patients, whether experimented upon or suffering at the hands of personal innovators, deserved protection. Clearly this chapter illustrates that they did not receive this. This is the consequence of a failure to regulate innovation.

Dr Simon Joseph, who was the Resident Surgical Officer in the Intensive Therapy Unit at the time of the first UK heart transplant in 1968 stated in 1999:

The thing that strikes me now, looking back on it, was the relative freedom that everybody had to do it. If one was making a world-shaking advance now, one would probably have to apply to statutory

234 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

235 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002

236 Treasure T. Lessons from the Bristol case. BMJ 1998;316:1685-6

237 Treasure T. Lessons from the Bristol case. BMJ 1998;316:1685-6

bodies for permission, acquire the funds and get it approved by many committees. I imagine that it would be much more difficult today.²³⁸

If such a structure exists it needs to ensure that the interests of patients, either those subjected to experimentation or exposed to personal innovators, are safeguarded. Three structures exist: self regulation by the medical profession, governmental control through regulatory bodies and the legal system. The next chapter will consider whether regulation through the medical profession itself has the ability to provide such protection.

²³⁸ Joseph S. in Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p13

THE REGULATION OF INNOVATION

CHAPTER 3:

THE PROFESSIONS AND SELF-REGULATION	60
Three forms of law	60
The introduction of self-regulation	61
The General Medical Council	62
The experiment of heart transplantation	64
The moratorium	66
Personal innovation: Bristol	67
Learning curves	69
Supervision	72
Openness	72
A hospital system	72
Evidence of acceptance of	
Recommendations	73
Supervision – revisited	73
Performance tables	75
The impact on consumer actions	77
The impact on providers	78
The reliability of league tables	79
Therapeutic Innovation and Self regulation	81
Criticism	82
Does self-regulation work?	83
SERNIP	85
Research	86
Regulating research	86
Concerns?	87
Fraud and misconduct	88
Conclusions	90

Chapter 3: The Professions and Self-Regulation:

The law plays a vital role in regulating the practice of medicine, with many regulatory schemes, both statutory and non-statutory, involved. The definition of law used in this thesis is that employed by Montgomery²³⁹, whereby the idea of law connotes rules that govern practice, and thereby covers those principles which people are bound to follow. A law is therefore an instruction given by a legitimate authority and as such there may be different types of 'law'.

THREE FORMS OF LAW:

With reference to the authorities which make the law:

Law in the strict sense is made by the courts or Parliament, is binding on all citizens, and usually enforced in the courts. Professional law on the other hand is made and policed by regulatory bodies, set up by statute but left largely to their own devices. This type of law binds only the members of the profession but is backed up by significant sanctions. The third type of law..., quasi-law, describes rules which may be made without explicit legal authority and which are most important for the guidance they offer rather than the sanctions which follow if they are disregarded.²⁴⁰

Professionals are more concerned with 'professional law' and doing what is right than avoiding punishment.²⁴¹ This form of law, that of self-regulation, will be reviewed in this chapter. Indeed, one of the central issues of the Bristol Inquiry was the question of self-regulation by the medical profession.²⁴²

Society has used the concept of the profession to organise and deliver many of the complex services it requires, with the rationale that the expertise necessary to the practice of certain vocations is not easily comprehensible to the ordinary citizen.²⁴³ Traditional professionalism came to apply to knowledge-based activities requiring long periods of education and training and entailing service for the common good.

According to Rosenthal, occupations attaining the status of a 'profession' have the following characteristics. They possess a systematic body of highly developed technical knowledge that is widely valued. There are strong standards of autonomy that emphasise self-regulation and altruism that submerge self-interest and emphasise service. There is a need for authority over clients, a distinct occupational culture and collegial etiquette and finally, there is recognition of this professional status by political, social and economic

239 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p5

240 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p5.

241 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p5.

242 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001.

243 Cruess RL, Cruess SR, Johnston SE. Professionalism: an ideal to be sustained. Lancet 2000;356:156-9.

leadership.²⁴⁴ They also publish formal codes of ethics and practice, and registers of their members are available to the public.²⁴⁵ An ethical ideal of service, monopoly over important knowledge and skills, and high social regard coalesce to establish high degrees of autonomy over work.

The past President of the General Medical Council (GMC) has stated that professionalism is at the heart of doctors' relationships with patients and the public. People normally associate professionalism with quality. It suggests expertise and reliable, consistent performance.²⁴⁶

It appears clear, therefore, that self-regulation is essential to the concept of being a profession. As Freidson stated:

As I noted in my analysis of medicine as a profession, autonomy is the test of that status. Professional people have the special privilege of freedom from the control of outsiders. Their privilege is justified by three claims. First, the claim is that there is such an unusual degree of skill and knowledge involved in professional work that non-professionals are not equipped to evaluate or regulate it. Second, it is claimed that professionals are responsible – that they may be trusted to work conscientiously without supervision. Third, the claim is that the profession itself may be trusted to undertake the proper regulatory action on those rare occasions when an individual does not perform his work competently or ethically. The profession is the sole source of competence to recognise deviant performance and to regulate itself in general. Its autonomy is justified and tested by self-regulation.²⁴⁷

The last two claims, those of professional responsibility and the enactment of proper regulatory mechanisms, will be examined to determine if self-regulation can oversee the introduction of innovation, whether of the experimental or personal variety described in previous chapters, and result in acceptable patient protection.

THE INTRODUCTION OF SELF-REGULATION:

Patients are rightly entitled to good standards of practice and care when being treated by their doctors. Essential elements are professional competence, good relationships with patients and colleagues and observance of professional ethical obligations.²⁴⁸ These standards can be traced back to the 4th century BC, in the form of the Hippocratic Oath, which set out an ideal by which doctors promised to practise, although today it looks inappropriately doctor centred.²⁴⁹ Self-regulation in the United Kingdom began in the 16th

244 Rosenthal MM. The Incompetent Doctor: Behind closed doors. Open University Press, Buckingham:1995, p2

245 Mills SY. Regulation in complementary and alternative medicine. BMJ 2001;322:158-60.

246 Irvine D. The changing relationship between the public and the medical profession. J R Soc Med 2001; 94: 162-9 at 166.

247 Freidson E (1970) The profession of medicine, New York, Harper & Row, p137.

248 GMC: Good Medical Practice, Duties of a doctor, 1995 p2.

249 Irvine D. The changing relationship between the public and the medical profession. J R Soc Med 2001; 94: 162-9.

century with the foundation of the Royal College of Physicians. This functioned both as a setter of standards and as a closed shop. Learning at the time was based on a few medical schools and an apprenticeship system.²⁵⁰

Following this, a number of independent bodies, such as the other Royal Colleges and the British Medical Association, emerged to represent specific areas of practice and these continue to play an important role today.²⁵¹

The statutory regulation of medical practice was then established with the creation of the General Medical Council (GMC) by the Medical Act of 1858. Throughout this period, standards and quality were implicit rather than explicit, with government and society trusting the medical profession to protect the public and, as mentioned, granting the profession considerable autonomy in the process.²⁵² Society believes that the professions will place the welfare of society above that of the profession.²⁵³ If society perceives that medicine is failing to meet its obligations, professional status may be withdrawn or modified.²⁵⁴ Self-regulation is a vehicle, not the goal or the core of professionalism.²⁵⁵

It is, however, important that there is inter-dependence of public policy and professional self-regulation. Klein has claimed that the aim of public policy is to make the medical profession accountable for its performance.²⁵⁶ The aim of professional self-regulation, on the other hand, is to make individual practitioners more accountable to their peers. The success of the former strategy depends crucially on the latter, on institutionalising self-regulation at the local level.²⁵⁷

THE GENERAL MEDICAL COUNCIL:

The GMC is the governing body of the medical profession. It is therefore essential that its role in regulating doctors be examined.

The GMC sets standards of care, competence and conduct so that the doctor patient relationship is maintained. In this respect, it has a statutory responsibility to issue guidance on medical ethics.²⁵⁸ It also has an extremely important role in medical education and ensures that only those who are suitably qualified can be registered.²⁵⁹ One of its main functions is the

250 Ham C, Alberti KGMM. The medical profession, the public, and the government. *BMJ* 2002;324:838-42.

251 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p137-8.

252 Ham C, Alberti KGMM. The medical profession, the public, and the government. *BMJ* 2002;324:838-42.

253 Mechanic D. Changing medical organization and the erosion of trust. *Milbank Q* 1996;74:171-89.

254 Cruess RL, Cruess SR, Johnston SE. Professionalism: an ideal to be sustained. *Lancet* 2000;356:156-9.

255 Emanuel EJ, Emanuel LL. What is accountability in health care? *Ann Intern Med* 1996;124:229-39.

256 Klein R. *Regulating the medical profession: doctors and the public interest*. Health care UK 1997/98. London: King's Fund, 1998..

257 Irvine D. The performance of doctors I: professionalism and self-regulation in a changing world. *BMJ* 1997;314:1540-42.

258 Medical Act 1983, s35

259 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p133-54.

maintenance of this register.²⁶⁰ The Medical Act 1983 gives the GMC the legal authority to prohibit or suspend doctors from practising. It must be remembered, however, that the GMC is

not ordinarily concerned with errors in diagnosis or treatment, or with the kind of matters which give rise to action in the civil courts for negligence unless the doctor's conduct in the case has involved such a disregard of his professional responsibility to his patients or such a neglect of his professional duties as to raise a question of serious professional misconduct.²⁶¹

It is only when the doctor's action or inaction brings the profession into disrepute that he or she will have to face charges before the GMC. Indeed one of its most important functions is to fill the gap in constraining actions that are not legally actionable yet would not be expected of the ethical practitioner.²⁶²

In the past, the GMC was heavily criticised because it could only discipline a doctor if he or she was found guilty of 'serious professional misconduct' or had been convicted of a criminal offence.²⁶³ The Medical (Professional Performance) Act 1995, however, has given the GMC new powers, extending its jurisdiction to enable it to investigate cases where there is evidence that a doctor's general performance is seriously deficient.

On the other hand, it has been claimed that regulation in whatever form can never substitute for a doctor's personal professionalism.²⁶⁴ As previously mentioned, professionals are more concerned with doing what is right than avoiding punishment.²⁶⁵

Professionally led regulation is predicated on the fact that the practice of medicine still involves a considerable degree of judgement in the fundamental functions of diagnosis about treatment. Consequently patients, in the privacy of the consulting room, are still critically dependent on their doctors' getting it right first time, knowing the limits of their competence and their honesty and integrity. Doctors practising within a regulatory framework of professional values and standards - professional conscience - are more likely to give of their best for their patients than doctors who are not, because there is peer pressure to do so.²⁶⁶

²⁶⁰ Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p141-2.

²⁶¹ GMC. Professional Conduct: Fitness to practice (April 1985), p10.

²⁶² Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. London:Butterworths, 6th ed, 2002, 1.36.

²⁶³ Irvine, D. The performance of doctors; the new professionalism. The Lancet 1999, 353; 1174-77.

²⁶⁴ Irvine, D. The performance of doctors; the new professionalism. The Lancet 1999, 353; 1174-77.

²⁶⁵ Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p5.

²⁶⁶ Irvine D. The changing relationship between the public and the medical profession. J R Soc Med 2001; 94: 162-9 at 166.

It is therefore prudent at this point to review whether self-regulation in the form of 'professional conscience' and 'peer pressure' described above protected patients in the two innovative clinical scenarios described in the last chapter, namely the early heart transplant years representing experimentation and the events in 'Bristol' illustrating personal innovation.

THE EXPERIMENT OF HEART TRANSPLANTATION:

Did self-regulation protect the first few patients undergoing organ transplantation? The answer is in the main no, although there were some encouraging signs. As one of the eminent surgeons of the time wrote

There can be little question that personal ambition, usually for career advancement or public acclaim, underlies much intense motivation in research work and the trial of new ideas, drugs, operations, or treatment. ... But ambition, no matter how praiseworthy, can certainly lead individuals astray.²⁶⁷

There is little doubt that, given the events described in the last chapter, the ambitions of many of the surgeons involved in the first heart transplants and artificial pump operations led to the interests of the patients being overridden. Self-regulation, clearly, was not successful in protecting these patients. The fact that Barnard undertook the first heart transplant, rather than Shumway who had undertaken most of the research, was because of his ego and desperation to be first. There was even evidence that the time was not yet right to commence transplantation because rejection problems had not yet been resolved and it would probably be a further decade before they were.²⁶⁸ Shumway himself felt that it was not yet the time to try this on humans, even for the sickest patients.²⁶⁹ There were also problems surrounding legal issues regarding death. No brain stem death criteria had been established. There was therefore the potential that doctors involved in heart transplants could have been charged with murder.^{270 271 272}

The failure of self-regulation can also be demonstrated by events in Houston where the competitiveness of the two renowned heart surgeons there led to patients being used as a means to an end. Cooley started performing heart transplants for personal reasons, with the aim of achieving recognition, despite having only practised on one cadaver. His later rush to use the first artificial heart in Haskell Karp also attracted severe criticism. The medical community was not expecting its use for some time. Furthermore it did not

267 Moore FD. Ethical Boundaries in Initial Clinical Trials. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 358-378 at 375-6.

268 Ross D. in: Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p291.

269 Shumway NE, Stinson EB, Dong E Jr. Cardiac homotransplantation in man. Transpl Proc 1969;1:739-45 at p739.

270 Bunker J. in: The Anesthesiologist and the Surgeon. Boston, MA: Little Brown, 1972. Transplanting the heart at Stanford; Shumway and the anesthesiologists', 123-138.

271 Anon. Medical news: Inquest on heart donor. BMJ 1968;ii:569.

272 Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p34

expect Cooley to undertake it as others in the field had more experience and had performed most of the research and animal trials. Once again, it appears that his ego and need to be first clouded his judgement.

Questions of consent and the experimental nature of the procedure were raised. Many in the medical community believed it was an act of betrayal and a severe breach of ethics. It was a reckless attempt, which was undertaken solely in the interests of ambition.²⁷³ Carefully laid out guidelines had not been followed. The surgeon had not asked for permission to perform the surgery from the Baylor Committee on Research Involving Human Beings because he knew he would be turned down.²⁷⁴

He also appears to have 'stolen' the pump from his senior colleague, DeBakey, who in turn also claimed the application of an unproved device was a breach of scientific ethics.²⁷⁵ His view was that assessment of the risks was still not complete.²⁷⁶

A confounding factor at the start of the transplantation era was the reaction of the media. The world wanted to believe that such operations were possible and public opinion in countries around the world virtually forced doctors into attempting heart transplants. Furthermore, the media gave the involved surgeons public recognition and support, and in some instances catapulted them to fame,²⁷⁷ thereby encouraging other surgeons to attempt the operation.

Within a few months the euphoria surrounding these heart operations disappeared once it was realised that the majority had failed. It is only at this point that a limited form of self-regulation, spurred on by the media, started to have an impact. Many doctors advocated caution.²⁷⁸ Even Cooley's colleagues in Houston were suggesting a halt in the transplantation programme.²⁷⁹

Many doctors in the UK disapproved of heart transplantation and believed those who had undertaken them should be disciplined.²⁸⁰ There was similar disapproval in the US.²⁸¹ The pressure to stop came from the physicians themselves, from colleagues in various ways, such as through face to face interaction or through what was published in medical journals, from the

273 Thorwald J. *The Patients*. New York: Hardcourt Brace Jovanovich, 1971 at p411.

274 Thompson T. *Hearts*. New York: McCall, 1971 at p213-4.

275 DeBakey in Thompson T. *Hearts*. New York: McCall, 1971 at p215.

276 deBakey M. in Thompson T. *Hearts*. New York: McCall, 1971 at p200.

277 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at 131.

278 Taussig HB. Heart transplantation. *JAMA* 1969;207:951.

279 Nora J. Thompson T. *Hearts*. New York: McCall, 1971 at p185.

280 Somerville J. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p27

281 Bunker J. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: Early Heart Transplant Surgery in the UK. Tansey EM, Reynolds LA (Eds). Welcome Trust 1999 at p28

institutions in which they worked or from patients and their families.²⁸² Thus Cooley stopped doing transplants because his stream of donors dried up. Colleagues were not referring any more patients, and patients and their families were becoming less enthusiastic about the procedure.²⁸³

The moratorium:

The first moratorium called was by the Montreal Heart Institute. The doctors there decided to suspend cardiac transplantation when the poor results being achieved were reviewed. This therefore was the first time during the heart transplantation era when a form of self-regulation was undertaken. Others, however, were critical of this decision, including Cooley²⁸⁴ and Barnard, who thought it was professionally unethical.²⁸⁵

In the United Kingdom a moratorium on heart transplantation was similarly prompted by concerns from the surgeons who undertook the first two transplants. However the moratorium was seen as the development of consensus and not central dictation.²⁸⁶ Ross believed the moratorium was self-imposed.

... the surgeons did have a sense of responsibility ...doctors should be given some credit for a sense of responsibility...²⁸⁷

Interestingly, the opinions of lay members of organisations concerned with the conduct of research and the growing authority of a professional community of bioethicists were also felt to be significant in the demand for a moratorium.²⁸⁸

Eventually the Board of Medicine of the National Academy of Sciences in the US further restricted cardiac transplantation to those institutions where the surgical expertise and a thorough understanding of the biological processes leading to rejection and its control were present.²⁸⁹ Thus Stanford became the only place to still undertake heart transplants, mainly because its performance was superior to everywhere else.²⁹⁰ The use of performance tables will be reviewed later in this chapter.

A similar self-imposed moratorium had occurred in the early 1960s when the first human liver transplants were attempted with very poor results. No further

282 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at 108.

283 Wellcome Witnesses to Twentieth Century Medicine vol 3: *Early Heart Transplant Surgery in the UK*. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at 45p

284 Cooley DA, Bloodwell RD, Hallman GL, Nora JJ. Transplantation of the human heart. *JAMA* 1968;205:479-86.

285 'Barnard CN. Heart transplants are defined by Dr Barnard. *Philadelphia Evening Bulletin*, 20/10/70.

286 Godber Sir G, letter to Dr Tilli Tansey, 1997, reported in *Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK*. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p35

287 Ross D. in *Wellcome Witnesses to Twentieth Century Medicine vol 3: Early Heart Transplant Surgery in the UK*. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p49

288 Fox RC, Swazey JP. *Spare Parts*. New York: Oxford University Press; 1992 at 24.

289 Board of Medicine of the National Academy of Sciences. Cardiac transplantation in man. *JAMA* 1968;204(9):147-8.

290 Thompson T. *Hearts*. New York: McCall, 1971 at p221

liver transplants were undertaken for more than three years.²⁹¹ This moratorium had also been described as a form of self-regulation, limiting further harm being brought to patients.²⁹² It had been imposed by the transplant surgeons themselves, without a need for consultant or hospital boards:

... [the] project ... was held in abeyance until the fundamentally ethical nature of science itself indicated that it was time again to move ahead.²⁹³

However, once again, it was only following poor results that a form of self-regulation was utilised, protecting later patients but notable by its absence when a few maverick surgeons decided their egos needed boosting. These surgeons were not solely responsible, however. The press, patients and public expectations also had a part to play. The role of the press can be illustrated by the misinformation it presented to the general public with respect to Blaiberg, Barnard's second patient. A syndicated photograph appeared to show him lying in the sea happily splashing in the waves as testimony to his remarkable recovery. In fact he was carried into the water, the entourage stepped back, cameras flashed and he was hauled out before drowning.²⁹⁴

PERSONAL INNOVATION- BRISTOL:

In 1998 the General Medical Council found three Bristol doctors guilty of serious professional misconduct. Events have been described in the previous chapter. Did self-regulation successfully protect the patients concerned? In this case the answer must be a resounding no. Indeed, Bristol has been described as a 'landmark in the history of self-regulation.'²⁹⁵

One of the surgeons had been made aware on several occasions of the concern of professional colleagues about the level of mortality and morbidity in paediatric cardiac surgery at the hospital. He failed to pay sufficient regard to the safety and best interests of the patients concerned and furthermore mislead two sets of parents when discussing risks. The other surgeon, again despite colleagues' concerns,²⁹⁶ performed a further two operations, one of which resulted in the death of a child.

The GMC identified troubling deficiencies in professional accountability, honesty and integrity, and the maintenance of standards of good medical practice.²⁹⁷ Although it could be argued that the GMC decision could be seen

291 Starzl TE. *The Puzzle People: Memoirs of a Transplant Surgeon*. Pittsburgh: University of Pittsburgh Press, 1992:105.

292 Starzl TE. *The Puzzle People: Memoirs of a Transplant Surgeon*. Pittsburgh: University of Pittsburgh Press, 1992.

293 Moore FD. *Annals of Surgery* 1968;168:414-5.

294 Hoffenberg R. Christian Barnard: his first transplants and their impact on concepts of death. *BMJ* 2001;323:1478-80.

295 Klein R. Competence, professional self regulation, and the public interest. *BMJ* 1998;316:1740-2 at 1740.

296 Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

297 Horton R. How should doctors respond to the GMC's judgments on Bristol? *Lancet* 1998;351:1900

to have illustrated that self-regulation 'works' professional self-regulation cannot be left entirely to the disciplinary function of the General Medical Council as by then it will often be too late.²⁹⁸ Indeed, the whole episode could have been avoided if *local* 'informal' self-regulation through peer pressure had materialised and concerns acted upon. Immediate colleagues, their employer, and Professional bodies outside Bristol, such as the Royal College of Surgeons and the Department of Health, although aware of the poor success rate, either failed to act or did not use their position of authority to force a change in practice.²⁹⁹ Clearly, if doctors do not monitor themselves effectively there is little doubt that external regulation will be imposed upon them³⁰⁰ and the right to self-regulate will be removed.

The subsequent public Inquiry has now published its findings³⁰¹ and the Government has issued its response.³⁰² The question of self-regulation was repeatedly raised during the Inquiry and one of the central features was the frustrating lack of clarity about where responsibility lay once things went wrong.³⁰³ The Inquiry stated:

The clinicians in Bristol had no one to satisfy but themselves that the service they provided was of appropriate quality.³⁰⁴

The Inquiry was thus clearly critical of the system of self-regulation. It was concerned that in the past there were no explicit standards for the care of patients.³⁰⁵ It was optimistic, however, that recently introduced Government initiatives, such as the development of clinical guidelines through the National Institute for Clinical Excellence (NICE) and monitoring performance through the Commission for Health Improvement (CHI) would lead to improved standards of care. These imply, and this appears to be endorsed by the Inquiry, a moving away from self-regulation towards some form of Government backed external regulation. This issue will be further examined in the next chapter.

Other relevant recommendations were that standards and performance should be monitored locally and nationally³⁰⁶ while recommendation 99

298 Anon. First lessons from the "Bristol case." *Lancet* 1998;351:1669

299 Anon. First lessons from the "Bristol case." *Lancet* 1998;351:1669

300 Smith R. Renegotiating medicine's contract with patients. *BMJ* 1998;316:1622-3

301 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

302 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002

303 Irvine, D. - The performance of doctors; the new professionalism. *The Lancet* 1999, 353; 1174-77.

304 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001 at para 19 p3.

305 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, para 90, p17.

306 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the

proposed that doctors undertaking procedures for the first time (i.e. personal innovators) need to be properly trained and directly supervised³⁰⁷.

These recommendations have a direct bearing on the regulation of innovation, especially when considering personal innovation. Thus further analysis of some of the issues highlighted by the Inquiry, especially the problems of learning curves and monitoring performance through performance tables is required.

Learning curves:

The concept of a learning curve for the development of operative skills has always been important in surgical training.³⁰⁸ The rapid introduction of laparoscopic surgical techniques brought this more sharply into focus than ever before. Around the late 1980s surgeons were under pressure from both the popular press and their patients to learn these techniques. They found themselves in the position of being asked to perform procedures with which they were not yet fully familiar, and the efficacy of which had not yet been elucidated.³⁰⁹

Formal teaching, however, often only took the form of intensive courses over one or two days after which the surgeons then took up the procedure within their own practice. Anecdotal evidence at that time suggested a relatively high rate of complications in the early period.³¹⁰

It is now becoming clear that the learning period for many laparoscopic procedures is relatively long, even for surgeons who have had ample experience in the corresponding open procedure.^{311 312} Furthermore the effects of the learning curve have been shown for a large number of laparoscopic procedures performed in general surgery. When laparoscopic cholecystectomy was introduced there was an increase in the incidence of bile duct injuries^{313 314 315 316} thereby offering evidence that the learning curve had contributed to a high rate of bile duct injuries.

Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, recommendation 143-147.

307 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, recommendation 99.

308 Treasure T. Lessons from the Bristol case. BMJ 1998;316:1685-6

309 Wright D, O'Dwyer PJ. The Learning Curve for Laparoscopic Hernia Repair. Seminars in Laparoscopic surgery, 1998; 5(4):227-32

310 See WA, Cooper CS, Fisher RJ. Predictors of laparoscopic complications after formal training in laparoscopic surgery. JAMA 1993;270:2689-92

311 Bennett CL, Stryker SJ, Ferreira MR. et al: The learning curve for laparoscopic colorectal surgery. Preliminary results from a prospective analysis of 1194 laparoscopic-assisted colectomies. Arch Surg 1997; 132 :41-4

312 Richardson MC, Bell G, Fullarton GM, et al: Incidence and nature of bile duct injuries following laparoscopic cholecystectomy: An audit of 5193 cases. Br J Surg 1996;83:1356-60

313 McMahon AJ, Fullarton CM, Baxter JN, et al.: Bile duct injury and bile leakage in laparoscopic cholecystectomy. Br J Surg 1995;82:307-13

Similar results regarding learning curves have been obtained for other operations such as laparoscopic fundoplication³¹⁷, where each individual surgeon's complication rate, number of re-operations, and conversion rate are higher in their first 20 cases, and for laparoscopic colon surgery, where the learning curve is overcome after somewhere between 35 and 50 cases.^{318 319 320}

Thus, as laparoscopic techniques have flourished over the past 10 years, it has become evident that surgeons must pass along a significant learning curve to develop these skills. This learning curve is relatively long and cannot be surmounted solely by the attendance at short intensive courses. Additional operative experience is required. Although proper training in laparoscopic surgery should decrease injuries to patients³²¹ the presence of experienced supervision appears to be a definite advantage during the learning phase. It also needs to be noted that during this learning period the outcome achieved may not only fall below the standard reported by other surgeons more experienced in the laparoscopic technique but also below those undertaking the comparative open technique. This is very important from the patient's perspective. If the patient is being operated on by a surgeon still learning the technique, not only may the result be worse than if undertaken by a more experienced surgeon but also worse than if the older technique was employed.

Continuing education with regard to new medical advances and ongoing training of surgical skills are expectations of the surgical community.³²² The main driving force for this arises from a desire to provide patients with the best possible treatment options. However the obligation not to harm patients is central to the ethical practice of medicine and must remain to the fore during the development of new techniques. Therefore, maximal benefit from a new procedure can only occur when it can be performed with minimal complications and optimal outcome.

314 Branum C, Schmitt C, Baillie J et al. Management of major biliary complications after laparoscopic cholecystectomy. *Ann Surg* 1993;217:540-1

315 Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomies. *N Engl J Med* 1991;324:1073-8

316 Richardson MC, Bell G, Fullarton GM, et al: Incidence and nature of bile duct injuries following laparoscopic cholecystectomy: An audit of 5193 cases. *Br J Surg* 1996;83:1356-60

317 Watson DI, Baigrie RJ, Jamieson CC. A learning curve for laparoscopic fundoplication. Definable, avoidable, or a waste of time? *Ann Surg* 1996;224:198-203

318 Agachan F, Joo JS, Weiss EG, et al. Intraoperative laparoscopic complications. Are we getting better? *Dis Colon Rect* 1996;39:S14-9

319 Agachan F, Joo JS, Sher M, et al. Laparoscopic colorectal surgery. Do we get faster? *Surg Endosc* 1997;11:331-5

320 Wishner JD, Baker JW Jr, Hoffman CC, et al. Laparoscopic-assisted colectomy. The learning curve. *Surg Endosc* 1995;9:1179-83

321 MacIntyre IMC, Wilson RG. Laparoscopic cholecystectomy. *Br J Surg* 1993;80:552-9.

322 Gates EA. New surgical procedures: can our patients benefit while we learn? *Am J Obstet Gynecol* 1997;270:1293-7

The recent General Medical Council inquiry into the Bristol paediatric cardiac surgical unit highlighted the problem of learning curves. The Senate of Surgery responded that there should be no learning curve as far as patient safety was concerned.³²³ To learn how to perform a new procedure without having a learning curve, however, is a dilemma that is not easily resolved. No surgeon would wish to knowingly attempt a procedure that is beyond his or her competence. Yet how does he or she learn how to undertake a new procedure that will ultimately benefit other patients?

Furthermore, how many cases does a surgeon need to perform before he or she can start to quote an accurate statistical risk? Health professionals understand the concept of small sample size and confidence intervals, but how is that to be explained to the patient or parent? Should one stratify patients by risk and quote different risks for patients undergoing what is apparently the same procedure? Even if this is what is required there is not sufficient data available to give patients accurate information. Similarly, if the surgeon is undertaking the procedure for the first time, and thus has no figures to quote, without some basis for confidence patients are unlikely to want to be experimented upon and used as a learning tool. Yet every surgeon has to perform a particular procedure for the first time. The assessment of any new technique therefore needs to elucidate not only the outcomes of the new procedure during the learning phase of the surgical community as a whole but also at the level of the individual surgeons.³²⁴

The Bristol Royal Infirmary Inquiry specifically addressed many of the concerns regarding how a healthcare professional is to acquire competence in a new clinical activity.³²⁵ Skills need to be enhanced while at the same time patient interests need to be safeguarded. The Inquiry recognised the problem of the 'learning curve' and that competence is acquired gradually with an upward gradient of success. It was however critical of the assumption that failure was initially inevitable and by that token justifiable.³²⁶

The Inquiry discussed three circumstances requiring consideration³²⁷:

a) The procedure was known and already performed in the trust but the healthcare professional was undertaking it for the first time (i.e. personal innovation)

323 Senate of Surgery. Response to the General Medical Council determination on the Bristol case. London: Senate of Surgery, 1998

324 Wright D, O'Dwyer PJ. The Learning Curve for Laparoscopic Hernia Repair. *Seminars in Laparoscopic surgery*, 1998; 5(4):227-32

325 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

326 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, chapter 25: 1-4.

327 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, chapter 25: p1.

b) The procedure was known but undertaken for the first time in the trust (personal innovation).

c) The procedure was being done for the first time anywhere (experimentation).

Scenario 'b' equates with what happened in Bristol while scenario 'c' is what happened when heart transplants and the mechanical heart were used for the first time.

From a patient's point of view, there is a paradox. Innovations are desirable and should be introduced, but they should be tried out on someone else first! Three guiding principles may offer a way around the paradox. The first is the need for supervision; the second is the need for openness and honesty with the patient; the third is the need for an agreed and established system within the hospital for managing innovation.³²⁸

Supervision:

A surgeon carrying out a procedure for the first time should be suitably trained and be directly supervised by colleagues who have the necessary competence and proficiency, until the relevant degree of expertise has been acquired; therefore the patient is not exposed to a risk greater than the norm. If necessary the surgeon must obtain appropriate training in a place where expertise in the procedure is established. The question of adequate supervision will be considered further later.

Openness:

A further safeguard for patients is the requirement that the surgeon be open and honest with them, or, in the case of children, with their parents. Patients are entitled to know what experience the surgeon has, how experimental or innovative a procedure is, and that this may be the first occasion the surgeon has carried out the procedure.³²⁹ Furthermore, it is not acceptable for surgeons to say that they would not be able to innovate if the patient always had to agree. This would put the surgeon's desire to innovate above the patient's right to choose. This issue will be returned to in later chapters.

A Hospital System:

Trusts should have a system in place to manage innovation. Such a system should recognise the need for training and ensure that it is made available. If a procedure is being carried out for the first time anywhere, a distinction should be drawn between undertaking a variation of an existing procedure and carrying out a genuinely new innovation. These are not polar opposites: any particular procedure may lie somewhere along a spectrum. In the Inquiry's view, when any new and hitherto untried invasive clinical procedure is attempted, the surgeon concerned should inform the trust or the local research ethics committee. The role of the

³²⁸ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, chapter 25: 1-4.

³²⁹ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, recommendation 102.

hospital's ethics committee will be examined further later. The lesson of Bristol is that when it comes to innovation it may not always be enough to leave the decision to the professional. Some system of reflection and accountability is essential.

Evidence of acceptance of recommendations:

There is some evidence that some of these recommendations have started being taken on board. For example, personal innovators at two paediatric cardiac centres recently wished to start undertaking the 'Ross' procedure for aortic valve replacement despite having no previous experience of the technique.³³⁰ This procedure is technically demanding with the potential for appreciable morbidity and mortality. There is, as would be expected, a significant learning curve and a higher mortality in the early stages of surgical experience.^{331 332}

To overcome this, the surgeons discussed various strategies to reduce the steepness of their learning curve.³³³ They all undertook a course in aortic root surgery, refined the surgical technique through cadaveric dissection, undertook the first operation with an expert, and later assisted each other with the operation. These strategies limited the mortality and minimised the morbidity that would have been associated with such an operation. Only time will tell whether similar structured programmes become more universally adopted.

Supervision- revisited:

The question of educating trainees, however, remains.

Severe and pressing problems remain when ... new personnel carry out standard operations for the first time. This ... problem – that of educating and gradually transferring responsibility to young men without, at the same time, jeopardizing the patient's safety - is the central focus of clinical education. It is most especially pressing and obvious in surgery. The young surgeon passes from the status of a "greenhorn" intern at the age of twenty-six to a phase of technical perfection at about the age of thirty-two, when, frequently, his sheer operative skill is unequalled by an older generation. But he has yet to acquire judgment, wisdom, forbearance, and human insight – qualities that require the passage of time in any physician's education. Nevertheless, during those seven or eight years the young man has operated on many patients, and in many instances has carried out an operation for the first time on some patient.³³⁴

330 Hasan A, Pozzi M, Hamilton JRL. New surgical procedures: can we minimise the learning curve? BMJ 2000;320:171-3

331 Stelzer P, Weinrauch S, Tranbaugh RF. Ten years of experience with modified Ross procedure. J Thorac Cardiovasc Surg 1998;115:1091-100

332 Gula C, Wain WH, Ross DN. Ten years' experience with pulmonary autograft replacements for aortic valve disease. Ann Thorac Surg 1979;28:392-6

333 Hasan A, Pozzi M, Hamilton JRL. New surgical procedures: can we minimise the learning curve? BMJ 2000;320:171-3

334 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical

It is hoped that higher surgical trainees will learn complex procedures under the direct tuition and supervision of an established consultant experienced in the particular technique. However, for technically complex operations, especially if the consultant performs them infrequently, there will be a natural reluctance to allow even an experienced trainee to undertake these procedures. This may be particularly so in the new era of performance tables, with surgeons' results possibly available to the public and consultants therefore responsible for the results of their trainees. Trainees may thus not have the opportunity to perform a particular procedure until they have been appointed to a consultant post. How therefore do they learn?

Operative experience and supervision by a consultant must be at the core of any surgical training programme. However there is surprisingly little objective data on general surgical training in the United Kingdom. An audit of surgical training by the Royal College of Surgeons of Edinburgh concluded that the numbers of trainees operating without supervision was unsatisfactory.³³⁵ Similarly a recent study provided evidence that a high proportion of colorectal surgery is still being undertaken by trainees with insufficient consultant supervision.³³⁶ A core aim of surgical training is consultant supervision during emergency surgery, but again such supervision is lacking. It can no longer be acceptable that inadequately supervised trainees care for critically ill patients. The national confidential inquiry into post-operative deaths suggests that this acknowledged deficiency has still not been adequately addressed.³³⁷ For too long the National Health Service has depended on trainees undertaking a significant proportion of unsupervised elective surgery and an even greater proportion of emergency surgery.^{338 339 340}

This lack of supervision is a matter of considerable concern.³⁴¹ The introduction of specialist training arrangements is likely to lead to greater problems. Considerable concern exists that the shortened training time, combined with the restriction on hours of work, will result in surgical trainees

procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p359.

335 Harper D. Royal College of Surgeons of Edinburgh gives consultant fellows feedback on their training activity. *BMJ* 1999;319:258

336 Aitken RJ, Thompson MR, Smith JAE, Radcliffe AG, Stamatakis JD, Steele RJC. Training in large bowel cancer surgery: observations from three prospective regional United Kingdom audits. *BMJ* 1999;318:702-3

337 Gray AJ, Hoile RW, Ingram C, Sherry KM. The report of the national confidential inquiry into postoperative deaths (NCEPOD). London: Royal College of Surgeons of England, 1997

338 O'Leary DJ, Collins C. Analysis of a year's general surgical activity in a district general hospital. *Ann R Coll Surg Engl* 1994;76(suppl):176-81

339 Wilson JA. Unsupervised surgical training: questionnaire study. *BMJ* 1997;314:1803-4

340 Galasko C, Mackay C. Unsupervised surgical training: logbooks are essential for assessing progress. *BMJ* 1997;315:1306-7

341 MacArthur DC, Nixon SJ, Aitken RJ. Avoidable deaths still recur after large bowel surgery. *Br J Surg* 1998;85:80-

being short of the necessary depth and breadth of experience for independent practice at the end of the defined training period.³⁴²

The present arrangements for patient care are no longer in harmony with the quality-first agenda being promoted by the Government³⁴³ and are thus unsustainable and unacceptable. It is abundantly clear that it is essential to give priority to the requirements for training. In particular, the relationship between training and a high quality service needs to be recognised and the service organised so that it is provided by consultants, trainees are properly supervised, and surgical patients receive the benefit of fully trained expertise in their care at all times.³⁴⁴

However, despite all this, there is still evidence that, even when fully trained, doctors still do not achieve the same results. For example, individual surgeons may influence the outcome after colorectal cancer surgery.³⁴⁵ The professionalism intrinsic to health care, along with the increasing demands from health care policy makers and consumers, has drawn increased attention to the study of the outcomes of medical and surgical treatment,³⁴⁶ reviewed in the next section.

Performance Tables:

Following the Bristol Royal Infirmary Inquiry³⁴⁷ the Government announced that the performance of individual cardiothoracic surgeons would be published in a drive to create a more open honest and patient-centred NHS, with information on consultants and units from other specialties likely to follow.³⁴⁸

These ‘consumer reports’ have been defined as guides on provider performance through practice profiles and comparative data.³⁴⁹ Of most interest is data that pertains to variations in clinical aspects of management.³⁵⁰

In the United Kingdom, increasing amounts of information on health care performance are entering the public domain, designed to keep patients informed about their health services. The Department of Health, for example, has published league tables for England allowing health professionals and

342 Bates T. Curricular training and the new deal. *Ann R Coll Surg Engl* 1996;78:61-2

343 Collins C. Surgical training, supervision, and service. *BMJ* 1999;318:682-3

344 Collins C. Surgical training, supervision, and service. *BMJ* 1999;318:682-3

345 McArdle CS, Hole D. Impact of variability among surgeons on postoperative morbidity mortality and ultimate survival. *BMJ*;1991;302: 1501-5

346 Topol EJ, Califf RM. Scorecard cardiovascular medicine: its impact and future directions. *Ann Intern Med* 1994;120:65-70

347 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, recommendations 148-154.

348 Vass A. performance of individual surgeons to be published. *BMJ* 2002;324:189.

349 Land G, Longo DR, Hoskins B, Fraas J. The development of a consumer guide on the quality of obstetrical services: the Missouri experience. *L Public Health Manage Pract* 1995;1:35-43

350 Jennett B. Variations in surgical practice: welcome diversity or disturbing differences. *BJS* 1988;75:630-1

their patients to scrutinize hospitals' performance for the first time since the NHS was established.^{351 352} These showed wide variations in death rates. Similar performance indicators for Wales also showed wide variation in the three measures that were included.³⁵³

The British Government clearly is committed to using league tables of hospital outcomes³⁵⁴ and to publish the performance of individual surgeons.³⁵⁵ If such information becomes readily available and easily comparable to that of one's peers, it would be possible to utilise it for the purposes of regulating innovation. Thus, if a group, be it a hospital or individual doctor, whose performance can be monitored and compared, is implementing a new technique already in general use then the results of treatment can be evaluated and poor performance rectified. This could have been very useful in preventing many of the unnecessary deaths that occurred in Bristol. The performance of the surgeons in Bristol could have been compared with their peers and if significantly worse the programme could have been stopped. Indeed, there is much evidence to show that the information was available but not acted upon.

Bristol was awash with data. There was enough information from the late 1980s onwards to cause questions about mortality rates to be raised both in Bristol and elsewhere had the mindset to do so existed.³⁵⁶

The problem, as previously mentioned, was that there was confusion throughout the NHS as to who was responsible for monitoring the quality of care.³⁵⁷

However, although there will clearly be variations in surgical practice it is not clear whether this is a welcome diversity or a disturbing difference.³⁵⁸ For example, many years ago the UK Cardiac Surgery Register revealed five to tenfold variations between regions in the rates for different types of operations.³⁵⁹ Success rates after renal transplantation have also been shown to vary widely between different surgical centres.³⁶⁰ Variations in avoidable

351 Quality and Performance in the NHS: Clinical Indicators. Prolog, London, 1999

(www.doh.gov.uk/indic/indicat.htm)

352 Quality and Performance in the NHS: High Level Performance Indicators. Prolog, London, 1999

(www.doh.gov.uk/indic/indicat.htm)

353 Dobson R. First clinical performance indicators for Wales show wide variation. *BMJ* 1999;318:1026

354 Wise J. Clinical indicators for hospitals announced. *BMJ* 1997;315:76

355 Vass A. performance of individual surgeons to be published. *BMJ* 2002;324:189.

356 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, p3

357 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, p9

358 Jennett B. Variations in surgical practice: welcome diversity or disturbing differences. *BJS* 1988;75:630-1

359 English TAH, Bailey AR, Dark JF, et al. The UK Cardiac Surgical Register 1977-82. *Br Med J* 1984;289:1205-8

360 Taylor RMR, Ting A, Briggs JD. Renal transplantation in the UK and Ireland- the centre effect. *Lancet* 1985;i:789-

deaths, complications and adverse long-term results should be highlighted and, in turn, concern surgeons as indicators of their performance.³⁶¹ It is improbable that patients receiving such widely divergent therapy were all getting optimal care.

In the USA, the most commonly cited reason for the public release of health care performance data is that they will enable consumers to select highly performing providers and avoid poorly performing ones.³⁶² The reasoning for the release of data in the UK, on the other hand, relates more closely to public accountability. There has been disquiet that for too long health care has been provided by a closed professional club, with the recipients of care denied access to meaningful data that would allow proper public scrutiny.³⁶³

Thus, a number of questions pertaining to these consumer guides and performance tables need to be asked. Firstly, once released, does the data have any impact on patient actions and provider behaviour? And secondly, are performance tables reliable?

The impact on consumer actions:

There is little doubt that improved dissemination of health care information amongst the public is in the best interests of the patient and will positively affect outcomes of care.^{364 365 366 367} Kaplan and Ware, in a summary of research in this area, report that patients want more information about their care and that an expanded role for patients in the care process substantially improves the outcome of care.³⁶⁸

However, it is of paramount importance that the information needs to be clear and presented in such a way as to help the public make informed choices. A recent set of performance Indicators were rushed out with such haste that there were even errata in the included errata slip.³⁶⁹ One commentator described the figures presented as 'impenetrable'.³⁷⁰

361 Jennett B. Variations in surgical practice: welcome diversity or disturbing differences. BJS 1988;75:630-1

362 Davies HTO, Marshall MN. Public disclosure of performance data: Does the public get what the public wants? The Lancet 1999, Volume 353:1639-1640.

363 Sirio CA, McGee JL. Public reporting of clinical outcomes: the data needs of health care stakeholders. Am J Med Qual. 1996;11:S78-S81

364 Chassin MR, Hannan EL, DeBuono BA. Benefits and hazards of reporting medical outcomes publicly. N Engl J Med. 1996;334:394-8

365 Pauly MV, Brailer DJ, Kroch G, Even-Shoshan O. Measuring hospital outcomes from a buyer's perspective. Am J Med Qual. 1996;11:112-22

366 Malcolm JA Jr. Plans proceed to publish physician specific data. Pa Med. 1992;95:18-19.

367 Sirio CA, McGee JL. Public reporting of clinical outcomes: the data needs of health care stakeholders. Am J Med Qual. 1996;11:S78-S81

368 Kaplan SH, Ware JE Jr. The patient's role in health care and quality assessment. In: Goldfield N, Nash DB, eds. Providing Quality Care: The Challenges to Clinicians. Philadelphia, Pa: American College of Physicians; 1989:25-69

369 Department of Health: NHS Performance Indicators; July 2002. Available on www.doh.gov.uk

370 Hutton P. President's Statement. Royal College of Anaesthetists, Bulletin 15, September 2002, 713

The impact on providers:

There is a significant body of evidence from descriptive and observational studies that published data can influence provider behaviour. For example, the results reported by Longo et al³⁷¹ confirm that consumer reports are associated with changes in the quality of hospital care, especially in areas of care identified as possibly out of alignment with care provided by high quality performing peers.

The best evidence in this regard appears to be that produced by the New York Department of Health through their cardiac surgery reporting system,³⁷² developed to collect clinical data on all patients undergoing cardiac surgery in New York State. Data on risk adjusted mortality were provided regularly to individual hospitals and cardiac surgery programmes to show their comparative level of performance.³⁷³

This documented a strong inverse relation between a surgeon's volume of coronary artery bypass grafting (CABG) procedures and the operative mortality associated with such surgery.^{374 375} 'Low volume' surgeons, that is those performing fewer than 50 operations per year, had consistently higher risk adjusted mortality rates than surgeons with high volumes of CABG procedures. In response to this, some hospitals restricted the privileges granted to these low volume surgeons. As a result, over four years 27 low volume surgeons stopped performing CABG in New York State.³⁷⁶ Of major importance is the fact that the system resulted in a 52% decline in the cardiac surgery death rate.³⁷⁷

Contrast this with the situation in the United Kingdom. In the UK cardiac surgical register, established in 1977,³⁷⁸ all data is anonymous. Since inception the presumption has been that access to national information would draw each surgeon's attention to his or her own performance and encourage local introspection and action. In other words, the UK system relies on self-regulation while in the US hospital management has a much greater influence.

371 Longo DR, Land G, Schramm W, Fraas J, Hoskins B, Howell V. Consumer reports in health care: do they make a difference in patient care? JAMA 1997;278:1579-84.

372 Chassin MR, Hannan EL, DeBuono BA. Benefits and hazards of reporting medical outcomes publicly. N Engl J Med. 1996;334:394-398

373 Hannan EL, Kilburn H Jr., Racz M, Shields E, Chassin MR. Improving the outcomes of coronary artery bypass surgery in New York State. JAMA 1994;271:761-6.

374 Hannan EL, O'Donnell JF, Kilburn H Jr., Bernard HR, Yazici A. Investigation of the relationship between volume and mortality for surgical procedures performed in New York State hospitals. JAMA 1989;262:503-10

375 Hannan EL, Siu AL, Kumar D, Kilburn H, Chassin MR. The decline in coronary artery bypass graft surgery mortality in New York state. JAMA 1995;273:209-13

376 Dziuban SW Jr., McIluff JB, Miller SJ, Dal Col RH. How a New York cardiac surgery program uses outcomes data. Ann Thorac Surg 1994;58:1871-6

377 Hannan EL, Kumar D, Racz M, Siu AL, Chassin MR. New York state's Cardiac Surgery Reporting System: four years later. Ann Thorac Surg. 1994;58:1852-7

378 English TAH, Bailey AR, Dark JF, Williams WG. The UK Cardiac Surgical Register 1977-82. BMJ 1984;289:1205-8

Furthermore the data in the UK's cardiac surgical register relates to individual units not individual surgeons.³⁷⁹ Hence a unit's figures can easily camouflage an errant performer. Furthermore reliable data collection facilities are not available in every unit. The Society of Cardio-thoracic Surgeons has recognized the shortcomings of the system³⁸⁰ and established a national database in 1994. The database, however, does not collect surgeon identifiers since in 1994 this would have been an insurmountable stumbling block to its launch.³⁸¹

Clearly the UK Society has yet to publish data in the same extensive way as now happens in the US. Despite Bristol, it is still not possible for a member of the public to scrutinise the mortality rate of his or her cardiac surgeon on the society's web-page.³⁸²

The reliability of league tables:

There are, however, many pitfalls in the collection of data for use in creating performance tables. The time-scale of collection for adverse events could lead to errors. If a patient suffers a catastrophic event during surgery yet survives for a day past three months that death is not deemed to be a reflection of surgical technique. Furthermore, what is called an 'improved' patient is a value judgement. Even simple measurements, such as length of stay in hospital after an operation, are not necessarily the best indicators of recovery. This particular measure is influenced by the health care system and the administrative culture in which the patient and physician function, as well as by the patient's expectation of hospital stay and the availability of community and family postoperative support.³⁸³

For league tables to be used to compare performance they must discriminate reliably and rapidly between hospitals and doctors that perform well and those that perform poorly. To act as levers for effective change differences identified by league tables must be sufficiently stable or definitive to represent a credible argument for change.

The standard NHS patient management systems, however, are generally not sophisticated enough to process this type of data.³⁸⁴ Furthermore, Davies and Crombie believe that the variable, and sometimes highly questionable, nature of the validity, reliability, and level of risk adjustment of the published data raise concerns about the meaningfulness of the information that is publicly disclosed.³⁸⁵

379 Keogh B, Dussek J, Watson D et al. Public confidence and cardiac surgical outcome. BMJ 1998;316:1759-60

380 Keogh B, Dussek J, Watson D et al. Public confidence and cardiac surgical outcome. BMJ 1998;316:1759-60

381 Keogh B, Dussek J, Watson D et al. Public confidence and cardiac surgical outcome. BMJ 1998;316:1759-60

382 Society of Cardiothoracic Surgeons. Surgical outcomes. www.ctsnet.org/section/outcome/ (accessed 1/8/03)

383 Carli F, Mayo N. Measuring the outcome of surgical procedures: what are the challenges? BJA 2001;87:531-3.

384 Keogh B, Dussek J, Watson D et al. Public confidence and cardiac surgical outcome. BMJ 1998;316:1759-60

385 Davies HTO, Crombie IK. Interpreting health outcomes. J Eval Clin Practice 1997;3:187-200

Thus a study that showed an increased mortality at Bristol, partly due to the low volume of surgery undertaken,³⁸⁶ may be flawed because the data was derived from the cardiac surgical register, hospital episode statistics, and the Bristol Inquiry. Comparing Bristol with the other cardiac centres is unfairly biased against Bristol because its mortality has been so closely scrutinised for the period covered by the Inquiry that they are almost certainly accurate. On the other hand, there has been no attempt to validate the volunteered information from the other sources.³⁸⁷ It is known that centrally tracked and volunteered 30 day mortalities vary considerably and can be up to 25% higher than the reported discharge mortality.³⁸⁸

There are three further fundamental problems when compiling annual league tables of performance. The first is the need to make accurate adjustments for differences in case-mix. The second is the uncertainty that occurs, no matter how accurate the adjustment for case-mix, when estimates of outcome are made for hospitals or doctors that treat relatively small numbers of patients each year.³⁸⁹ The third problem is the lack of consistency in the apparent performance over time.

For example, a study by Parry et al³⁹⁰ showed that individual neonatal intensive care units had wide and overlapping confidence intervals when ranked by mortality in annual league tables, making it impossible to discriminate between them. Variation in ranking from year to year was explained by random variation within units rather than systematic differences between them.

Furthermore, even if it is possible to find hospitals that consistently perform better than others, it may not be obvious why they perform better.³⁹¹ Thus the finely designated rankings that are implied by such annual league tables cannot be justified and are likely to encourage doubts over whether optimal care has been delivered. The resulting anxiety, stigma and guilt would be unnecessary and mostly unfounded.³⁹²

Another problem is that auditing performance without proper correction for case-mix will subject surgeons to unfair comparisons and ensure that some patients, usually the illest, would be denied surgery.³⁹³ Understandably

386 Spiegelhalter DJ. Mortality and volume of cases in paediatric cardiac surgery: retrospective study based on routinely collected data. *BMJ* 2002;324:261-4.

387 Gibbs JL, Cunningham D. Volunteered mortality data may be unreliable. *BMJ* 2002;324:1096.

388 Gibbs JL, Cunningham D. Volunteered mortality data may be unreliable. *BMJ* 2002;324:1096.

389 Goldstein h, Spiegelhalter DJ. League tables and their limitations: statistical issues in comparisons of institutional performance. *J R Statist Soc* 1996;159:385-443

390 Parry GJ, Gould CR, McCabe CJ et al. Annual league tables of mortality in neonatal intensive care units: longitudinal study. *BMJ* 1998;316:1931-5

391 Pearson G, Shann F, Barry P et al. Should paediatric intensive care be centralised? Trent versus Victoria. *Lancet* 1997;349:1213-7

392 Parry GJ, Gould CR, McCabe CJ et al. Annual league tables of mortality in neonatal intensive care units: longitudinal study. *BMJ* 1998;316:1931-5

393 Omoigui NA, Miller DP, Brown KJ et al. Outmigration for coronary bypass surgery in an era of public

surgeons may be reluctant to treat riskier patients. Thus, in the US, a survey of cardiologists and cardiac surgeons found that 59% of cardiologists reported increased difficulty in finding surgeons willing to perform coronary artery bypass graft surgery in severely ill patients who required it while 63% of the cardiac surgeons reported that they were less willing to operate on such patients.³⁹⁴ This latter figure has been confirmed in a later study by other investigators.³⁹⁵

Thus, the most disturbing finding is that access to care had decreased for severely ill patients who needed coronary artery bypass graft surgery. Similarly, a recent study suggested that the movement of severely ill patients to an adjacent State had been a measurable effect of New York State's public reporting of data on coronary artery bypass graft surgery.³⁹⁶

A further complicating factor is that, although operative mortality is always attributed to the surgeon, this ignores the subtle but important influences of cardiological management and referral, anaesthetic care and intensive care resources.³⁹⁷ Indeed, a recent editorial highlighted the importance of anaesthetic management in influencing surgical wound healing, arguably the commonest cause of postoperative morbidity, long hospital stays, and increased costs.³⁹⁸ These parameters are some of those used to compare surgical outcome and yet may be outwith surgical control. In other words, a surgeon may be criticised for his postoperative morbidity when compared to his colleagues but it may all be the fault of his anaesthetist!

THERAPEUTIC INNOVATION AND SELF REGULATION:

The adoption of new operative procedures and the use of certain implants, prosthesis and new imaging techniques is often based on uncertain evidence, especially in terms of safety. The recent death of a patient undergoing the innovative technique of rapid opiate detoxification under general anaesthesia highlights many of the problems. Accusations were made in court that, firstly, the patient did not give informed permission and secondly that claims that the treatment was completely safe were undoubtedly false.³⁹⁹ As will be discussed in a later chapter the lack of valid consent is a major recurring concern when considering innovative techniques.

The Advisory Group on Health Technology Assessment has recommended that research trials should be undertaken to assess recently introduced

dissemination of clinical outcomes. *Circulation* 1996;93:27-33

394 Schneider EC, Epstein AM. Influence of cardiac surgery performance reports on referral practices and access to care. *N Engl J Med* 1996;335:251-6

395 Burack JH, Impellizzeri P, Homel P, Cunningham JN Jr: Public reporting of surgical mortality: a survey of New York State cardiothoracic surgeons. *Ann Thor Surg* 1999;68:1195-200.

396 Omoigui NA, Miller DP, Brown KJ, et al. Outmigration for coronary bypass surgery in an era of public dissemination of clinical outcomes. *Circulation* 1996;93:27-33

397 Keogh B, Dussek J, Watson D et al. Public confidence and cardiac surgical outcome. *BMJ* 1998;316:1759-60

398 Buggy D. Can anaesthetic management influence surgical-wound healing? *Lancet* 2000;356:355-7

399 Mayor S. Specialists criticise treatment for heroin addiction. *BMJ* 1997, 314,p1365.

technologies when their effects are unknown.⁴⁰⁰ This would imply a well regulated strategy for the introduction of innovative techniques so that patient safety is the foremost consideration.

Criticism:

Laudable though such a declaration may be, the reality is that in many instances this does not appear to happen. McKinlay has presented a powerful critique of the way in which medical innovations become standard medical practice.⁴⁰¹ He argues that the popular image, that is that medical innovations become accepted as the standard of care following careful evaluation of their usefulness and effectiveness, does not describe the reality. Rather, 'routinisation' of innovations often follows a trajectory that confounds or appears to obviate the need for systematic evaluation, as exemplified by the introduction of laparoscopic surgery.

He outlines several stages in what he calls the career of a new medical technology. First are the promising reports, which usually appear in professional journals as anecdotal accounts, but which can give the impression that an innovation has tremendous promise.

The careers of most medical innovations seem to be launched with the appearance of an enthusiastic report on some promising performance, increasingly in the mass media.⁴⁰²

The series of promising reports may lead to a pilot study, the stated intention of which is to investigate the innovation's potential. However, McKinlay observes that large scale pilot studies may have a paradoxical effect. By introducing a sizeable number of practitioners and patients to the new technology, the pilot may appear to demonstrate, rather than investigate, the usefulness of the innovation. Quickly it comes to seem too valuable to be withheld from patients who could benefit from it. The second stage is marked by a period of consolidation of support by powerful interest groups, such as professional associations, which mobilise enthusiasm for the innovation, and institutions, which commit resources to it. Finally, if the state acts to implement social policy in support of the innovation, its career can be viewed as having passed the point of no return.⁴⁰³ He further points out that consumer enthusiasm for the innovation is generally the very last piece in the

400 Department of Health: Assessing the Effects of Health Technologies: Principles, Practice, Proposals. Report prepared by the Advisory Group on Health Technology Assessment for the Director of Research and Development, Department of Health 1992.

401 McKinlay JB. From 'promising report' to 'standard procedure': seven stages in the career of a medical innovation. In: Technology and the future of health care, Milbank Reader. Ed Milbank JB, vol 8, p233-270, MIT Press, Cambridge, MA, 1982

402 McKinlay JB. From 'Promising Report' to 'Standard Procedure': Seven Stags in the Career of a Medical Innovation. Millbank memorial fund Quarterly 1981;59:374-411 at 377.

403 McKinlay JB. From 'promising report' to 'standard procedure': seven stages in the career of a medical innovation. In: Technology and the future of health care, Milbank Reader. Ed Milbank JB, vol 8, p246, MIT Press, Cambridge, MA, 1982

puzzle and must be constructed by, and receive impetus and direction from, professional interests that are already committed to it.⁴⁰⁴

Thus, the large population which will require hip replacements in the future may reasonably expect orthopaedic surgeons to choose their prostheses on the basis of valid and reliable information.⁴⁰⁵ However, only a handful of the artificial hip joints on the market have been clinically evaluated for quality and efficacy, there being little or no scientific evidence that the newer, more expensive, implants are any better than the established designs. Some will be worse and result in considerable patient suffering and societal cost when they fail and need to be replaced.⁴⁰⁶ Though such hip joints have to meet British Safety Standards they only have to be shown to work in the laboratory or in animals, not in humans. Indeed, it could be argued that patients who receive a new hip joint that has only recently been released on the market are actually being involved in a research project without their knowledge, under the pretence of post-marketing surveillance. Adequately informed consent is conspicuous by its absence.

Does self-regulation work?

So, does self-regulation adequately regulate innovation? Jaffe believed (albeit in 1970) that experimenting doctors must and do develop their own controls.⁴⁰⁷ These controls include those which the experimenter imposes upon himself, including internalised controls of conscience and the acceptance of socially required limitations to his conduct.

The informed conscience of the experimenter is the first and most crucial guarantee. Whatever other and later safeguards there may be – whether committee scrutiny or lawsuit – the experimenter is the strategic center of responsibility.⁴⁰⁸

There are many examples where this has occurred. The stresses that an early heart surgeon named Cutler experienced in losing his patients when he first attempted heart valve surgery on them impelled him to call a personal halt to the operations.⁴⁰⁹ Similarly the previously described moratoria introduced during the early liver and heart transplant years were in the main demanded by the surgeons themselves.

404 McKinlay JB. From 'promising report' to 'standard procedure': seven stages in the career of a medical innovation. In: Technology and the future of health care, Milbank Reader. Ed Milbank JB, vol 8, p243, MIT Press, Cambridge, MA, 1982

405 Morris R. Evidence-based choice of hip prostheses. J Bone Joint Surg (Br) 1996;78-B:691-3.

406 Murray DW, Carr AJ, Bulstrode CJ. Which primary total hip replacement? J Bone Joint Surg (Br) 1995;77-B:520-7.

407 Jaffe LL. Law as a System of Control. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 197-217.

408 Jaffe LL. Law as a System of Control. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 197-217 at 201

409 Swazey JP, Fox RC. The Clinical Moratorium. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970. 315-357

There are many others, however, where the interests of patients have been secondary to the self-serving interests of the professionals concerned, as exemplified by the early heart operations and 'Bristol'. One particular failure concerned the selling of a 'cure for AIDS', despite there being no evidence for this claim. The GMC was heavily criticised for failing to act.⁴¹⁰ However a problem largely unrecognised by the general public is that the GMC can only act by way of information received.⁴¹¹ Frequently the only information provided to them is from other doctors. Of more concern in the above case was the failure of many doctors who, aware of the unethical experiments, failed to communicate their anxieties and state their views publicly.⁴¹² Campbell believes the GMC's rules on doctors not disparaging other doctors or face a potential charge of serious professional misconduct may act against the public interest.

The public is ... entitled to conclude that this part of the regulatory process scandalously sets aside the welfare of patients. It seems to be deliberately intended to silence doctors from disclosing legitimate matters of medical concern.⁴¹³

However, Smith believes doctors do not shop their colleagues due to the GMC's rules but more because they find it deeply distasteful⁴¹⁴ and it is only when certain boundaries are breached do they voice their concerns.

What those limits are is not always entirely clear. For example, Mason et al highlight the difficulty of distinguishing courageous from unethical experimentation. 'Human nature being what it is the answer often depends on the outcome.'⁴¹⁵ They illustrate their argument with the case of baby Fae.

In 1984 Bailey attempted a baboon heart transplant into a fifteen day old baby known only as Baby Fae.⁴¹⁶ The recipient survived for 20 days. However the operation caused huge controversy. It was felt to be an example of premature experimentation which failed the test of a reasonable chance.⁴¹⁷ Clearly, boundaries of acceptable behaviour had been breached.

It could be argued that virtually any innovation should undergo peer review and ethical and legal assessment, and this will be considered again later. However, such a requirement would be a significant burden and seriously curtail any advances, to the detriment of current and future patients. On the other hand, there may be an argument that, when viewed from the standpoint

410 Campbell D. An investigative journalist looks at medical ethics. *BMJ* 1989;289:1171-2.

411 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. London:Butterworths, 6th ed, 2002, 1.40.

412 Campbell D. An investigative journalist looks at medical ethics. *BMJ* 1989;289:1171-2.

413 Campbell D. An investigative journalist looks at medical ethics. *BMJ* 1989;289:1171-2 at 1172..

414 Smith R. Doctors, unethical treatments, and turning a blind eye. *BMJ* 1989;298:1125-6.

415 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. London:Butterworths, 6th ed, 2002, 19.51.

416 Bailey LL, Nehlsen-Cannarella SL, Concepcion W, Jolley WB. Baboon-to-human cardiac xenotransplantation in a neonate. *JAMA* 1985;254:3321-9.

417 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. London:Butterworths, 6th ed, 2002, 19.52.

of patient autonomy and issues of consent are considered, a different conclusion may be reached.

Thus Annas alleges that many of the early transplantation procedures were in reality purely non-therapeutic and intended only for the benefit of society.⁴¹⁸ However, in the practice of medicine there must always be a first time when a new method of treatment is employed or a new operation is performed. The difficulty is to protect individual patients while at the same time allowing medicine to progress, to the benefit of society in general.

SERNIP:

Medicine is not always scientific; many advances are made fortuitously or as a result of nothing more than intuition. Medical practitioners are expected and required to vary their therapeutic practice to take into account the individual characteristics and reactions of their patients. Variation is therefore inevitable in medical practice.

However, although it is accepted that routine clinical practice involves a degree of uncertainty and a degree of experimental observation, clinicians cannot have unlimited liberty to try new techniques. Although many professionals would view this as an attempt to restrict clinical freedom, recent concerns over the introduction and use of laparoscopic procedures led the Academy of Medical Royal Colleges to set up SERNIP, the Safety And Efficacy Register of New Interventional Procedures.⁴¹⁹ The aims of the register were firstly to monitor the use of novel procedures and protect the public from excessive enthusiasm and secondly, to co-ordinate the experience of doctors who are currently developing new techniques, thereby allowing rapid dissemination of data to those in that particular field.

It was, however, voluntary and clinically controlled. It was therefore, from the innovative doctor's point of view, at best a minor hurdle to be overcome and at worst something to be ignored with impunity. There was no requirement for an innovator to submit any information or clinical data. Furthermore, it only considered experimental procedures and was not concerned with personal innovation. Once the safety and efficacy of a technique was established the committee would advise that it could be put into general use. This element of self-regulation was clearly not working.

The importance of SERNIP, however, lay in the fact that it suggests that the Royal Colleges considered medical innovation to be a separate entity from either therapy or research. It also implies that the Royal Colleges were concerned about the proliferation of unregulated innovation and were prepared to limit clinical freedom. The profile and impact of the register was, however, limited⁴²⁰ and responsibility recently taken over by the National Institute for Clinical Excellence.

⁴¹⁸ Annas G. Death and the Magic Machine. *Western New England Law Review* 1987;9:89 at 98.

⁴¹⁹ Bower H. A safety net cast over new surgery. *Hospital Doctor*, 16th May, 1996, p5.

⁴²⁰ Campbell B, Maddern G. Safety and efficacy of interventional procedures. *BMJ* 2003;326:347-8.

RESEARCH:

It is therefore clear that, in the past, self-regulation did not succeed in regulating innovation and protecting patients. It may be that difficulties have arisen because the regulatory system failed to recognise innovation as a separate entity. Research, however, has always been recognised as being distinct from therapy. Indeed, some believe that the importance attached to research led to the era of 'modern medicine' and this change in emphasis dictated that medical practice should be subject to central control.⁴²¹ It may therefore be appropriate to review whether self-regulation has been successful in protecting patients in the recognised and established environment of the research setting. If this has been successful, it could be argued that similar protection could be afforded to patients subjected to innovation, provided such innovation can be differentiated from both research and normal therapeutic practice.

Regulating research:

The main impetus for regulating medical research and formalising a set of ethical guidelines arose out of the Nazi war crimes trials at Nuremberg, resulting in the Nuremberg code.^{422 423} This later led the World Medical Association to draw up the Declaration of Helsinki.⁴²⁴ The ethical principle of respect for the research subject's autonomy underpins research regulation.

In many respects the regulation of research from a legal perspective typifies the third type of law defined by Montgomery.

The third type of law..., quasi-law, describes rules which may be made without explicit legal authority and which are most important for the guidance they offer rather than the sanctions which follow if they are disregarded. ... Its force is therefore sometimes ethical rather than strictly legal.⁴²⁵

The most detailed guidance on the proper conduct of research has come from the Royal College of Physicians.⁴²⁶ The Department of Health in turn published guidelines instructing health authorities to set up Local and Multi-Centre Research Ethics Committees (LRECs and MRECs) which were to be reconstituted and conform to its guidelines.^{427 428} The Scottish MREC was

421 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. London: Butterworths, 6th ed, 2002, 13.

422 Dictionary of Medical Ethics. Duncan AS, Dunstan GR, Welbourn RB (eds). Darton, Longman and Todd, London, 1981

423 Katz J. Experimentation with human beings. Russell Sage Foundation, 1972, p305-6

424 The World Medical Association. The Declaration of Helsinki. Recommendations guiding medical doctors in biomedical research involving human subjects. 1964 (revised 1975, 1983, 1989, 1996 and 2000).

425 Montgomery J. Health Care Law. 2nd ed. Oxford: Oxford University Press, 2003, p5.

426 Royal College of Physicians, Research Involving Patients (London: RCP, 1990); Royal College of Physicians, Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects (London: RCP, 1990).

427 Department of Health. Local Research Ethics Committees, London: Department of Health 1991.

428 Department of Health. Ethics committee review of multi-centre research. London: Department of Health, 1997. (HSG(97)23.)

instituted in April 1997.⁴²⁹ Although the existence of these RECs is now well established, their composition and functions are still very varied and there are serious concerns regarding their functioning. They are not audited, they do not appear to monitor research and appear to be accountable to nobody.⁴³⁰ More recently, the European Trials Directive 2001/20/EC was developed with the intention of simplifying and harmonising regulation of clinical trials across the European Community. The provisions of this directive have been translated into United Kingdom regulations through the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), which came into force on the 1st May 2004. This should lead to tighter control than occurred previously, with new responsibilities placed on those managing and conducting clinical trials.

Concerns?

Despite this, there are still many questions surrounding the use of patients in research. The GMC clearly states that “if taking part in clinical trials of drugs or other research involving patients [the doctor] must make sure that the research is not contrary to the patients’ interests”.⁴³¹ As previously discussed, some forms of therapeutic research and all non-therapeutic research do not lead to any gain for the research subject. Similarly, there appear to be problems with the use of placebos. This is acceptable if no current active treatment exists. However, it is questionable whether it is ethically acceptable to allow a patient the possibility of only receiving a placebo when an active treatment already exists. Of more concern is the fact that these patients may be unaware they are being denied effective forms of treatment merely to comply with an administration’s (such as the US Federal Drug Administration) policies.⁴³²

Divergent views on many ethical aspects of medical research are held not only by individuals and the general public but also by the institutional research ethics committees. To ensure that societal values are upheld, even developed and clarified, the safety and quality of these committees’ judgements need to be subject to the audit that the committees demand of their client researchers.⁴³³ This leads to further problems. It is now virtually impossible to publish a research study in a peer-reviewed journal without it first having been passed by the local REC. However, because unethical research is virtually never published, the committee that originally approved it cannot easily be subject to peer accountability or the potential for societal discussion and judgement.

Commercial research is another area where, because it might not be in the interests of the study sponsors, findings may be kept secret, with serious

429 Scottish Office. NHS MEL (1997) 8

430 Neuberger J. 1992. Ethics and Health Care. The Role of Research Ethics Committees in the United Kingdom. King’s Fund Institute.

431 GMC. Good medical practice: Duties of a doctor, 1995, p13

432 Savulescu J, Chalmers I, Blunt J. Are research ethics committees behaving unethically? Some suggestions for improving performance and accountability. *BMJ* 1996;313:1390-3.

433 Pearn J. Publication: an ethical imperative. *BMJ* 1995;310: 1313-1315.

consequences. This failure to publish is usually undertaken in an effort to try to maintain the company's image when research results have not been favourable. Thus, participants may not become aware of any risks which would otherwise have been revealed. Worse still, the study may be repeated with more patients suffering harm. It has thus been suggested that registering all clinical trials at inception could avoid this problem.⁴³⁴

The present situation is also difficult to defend in terms of public accountability. It has been argued that to maintain the public's confidence in those who carry out research the public must believe that research investigations are submitted to rigorous ethical scrutiny and professional self-discipline. Furthermore, it is suggested that ethical conduct is the best way to protect volunteers and patients.⁴³⁵

It has thus been argued that clinical research must be self-regulating if it is to be properly regulated. Codes, guidelines, committee review, and legal control will not produce a maximum of well conducted research unless they function to stimulate ethically informed behaviour from the researchers themselves.⁴³⁶ It must be pointed out that very similar arguments have been proposed for the self-regulation of therapy and the introduction of innovative treatment, as previously discussed. It is debatable, however, whether self-regulation alone is sufficient.

Fraud and misconduct:

Concern is growing over scientific fraud and misconduct in research. Although the possibility of misconduct can be minimised by a hierarchy of supervision⁴³⁷ it unfortunately still occurs. Farthing argues that without regulation there is the risk that ineffective or dangerous drugs might be used. He has similar concerns surrounding the dishonest reporting of the safety of new surgical procedures if there is selective discounting of cases that were not so successful.⁴³⁸

In New Zealand the Cartwright report published in 1988 followed an inquiry into allegations of a research programme undertaken at the National Women's Hospital in Auckland.⁴³⁹ The research entailed withholding conventional treatment from patients with carcinoma in situ of the cervix to study the natural course of the disease. It had been approved by the hospital ethics committee. The chairman of the committee stated that the study 'merged into general treatment.'⁴⁴⁰ Even an internal hospital review following

434 Chalmers I. Under-reporting research is scientific misconduct. JAMA 1990;263:1405-1408

435 British Medical Association. The handbook of medical ethics, BMA, 1980, p 25.

436 Byrne P. A European perspective in regulating clinical research. BMJ 1989;299:218.

437 Pearn J. Publication: an ethical imperative. BMJ 1995;310: 1313-1315.

438 Farthing MJG. An editor

's response to fraudsters. BMJ 1998;316:1729-31.

439 Cartwright SR. The report of the committee of inquiry into allegations concerning the treatment of cervical cancer at National Women's Hospital and into other related matters. Auckland Government Printing Office, 1988.

440 Bonham. Quoted in Paul C. The New Zealand cervical cancer study: Could it happen again? BMJ 1988;297:533-9 at 533.

concerns raised by other members of staff failed to stop the trial. Furthermore, despite the study being widely known beyond New Zealand only one gynaecologist expressed concern and tried to intervene.⁴⁴¹ There was a failure to put the safety of patients before the reputation of colleagues. One of the medical advisors to the inquiry wrote:

In the past the principle safeguard for the patient has been the integrity and good faith of the doctor. When that good faith is brought into question at the highest levels in the hospital there must be recourse to other mechanisms to protect the patient.⁴⁴²

That same year Lock published the results of a personal survey which concluded that research misconduct existed in the UK and urgent action was needed to prevent the problem by establishing an organisation similar to those already in place in the US.⁴⁴³

In the US Congress reacted to cases of scientific fraud by setting up congressional inquiries⁴⁴⁴ and an Office of Research Integrity.⁴⁴⁵ A Commission on Research Integrity⁴⁴⁶ and the National Academy of Sciences also reported⁴⁴⁷, refining definitions and suggesting a whistleblower's bill of rights. Similar agencies have been set up in Denmark, Norway, Finland and Australia.⁴⁴⁸ These agencies function independently of academic institutions, funding agencies or other professional regulatory bodies.

It is clear, however, that the UK lags 15 years behind the US in recognising the problem and seeking solutions.⁴⁴⁹ For many a year many in the medical profession did not believe it occurred.⁴⁵⁰

It was only when a leading gynaecologist, Malcolm Pearce, fraudulently published two papers that the British medical profession was finally

441 Paul C. The New Zealand cervical cancer study: Could it happen again? *BMJ* 1988;297:533-9.

442 Paul C. The New Zealand cervical cancer study: Could it happen again? *BMJ* 1988;297:533-9 at 538.

443 Lock S. Misconduct in medical research: does it exist in Britain? *BMJ* 1988;297:1531-5.

444 Rennie D, Gunsalus CK. Scientific misconduct. New definition, procedures, and office – perhaps a new leaf. *JAMA* 1993;269:915-7.

445 Rennie D. An American perspective on research integrity. *BMJ* 1998;316:1726-8.

446 Commission on Research Integrity. Integrity and misconduct in research. Report of the Commission on research Integrity to the Secretary of Health and Human Services, the House Committee on Commerce and the Senate Committee on Labor and Human Resources. Rockville, MD: US Department of Health and Human Services, Public Health Service, 1995.

447 National Academy of Sciences. Responsible science. Ensuring the integrity of the research process. Vol II. Washington DC: National Academy Press, 1993.

448 Lock S. Recent misconduct: a resume of recent events. In: Lock S, Wells F, eds. *Fraud and misconduct in medical research*. London: BMJ Publishing Group, 1996.

449 Rennie D, Gunsalus CK. Regulations on scientific misconduct: lessons from the US experience. In: *Fraud and Misconduct in Biomedical Research*. Lock S, Wells F, Farthing M (eds). London: BMJ books, 2001, 3rd ed, 13-31.

450 Lock S. Research misconduct 1974-1990: an imperfect history. In: *Fraud and Misconduct in Biomedical Research*. Lock S, Wells F, Farthing M (eds). London: BMJ books, 2001, 3rd ed, 51-63.

galvanised.⁴⁵¹ Despite this, the president of the GMC as recently as 1999 stated that, compared with the well-established pattern of research misconduct in the USA he had not had strong evidence of such a problem in Britain.⁴⁵²

The bestowal of a medical or scientific degree is not accompanied by a guarantee of honesty.⁴⁵³ Because professionals do not always behave in the way expected of them, there must be some higher body to force regulation on them.⁴⁵⁴ 'It makes no sense to leave the regulations governing research misconduct to be developed by individual research institutions, not least because some central oversight to ensure compliance is wise and necessary.'⁴⁵⁵

Farthing argues that the preservation of research integrity is another aspect of public health and thus requires an inspectorate body.⁴⁵⁶ Such an organisation would need to work closely with other professional bodies responsible for maintaining standards.

However, despite a recent agreement that the time had come to act decisively on research misconduct and set up a national body to lead the response to the problem⁴⁵⁷ nothing has happened, prompting a severe rebuke from the editors of three of the main UK journals.⁴⁵⁸ If the leaders of medicine do not act they risk the loss of public confidence in medical research. Once again self-regulation appears to be failing.

CONCLUSION:

Medical self-regulation is under the microscope. For a decade, there has been growing public concern regarding the way the General Medical Council and the Royal Colleges have operated professional self-regulation. To many, these institutions have reflected more general attitudes in the profession and have appeared unduly protective of doctors rather than of patients. They have been accused of being inward-looking, self-interested, unaccountable, ineffective, and increasingly at odds with public interest.^{459 460 461}

451 Lock S. Research misconduct 1974-1990: an imperfect history. In: *Fraud and Misconduct in Biomedical Research*. Lock S, Wells F, Farthing M (eds). London: BMJ books, 2001, 3rd ed, 51-63.

452 General Medical Council. Letter from the President, 1 December 1999. Reported in Lock S. Research misconduct 1974-1990: an imperfect history. In: *Fraud and Misconduct in Biomedical Research*. Lock S, Wells F, Farthing M (eds). London: BMJ books, 2001, 3rd ed, 51-63.

453 Rennie D. An American perspective on research integrity. *BMJ* 1998;316:1726-8.

454 Rennie D, Gunsalus CK. Regulations on scientific misconduct: lessons from the US experience. In: *Fraud and Misconduct in Biomedical Research*. Lock S, Wells F, Farthing M (eds). London: BMJ books, 2001, 3rd ed, 13-31.

455 Rennie D. An American perspective on research integrity. *BMJ* 1998;316:1726-8 at 1727.

456 Farthing MJG. An editor's response to fraudsters. *BMJ* 1998;316:1729-31.

457 Misconduct in biomedical research: final consensus statement. In: Nimmo WS, ed. Joint consensus conference on misconduct in biomedical research. *Proc R Coll Phys Edin* 2000;3(suppl 7):2.

458 Farthing M, Horton R, Smith R. UK's failure to act on research misconduct. *Lancet* 2000;356:2030.

459 Smith R. Profile of the GMC: the day of judgement comes closer. *BMJ* 1989;298:1241-44.

460 Horton R. UK Medicine: What are we to do? *Lancet* 1998;352:1166.

461 Smith R. All changed, changed utterly. *BMJ* 1998;316:1917-18.

Licensing bodies have the obligation to discipline unprofessional and incompetent behaviour. These institutions serve an essential function and professionalism can only survive if they function properly, which requires the support and participation of individual doctors.⁴⁶² There is, however, recognition that there are deep seated flaws in the culture and regulation of the medical profession⁴⁶³, as illustrated by the Bristol affair, problems with organ retention at Alder Hey, retention of organs in Scotland⁴⁶⁴, the murders committed by Dr Shipman and the appalling treatment of patients by the gynaecologist Dr Ledward⁴⁶⁵. These

cultural flaws show up as excessive paternalism, lack of respect for patients and their right to make decisions about their care and secrecy and complacency about poor practice.⁴⁶⁶

There is therefore a need to change the basis of professional regulation so that the profession performs as the public and individual patients expect. When colleagues and patients had concerns regarding the care provided by Rodney Ledward they reported being unsure whose responsibility it was to take action.⁴⁶⁷

The danger that power will be misused is inherent in any system that assigns authority to a group of people to police themselves.⁴⁶⁸ The recent highly publicised events mentioned above have encouraged the view that the medical profession fails to meet many of the obligations required to sustain its professionalism.⁴⁶⁹ A better informed community is asking for accountability, transparency, and sound professional standards.⁴⁷⁰

Autonomy is granted by the ultimate source of power in western societies: the state. The state grants the profession the legal right to regulate itself. If the state believes that a profession is not regulating itself in a manner that is appropriate then that right can be removed.⁴⁷¹ Public trust in the medical profession is the key to the political arrangement.

462 Cruess RL, Cruess SR, Johnston SE. Professionalism: an ideal to be sustained. *Lancet* 2000;356:156-9.

463 Irvine D. The changing relationship between the public and the medical profession. *J R Soc Med* 2001; 94: 162-9.

464 Final Report of the Independent Review Group on Retention of Organs at Post-mortem. Scottish Exec, 2001.

465 Ritchie J, Mellows H, Chalmers J, Bash J. The report of the inquiry into quality and practice within the National Health Service arising from the action of Rodney Ledward. London: Department of Health, 2000.

466 Irvine D. The changing relationship between the public and the medical profession. *J R Soc Med* 2001; 94: 162-9 at 162

467 Ritchie J, Mellows H, Chalmers J, Bash J. The report of the inquiry into quality and practice within the National Health Service arising from the action of Rodney Ledward. London: Department of Health, 2000.

468 Wynia MK, Latham SR, Kao AC, Berg J, Emanuel LL. Medical Professionalism in Society. *NEJM* 1999;341:1612-6.

469 Cruess RL, Cruess SR, Johnston SE. professionalism: an ideal to be sustained. *Lancet* 2000;356:156-9.

470 Dunning AJ. Status of the doctor- present and future. *Lancet* 1999;354:SIV18.

471 Salter B. Change in the governance of medicine: the politics of self-regulation. *Policy and Politics* 1999;27(2):144-5.

Events such as Bristol have illustrated the reluctance of doctors to confront under-performance in colleagues and to make critical judgements.⁴⁷² This reluctance is generally grounded in real difficulties, with problems about the lack of absolute, valid and reliable clinical guidelines; questions regarding what constitutes an acceptable degree of variation in practice and outcomes; and the influence of case mix on these outcomes. Consequently reliable and consensus evidence for what constitutes best practice tends not to be available. However, clear evidence for what constitutes poor practice is far more certain and widely recognised.⁴⁷³

Thus the Government and National Health Service management are introducing their own plans for strengthening institutional responsibility for the standard of patient services through external review and clinical governance.^{474 475} These measures will be examined in the next chapter.

472 Treasure T. Lessons from the Bristol case: more openness- on risks and an individual surgeon's performance. *BMJ* 1998;316:1685-86.

473 Irvine, D. The performance of doctors; the new professionalism. *The Lancet* 1999, 353; 1174-77.

474 Secretary of State for Health. *The new NHS: modern, dependable* (Cmnd 3807). London: HMSO, 1997.

475 Secretary of State for Health. *A first class service: quality in the new NHS*. London: Department of Health, 1998.

THE REGULATION OF INNOVATION:

CHAPTER 4:	
REGULATION BY GOVERNMENT	94
Government proposals	95
National Institute for Clinical Excellence	95
Evidence-based medicine	97
Limitations	97
Rationing and cost-effectiveness	102
Limitations	104
Variation	107
Limitations	107
Clinical guidelines	108
Benefits	108
Limitations	109
The Commission for Health Improvement	113
Limitations	115
Regulating Innovation	116

CHAPTER 4: REGULATION BY GOVERNMENT

Regulation is a sustained and focussed control exercised by a public agency over activities that are valued by a community.⁴⁷⁶ The key features of regulation are that it involves a third party, the regulator, in transactions and inter-organisational relationships.⁴⁷⁷ It places responsibility for overseeing performance with a single entity, the regulator. The recent rise in NHS regulation is part of the growth of the regulatory state⁴⁷⁸ or audit society⁴⁷⁹, the result of a shift in how society holds public services to account. Recent NHS reforms have seen the transfer of power from health professionals – principally doctors – to a new class of employee: the general manager.⁴⁸⁰ The rationale for putting managers in charge of the NHS was described in the ‘Griffiths’ report.⁴⁸¹

Initially, at least, managers were engaged in managing down to the level of clinical consultation, but not beyond. The interface between the public and the health professional remained out of bounds. Clinical decision-making was left largely independent and untouched by direct managerial mechanisms, although it was influenced by organisational and resource constraints and, in turn, influenced them. However, Charlton believes that since 1983, it has been the long-term intention that the primary focus of NHS activity was to be the management of the organisation rather than the personal interactions between the clinicians and patients.⁴⁸² Since that time, what has been established is managerial financial control. This encroaches on clinical independence by seeking increasing control of decision-making. Over the years the managerial agenda has therefore moved towards direct influence of decision-making processes in the clinical consultation, and also towards pre-determination of the possible outcomes of doctor-patient interactions.⁴⁸³

The mess over the introduction of Sildenafil (Viagra) into the NHS,^{484 485} especially the delay and the botched criteria as to who would get it,⁴⁸⁶ made it clear that a better mechanism for the introduction of new drugs and technology into the NHS was needed. There was clearly a lack of capacity at

476 Selznick P. Focusing organisational research on regulation. In: Noll R, ed. *Regulatory policy and the social sciences*. Berkeley: University of California Press, 1985:363-8.

477 Walshe K. The rise in regulation in the NHS. *BMJ* 2002;324:967-70.

478 Majone G. The rise of the regulatory state in Europe. *West European Politics* 1994;17(3):77-101.

479 Power M. *The audit society: rituals of verification*. Oxford: Oxford University Press, 1997.

480 Charlton BG. Management of science. *Lancet* 1993;342:99-100.

481 Griffiths R. Report of the NHS management inquiry. (1983) DHSS, London.

482 Charlton BG. The new management of scientific knowledge in medicine: a change of direction with profound implications. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 13-31

483 Charlton BG. The new management of scientific knowledge in medicine: a change of direction with profound implications. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 13-31 at 19.

484 Department of Health. Health Service Circular 1998/158, 16 September.

485 *R v Secretary of State for Health, ex parte Pfizer Ltd* 1999. *Lloyds Rep Med* 289

486 Chisholm J. Viagra: a botched case for rationing. *BMJ* 1999;318:273-4.

national level to appraise healthcare interventions before or even after their introduction into the health service. This had several adverse consequences: no guidance was available, local policies varied, and unproven interventions entered routine use.⁴⁸⁷

GOVERNMENT PROPOSALS:

In view of this, the Government thus published a consultation document on quality in the National Health Service.⁴⁸⁸ Part of the proposals described the creation of a National Institute for Clinical Excellence (NICE) and a Commission for Health Improvement (CHI) as special health authorities with powers intended to influence the clinical practice of doctors. NICE would provide national standards of treatment while CHI would ensure that those national standards were met.

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE:

NICE was established with three broad functions.⁴⁸⁹ First it would appraise new technologies, effectively vetting those deemed ineffective, or too costly, or otherwise inappropriate for use in the NHS.⁴⁹⁰ In this respect, it is the first national body with power to issue such recommendations covering the full range of health technologies.⁴⁹¹ As mentioned in the last chapter, following the Bristol Inquiry report^{492 493}, NICE took over responsibility for assessing the efficacy and safety of new interventions, work previously carried out by SERNIP. Second, it would issue 30-50 'evidence-based' clinical guidelines per annum for the management of medical conditions. Third, it would be responsible for approving models of clinical audit for compulsory use by hospital doctors.

In 1999, the editor of the British Medical Journal, in a leading article, stated that the newly introduced NICE should be useful for managing the introduction of new technologies.⁴⁹⁴ A thesis on the regulation of innovation therefore needs to examine the role NICE could play in this regulation. Most of its recommendations to date have specified conditions for use for new therapy. This in turn requires guidelines covering the full range of treatment options. Thus, two of its three functions are closely linked. Firstly it will appraise and make recommendations about the introduction of a particular technology and then produce guidelines about the use of that technology.

487 Dent THS, Hawke S. Too soon to market: doctors and patients need more information before drugs enter routine use. *BMJ* 1997;315:1248-9.

488 Secretary of State for Health. *A first class service: quality in the NHS*. London: Stationery Office, 1998.

489 National Institute for Clinical Excellence. *A guide to NICE*. London: NICE, 2003.

490 Loughlin M. 'Quality' and 'excellence': meaning versus rhetoric. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 1-12.

491 Sculpher M, Drummond M, O'Brien B. Effectiveness, efficiency and NICE. *BMJ* 2001;322:943.

492 Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001.

493 Department of Health. *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*. CM 5363. London:HMSO. 2002, p58 at 4.10.

494 Smith R. NICE: a panacea for the NHS? *BMJ* 1999;318:823-4.

The Commission for Health Improvement was responsible for tackling variations in the quality of patient care, monitoring the implementation of guidelines and investigating clinical problems in the NHS. In response to recommendations in the Bristol Inquiry report⁴⁹⁵ its remit was expanded and given 'more teeth'.⁴⁹⁶ In April 2002 the government proposed its amalgamation with part of the Audit Commission, to be called the Commission for Healthcare Audit and Inspection (CHAI).⁴⁹⁷ This new body will combine the role of the Commission for Health Improvement, the role of the Audit Commission in its NHS related work, and the private health sector inspection role of the new National Care Standards Commission. The emphasis of this new body is inspection^{498 499} and should be in place by April 2004.

NICE and CHI (or CHAI) apply to the NHS in England. Scotland has her own version of NICE but with each of its functions looked after by a separate body, the Health Technology Board for Scotland (HTBS) appraising new technology, the Scottish Intercollegiate Guidelines Network (SIGN) creating guidelines and the Clinical Resource and Audit Group (CRAG) encouraging national clinical audit.

The Scottish equivalent of CHI was the Clinical Standards Board for Scotland. This was established as a special health authority in April 1999 following the Carter report on acute services, which recommended that there should be a single mandatory system of accreditation for hospitals and primary care.⁵⁰⁰ The Board's task was to develop and run a national system of quality assurance and accreditation of clinical services, with the aim of promoting public confidence in NHSScotland. On January 1st, 2003, the CSBS became part of a new organisation called NHS Quality Improvement Scotland (NHSQIS).

However, since little has been written about any of the Scottish bodies, NICE and CHI will be reviewed and differences from the Scottish equivalents, if any, will be highlighted.

In an article in *The Lancet*, the chairman of NICE, Professor Sir Michael Rawlins described his main concerns relating to treatment in the NHS before the introduction of NICE.⁵⁰¹ He believed that all decisions in the health service

495 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002, p62 at 4.20

496 House of Commons. The National Health Service Reform and Healthcare Professions Act. London: HMSO, 2002.

497 Commission for Health Improvement. Corporate strategy to 2005 and business plan 2002-2003. London: HMSO, 2002.

498 Dewar S, Finlayson B. The I in the new CHAI. BMJ 2002;325:848-50.

499 Moore W. NHS to receive an extra £40bn over next five years. BMJ 2002;324:993.

500 Scottish Office. Quality assurance and accreditation. In: Acute services review report. Edinburgh: Scottish Office Publications, 1998.

501 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. The Lancet 1999;353:1079-82.

should be made on the basis of sound evidence, that ‘unexplained’ variations in the way patients were treated should be eliminated where possible, and that treatments employed should be cost-effective. Each of his concerns, i.e. lack of evidence, cost effectiveness, and variation in treatment will be analysed.

The second of NICE’s three functions, the production of guidelines, and the role of CHI/ CHAI will be reviewed shortly. The production of guidelines may prove challenging over the long term, given the magnitude of the task and the paucity of evidence.⁵⁰² This is therefore where to start; reviewing what evidence is available to enable guidelines for treatment or innovative technology to be generated.

Evidence-based medicine:

Evidence-based medicine (EBM) is the conscious, explicit and judicious use of current best evidence in making decisions about the care of individual patients⁵⁰³, obtained by reviewing the evidence available from randomised clinical trials (RCTs) and meta-analysis of current research. NICE’s decisions are based on this evidence. Meta-analysis refers to the quantitative synthesis of the results of primary studies.⁵⁰⁴ EBM stresses the examination of evidence from clinical research and de-emphasises intuition, unsystematic clinical experience and pathophysiological rationale as sufficient grounds for decision making. EBM is now highly fashionable, perhaps particularly with those who do not actually treat patients themselves. It seems irrefutable that medicine should be practised on the basis of the best available evidence of the risks and benefits of any intervention. This has always been the aim of medical practice, but what is new is a change of attitude to the sort of evidence needed for medical practice to be truly evidence based.

However, views on the value of EBM are literally, poles apart. On the one hand there is a belief that ‘meta-analysis is clearly superior to the narrative approach to reviewing medical research.’⁵⁰⁵ Others, however, hold a diametrically opposite view. The ‘knowledgeable, thoughtful, traditional review remains the closest thing we have to a gold standard of summarizing disparate evidence in medicine’⁵⁰⁶

Limitations:

Kleinert believes that the modern trend to search for precise answers in the form of numbers and probabilities can only have a limited role in human sciences such as medicine.⁵⁰⁷ Similarly, although Feinstein acknowledges that randomised clinical trials have provided answers in clinical medicine, he

502 Raftery J. NICE: faster access to modern treatments? Analysis of guidance on health technologies. BMJ 2001;323:1300-3.

503 Sackett D, Richardson WS, Rosenberg W, Haynes P. Evidence based medicine. Churchill Livingstone, London: 1996.

504 Glass G. Primary, secondary, and meta-analysis of research. Educ Res 1976;10:3-8.

505 Davey Smith G, Egger M. Unresolved issues and future developments. Brit Med J 1998;316:221-5 at 224.

506 Bailer JC 3rd. Meta-analysis and large randomised, controlled trials. N Engl J Med 1998;338:62

507 Kleinert S. Rationing of healthcare- how should it be done? Lancet 1998;352:1244.

believes these are mainly about therapeutic agents whose average efficacy has been unequivocally shown.⁵⁰⁸

The seduction of EBM is that, *statistically*, the bigger the database from which the average is constructed, the more confidence there is in *what the average is*, but this does not make the average applicable to more patients.⁵⁰⁹ Indeed, it is precisely the idea of the *average* efficacy that misleads. Patients differ systematically from one another and often these differences are unknown. One of the fundamental flaws of EBM is that it fails to cater for the individual.⁵¹⁰

A clinical trial will show how many patients from a group will benefit from treatment and how many will suffer an adverse effect, but it can never predict the outcome in a particular individual. A doctor may explain to his patients that he can do no more than give a probability of success or failure; in following evidence the doctor must accept that he is going to treat a whole group of patients in the standard way. In short he is going to practice medicine by numbers.⁵¹¹ Furthermore, RCTs seldom focus on safety issues.⁵¹² Adverse drug effects are often unanticipated and are predominantly investigated by observational studies.⁵¹³ Individual RCTs often do not suffice to detect adverse effects, especially if the effects are rare and late.⁵¹⁴

Thus RCTs cannot provide precise and unambiguous guidance for clinical practice.^{515 516} Most are conducted on unrepresentative populations of heterogeneous subjects and employ suboptimal levels of experimental control.⁵¹⁷ The conditions of randomised controlled trials are not the conditions of clinical practice. Patients in such trials receive greater attention from medical and nursing staff. Furthermore, the constraints on the patients entered into trials are often very tight, which means that the result of the trial may not be applicable to the general population. Patients are frequently excluded because they do not meet the eligibility criteria for entry, such as being too old or too ill. A recent study advocating aspirin for the prevention of cerebral infarction⁵¹⁸ specifically excluded patients at risk of adverse events

508 Feinstein AR. Clinical judgement revisited: the distraction of quantitative models. *Ann Intern Med* 1994;120:799-805.

509 Goodman NW. NICE and the new command structure: with what competence and with what authority will evidence be selected and interpreted for local clinical practice? in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 33-50 at 37

510 Ellis SJ. Some unanswered questions about NICE. *J R Soc Med* 1999;92:538-9

511 JR Hampton - Evidence based medicine, practice variations and clinical freedom. *Journal of Evaluation in clinical practice* 1997; 3(2):123-131

512 Cuervo LG, Aronson JK. The road to health care. *BMJ* 2004;329:1-2.

513 Vandenbroucke JP. Benefits and harms of drug treatments. *BMJ* 2004;329:2-3.

514 Jick H. The discovery of drug-induced illness. *N Engl J Med* 1977;296:481-5.

515 Charlton BG. Megatrials are based on a methodological mistake. *British J of General Practice* 1996;46:429-31.

516 Goodman NW. Anaesthesia and evidence-based medicine. *Anaesthesia* 1998;53:353-68

517 Goodman NW. Who will challenge evidence-based medicine? *J Royal Coll Phys Lond* 1999;33:249-51.

518 Antithrombotic Trialists' Collaboration. Prevention of death, myocardial infarction and stroke by antiplatelet therapy in high risk patients. *BMJ* 2001;323:71-86.

with aspirin, tending to include younger patients with lower multiple morbidity. It is therefore probable that aspirin is not as safe as suggested.⁵¹⁹

Similar concerns have arisen regarding the complication rate of surgical treatment for carotid artery stenosis⁵²⁰ and clinical trials of treatment for myocardial infarction where the death rate is consistently lower than in hospital practice.⁵²¹ The extent to which trial results can be carried directly into routine practice is thus always a matter of some doubt.

There is ample evidence that many trials are methodologically weak and increasing evidence that deficiencies translate into biased findings.^{522 523} For example it is well known that the pharmaceutical industry is heavily involved in sponsoring medical research, many academic investigators having affiliations that could influence research and publication.⁵²⁴ Such research is likely to reach conclusions that are favourable to industry. Doctors are often paid to recruit patients to clinical trials sponsored by pharmaceutical companies. Such payments are not at present disclosed to potential trial patients.⁵²⁵

Even the US regulatory authority, the Food and Drug Administration (FDA), has links with the pharmaceutical industry. Concerns have been raised following its decisions regarding the marketing of the drug alosetron.^{526 527 528} Critics have alleged that the regulatory agency has become a servant of industry, where dissenting voices are intimidated and ostracised and scientific debate repressed.⁵²⁹ Many have therefore called for an end to industry's funding of the FDA's drug reviews.⁵³⁰

The technique of meta-analysis is also flawed. The statistical averaging of different trials performed in different places by different people for different purposes merely generates a meaningless statistical artefact. Making matters worse is the problem of publication bias where small negative trials either are not reported by investigators or are not accepted for publication by editors. To

519 Cleland JGF. Preventing atherosclerotic events with aspirin. *BMJ* 2002;324:103-5.

520 Swales J. The National Health Service and the science of evaluation: two anniversaries. *Health Trends* 1998;30:20-2.

521 Brown N, Young T, Gray D, Skene AM, Hampton JR. Inpatient deaths from acute myocardial infarction 1982-1992: analysis of data in the Nottingham heart attack register. *BMJ* 1997;315:159-64.

522 Juni P, Altman DG, Egger M. Assessing the quality of controlled clinical trials. *BMJ* 2001;323:42-6.

523 Mayor S. Researchers claim clinical trials are reported with misleading statistics. *BMJ* 2002;324:1353.

524 Hopkins J. Industry is deeply involved in funding US research. *BMJ* 2003;326:179.

525 Rao JN, Sant Cassia LJ. Ethics of undisclosed payments to doctors recruiting patients in clinical trials. *BMJ* 2002;325:36-7.

526 Lievre M. Alosetron for irritable bowel syndrome. *BMJ* 2002;325:555-6.

527 Moynihan R. Alosetron: a case study in regulatory capture, or a victory for patients' rights? *BMJ* 2002;325:592-5.

528 Lievre M. Alosetron for irritable bowel syndrome. *BMJ* 2002;325:555-6.

529 Moynihan R. Alosetron: a case study in regulatory capture, or a victory for patients' rights? *BMJ* 2002;325:592-5.

530 Horton R. The FDA and the Lancet: an exchange. *Lancet* 2001;358:417-8.

put it bluntly, meta-analysis is a logically incoherent technique of zero scientific credibility.^{531 532}

There are also difficulties in assessing the quality of trials.⁵³³ An editorial comment⁵³⁴ on one description of quality rating⁵³⁵ was that the findings really cast serious doubts on the validity of current clinical research. There are even greater problems with the development and introduction of new diagnostic procedures. Their evaluation is much less advanced than that of new treatments. Unlike drugs there are generally no formal requirements for adoption of diagnostic tests in routine care. The methodology of diagnostic research is poorly defined compared with study designs on treatment effectiveness and flaws are common.⁵³⁶

For example Dickersin⁵³⁷ cited media reports that mammography for women under 50 'saves lives'. This is true. Of 10,000 40-49-year-olds screened, 30 will be diagnosed with breast cancer and treated. Some of these women would otherwise have died. But these 30 will be from 640 who had abnormal mammograms, of whom 150 had biopsies. Will the women eventually pronounced clear be reassured? Will they be grateful for the worry they went through? How are these factors to be measured when the research merely looks at outcomes? Dickersin also points out that some of the 30 women diagnosed with cancer would have been treated for an *in-situ* lesion, the natural history of which is unknown.

More worrying is the dispute that recently erupted following a review that stated that there was no reliable evidence to support the screening for breast cancer with mammography.⁵³⁸ It held there was no reliable evidence that it reduced mortality but merely led to more aggressive treatment. The editors of the Cochrane Breast Cancer Group insisted changes had to be made if the review was to be published in the Cochrane Library. The authors disagreed. According to the editor of the Lancet, interference by Cochrane editors to insert what the authors believed to be invalid analyses eroded the academic freedom of the investigators.⁵³⁹

Thus, Goodman believes that the closer health service workers are to treating patients, the less enthusiastic they are likely to be about evidence based medicine as the only, or at least the best, basis for treatment.⁵⁴⁰ The basic

531 Feinstein AR. Meta-analysis: statistical alchemy for the 21st century. J Clin Epidemiol 1995;48:71-9

532 Charlton BG. The uses and abuses of meta-analysis. Fam Prac 1996;13:397-401.

533 Cleland JGF. Preventing atherosclerotic events with aspirin. BMJ 2002;324:103-5.

534 Ioannidis JPA, Lau J. Can quality of clinical trials and meta-analysis be quantified? Lancet 1998;352:590-1.

535 Moher D, Pham B, Jones A, et al. Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analysis? Lancet 1998;352:609-13.

536 Knottnerus JA, van Weel C, Muris JWM. Evaluation of diagnostic procedures. BMJ 2002;324:477-80.

537 Dickersin K. Breast screening in women aged 40-49 years: what next? Lancet 1999;353:1896-7.

538 Olsen O, Gotzsche PC. Cochrane review on screening for breast cancer with mammography. Lancet 2001;358:1340-42.

539 Horton R. Screening mammography- an overview revisited. Lancet 2001;358:1284-5.

540 Goodman NW. NICE and the new command structure: with what competence and with what authority will

concern regarding EBM is that information collected from populations is being applied to individual patients.

The basic error of EBM is quite simple. It is that epidemiological data do not provide the information necessary to treat individual patients. The error is intractable and intrinsic to the methodological nature of epidemiology, and no amount of statistical jiggery-pokery with huge data sets can make any difference.⁵⁴¹

NICE, which utilises EBM in its deliberations, must also share in these criticisms:

NICE imposes a 'one size fits all' population view. This is undoubtedly more comfortable for the Department of Health and other parts of the NHS's management than the potential anarchy (from their point of view) that could result from empowering clinicians and patients to make their own decisions.⁵⁴²

Evidence alone does not make decisions. Thus an evidence-based decision will vary from one patient to another according to individual circumstances.⁵⁴³ Tanenbaum showed that the traditional practice model predominated in medical decision-making.⁵⁴⁴ In other words, clinical doctors are more likely to be influenced in their practice by their own (and close colleagues') experience with similar types of patient, and by their own reasoning about treatment logic, than by the publication of meta-analyses of large numbers of cases. In contrast, the health services research model places clinical observations at the bottom of the hierarchy of evidence.

EBM restricts consideration to the RCT but many questions cannot be answered by this technique.⁵⁴⁵ If EBM evaluates all available evidence, then it is doing no more than any respectable medical journal with its combination of review articles, opinion and primary research. The evidence merely supports decision-making but the evidence cannot make the decision. The values of the patient and the community, including the medical community, must be part of any decision.⁵⁴⁶

In scientific practice, rival theories are proposed by the many individuals and groups working in a particular field. Despite disagreement, some scientific theories are accepted and built upon, while others are either ignored or rejected. The ultimate judge of scientific validity is when other scientists use

evidence be selected and interpreted for local clinical practice? in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 33-50.

541 Charlton BG. Book review of evidence-based medicine. *J Eval Clin Prac* 1997;3:169-72 at 169.

542 Lipman T. NICE and evidence based medicine are not really compatible. *BMJ* 2001;322:489-90 at 489.

543 Haynes RB, Devereaux PJ. Physicians' and patients' choices in evidence based practice. *BMJ* 2002;324:1350.

544 Tanenbaum SJ. Knowing and acting in medical practice: outcomes research. *Journal of Health Politics, Policy and Law* 1994;19:27-44.

545 Ellis SJ, Adams RF. The cult of the double-blind placebo-controlled trial. *Br J Clin Prac* 1997;51:36-9.

546 Smith R. The failings of NICE. Time to start work on version 2. *BMJ* 2000;321:1363-4.

that theory in their own work. It is this testing by use, by others, in practice and in competition with other theories, which stands at the root of the objectivity of science. Thus the propositions of valid science have been tested by use.⁵⁴⁷

The failure of RCTs and meta-analysis to deliver objective and authoritative guidelines means that NICE recommendations will inevitably suffer from the same lack of intellectual credibility that afflicts the many other sources of supposedly definitive guidelines emanating from the DOH-sponsored guidelines industry. NICE guidelines will differ from existing sources of medical advice only because they will be mandatory and enforced on doctors by sanctions,⁵⁴⁸ a point returned to later.

Rationing and Cost-effectiveness:

Any system of rationing has to be ethical, explicit, transparent, fair, flexible, consistent and capable of timely response to developments.⁵⁴⁹ The Government has a number of options available to attempt to meet rising demand in health care. *Supply-side* measures include limiting supply while *demand-side* adjustments are aimed at reducing or containing demand for health care.

Early official documents focused on clinical effectiveness as the underpinning principle for NICE.⁵⁵⁰

Patients want to receive **effective** health care, i.e. care [in respect of which] there is a reasonable expectation [of] a positive impact on their health!⁵⁵¹

However, more recent documents and comments from NICE's chairman have made it clear that matters of cost will also be considered⁵⁵², implying a shift to cost-effectiveness. Indeed, a recent article co-written by the chairman of NICE highlighted the fact that its advice is based on economic evaluation and cost must be taken into account.⁵⁵³

NICE's decisions are based on an assessment of the technology under review, usually prepared by independent researchers commissioned by the Health Technology Assessment programme, and submissions from patient

547 Charlton BG. The new management of scientific knowledge in medicine: a change of direction with profound implications. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 13-31 at 16.

548 Charlton BG. The new management of scientific knowledge in medicine: a change of direction with profound implications. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 13-31 at 15.

549 Ellis SJ. Some unanswered questions about NICE. J R Soc Med 1999;92:538-9

550 Secretary of State for Health. A first class service: quality in the NHS. London: Stationery Office, 1998.

551 Evans RG. The dog in the night-time: medical practice variations and health policy. In The Challenge of medical practice variations. Ed Anderson TF, Mooney G. Macmillan, Basingstoke, 1990, 118-9.

552 Anon. NICE to sort clinical 'wheat from chaff'. BMJ 1999;318:416.

553 Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgments. BMJ 2004;329:224-7..

and professional groups. These are considered by the appraisals committee, which then advises the institute on what the guidance to the NHS should be.⁵⁵⁴

In August 1999, NICE issued interim guidance⁵⁵⁵ for manufacturers on how assessments would take place. The guidance stated that all the clinical benefits of an intervention would be assessed, including effects on quality of life as well as effects on mortality, and these would be set against estimates of the associated costs. In reaching its judgement, NICE would have regard to the Secretary of State's clinical priorities; the degree of clinical need of patients with a particular condition; the broad balance of benefits and costs; and the effective use of available resources. The guidance also states that NICE would be 'sympathetic' to the longer-term interest of the NHS in encouraging innovations provided they are 'of good value to patients'.

It seems very likely that this will be how NICE will evaluate new technology following its taking over of the functions of SERNIP. As the regulatory process has so far focused upon proof of efficacy invariably using placebo-controlled clinical trials, the lack of 'head-to-head' data, where the comparator is the current standard therapy, may prove unhelpful to manufacturers. In this respect, it is unclear how NICE will evaluate new interventional procedures since these are mainly surgical in nature and thus extremely difficult for them to be subjected to placebo-controlled trials. Surgery by its nature does not lend itself readily to these trials as sham operations engender invasive procedures with the possibility of non-trivial morbidity.⁵⁵⁶ Furthermore, there may be instances where a completely new intervention is proposed with no possibility of comparison, as for example, the first heart transplants.

A further problem is that Rawlins typically equates the 'excellence' of a particular technology not only with its *clinical* but also with its *cost-effectiveness*. 'NICE will sometimes be forced to reject a particular technology' despite its effectiveness in a clinical context 'in the interests of the service as a whole'.⁵⁵⁷ In such a case, NICE would have to make a judgement that the benefits purchased for some patients would be outweighed by the sacrifices borne by others, given the financial cost of the technology and the limitations on NHS funding.

In this respect it is interesting to note that when the moratorium on heart transplantation in the UK was introduced the letter from the Chief Medical Officer cited resource reasons as being partly responsible.

... diversion of resources from other hospital work is a matter which involves the Board. ... Special resources should not at present be

554 Dent THS, Sadler M. From guidance to practice: Why NICE is not enough. *BMJ* 2002;324:842-5.

555 NICE 1999: Appraisal of new and existing technologies: interim guidance for manufacturers and sponsors. August 1999, 19A 050 899.

556 Ridgway PF, Darzi AW. Placebos and standardising new surgical techniques. *BMJ* 2002;325:560.

557 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. *The Lancet* 1999;353:1079-82 at 1082

made available in Britain for cardiac transplantation in man (still considered to be largely experimental) at this stage.⁵⁵⁸

The defensibility of cost-effectiveness as a rationing criterion follows from two further considerations. First, given the rate of medical technical innovation and of public knowledge about it, there is every possibility that a single criterion of effectiveness would fail to rule out sufficient interventions to allow the NHS to operate within any conceivably realistic budget allocation. Second, a criterion of cost-effectiveness helps to minimise opportunity costs – the possibility that substantial resources will be devoted to ‘hopeless cases’, while effective interventions are denied to patients with a substantial prospect of benefit.⁵⁵⁹

Indeed, some believe that NICE is not doing enough and should become a national healthcare rationing agency.⁵⁶⁰ Rationing of new technologies is essential for political as well as economic reasons. Without politically acceptable ways of doing this, technology will continue to fuel the widening gap between public expectations and public willingness to pay for the NHS.⁵⁶¹

Limitations:

This argument, however, has a number of weaknesses. Earlier it was mentioned that NICE would have to make value judgements on what would be accepted and rejected. The ‘value’ component to this calculation, however, is riddled with the sort of controversies which preoccupy those who are prepared to honestly debate rationing. Smith believes that transparency is vital in an issue as difficult as rationing healthcare. Deciding where cost effectiveness ends is not a technical but an ethical judgement.⁵⁶² In deciding which treatments are worth funding, it is unclear what concept of value the decision-makers of NICE are employing. The first NICE decision to disallow the anti-flu drug Relenza (zanamivir) used criteria manufactured *ad hoc* for the purpose of rationalising a politically motivated decision. It then reversed its decision following widespread criticism⁵⁶³ including from the Consumers’ Association, which, in a submission to the Health Select Committee, stated:

[we] have identified serious shortcomings in NICE appraisals of health technologies that raise questions about the institute’s role, the credibility of its guidance and how useful the guidance is to healthcare professionals and patients. The institute has also appeared reluctant to respond to concerns raised about its guidance.⁵⁶⁴

⁵⁵⁸ Anon. Cardiac Transplantation. *BMJ* 1973;(i):431.

⁵⁵⁹ Harrison S, Dowswell G. The selective use by NHS management of NICE-promulgated guidelines: a new and effective tool for systematic rationing of new therapies? in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR. Hurwitz B. Aesculapius Medical Press, London. 2000; 89-101 at 94

⁵⁶⁰ Maynard A, Bloor K, Freemantle N. Challenges for the National Institute for Clinical Excellence. *BMJ* 2004;329:227-9.

⁵⁶¹ Cookson R, McDaid D, Maynard A. Wrong SIGN, NICE mess: is national guidance distorting allocation of resources? *BMJ* 2001;323:743-5.

⁵⁶² Smith R. The failings of NICE. Time to start work on version 2. *BMJ* 2000;321:1363-4.

⁵⁶³ O’Neale Roach J. NICE recommends flu drug for “at risk” patients. *BMJ* 2000;321:1305.

⁵⁶⁴ Smy J. Can NICE get away from its pantomime image? *Hospital Doctor* 21st March 2002;14-17.

Ellis believes that there are serious flaws in the use of cost-effectiveness as a basis of rationing. Any cost saving is usually from a social budget and therefore is not recoverable. Thus, cost-effectiveness comparisons can inform debate but cannot direct it.⁵⁶⁵ Cynically he noted that the most cost-effective patient was a dead patient.

Two key issues lie at the heart of rationing or setting priorities for healthcare. The first is legitimacy; that is, under what conditions is authority over rationing placed in the hands of a particular organisation. The second is fairness; under what conditions do patients or doctors accept a particular decision.⁵⁶⁶ Does NICE have the right to pronounce authoritatively on what is equitable? Who should make rationing decisions, according to what implicit or explicit criteria, and by what mechanisms should these decisions be implemented? The answers are beyond the scope of this thesis but question whether NICE has a monopoly on value judgements. The House of Commons health select committee criticised NICE, stating the institute's decision making process needed to be more transparent.⁵⁶⁷

In the context of the health service, the need to be cost-effective quite obviously places limits on the pursuit of 'clinical excellence'. Even then, the single criterion of effectiveness is not straightforward in practice. It is not uncommon to find disputes about who is authorised to determine at what level of probability (or at what 'numbers-needed-to-treat') an intervention is counted as sufficiently effective for NHS provision.

For example, when considering the use of drugs called statins to lower cholesterol, setting limits could reduce the potentially enormous costs of treating all patients who might potentially benefit.⁵⁶⁸ The problem is to decide what level of risk justifies the expense of long-term statin therapy. Treating the highest risk group not only gives the greatest benefit but costs least, for there are fewer such people in the population. At least for primary prevention, the cost of statin therapy for *all* possible patients would be difficult to justify in comparison with other therapies, such as hip replacements. It therefore is necessary to define a level of risk below which statin therapy will not be available on the NHS. In short, the decision as to how to use statins is political and financial, not medical. More important, however, is the recognition that a limit on the introduction of an innovative practice or treatment has been set.

A further problem is that the criteria of effectiveness and cost-effectiveness are not the only ones which surface in discussions about appropriate rationing criteria. One alternative is the *rule of rescue*, which gives priority to persons in

⁵⁶⁵ Ellis SJ. Some unanswered questions about NICE. *J R Soc Med* 1999;92:538-9

⁵⁶⁶ Daniels N, Sabin JE. Limits to health care: fair procedures, democratic deliberation and the legitimacy problem for insurers. *Philosophy and Public Affairs* 1997;26:303-50.

⁵⁶⁷ www.parliament.uk/commons/selcom/hlthhome.htm

⁵⁶⁸ Ramsey LE, Haq IU, Jackson PR, Yeo WW, Pickin DM, Payne JN. Targeting lipid-lowering drug therapy for primary prevention of coronary disease: an updated Sheffield table. *Lancet* 1996;348:387-88

acute or life-threatening conditions, and locates moral content in trying, rather than in succeeding. Thus the patient who has no other hope is surely entitled to grasp an outside chance and the doctor is entitled and perhaps even ought to provide it.⁵⁶⁹ Such arguments could have been made for the introduction of the first transplants and the use of the first artificial heart. People see themselves as having rights to treatment irrespective of calculations of effectiveness. This has led to legal cases, such as the 'Child B' case⁵⁷⁰, where patients have challenged the refusal of health authorities to provide access to many of the newer and more expensive treatments. The courts, however, appear reluctant to intervene.

In the Child B case Cambridge Health Authority refused to underwrite expensive experimental treatment for a child with leukaemia, when those treating the child thought the intervention had a limited chance of success and could not be justified.⁵⁷¹ Indeed, the health authority's solicitor argued that the only basis on which the treatment could be justified was for experimental or research purposes⁵⁷², thereby suggesting that the two were different entities.

... To describe the treatment, which the health authority declined to fund, as 'experimental' was not inappropriate, since it was not one that had a well tried track record of success and was at the frontier of medical science.⁵⁷³

The media, however, paid little attention to the clinical considerations and presented the case as an example of rationing based on financial considerations.⁵⁷⁴ In turn, the trial judges stated that difficult and agonising judgements had to be made on how a limited budget was allocated to the maximum advantage of the maximum number of patients and the court could not make such a judgement. The courts were not arbiters as to the merits of cases of this kind. Their sole function was to rule on the lawfulness of decisions made and could not substitute their own judgment for that of the authority, which was legally charged with making it. The health authority had not acted in a way which exceeded its powers or which was unreasonable.

Rationing is thus a practical necessity for the NHS. The aim of NICE is to provide a mechanism and specific criteria for rationing, concentrated in practice on the introduction of new therapies and technologies. However, it is not necessarily the case that there is a public and political consensus about the criteria of effectiveness and cost-effectiveness, and in any case the criterion of effectiveness is in practice as political as it is technical. As has already been mentioned, despite the apparent ascendancy of the view that 'good' evidence in respect of medical care interventions consists primarily of evidence drawn from RCTs, it does not follow that most clinicians accept this.

⁵⁶⁹ Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. London:Butterworths, 6th ed, 2002, 19.36.

⁵⁷⁰ *R v Cambridge Health Authority, ex parte B (a minor)* (1995) 23 BMLR 1 (CA).

⁵⁷¹ *R v Cambridge Health Authority, ex parte B (a minor)* (1995) 23 BMLR 1 (CA).

⁵⁷² Weale S. Dying girl is denied treatment. *Guardian* 1995; March 10:1

⁵⁷³ *R v Cambridge Health Authority, ex parte B (a minor)* (1995) 23 BMLR 1, 10 (CA).

⁵⁷⁴ Entwistle VA, Watt IS, Bradbury R, Pehl LJ. Media coverage of the Child B case. *BMJ* 1996;312:1587-91.

Furthermore, even if they do, they do not regard its conclusions as being more or less uniformly applicable to the patients in their care.⁵⁷⁵ This will be considered further when discussing clinical freedom.

Variation:

Rawlins believes that 'unexplained' variations in the way patients are treated should be eliminated where possible.⁵⁷⁶ While he does not aim to rule out variation altogether, there is a predisposition against it. The onus is upon those who support a plurality of approaches to any given problem to defend this. This is why the word 'variations' is usually preceded by some negative qualifying term such as 'inappropriate', 'unexplained' or 'unacceptable'⁵⁷⁷ and the image of a service in which practice is much more standardised than at present is presented as something of an utopian ideal. The existence of widespread variation in practice is presented as a 'cause for concern'.⁵⁷⁸

Limitations:

Earlier it was mentioned that EBM fails to cater for the individual patient. For example Ellis showed that if NICE, utilising EBM, undertook a cost-benefit analysis of anti-epileptic drugs the logical recommendation would be for the use of phenobarbitone.⁵⁷⁹ It is, however, inappropriate for most patients. The availability of many drugs therefore allows tailoring of treatment to the individual.

Each patient's condition is determined by a unique set of circumstances. Given the complex and diverse nature of human subjects, variation in the way they are treated is only to be expected. This is because variation in practice is often a product of variation in judgement or interpretation of evidence.

Individual judgement is not infallible, but nor can we do without it: to condemn it as 'subjective' in some reprehensible sense is to make scientific reasoning impossible.⁵⁸⁰ Individual judgement is therefore essential.

...the processes of science and of NICE are profoundly different – one is democratic, the other autocratic; one is oriented toward practice, the other to policy; one is tested against the natural world, the other against political expediency.⁵⁸¹

575 Harrison S, Dowswell G. The selective use by NHS management of NICE-promulgated guidelines: a new and effective tool for systematic rationing of new therapies? in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000; 89-101 at 99

576 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. The Lancet 1999;353:1079-82.

577 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. The Lancet 1999;353:1079-82.

578 Loughlin M. 'Quality' and 'excellence': meaning versus rhetoric. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 1-12, p7

579 Ellis SJ. Some unanswered questions about NICE. J R Soc Med 1999;92:538-9

580 Loughlin AJ. Alienation and value-neutrality. Ashgate Publishing Ltd, Aldershot. 1998, pp. 95-121

581 Charlton BG. The new management of scientific knowledge in medicine: a change of direction with profound implications. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 13-31, at 27

Although it may seem remarkable that there is still a wide variation in the way apparently identical clinical problems are handled in different countries, or even in different parts of the same country, there are many reasons for this. Differences in clinical practice may be due to different health care systems and, as mentioned, the availability of resources, to different perceptions by doctors of the relative values of different treatments, and differences in the characteristics of patients treated and in their expectations.⁵⁸² Differences are frequently cultural⁵⁸³ and are not necessarily 'bad' but may be a reaction to local factors and in many cases are due to doing what the patients require and request.

Clinical Guidelines:

In the 4th century BC, Plato examined the difference between skills based on practical expertise and those based solely on following instructions or obeying rules. He speculated that, if the second option were to occur, doctors would set up councils to decide how medicine should be practised. These views would then be published to dictate the way in which the treatment of the sick was to be practised.⁵⁸⁴ In essence he was describing the clinical guidelines movement of today.

Clinical guidelines are systematically developed statements designed to help practitioners and patients make decisions about appropriate health care for specific clinical circumstances.⁵⁸⁵ They are intended to present a synthesis of current evidence and recommendations undertaken by expert clinicians.⁵⁸⁶ They can therefore approve or reject the use of a particular innovative treatment.

There is, however, increasing attention being paid to the methodology of guideline development and the validity of their recommendations.

Benefits:

A number of benefits have been claimed.⁵⁸⁷ Guidelines promote interventions that are of proven benefit and discourage ineffective ones. They reduce inconsistencies of care. It is well known that patients with identical clinical problems frequently receive different care depending on their clinician, hospital, or location. Guidelines may also empower patients to make more informed healthcare choices, provided they are familiar with the guidelines relevant to their care. They can also influence public policy. Thus, a guideline

582 JR Hampton - Evidence based medicine, practice variations and clinical freedom. *Journal of Evaluation in clinical practice* 1997; 3(2):123-131

583 Clare A. National variations in medical practice. Culture influences medicine more than science does. *Brit Med J* 1989;298:1334

584 Plato. *Statesman*. Annas J, Waterfield R, eds. Cambridge University Press, 1995, 60-1.

585 Field MJ, Lohr KN, eds. *Guidelines for clinical practice. From development to use*. Washington DC: National Academy Press, 1992.

586 "Guidelines for Guidelines" Advisory Committee Guidelines for Guidelines: Principles to guide the evaluation of clinical practice guidelines. Auckland: Adis International;1996.

587 Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. *BMJ* 1999;318:527-30.

may recommend a particular treatment or service that was not available in a particular area or hospital. Following the guideline recommendation there would be strong pressure to introduce that service. Guidelines may also benefit researchers by highlighting gaps in evidence needing further investigation. Individual clinicians may use guidelines as an information source for continuing professional education. They can be used as instruments for self-assessment or peer review and to learn about gaps in performance.⁵⁸⁸

Limitations:

As previously mentioned the main problems with guidelines are that they are not very good at recommending treatment for an individual patient, they are frequently founded on limited evidence and they can be subjective. Furthermore, as highlighted by the Bristol Inquiry, guidelines appear from a variety of bodies giving rise to confusion and uncertainty.⁵⁸⁹

The more guidelines can be applied to individual patients, the more useful they will be for real life clinical decision-making.⁵⁹⁰ However, the recommendations in guidelines are frequently inflexible, leaving insufficient room for clinicians to tailor treatment to the individual patient's circumstances and medical and social history. Medical knowledge is complex in nature. Medical information is also often statistical ('we are 75 per cent certain that ...') and is basically analogue (positive merging into negative) rather than digital (yes or no). Guidelines are essentially digital. To round off analogue information into digital form is to run the risk that accuracy and honesty are sacrificed for the benefit of simplicity.

Furthermore, clinical knowledge and understanding of the individual patient are frequently subjective. In contrast, much of the evidence used to create guidelines is not in a form relevant to individual patient care. Dealing with an integrated set of problems as if each problem was capable of solution in isolation and could be addressed sequentially is not likely to reveal integrated solutions. Blanket recommendations fail to permit shared decision-making and ignore patients' preferences.⁵⁹¹

Farmer has also stressed that guidelines should not be developed by academics and senior clinicians insulated from the day to day pressures in providing medical care, warning that 'unless a guideline accurately reflects the routine working practices of most doctors it will act only as a gold standard to be admired.'⁵⁹²

588 Feder G, Eccles M, Grol R, Griffiths C, Grimshaw J. Using clinical guidelines. *BMJ* 1999;318:728-30.

589 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, p17 at 91

590 Jackson R, Feder G. Guidelines for clinical guidelines. *BMJ* 1998;317:427-8

591 Woolf SH. Shared decision-making: the case for letting patients decide which choice is best. *J Fam Pract* 1997;45:205-8.

592 Farmer A. Medical practice guidelines: lessons from the United States. *BMJ* 1993;307:313-7.

There could be very good reasons for non-guideline treatments arising from factors that were not (and could not reasonably be expected to be) covered by the guidelines for treatment of individual conditions. If the management of complex patients could simply be reduced to guidelines and be wholly algorithmic, then all doctors would need to do is program computers with such guidelines. Knowledge of guidelines will compensate for lack of clinical experience.

There is also little doubt that the research used to create evidence based clinical guidelines is inadequate.⁵⁹³ As discussed earlier, it cannot be assumed that the results even of a large clinical trial are sufficiently reliable to form the evidence base for clinical practice. Meta-analysis can also be seriously flawed.

Because the evidence about what to recommend is frequently lacking, misleading or misinterpreted⁵⁹⁴ subjective value judgements have to be made by the appraisers when benefits are weighed against harms. This may be wrong for the individual patient. Patients may have different perspectives on health care processes, priorities and outcomes from those of health care professionals. Guidelines need to involve patients to reflect their needs and concerns.

The current system of grading recommendations is also misinterpreted by many⁵⁹⁵ and leads to development groups being unable to make high-grade recommendations in areas of medical practice where randomised clinical trials may not be possible, such as many surgical techniques, or not ethical, as for example the use of oxygen in asthmatic attacks where no evidence is available.

Another problem with the lack of evidence is that innovations will suffer by not being recommended because there is little evidence about their value, a form of catch 22 situation. Surgical innovation, in particular, will suffer because of the difficulties that arise in trying to organise a randomised controlled trial. This is especially so for placebo controlled trials as the invasive nature of surgery could lead to non-trivial morbidity. The learning curve associated with the introduction of a new technique described in greater detail earlier, leads to another problem in that randomising between a familiar and unfamiliar operation will lead to bias against the new operation.⁵⁹⁶ Also surgical technique usually progresses via small modifications which individually produce no detectable benefits but collectively do. For example, during the historical progression through hand washing via the use of antiseptics to the aseptical surgical environment, the increment with each step was so small

593 Jackson R, Feder G. Guidelines for clinical guidelines. *BMJ* 1998;317:427-8

594 Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. *BMJ* 1999;318:527-30.

595 Harbour R, Miller J. A new system for grading recommendations in evidence based guidelines. *BMJ* 2001;323:334-6.

596 McCulloch P, Taylor I, Sasako M, Lovett B, Griffin D. Randomised trials in surgery: problems and possible solutions. *BMJ* 2002;324:1448-51.

that scepticism persisted.⁵⁹⁷ Small randomised trials of components of this progression have shown no benefits.⁵⁹⁸

A further problem is that guidelines quickly become outdated. One study found half were out of date in less than six years.⁵⁹⁹ There is also a significant lag time between the evidence appearing and its use in the production of a guideline. More worryingly, once the guideline is produced, it would not have considered the latest information and could be up to four years out of date.⁶⁰⁰

There are other concerns regarding guidelines. Many covering the same area are contradictory or vary considerably in their content and implications for clinical decisions and patient benefit.⁶⁰¹ Conflicting guidelines from different professional bodies can be confusing.⁶⁰² This was highlighted by the Bristol Inquiry.⁶⁰³ The Government, in its response to the Inquiry stated that where NICE guidance existed it provided the standard. Indeed, if conflicts existed with other advice, such as from professional bodies, it stated that NICE guidance would be paramount.⁶⁰⁴

Guidelines also reflect the contrasting agendas of the various interested parties. Professional groups may be keen to extend their influence, pharmaceutical companies to increase market share, and local and national bodies seek to promote public health while restraining public expenditure.⁶⁰⁵ The source of the guideline thus needs to be taken into account when interpreting its implications.

A recent study looking at the relationship between authors of clinical practice guidelines and the pharmaceutical industry revealed that eighty-seven percent of responding authors had some form of interaction with the pharmaceutical industry.⁶⁰⁶ Of greater concern was the fact that fifty-nine percent had

597 Wangenstein OH, Wangenstein SD. The rise of surgery. Minneapolis, MN: University of Minnesota Press, 1978:425-31.

598 Tunevall TG. Postoperative wound infections and surgical face masks: a controlled study. *World J Surg* 1991;15:383-7.

599 Shekelle PG, Ortiz E, Rhodes S, Morton SC, Eccles MP, Grimshaw JM, Woolf SH. Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines. *JAMA* 2001;286:1461-7.

600 North of England Asthma Guidelines Development Group. North of England evidence based guidelines development project: summary version of evidence based guideline for the primary care management of angina. *BMJ* 1996;312:827-32.

601 Thomson R, McElroy H, Sudlow M. guidelines on anticoagulant treatment in atrial fibrillation in Great Britain: variation in content and implications for treatment. *BMJ* 1998;316:509-13.

602 Feder G. Management of mild hypertension: which guidelines to follow? *BMJ* 1994;308:470-1.

603 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, p17 at 91

604 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002, p58 at 4.11.

605 Haycox A, Bagust A, Walley T. Clinical guidelines- the hidden costs. *BMJ* 1999;318:391-3.

606 Choudhry NK, Stelfox HT, Detsky AS. Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry. *JAMA* 2002;287:612-7.

relationships with companies whose products were specifically considered or included in the guideline they authored. This subjective element to the recommendations in clinical guidelines makes them particularly vulnerable to bias.⁶⁰⁷ For example, one of the criticisms of the NICE decision on laparoscopic herniorrhaphy⁶⁰⁸ to restrict its use was that only one of the 23 members on the appraisal panel was a surgeon.⁶⁰⁹

Inappropriate recommendations against a particular treatment, such as has occurred with laparoscopic hernia repair, may lead providers to withdraw funding. Indeed, NICE made it clear that the reasons for its choice had more to do with control of NHS costs than with clinical excellence. However, its calculations have been challenged on several grounds.⁶¹⁰ This has led the Association of Endoscopic Surgeons to urge its members to ignore NICE guidelines discouraging the use of laparoscopic surgery for hernia repair.⁶¹¹ This implies doctors are disregarding government-backed regulation.

The opinions, clinical expertise and composition of the guideline development group thus influence recommendations.⁶¹² The beliefs to which experts subscribe, often in the face of conflicting data, can be based on misconceptions and personal recollections that misrepresent population norms.⁶¹³ Variation in practice is often a product of variation in judgement or interpretation of evidence. Rawlins accepts this, acknowledging that even clinical guidelines which are 'based on a rigorous and systematic review of all the relevant data must necessarily carry an element of judgement in their interpretation that may not be universally shared'.⁶¹⁴ However, he does not explain how this acknowledgement is consistent with the decision to treat one set of judgements as intellectually 'authoritative', simply because the persons making those judgements have the backing of the political authorities.⁶¹⁵ Indeed, the editor of the British Medical Journal suspects that political clout is as important as evidence in the final decision.⁶¹⁶ NICE redefines 'science' as being whatever the outcomes of its deliberations are. Since decisions are in the hands of the few, this decision-making process is readily corrupted by political expediency, external pressure or self-interest. If the only backing for the claim to have 'authority' is the support of the powers that be, then such

607 Tonks A. Authorsof guidelines have strong links with drugs industry. *BMJ* 2002;324:383.

608 National Institute for Clinical Excellence. Guidance on the use of laparoscopic surgery for inguinal hernia. London: NICE, 2001.

609 Motson RW. Why does NICE not recommend laparoscopic herniorrhaphy? *BMJ* 2002;324:1092-4.

610 Motson RW. Why does NICE not recommend laparoscopic herniorrhaphy? *BMJ* 2002;324:1092-4.

611 Bratby L. Doctors warn NICE is losing its credibility. *Hospital Doctor* 24th May 2001, 1-2.

612 Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. *BMJ* 1999;318:527-30.

613 Kane RL. Creating practice guidelines: the dangers of over-reliance on expert judgement. *J Law Med Ethics* 1995;23:62-4.

614 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. *The Lancet* 1999;353:1079-82 at 1081

615 Loughlin M. 'Quality' and 'excellence': meaning versus rhetoric. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 1-12,p10

616 Smith R. The failings of NICE. Time to start work on version 2. *BMJ* 2000;321:1363-4.

organisations represent a serious threat to academic freedom and scientific progress.

The use of guidelines is demanded by government.^{617 618} Governments want tools to be able to control the allocation of health care resources through containment or redirection of costs. Hence the principal reason for clinical guidelines' current popularity is economic.⁶¹⁹ Guidelines are essentially clinical laws. Once expertise no longer resides in the clinician but in guidelines, corruption of or deviation from such guidelines would result in medical treatments being based on personal whim or quackery.⁶²⁰ There may thus be implications from a legal point of view. This aspect will be analysed in the next chapter.

THE COMMISSION FOR HEALTH IMPROVEMENT:

The Commission for Health Improvement (CHI) was responsible for tackling variations in the quality of patient care and monitoring the implementation of guidelines produced by NICE. More recently, it was amalgamated with part of the Audit Commission to create a new independent inspectorate, the Commission for Healthcare Audit and Inspection (CHAI), following the Government's announcement in the Department of Health paper, *Delivering the NHS Plan*.⁶²¹ This new body became fully operational in April 2004. However, all of its functions relevant to this thesis were present in the former body and much of the literature still refers to CHI. This thesis will therefore continue referring to CHI rather than CHAI, unless there is a specific requirement not to.

NICE and CHI (or CHAI) have two important roles. On the one hand, they act on behalf of, and in the name of, patients. On the other hand, they are also instruments of the political process. In this respect, like other audit and inspection organisations, they function as 'buffers' between the health care system and the political system. From a functional standpoint, the Prime Minister envisaged the development of CHI into

a standards watchdog that will go round every hospital and Primary Care Group in the country promoting good practice and high standards and rooting out the bad . . . [it] will check that the best treatments as recommended by the National Institute for Clinical Excellence are being used.⁶²²

The Scottish equivalent of CHI was the Clinical Standards Board for Scotland (CSBS). The two had very similar functions. The CSBS was a statutory body, established as a special health board in April 1999 following the Acute

617 Secretary of state for Health. *The new NHS*. London: Stationery office, 1997. (Cm 3807).

618 Department of Health. *A first class service: quality in the NHS*. London: Department of Health, 1998.

619 Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. *BMJ* 1999;318:527-30.

620 Plato. *Statesman*. Annas J, Waterfield R, eds. Cambridge University press, 1995, 60-1.

621 www.doh.gov.uk

622 McSmith A. Prime Minister launches NHS Inspectorate. *BMJ* 1999;319:1217.

Services Review report published in July 1998.⁶²³ Its role was to promote public confidence that the services provided by the NHS in Scotland were safe and that they met nationally agreed standards and to demonstrate that, within the resources available, the NHS was delivering the highest possible standards of care. As previously mentioned, this body has now been replaced by NHS Quality Improvement Scotland.

The CSBS's system of assuring quality and accreditation was designed to complement the duty that had been laid upon the board of each NHS body by the Health Act 1999 to monitor and improve the quality of health care which it provided to individuals. The CSBS specifically claimed not to be an inspectorate, although it published reports on the performance of the NHS. Following the publication in March 2001 of its first set of clinical standards, the CSBS set about reviewing NHS Trusts' performance against these standards, publishing reports which give both a national overview and information on the performance of each Trust. The accreditation process involves a number of stages. Once the standards have been finalised, each relevant Trust is asked to undertake a self-assessment exercise of their service against the standards. A review team then visits the Trust on behalf of the Board and follows up this self-assessment exercise with an external peer review of performance in relation to the standards. The Board reports the findings for that Trust, based on the self-assessment exercise and the external peer review. Furthermore, targets of achievement are ratcheted up as performance improves. This function has now been undertaken by NHS QIS.

Interestingly, the CSBS, in its publication 'Clinical Standards'⁶²⁴ claimed that the standards it produced would be based upon and be consistent with other recognised standards, quoting for example the guidelines produced by SIGN. This implies that it believed the guidelines produced by SIGN were actually standards. Furthermore it warned that the standards were 'mandatory' in that no profession could opt out.⁶²⁵ The statement on standards explained the level of performance to be achieved and divided the document into numbered criteria 'making [it] easier ...for the assessment process.'⁶²⁶ The legal implications of the production of guidelines and standards will be discussed in the next chapter.

A particularly important issue for CHI and the NHS QIS is the fact that, like any audit or inspection function, its role is highly dependent on the quality of clinical guidelines issued by the relevant body, such as NICE or SIGN. In its response to the Bristol Inquiry the Government reiterated that NICE was the foremost body charged with providing authoritative guidance to the NHS through guidelines and technology appraisals.⁶²⁷ Furthermore, NICE

623 Scottish Office. Acute Services Review Report, July 1998.

624 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh; CSBS: 2001.

625 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh; CSBS: 2001 at p10.

626 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh; CSBS: 2001 at p11.

627 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002, p57 at 4.7

guidance, if present, provided the standard and if there was conflict NICE guidance would be paramount.⁶²⁸ In the future clinical governance is likely to ensure that local information systems are sufficiently developed to detect such variations more sensitively, and this internal information will thus become available for external inspection by CHI/NHS QIS or the newer bodies such as CHAI. In some cases, such divergences will be perfectly justified on clinical grounds. In others, they will be judged to be clinically unjustifiable.

Limitations:

One of the first problems to be considered is that it is not clear how local or national mechanisms of monitoring and inspection will judge between good decision skills and sub-optimal care. CHI and NHS QIS squads will have a distinct advantage because they will have the luxury of making judgements in retrospect. Guidelines thus allow narrow interest groups to impose their priorities on the health service, representing the exercise of power without responsibility.⁶²⁹ Furthermore, auditors and managers may unfairly judge the quality of care that is based on criteria from invalid guidelines.⁶³⁰ The main problem when CHAI comes into being however will be the 'misguided emphasis'⁶³¹ on inspection, which is not in keeping with a more developmental and holistic approach to improvement.⁶³²

It is therefore envisaged that clinicians under review (or appraisal) will alter their practice, possibly leading to defensive and risk-averse strategies as illustrated by the cardiac surgery experience in New York. There the publication of performance report resulted in surgeons being reluctant to operate on higher risk patients.^{633 634}

Thus it is unclear whether CHI or indeed the NHS QIS are a genuine experiment in quality control, which will be sensitive to local operating conditions, or a tool of a central government ideologically committed to central control of professional groups. Guidelines generate systematic and paternalistic pressure for the many to conform to the views of the few.⁶³⁵

There is some confusion regarding the proposed new commission's purpose. CHAI's four roles, setting standards, audit, inspection and enforcement create tensions with the claim that the new commission will act as 'lawmaker,

628 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002, p58 at 4.11.

629 Haycox A, Bagust A, Walley T. Clinical guidelines- the hidden costs. BMJ 1999;318:391-3.

630 Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. BMJ 1999;318:527-30.

631 Dewar S, Finlayson B. The I in the new CHAI. BMJ 2002;325:848-50 at 849.

632 Calman K, Hunter D, May A. Make or break time? A commentary on Labour's health policy two years into the NHS Plan. Durham: University of Durham School for Health, 2002.

633 Green J, Wintfeld N. Report cards on cardiac surgeons. N Engl J Med 1995;332:1229-32.

634 Schneider EC, Epstein AM. Influence of cardiac surgery performance reports on referral practices and access to care. N Engl J Med 1996;335:251-6.

635 Haycox A, Bagust A, Walley T. Clinical guidelines- the hidden costs. BMJ 1999;318:391-3.

prosecutor, judge, jury and probation officer'.⁶³⁶ Furthermore this new system is not as protective of patients' interests as might be expected. The Government refused to fully endorse recommendations by the Bristol Inquiry when it recommended

Trusts which do not meet the necessary standards to ensure the safety of patients and a good quality of care should not be permitted to offer, or continue to offer, the relevant service.⁶³⁷

The Government rejected this.

Giving CHI the role of withdrawing an NHS Trust's validation and effectively requiring it to stop offering some or all of its services, without consideration of alternative service provision, could have a major and detrimental impact on the delivery of services to sectors of the population. It could lead to a loss of NHS capacity at a time when the Government is seeking to expand it in order to offer more patients more high quality treatment more quickly.⁶³⁸

This implies that the Government is more concerned with volume of service and service provision than with the actual quality. It implies that if CHI had been able to find problems in the paediatric cardiac services in Bristol it would not have been allowed to close the unit down.

REGULATING INNOVATION:

One of the stated aims of NICE was to improve standards of patient care and to reduce inequities in access to innovative treatment.⁶³⁹ The original discussion paper noted the need to avoid 'placing disproportionate burdens on those who are developing clinical innovations for use in the NHS or risking delay in the effective introduction of those innovations offering worldwide benefits to patients'.⁶⁴⁰

However, the Association of the British Pharmaceutical Industry (ABPI) has expressed grave reservations about the potential impact upon innovation and the attractions of the UK market as a place to research and to plan to launch innovative new products.

Realistic health economic evaluation cannot be made until the product has been in widespread use for a number of years, and further

⁶³⁶ Dewar S, Finlayson B. The I in the new CHAI. *BMJ* 2002;325:848-50 at 849.

⁶³⁷ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, recommendation 141.

⁶³⁸ Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002, p62 at 4.21.

⁶³⁹ NHS Executive. Faster access to modern treatment: how NICE appraisal will work. Leeds: February 1999.

⁶⁴⁰ NHS Executive. Faster access to modern treatment: how NICE appraisal will work. Leeds: 1999, para 7.

delaying entry into the NHS would have a negative impact on health care services and be a disservice to patients.⁶⁴¹

Thus, some fear that NICE will in practice merely regularise reduced access to the more expensive and innovative medicines⁶⁴² and techniques. The process at present potentially discriminates against innovation by allowing insufficient time to make a proper assessment of the risks and benefits of that innovation.⁶⁴³ Small advances embodied in the pharmacological properties of what at first looks like a 'me-too' drug can, in time, prove very useful and stimulate further research. For example, the newer calcium blockers, HMG co-A reductase inhibitors and newer neuroleptics all belong to classes of drugs where small differences in pharmacology have eventually turned out to have significant therapeutic benefit. Surgical innovation, which frequently occurs in small steps, is likely to suffer for the same reason.

It would be a serious matter if measures at policy level designed to improve the quality, availability and cost-effectiveness of patient care inhibited scientific and therapeutic innovation. No one at present can predict what impact NICE and CHI will have on scientific and therapeutic innovation. However, the NHS has not explicitly used its commissioning processes to encourage innovation, and indeed has tended to resist the introduction of new interventions until they have been adequately evaluated.⁶⁴⁴ A Department of Health report recommended that unevaluated new forms of health care should be provided by the NHS but only within the context of properly designed research to assess their effects.⁶⁴⁵ While this is eminently sensible, it is presently clear that NICE does not have sufficient capacity to deal with all new chemical compounds coming to the market, never mind extensions of use or surgical procedures.⁶⁴⁶

It thus seems likely that, following the adoption of its new role, NICE will slow down the introduction of new procedures. This is already happening with regard to new drugs. For example, Temozolomide was licensed in Europe for treatment of certain brain tumours in February 1999 but did not get NICE approval until mid 2001.⁶⁴⁷ Unlike the previous voluntary nature of SERNIP registration of new procedures through NICE is now mandatory. Furthermore clinicians will have to inform the institute when they plan to use a procedure they have no experience with or have only used outside the NHS.⁶⁴⁸ They will also need their hospital's approval and to tell patients they are unsure about

641 The Association of the British Pharmaceutical Industry. NICE and medicines. ABPI 1999;BSC/6/99/4K

642 Ellis SJ. Some unanswered questions about NICE. J R Soc Med 1998;91:538-9.

643 Dodds-Smith I. NICE and the ultimate decision makers: the legal framework for prescription and reimbursement of medicines. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000;103-125

644 Dent THS, Sadler M. From guidance to practice: Why NICE is not enough. BMJ 2002;324:842-5.

645 Department of Health. Assessing the effects of health technologies. London: DOH, 1991.

646 Ellis SJ. Some unanswered questions about NICE. J R Soc Med 1999;92:538-9

647 Newlands E. reported in Smy J. Can NICE get away from its pantomime image? Hospital Doctor 21st March 2002;14-17.

648 Kmietowicz Z. NICE to start assessing diagnostic and treatment procedures. BMJ 2003;326:412.

the procedure's safety and efficacy. Guidance will be issued after expert opinion has been sought, usually within 18 months of registration.

One problem is that the whole process is time consuming and thus not likely to encourage innovation. It could of course be argued that this is no bad thing. With respect to the introduction of heart transplants it seems likely that the new system would not have allowed the new operation to take place in the UK in the early years and furthermore there would not have been the time to evaluate it. One aspect of innovation is the rapidity with which it spreads throughout a community if unregulated, as evidenced by the introduction of heart transplants. Thus, under this new system Cooley would not have been allowed to experiment with the artificial heart. Prior to its proposed introduction registration with NICE would have been mandatory, he would have needed approval from the hospital and he would have had to discuss the uncertainty of the success of the operation with the patient.

Bristol, on the other hand, would almost certainly still have occurred, thereby showing there are still flaws in this system. It would doubtless have accepted the need for the introduction of the 'switch' operation. The problem, however, was not its introduction but the fact that certain centres adopted it when the surgeons there were not capable of undertaking it safely. The question therefore is whether the hospitals concerned would have refused their surgeons, some of whom were quite high ranking, the chance to undertake the operation. It is unlikely the Chief Executive of the Bristol Trust would have refused Wisheart, its medical director, the opportunity to undertake these procedures.. The fact that the unit was a Supra Regional Centre for Heart Surgery makes refusal even more unlikely. After all Supra Regional Centres undertake the most difficult and complex cases, referred from other, 'less specialised' units. It would have been embarrassing for the trust if it did not allow its Supra Regional Centre to undertake an operation available in other centres.

Other problems include not having systems currently in place to assess and evaluate these new procedures at the hospital level and a lack of clarity about what needs to be registered. An editorial co-authored by the new Chairman of NICE's advisory committee on interventional procedures stated:

What precisely is a new procedure? If an existing procedure is modified, how much modification makes it new? If new technology is used for an established procedure, is that new? Should doctors be restricted in undertaking new procedures? How can compliance with submission data and guidance be achieved? What data should be publicly available and what should be done if outcomes vary between doctors?⁶⁴⁹

Clearly many questions still remain. Until they are answered it is unlikely that the system will be much use in offering patients protection from experimentation. Indeed, the growth of evidence based medicine will lead to a limitation to a doctor's freedom to practice. This is to be added to the ever

649 Campbell B, Madder G. Safety and efficacy of interventional procedures. *BMJ* 2003;326:347-8 at 348.

increasing list of limitations that already includes training and licensing, peer pressure, audit, the risk of litigation and so on.

Thus, the role of the recently introduced National Clinical Assessment Authority (NCAA) is to work with doctors and employers to address underperformance and incompetence, incorporating a system for preventing, recognising and dealing with the poor clinical performance of doctors.⁶⁵⁰ Thus from April 2001 employers have been able to refer doctors to the NCAA. On the basis of clinical data, discussion with the doctor and other staff, and a visit, the assessment authority's team of medical and lay assessors will make a judgement about the doctor's performance and recommend a course of action. The most serious cases will be referred to the GMC. The NCAA should boost local accountability at the employer level but will also require co-ordination of clinical governance initiatives, revalidation through the GMC and the work of the royal colleges and the Commission for Health Improvement (now known as the Commission for Health Audit and Improvement).⁶⁵¹

Similarly the recently proposed Council for the Regulation of Healthcare Professionals is an attempt to increase the accountability of the medical profession.⁶⁵² It will have the power to direct the GMC and the other nine regulatory authorities for the other health professionals. In other words it will dictate their policies.⁶⁵³ Supervisory regulation of the 'regulators' is moving out of the administrative sphere and into that of clinical health care.⁶⁵⁴

The government also intends to re-organise postgraduate medical education by proposing the setting up of a Medical Education Standards Board (MESB).⁶⁵⁵ This will replace the Joint Committee on Postgraduate Training for General Practice and the Specialist Training Authority. Half of its members will be lay and as a single body will oversee curricula, standards and the registration of all medical trainees. Originally the Bristol Inquiry recommended that the MESB should be part of and answerable to the GMC.⁶⁵⁶ This was rejected by the Government who stated that postgraduate training needed to take account of the service requirements.⁶⁵⁷ This essentially proposes a state takeover of postgraduate medical education and training.⁶⁵⁸ Self-regulation is slowly being extinguished. Indeed, legislation designed to protect the

650 Department of Health. Assuring the quality of medical practice: implementing supporting doctors protecting patients. London: Department of Health, 2001.

651 Dewar S, Finlayson B. Dealing with poor clinical performance. *BMJ* 2001;322:66.

652 NHS Reforms and Health Professions Bill 2001.

653 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. London: Butterworths, 6th ed, 2002, 1.37.

654 Walshe K. The rise of regulation in the NHS. *BMJ* 2002;324:967-70.

655 Department of Health. Postgraduate medical education and training. The Medical Education Standards Board. London: DoH, 2001.

656 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, recommendation 81.

657 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London: HMSO, 2002, p153

658 Pereira Gray D. Deprofessionalising doctors? *BMJ* 2002;324:627-8.

independence and integrity of the medical profession is conspicuous in its absence.⁶⁵⁹

From the Government's perspective, the quasi-independent status of regulatory agencies distances politicians from difficult issues or unpleasant decisions, especially with regards to resources and rationing. It moves the blame for unavailability from politicians to those on the committee. However, although the responsibility for problems is shifted to the regulator, the reach and scope of government is retained, or even increased.⁶⁶⁰ This is because these regulators are essentially agents of the government, accountable to the Department of Health and their boards are appointed by the Secretary of State.

Government regulation will not, however, solve all the problems. Charlton states

the implementers of the Griffiths report seem not to have appreciated that an organisation depending on the skills of autonomous health professionals will not function properly if it has imposed on it a hierarchical, line-managed, heavily regulated structure imported from businesses based on simpler and more routine activities, and lacking the necessary personal relationship between providers and clients which characterises medicine.⁶⁶¹

Similarly, in New Zealand, which suffered one of the worst failures of good medical practice⁶⁶², external controls were proposed as solutions. However an article written by one of the advisors to the original report concludes that external controls are blunt instruments for finding solutions and require a functioning internal morality.⁶⁶³

The external controls, designed as if they had the whole task of regulating the moral conduct of doctors, have been clumsy and unsatisfactory... [with] little room for interpretation, and the dangers of dogmatic interpretation are being felt. ... Complex regulations can disempower those forced to observe them. If they accept they cannot be trusted there is a risk they will become less trustworthy and obey the letter of the law only. ... Distaste for the self serving nature of some professional activity should not blind us to instances where internal morality has worked in the interests of patients.⁶⁶⁴

659 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. London:Butterworths, 6th ed, 2002, 1.39.

660 Walshe K. The rise in regulation in the NHS. *BMJ* 2002;324:967-70.

661 Charlton BG. The new management of scientific knowledge in medicine: a change of direction with profound implications. in NICE, CHI and the NHS reforms. Ed Miles A, Hampton JR, Hurwitz B. Aesculapius Medical Press, London. 2000. 13-31 at p20.

662 Cartwright SR. The report of the committee of inquiry into allegations concerning the treatment of cervical cancer at National Women's Hospital and into other related matters. Auckland Government Printing Office, 1988.

663 Paul C. Internal and external morality of medicine: lessons from New Zealand. *BMJ* 2000;320:499-503.

664 Paul C. Internal and external morality of medicine: lessons from New Zealand. *BMJ* 2000;320:499-503 at 502.

In other words, external control is unlikely to be successful on its own and as has been shown in this chapter is unlikely to lead to patient protection from the effects of innovation.

THE REGULATION OF INNOVATION:

CHAPTER 5:	
LEGAL REGULATION	123
Medical Malpractice	123
Battery	123
Negligence	124
Duty of care	124
Standard of care	124
Causation	127
Criminal Law	128
Innovation	128
Analysis of Liability	132
Justifying the experiment	136
‘Recognised risk avoidance’	137
Legal limitations	139
<i>Karp v Cooley</i>	142
The law regarding guidelines	145
Personal Innovation	151
<i>Nettleship v. Weston</i>	152
Reconciling different requirements	156
Change the law	156
Supervision	162
Hospital liability?	163
Conclusion	166

CHAPTER 5: LEGAL REGULATION.

The previous two chapters have argued that professional self-regulation and regulation by government or similar official bodies, two of the three different laws described by Montgomery⁶⁶⁵, have failed, or would fail, to protect patients when they are subjected to innovative treatment, whether of the experimental type or as a result of personal innovation. It is therefore appropriate to examine the third form of law described.

Law in the strict sense is made by the courts or Parliament, is binding on all citizens, and usually enforced in the courts.⁶⁶⁶

MEDICAL MALPRACTICE:

The most important laws relevant to this discussion concern medical malpractice. Most claims in respect of medical injury are brought in tort, that is, on the basis of a non-contractual civil wrong.⁶⁶⁷

Malpractice litigation has numerous functions. It provides an incentive to practitioners to maintain a high standard of care and allows injured parties to bring an action as a way of gaining retribution against health professionals, who they believe need to be punished for harming them. Finally, malpractice law is concerned with compensation.⁶⁶⁸

An act of medical malpractice may give rise to two common law actions in court. The first is that of trespass to the person, or battery. The second, that of negligence, forms the basis of most malpractice claims and is the foundation of the modern law determining a medical practitioner's liability to a patient.⁶⁶⁹ At this point it is appropriate to state that, since the vast majority of litigation is found in English law or in jurisdictions derived from English law, English terms will be used. Scottish terms will be used when discussing Scottish cases.

Battery:

A battery (or assault in Scotland) is an intentional or reckless unlawful application of force to another person and is a crime as well as a tort at common law.⁶⁷⁰ Theoretically many procedures undertaken by a doctor might be considered batteries, such as injections, surgery or manipulations, if performed without the consent of the patient. The touching of a person in this manner without consent violates an individual's right of self-determination and constitutes an act of trespass to the person.

The attraction for litigants in suing in battery is that proof of damage is not an essential part of the cause of action. Thus liability can be established even in

665 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p5.

666 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p5.

667 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 9.9

668 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p165

669 Nelson-Jones R, Burton F. Medical Negligence Case Law. Fourmat Publishing, London, 1990, p3

670 Lewis CJ. Medical Negligence: a practical guide. 4th ed. Butterworths: London, 1998, 281.

cases where a patient either suffers no physical harm or suffers harm that is not a direct result of the tort, thereby circumventing some of the difficulties of establishing negligence, as will be discussed below. For example, a woman may consent to relatively minor gynaecological surgery but during the course of the operation the surgeon may find a disease or complication that requires major surgery and where sterilisation would be beneficial. The subsequent sterilisation may in fact result in the woman regaining health. She would however be able to sue for battery if she could demonstrate that she gave no consent for the sterilisation to be undertaken at that time. Such a situation occurred in *Devi v. W. Midlands RHA*⁶⁷¹ in which a surgeon, performing an abdominal operation to repair a perforation of a patient's uterus, decided it was also in her interests to be sterilised. While from the medical perspective it may in fact have been in her interests to be sterilised, consent had not been given. The patient sued in battery and the defendants admitted liability. Although there had been agreement for an operation to repair the uterus, there was no consent for the sterilisation to be performed as well. The law of consent will be examined in greater detail in the next chapter.

Negligence:

On the other hand, to win a negligence case the plaintiff is required to prove three things. Firstly the plaintiff must prove that a duty of care existed, that is, the professionals sued were responsible for the victim's care at the time of the mishap. The second is to show that the professionals failed to reach the standard of care that is required by law. Finally victims have to show that the injuries they suffered were caused by the failure to practice properly.⁶⁷² If the patients win their case, they are entitled to damages; an amount of money to compensate them for their injuries.

Duty of care:

Establishing a duty of care is not usually a problem when patients are in hospital. Similarly, where health professionals could have foreseen that what they did would affect other people then they may have a duty of care towards them.⁶⁷³ However, there are also limits to duty of care. For example, in general, professionals who pass a road traffic accident have no legal obligation to stop and assist anybody who has been injured⁶⁷⁴, although they may have a professional ethical obligation to do so.⁶⁷⁵

Standard of care:

In most cases of medical negligence the key question is whether the professional has reached the standard of care required of them by the law. That standard was established in different cases north and south of the border.

⁶⁷¹ *Devi v. W. Midlands Regional Health Authority* [1981] CA Transcript 491

⁶⁷² Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p166

⁶⁷³ Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p167

⁶⁷⁴ *F v. W. Berkshire HA* [1989] 2 All ER 545, 567

⁶⁷⁵ General Medical Council, *Good Medical Practice*. London: GMC, 1995, para. 4

In Scotland the standard was established in the case of *Hunter v. Hanley*.⁶⁷⁶ In this case the Lord President (Clyde) stated:

In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one clearly is not negligent merely because his conclusion differs from that of other professional men, nor because he has displayed less skill and knowledge than others would have shown. The true test in establishing negligence in diagnosis or treatment on the part of the doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care.

Two years later, the issue was examined further in the English case of *Bolam v. Friern Hospital Management Committee*.⁶⁷⁷ In this case the plaintiff suffered fractures during a course of electro-convulsive therapy. At the time there were different views regarding the use of relaxant drugs. However one school of thought was that relaxant drugs only increased the risk of treatment. The court held that a doctor was not guilty of negligence if he acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.⁶⁷⁸ This has become known as the 'Bolam test'. Although the case was decided in 1957 it did not become the cardinal test for medical negligence until adopted by the House of Lords in *Whitehouse v. Jordan* in 1981.⁶⁷⁹ A child had suffered brain damage at birth and it was alleged that this was due to the doctor's use of forceps. The House of Lords held that the proper test for establishing whether reasonable care had been used was the *Bolam* test.

It is to be noted that there may be a subtle difference between *Bolam* and *Hunter*. The former speaks of '...a responsible body of medical opinion.' By contrast, Lord President Clyde gave his third criterion defining medical negligence as a practice which would be adopted 'by *no* (my italics) doctor of ordinary skill ... acting with ordinary care.' However, McNair J suggested in *Bolam* that any difference was just a question of expression.⁶⁸⁰

Whatever any possible subtle differences, both tests of negligence state that professionals are to be judged against the standards of their peers. Therefore, if experts from the defendant's profession who are called to give evidence are prepared to accept that the actions were proper, the negligence claim will fail. Thus the experts merely have to regard the defendants' actions as being within the range of acceptable practice. This, in turn, means a minimal level of acceptable practice, not what the expert would have liked to see happen.⁶⁸¹

⁶⁷⁶ *Hunter v. Hanley* [1955] SC 200, SLT 213 at 217.

⁶⁷⁷ *Bolam v Friern HMC* [1957] 2 All ER 118, [1957] 1 WLR 582

⁶⁷⁸ *Bolam v Friern HMC* [1957] 2 All ER 118, 121

⁶⁷⁹ *Whitehouse v. Jordan* [1981] 1 All ER 267, [1981] 1 WLR 246, HL

⁶⁸⁰ *Bolam v. Friern Hospital Management Committee* [1957] 2 All ER 118 at 122

⁶⁸¹ Montgomery J. *Health Care Law*. 2nd ed. Oxford: Oxford University Press, 2003, p170

Standard medical practice must also be judged by the standard of a reasonable person with the knowledge prevailing at the time of the incident. In *Roe v. Minister of Health*⁶⁸² a patient suffered paralysis following a spinal anaesthetic. This anaesthetic had been kept in glass vials stored in disinfectant. This disinfectant leaked into the anaesthetic through microscopic cracks in the glass. This was impossible to detect and had not been known at the time. Thus the defendant was found not guilty of negligence.

In *Maynard v. W.Midlands RHA*⁶⁸³ the House of Lords stated that it would not choose between different bodies of medical opinion, implying that there could be no judicial intervention to declare standard medical practice to be negligent.

For in the realms of diagnosis and treatment, negligence is not established by preferring one respectable body of professional opinion to another. Failure to exercise the ordinary skill of a doctor (in the appropriate speciality, if he be a specialist) is necessary.⁶⁸⁴

This is not unreasonable. Non-experts cannot presume to know, where different opinions on technical matters are competently held, or scientifically justified, which school of thought is the appropriate or correct one.⁶⁸⁵ As previously mentioned, professionals possess highly developed technical knowledge that is widely valued.⁶⁸⁶ The unusual degree of skill and knowledge involved in professional work suggests that non-professionals are unable to evaluate or regulate it. The profession is thus held to be the sole source of competence to recognise deviant performance.⁶⁸⁷ This epitomises the professional standard test which maintains that the determination of the legal duty is left to the judgement of doctors following the Bolam test, irrespective of whether the defendant is dealing with diagnosis, treatment or, as will be discussed in the next chapter, disclosure of information during the consent process. It is clear therefore that the courts are extremely reluctant to interfere with the standards of medical practice. Doctors themselves set the standard of care required of them and all that the laws of negligence appear to do is reinforce existing professional standards.⁶⁸⁸

This appears to run against the normal principles of negligence, which require the judiciary to scrutinise standard practice to see whether it is reasonable. Usually where judges find that professional practice is unacceptable they can hold the defendants to be negligent even though their professional colleagues believe they acted appropriately, as shall be discussed in the next chapter. However in medicine they tend to rely on accepted professional practice far

682 *Roe v Minister of Health* [1954] 2 QB 66; [1954] 2 All ER 131

683 *Maynard v. W.Midlands RHA* [1985] 1 All ER 635

684 *Maynard v. W.Midlands RHA* [1985] 1 All ER 635, 1 WLR 634, 639.

685 McLean SAM. *A Patient's Right to Know*. Dartmouth: Aldershot, 1989, p79.

686 Rosenthal MM. *The Incompetent Doctor: Behind closed doors*. Open University Press, Buckingham:1995, p2

687 Freidson E. *The profession of medicine*, New York: Harper & Row, 1970, p137.

688 Montgomery J. *Health Care Law*. 2nd ed. Oxford: Oxford University Press, 2003, p170

more than would usually be the case in relation to other professionals.⁶⁸⁹ It would appear, therefore, that the position in negligence cases seems to be rather more favourable to the medical profession than to other professions.⁶⁹⁰ *Bolam* and *Hunter* permit medical experts to establish the standard of care and not the courts, with determination of a legal duty being left to the judgement of doctors.

Some cases, such as *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital*⁶⁹¹, *Bolitho v. Hackney HA*⁶⁹² and *Pearce v. United Bristol Healthcare NHS Trust*⁶⁹³ appear to qualify this to a certain degree and will be discussed later. However, for the moment we will hold that the fundamental principle is that medical negligence is to be judged against the standards of the medical profession (i.e.: *Hunter v. Hanley* or the Bolam Test), as stated quite categorically by Lord Scarman

... the law imposes the duty of care: but the standard of care is a matter of medical judgment.⁶⁹⁴

Causation:

The third step in proving a negligence claim is to show that the failure to provide a satisfactory standard of care caused the injuries that the victim suffered. Unless this can be proved the claim will fail even if the defendants were clearly at fault. Where the injury is caused by the care a health professional gives, such as when a nerve is damaged during the course of an operation, it is relatively easy to show that the professional's actions caused the injury.

In many cases, however, proving that the defendant caused the injury is very difficult, especially if the underlying disease or condition can itself lead to the injury suffered. Any uncertainty will operate in favour of the defendant. Often it cannot be proved that the patient's injuries were not a result of natural causes, such as the underlying medical problems or an unavoidable accident. For example, in *Kay v. Ayrshire and Arran Health Board*⁶⁹⁵ the plaintiff received a massive overdose of penicillin as treatment for his meningitis and later developed deafness. Unfortunately for the plaintiff, the weight of medical evidence was that the deafness was caused by the meningitis and not by the overdose of penicillin, and the case was lost. The patient therefore failed to establish that, on the balance of probabilities, his or her injuries were caused, or were materially contributed to, by the fault of the health professional. The claim failed.

⁶⁸⁹ Montgomery J. Health Care Law. 2nd ed. Oxford: Oxford University Press, 2003, p170

⁶⁹⁰ Montgomery J. Health Care Law. 2nd ed. Oxford: Oxford University Press, 2003, p170

⁶⁹¹ *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1984] 1 All ER 1018, [1985] AC 871, [1985] 1 All ER 643, HL.

⁶⁹² *Bolitho v. Hackney HA* [1993] 4 MLR 381

⁶⁹³ *Pearce v. United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, CA.

⁶⁹⁴ *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 at 881.

⁶⁹⁵ *Kay v. Ayrshire and Arran Health Board* [1987] 2 All ER 417, [1987] SLT 577, HL

Criminal Law:

In most circumstances malpractice is only the concern of the civil law. However, in extreme cases there may also be criminal implications. For example, where a mistake causes the death of a patient, it is possible that the health professional could be prosecuted for manslaughter. For this to proceed, there must have been not merely negligence, but gross negligence. In *R v. Bateman*⁶⁹⁶ it was held that the accused had to show such disregard for the life and safety of others as to amount to a crime against the State and conduct deserving punishment. The legal test of gross negligence has recently been considered by the House of Lords.⁶⁹⁷ Doctor Adomako was an anaesthetist who, for over four minutes, failed to notice that an endotracheal tube passed into the patient's windpipe had become disconnected during an operation under general anaesthetic. An alarm sounded but the connection of the tube was not checked until the patient had suffered a cardiac arrest. One expert prosecution witness stated that a competent anaesthetist should have spotted the problem within fifteen seconds. The defendant accepted that he had been negligent, but denied that he was grossly negligent so as to be guilty of involuntary manslaughter. The House of Lords held that the question of whether the degree of culpability was such that the anaesthetist should be liable to criminal sanctions was a matter for the jury. Lord Mackay accepted that this was essentially a circular proposition: that criminal negligence is when a jury thinks the negligence was criminal.⁶⁹⁸ The House of Lords however declined to offer a more precise definition. It did, however, approve tests from earlier cases that adopted a suggestion that gross negligence describes cases where the defendant has shown such disregard for the life and safety of others as to deserve punishment. While this remains a circular definition, it does focus attention on the recklessness of the professional's behaviour; that is, the failure to concentrate on the patient's interests.

There are a number of situations indicative of the sort of case that might constitute manslaughter due to criminal negligence. The first of these is where health professionals have shown an obvious indifference to the risks to the patient. The second is where they were aware of the risk but decided to run it. The third is where their attempts to avoid a known risk were so grossly negligent that the jury believed that they deserved to be punished. The fourth is where there was inattention or a failure to advert to a serious risk that went beyond mere inadvertence.⁶⁹⁹ The vast majority of negligence cases, however, are settled under civil law. The question is therefore how, from a clinical negligence point of view, the law would consider cases of innovation.

INNOVATION:

Preceding chapters have established innovation as a distinct entity from normal treatment and research. Furthermore, this innovation can be of two varieties: experimentation and personal innovation. The early heart transplant

696 *R v. Bateman* [1925] 94 LJKB 791

697 *R v. Adomako* [1994] 2 All ER 79

698 *R v. Adomako* [1994] 5 Med LR 277, 282 (HL).

699 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p188

era has been used as an example of the former while the events in Bristol illustrate the latter.

Historically the law has regarded failed innovation as a form of negligence,⁷⁰⁰ the physician's obligation being to attempt to cure only by application of orthodox techniques. The early case of *Slater v. Baker* in 1797⁷⁰¹ turned upon this. A noted English surgeon had agreed to treat and straighten the plaintiff's broken leg. The accepted method was to apply compression until the broken bone knitted together, but Baker used a device he had recently developed to extend the leg. When the bone failed to heal properly the plaintiff sued for breach of contract and succeeded; the physician, who by implication, had agreed to use proper skill and methods, was held to have acted ignorantly and unskillfully, contrary to the known rule and usage of surgeons. Proper practice of medicine required knowledge and application of accepted methods of treatment. The later case of *Carpenter v. Blake*⁷⁰² held that if there was an approved practice it must be used.

In neither case did the doctor defend his conduct in terms of deliberate experimentation. Furthermore some believe that the innovative doctor cannot rely on Bolam since no supportive body of medical opinion is available.

The pioneer is alone in more senses than one.⁷⁰³

However, it is important for innovation to occur so that medical knowledge improves and society benefits. In certain cases it may be warranted. Even the recently revised Declaration of Helsinki, which concerns itself with the regulation of research, stated:

In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.⁷⁰⁴

In chapter 1 it has already been argued that innovation is distinct from research and the above brief discussion of innovative treatment by the Declaration of Helsinki does not refute this. Resort to an innovative technique therefore may be appropriate in certain cases but must be made with caution.⁷⁰⁵

700 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9 at 636

701 *Slater v. Baker*, 2 Wils [KB] 359; 95 Eng Rep 860, 1797

702 *Carpenter v. Blake* 60 Barb.N.Y.488 (1871).

703 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 19.35

704 Declaration of Helsinki (2000): World Medical association. Bulletin of Medical Ethics 2000;162:8-11 at paragraph 32.

705 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 9.38.

Indeed, some discretion to develop medical practice is allowed by the courts. In the Scottish case of *McHardy v. Dundee General Hospitals' Board of Management*. Lord Cameron stated:

I think it is well that the search for further knowledge and experience should not be inhibited by undue apprehension of charges of negligence for the consequences to a patient of treatment or diagnosis where such may diverge from the normal.... Medicine is not an exact science and the solutions of its problems are not susceptible of mathematical calculation, while the frontiers of medical knowledge are always moving and advance may often be achieved only at the cost of what in retrospect appear to be errors and divergences from the correct path as that is ultimately mapped out.⁷⁰⁶

Similarly, Lord Diplock in *Sidaway v. Board of Governors of the Bethlem Royal Hospital* stated that:

Those members of the public who seek medical or surgical aid would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well tried method of treatment only, although its past record of success might be small, if he wanted to be confident that he would not run the risk of being held liable in negligence simply because he tried some more modern treatment, and by some unavoidable mischance it failed to heal but did some harm to the patient. This would encourage 'defensive medicine' with a vengeance.⁷⁰⁷

More recently, the English High Court (later endorsed by the High Court in Belfast) has permitted the injection of an unlicensed experimental treatment into the brains of two teenagers suffering from variant Creutzfeldt Jacob disease (vCJD).^{708 709} Both patients were in the advanced stages of the disease. There was no cure and no recognised effective drugs capable of prolonging life or arresting the continuing neurological deterioration. The proposed treatment, identified abroad, was untested on humans, and its efficacy and risks therefore unknown. The research that had been undertaken, although submitted for peer review, was at the time unpublished. Thus no validation of the experimental work was available. The patients' parents, however, wanted their children to receive it. The hospital's solicitors expressed concerns and requested a declaration as to the lawfulness of its administration.

At trial the judge stated:

The 'Bolam test' ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the 'Bolam test' to be complied with

706 *McHardy v Dundee General Hospitals' Board of Management*. (1960) SLT (Notes) 19

707 *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643, HL at 657.

708 *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669

709 Dyer O. Family finds hospital willing to give experimental CJD treatment. *BMJ* 2003;326:8.

to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted. ... I do however have evidence from responsible medical opinion which does not reject the research.⁷¹⁰

It was held that where there was no alternative treatment available and the disease was progressive and fatal, it was reasonable, therefore, to consider experimental treatment with unknown benefits and risks. Furthermore,

the proposed treatment complied with the requirement for a doctor to act at all times in accordance with a responsible and competent body of relevant medical opinion (the professional standard test).⁷¹¹

One of the doctors concerned had stated;

... animal testing models will only take us so far; ultimately, the only proper place for the study of CJD is in CJD patients. Whilst it would be a very considerable leap to a new disease and a new species if the PPS treatment was carried out on humans, such a leap had to be made at some time.⁷¹²

The experts advising the court concluded that there was a rational basis for believing the new treatment could have a positive effect. There was, however, no scientific proof. Although the treatment was risky, the experts could not see grounds for denying the patients treatment, especially considering the strong views of the patients' families. Indeed, there were concerns about the effect on the families if treatment was withheld.

The judge concluded that:

... there was a responsible body of relevant professional opinion which supports this innovative treatment. That is, in my view, subject to the seriousness of the risks involved and the degree of benefit that might be achieved.⁷¹³

The Official Solicitor also supported the proposals for treatment. However, it was recognised that even if the court gave its approval, approval was still needed from the hospital's Clinical Governance Committee and the Drugs and Therapeutic Committee. The judge criticised this. While accepting that the committees must exercise their own discretion in the applications made to them, she hoped that in the future the hospital trust would have an opportunity to form its own conclusions before the court made its decision.

Unfortunately, advice to the Department of Health from its CJD therapy Advisory Group and from the Committee on Safety of Medicines was that neither recommended the proposed treatment. The hospital's two committees

⁷¹⁰ *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669, 680-1.

⁷¹¹ *Simms v Simms and another, A v A and another*. [2003] 1 All ER at 669

⁷¹² *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669, 675-6.

⁷¹³ *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669, 681.

also were unable to approve the treatment so that it could take place in their hospital. Eventually, the family found a different hospital willing to administer the experimental treatment.⁷¹⁴

It is clear, therefore, that the courts do sanction experimental therapy. To allow such experimental treatment to be administered the court would need to consider evidence of any previous trials of the treatment and would take into consideration any dangers it entailed. It is possible that a court would decline to endorse the use of an untried procedure if the patient was thereby exposed to considerable risk of damage. Other factors which might be taken into account would be the previous response of the patient to more conventional treatment, the seriousness of the patient's condition and the attitude of the patient himself towards the novelty and risk. Pivotal to any decision would be the views of experts witnesses, so called 'responsible medical opinion'. In the above case of experimental treatment for vCJD expert court witnesses were largely in agreement about the potential risks and benefits of the treatment and believed the treatment should proceed.⁷¹⁵ The court endorsed this view.

It is not clear what decision would have been taken had the court known of the contrary view taken by the hospital trust's two committees, the Department of Health's CJD Therapy Advisory Committee and the Committee on Safety of Medicines. However, the judge criticised the fact that further approval was needed from the hospital's two committees. Furthermore, she could have given permission for the treatment to go ahead, subject to approval of these committees, but didn't. She gave approval for the treatment to be administered in the knowledge that there may well have been dissenting opinion. Indeed, the same judge (Dame Elizabeth Butler-Sloss) recently gave permission for another vCJD patient to receive the same experimental treatment.⁷¹⁶ It therefore appears that the judge was prepared to accept expert medical opinion on the acceptability of experimental treatment.

Analysis of Liability:

Whether a health carer is held liable in negligence if he departs from accepted practice will be determined as a question of fact.⁷¹⁷ The previously mentioned Scottish case of *Hunter v. Hanley*⁷¹⁸ illustrates the approach the law takes regarding experimental treatment. Indeed it is one of the few cases specifically to address this issue. The case involved an injection by a doctor into a patient during which the hypodermic needle being used broke and part of it remained inside the patient's body. The plaintiff claimed that the defendant used a needle that was the wrong size and hence unsuitable for the intended purpose.

It has already been stated that the court held that

⁷¹⁴ Dyer O. Family finds hospital willing to give experimental CJD treatment. BMJ 2003;326:8.

⁷¹⁵ Simms v Simms and another, A v A and another. [2003] 1 All ER 669.

⁷¹⁶ Dyer C. Second vCJD patient to receive experimental treatment. BMJ 2003;327:886.

⁷¹⁷ Khan M, Robson M, Swift K. Clinical Negligence. 2nd ed. London: Cavendish Publishing, 2002, at p171.

⁷¹⁸ Hunter v. Hanley 1955, SC200

in the realm of diagnosis and treatment there was ample scope for genuine difference of opinion and one man clearly was not negligent merely because his conclusion differed from that of other professional men...⁷¹⁹

In this case the doctor departed from standard acceptable practice. Lord President Clyde continued that,

... in regard to allegations of deviation from ordinary professional practice ... such a deviation is not necessarily evidence of negligence. Indeed it would be disastrous if this were so, for all inducement to progress in medical science would then be destroyed. Even a substantial deviation from normal practice may be warranted by the particular circumstances. To establish liability by a doctor where deviation from normal practice was alleged, three facts required to be established. First of all it must be proved that there is a usual and normal practice; secondly it must be proved that the defender has not adopted that practice; and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care. ... If this is the test, then it matters nothing how far or how little he deviates from the ordinary practice. For the extent of deviation is not the test. The deviation must be of a kind which satisfies the third of the requirements just stated.⁷²⁰

So, for a negligence allegation to be established, it must be shown that no 'ordinary' doctor would have undertaken the experimental treatment. The court also implied that progress in medical science was something to be safeguarded, a sentiment reiterated in *McHardy v. Dundee General Hospitals' Board of Management*.⁷²¹

There has also been support for experimental treatment in the US courts.

Therapeutic innovation has long been recognised as permissible to avoid serious consequences. The everyday practice of medicine involves constant judgmental decisions by physicians as they move from one patient to another in the conscious institution of procedures, special tests, trials and observations recognised generally by their profession as effective in treating the patient or providing a diagnosis of a diseased condition. Each patient presents a slightly different problem to the doctor. A physician is presumed to have the knowledge and skill necessary to use some innovation to fit the peculiar circumstances of each case.⁷²²

719 *Hunter v. Hanley* 1955, SC200 at 204

720 *Hunter v. Hanley* 1955, SC200 at 206

721 *McHardy v. Dundee General Hospitals' Board of Management*. (1960) SLT (Notes) 19.

722 *Brook v. St John's Hickey Memorial Hospital* 380 NE 2d 72 (1978) (Supreme Court of Indiana)

A more recent case concerned a patient, diagnosed with an aggressive form of breast cancer, who requested her health insurance company to pay for high-dose chemotherapy (HDCT).⁷²³ The company initially refused payment. The importance of the case, however, lay in raising the critical issue of what was meant by experimental drug therapy. Indeed the distinction between research and experimental therapy was particularly important because on it turned the decision of who should ultimately pay for the treatment.

The principle on which to base this decision is that those who benefit from an undertaking should be the ones who pay for that undertaking.⁷²⁴ With respect to drug research, the primary beneficiaries are the people who will (or may) use these drugs in the future. Thus, the cost of such research should be paid by future users. This goal can be achieved in several ways, the easiest of which requires that the sponsor of a clinical drug trial pays for all costs associated with the trial and then passes on these costs to future drug users as a portion of the price of the drug.

If, on the other hand, the drug is being administered in an experimental manner, the primary beneficiaries are the specific patients who receive the novel medication. This implies that the patient should bear the financial burden of this therapy. If the patient has an insurance plan from an insurance company that has agreed to pay the patient's necessary medical expenses, then that insurance company should meet the costs of the innovative treatment.

If the trial of HDCT undertaken in this case were done primarily to acquire new knowledge for the benefit of future users of the treatment, this should be considered to be research. It then would be unjust to require that a single individual subject, or that person's health insurance company, bear the costs associated with such research. All those who stood to benefit from such an undertaking ought to bear its costs, that is, any future users and thus the drug company should pay for its use. However the court considered that the use of HDCT was experimental treatment primarily for the benefit of the individual patient. Thus the court held that the health insurance company had to pay for the costs associated with the use of this experimental treatment.⁷²⁵

In a similar case a patient tried to force her insurance company to pay for autologous bone marrow transplantation for treating breast cancer. Once again, an insurance company refused coverage stating that the procedure was still experimental. A federal judge ruled in her favour:

To require that the plaintiff or other plan members wait until somebody chooses to present statistical proof ... that would satisfy all the experts

⁷²³ Henderson v. Bodine Aluminium, Inc., 70F. 3d 958 (8th Cir 1995)

⁷²⁴ Brushwood DB. Challenging denial of coverage for innovative therapy. Am J Health-Syst Pharm. 1997; 54:

572-4

⁷²⁵ Henderson v. Bodine Aluminium, Inc., 70F. 3d 958 (8th Cir 1995)

means that plan members would be doomed to receive medical procedures that are state of the art.⁷²⁶

Thus US courts appear to be supportive of the concept of experimental treatment and that patients be given such treatment. These cases have shown that the law may be required to determine what is within the realms of standard treatment, what is experimental and what is research. The law approaches the existence or absence of a standard treatment or treatments for a given condition as a matter of evidence. The test is objective rather than subjective, accepting an identifiable body of contemporary medical knowledge. It must be presupposed that some professional consensus exists on how given conditions may properly be managed.⁷²⁷ A responsible body of medical opinion could then decide what is accepted practice. However, there may also be another body of medical opinion (and equally 'responsible') claiming that a certain form of treatment was not standard. Within a hierarchical organisation such as the medical profession, differences over validation may be difficult to separate from the status of the disputing groups.

For example, in the early stages of the introduction of laparoscopic cholecystectomy there is little doubt that a responsible body of medical opinion (the so-called early adopters⁷²⁸) believed that this had become the standard treatment. Others (the early majority, late majority and laggards⁷²⁹) believed it was too early to claim it was standard treatment. It is unclear what a court of law would have held. *Hunter v. Hanley*⁷³⁰ and *Bolam v. Friern Hospital Management Committee*⁷³¹ both accepted that if a doctor acted in accordance with a responsible body of medical opinion he was not guilty of negligence.

Indeed, some believe that

Bolam provides some protection for the innovative or minority opinion. If this protection is removed, then the opinion which the cautious practitioner will wish to follow will be that which involves least risk. This may have an inhibiting effect on medical progress: after all, many advances in medicine have been made by those who have pursued an unconventional line of therapy. Such doctors may quite easily be regarded as negligent by a judge given to favouring conventional medical opinion.⁷³²

Dickens, however, believes that courts would probably recognise the distinction between negligent treatment, whether in departure from orthodox management or otherwise, and deliberate use of a new procedure, giving the

726 Howe R. Patient wins coverage for treatment. Washington Post 1990;19Apr:C:1.

727 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9

728 Rogers EM. Diffusion of Innovations. 3rd ed. Free Press: New York. p246

729 Rogers EM. Diffusion of Innovations. 3rd ed. Free Press: New York. p246

730 Hunter v. Hanley 1955, SC200

731 Bolam v. Friern Hospital Management Committee [1957] 2 All ER 118, [1957] 1 WLR 582

732 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 9.30.

patient or subject full information and taking all possible safeguards against adverse reactions, including for instance conducting prior testing on animals when appropriate.⁷³³

Innovation is not [research] when orthodox medicine provides no adequate treatment for a given condition, so the pursuit of a new treatment when none exists is not impaired by the most demanding degree of informed consent... When, however, a patient can be given orthodox therapy any variation or withholding of that therapy is proper only with his fully informed consent. Thus an acceptable social balance is struck between the needs of medical progress by innovation and [research], and the patient's right not unknowingly to be exposed to risk in diagnosis or treatment in advancing medical knowledge.⁷³⁴

The courts appear to agree. In *Wilsher v. Essex Area Health Authority* Mustill LJ stated:

In the first place, there is the situation where the doctor embarks on a form of treatment which is still comparatively untried, which techniques and safeguards which are still in the course of development, or where the treatment is of a particular technical difficulty. In such a case, if the decision to embark on the treatment at all was justifiable and was taken with the informed consent of the patient, the court should, in my judgment, be particularly careful not to impute negligence simply because something has gone wrong.⁷³⁵

Justifying the experiment:

It could thus be argued that the experimenting doctor will need to justify his experimental treatment, some commentators claiming that whether or not the use of an innovative technique could amount to negligence depends on to what extent its use could be justified in the case in question.⁷³⁶ Professionals will be called upon to justify novel therapies or procedures and, provided that they are done properly, this should not lead to an allegation of negligence being accepted by the courts.⁷³⁷

A doctor might not be negligent if he tried a new technique but if he did he must justify it before the court. If his novel or exceptional treatment had failed disastrously he could not complain if it was held that he went beyond the bounds of due care and skill as recognised generally.⁷³⁸

Thus in a recent unreported Scottish case the pursuer was prescribed chloramphenicol by her doctor as a result of which she developed aplastic

⁷³³ Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9

⁷³⁴ Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9 at 639

⁷³⁵ *Wilsher v. Essex Area Health Authority* [1986] 3 All ER 801, 812.

⁷³⁶ Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 9.38.

⁷³⁷ Montgomery J. Health Care Law. 2nd ed. Oxford: Oxford University Press, 2003, p170

⁷³⁸ *Landau v. Werner* (1961) 105 Sol Jo 1008, CA

anaemia requiring a bone marrow transplant.⁷³⁹ The judge was not prepared to hold as negligent a decision that had been arrived at after great thought and weighing up of all possibilities.

Within the framework of a balanced judgment, I consider the decision ... can be rationally and responsibly supported. ...within the options reasonably available to him ... it was a reasonable course to adopt.⁷⁴⁰

In other words, the doctor justified his experimental treatment before the court.

'Recognised risk avoidance':

A similar approach was taken by the court in *Clark v. McLennan*.⁷⁴¹ In this case the claimant suffered from stress incontinence following childbirth. The defendant operated six weeks after the birth but the operation failed. The accepted practice at the time was for surgery to be delayed for at least three months. Indeed, none of the witnesses knew of a case where the operation had taken place earlier than three months. It was held that the defendant was negligent in failing to take a precaution, resulting in damage. The defendant had tried something innovative. However, the most controversial aspect of this case was the implication that the burden of proof had been reversed.

Where ... there is but one orthodox course of treatment and the doctor chooses to depart from that, his position is different. It is not enough for him to say as to his decision simply that it was based on his clinical judgment. One has to inquire whether he took all proper facts into account which he knew or should have known, and whether his departure from the orthodox course can be justified on the basis of these factors. ...

Must the medical practitioner justify his departure from the usual practice?...

It seems to me that it follows from *McGhee* that where there is a situation in which a general duty of care arises and there is a failure to take a precaution, and that very damage occurs against which the precaution is designed to be a protection, then the burden lies on the defendant to show that he was not in breach of duty as well as to show that the damage did not result from his breach of duty.⁷⁴²

In the Scottish case mentioned, *McGhee v. National Coal Board*⁷⁴³, it was held that liability will be imposed if it can be established that the negligence of

⁷³⁹ *Duffy v. Lanarkshire Health Board* (1998, unreported).

⁷⁴⁰ Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.39-40.

⁷⁴¹ *Clark v. McLennan* [1983] 1 All ER 416.

⁷⁴² *Clark v. McLennan* [1983] 1 All ER 416, 427.

⁷⁴³ *McGhee v. National Coal Board* [1973] 1 WLR 1.

the defender materially increased the risk of the plaintiff being damaged in the way in question.⁷⁴⁴

Furthermore, Lord Wilberforce stated:

And if one asks which of the parties, the workman or the employers, should suffer from this inherent evidential difficulty, the answer as a matter of policy or justice should be that it is the creator of the risk who, *ex hypothesi*, must be taken to have foreseen the possibility of damage, who should bear its consequences.⁷⁴⁵

The 'recognised risk avoidance' concept⁷⁴⁶ illustrated by *Clark* would be very useful in negligence cases concerning innovation. Thus a plaintiff could argue that it is for the defendant to justify the use of the innovative therapy; there was a standard way of performing the operation, the defendant departed from it and introduced an innovative treatment. So it was for the defendant to justify its use.

This concept is very similar to that of *res ipsa loquitur*. What this doctrine does is give rise to an inference of negligence on the defendant's part⁷⁴⁷, as in the case of *Cassidy v. Ministry of Health*.⁷⁴⁸ Here the judge believed the plaintiff was entitled to say:

I went into hospital to be cured of two stiff fingers. I have come out with four stiff fingers and my hand is useless. That should not have happened if due care had been used. Explain it if you can.⁷⁴⁹

Similarly, in the original trial in *Wilsher v. Essex Area Health Authority*⁷⁵⁰ (of which more shortly) the judge held that since negligence had been proved, the burden of disproving that that negligence had caused the child's injuries moved to the defendants. It was up to the defendants to prove that the resulting condition was due to other possible causes.

However, it must be pointed out that, attractive as it may be for a plaintiff to utilise the doctrine of *res ipsa loquitur*, the courts have shown general antipathy towards it.^{751 752} In *Wilsher*⁷⁵³ the House of Lords condemned such an approach. They held that the burden of proving causation rested on the claimant alone and did not move to the defendants, even though negligence

744 *McGhee v. National Coal Board* [1973] 1 WLR 1, at 4.

745 *McGhee v. National Coal Board* [1973] 1 WLR 1, at 6

746 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.70

747 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.61.

748 *Cassidy v. Ministry of Health* [1951] 2 KB 343, [1951] 1 All ER 574, CA.

749 *Cassidy v. Ministry of Health* [1951] 2 KB 343 at 365, [1951] 1 All ER 574 at 588, CA.

750 *Wilsher v. Essex Area Health Authority* [1986] 3 All ER 801.

751 *Ratcliffe v. Plymouth and Torbay Health Authority* (1998) 42 BMLR 64, [1998] Lloyd's Rep Med 162, CA.

752 *Gray v. Southampton and South West Hampshire Health Authority* (2000) 57 BMLR 148.

753 *Wilsher v. Essex AHA* [1987] QB 730, [1986] 3 All ER 801, CA; revsd [1988] AC 1074, [1988] 1 All ER 871, HL.

had been proved or admitted.⁷⁵⁴ They held that the coincidence of a breach of duty and injury could not, of itself, give rise to a presumption that the injury was so caused.

Whether we like it or not, the law ... requires proof of fault causing damage as the basis of liability in tort.⁷⁵⁵

Legal limitations:

The problem with the Law's approach is that rules created for assessing negligence in the normal therapeutic setting, i.e. what is the standard of care and has the duty to provide this been breached, are being used for assessing the acceptability of innovative practice. The risk avoidance concept mentioned earlier, in which the defendant would have to justify the use of the innovative treatment, despite support from legal commentators^{756 757}, appears, at first, not to be acceptable to the courts. The belief that the courts refuse to accept the risk avoidance concept, however, follows the determination in *Wilsher*, which did not concern innovative treatment but a simple misplacement of a catheter into the wrong vessel. There was no suggestion that this misplacement constituted a new approach to treatment.

Furthermore, it should be pointed out that the recognised risk avoidance concept concerns the *standard of care* while the House of Lords in *Wilsher* refused to accept the shifting of the burden of proof with respect to *causation*. In other words, the risk avoidance concept could still be used for assessing innovative treatment and this would still be compatible with the judgement in *Wilsher*. The justification for this is that when innovative treatment is attempted, it stands to reason that there may be a greater risk to the patient, simply because the doctor is attempting something unknown or that he himself hasn't attempted before. The courts must, in some way, take this extra risk to the patient into consideration. This could be achieved by the doctor having to justify his use of innovative treatment before the court. It may, for example, be that there was no extra risk when attempting a particular innovative intervention or the potential benefit was so great that the extra risk was justified. The important point is that it is for the doctor to justify what he has done.

As mentioned, this would still be compatible with the decision in *Wilsher* that the coincidence of a breach of duty and injury could not, of itself, give rise to a presumption that the injury was so caused.⁷⁵⁸ Even though the doctor may not be able to justify the innovative treatment, it would still be for the plaintiff to prove causation arising out of the unjustified treatment. Thus

it may be more accurate to speak in terms of evidential presumptions: the fact, if it is established, that the defendant failed to act in

754 *Wilsher v. Essex Area Health Authority* [1988] 1 All ER 871, 882-3, HL.

755 *Wilsher v. Essex AHA* [1988] 1 All ER 871, 883.

756 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.38.

757 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p170

758 *Wilsher v. Essex AHA* [1988] 1 All ER 871, 883.

accordance with accepted practice supports a *prima facie* inference of negligence, which it is then up to the defendant to rebut.⁷⁵⁹

As has been argued throughout this thesis, the medical act is not homogenous. It does not slot conveniently into either therapy or research. There is a continuum, depending on the varying balance between the extent of treatment for the particular individual patient and how much new knowledge will be acquired. The law fails to recognise this and is thus unable to examine the subtleties of each individual medical act.

The test requiring support from a responsible body of opinion was created for normal therapeutic interactions. Indeed, following *Simms*⁷⁶⁰, the judge allowed further treatment to go ahead, despite opposition from two hospital committees, the Department of Health's CJD Advisory Committee and the Committee on Safety of Medicines. It could almost be argued that, since there was a responsible body of medical opinion that believed the treatment to be reasonable, the judge accepted it in the same way she would have used *Maynard*⁷⁶¹ in a negligence case. That is, provided there was a responsible body of opinion accepting the treatment, it didn't matter that there was an equally responsible body rejecting it. It could even be argued that the central issue in *Simms* was whether the innovative treatment proposed was justified, virtually using the risk avoidance concept described earlier. Since the risks were great, the doctors needed to justify its use before the court by emphasising the potential benefits. Since they were able to do so, it was held to be acceptable treatment. However, it must be pointed out that this was not a negligence case. Had it been, different rules of engagement would have been utilised, with the plaintiff having to prove negligence on behalf of the pioneering doctors.

This problem of utilising normal rules of negligence can be further illustrated by the case of *DeFreitas v. O'Brien and Connelly*.⁷⁶² The defendant had claimed that it was clinically justified to undertake a particularly delicate operation while the plaintiffs argued that the average orthopaedic surgeon would not have operated in the circumstances. It was held that embarking on an inherently difficult procedure might be negligent if done by a generalist, but acceptable if undertaken by an experienced specialist.⁷⁶³ Thus the super-specialist can undertake procedures that others might regard as being inappropriate or too risky. In the Court of Appeal it was held that a small number of medical practitioners could constitute a 'responsible body of medical opinion' against which the practices of a doctor could be measured.⁷⁶⁴ The body of spinal surgeons did not have to be substantial. It was sufficient that the court was satisfied that it was a responsible body. This approach has been criticised.

⁷⁵⁹ Stauch M, Wheat K, Tingle J. Sourcebook on Medical Law. 2nd ed. London: Cavendish, 2002, p327.

⁷⁶⁰ *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669.

⁷⁶¹ *Maynard v. W. Midlands RHA* [1985] 1 All ER 635.

⁷⁶² *DeFreitas v. O'Brien and Connelly* [1993] 4 Med LR 281, [1995] 6 Med LR 108, CA.

⁷⁶³ *DeFreitas v. O'Brien and Connelly* [1993] 4 Med LR 281, 296-7.

⁷⁶⁴ *DeFreitas v. O'Brien and Connelly* [1995] 6 Med LR 108, 115, CA.

In determining whether or not a practice is responsible, the first thing that the court should do is to see who has adopted the practice and count heads. It follows that the greater the number adopting a practice, the more likely it is that the practice is both accepted and responsible. What is not being advocated is that the matter can be determined *solely* by counting heads; before anything else the court should examine the risk in relation to the precautions adopted, if any. *DeFreitas* sets a worrying precedent in that perhaps now a small fringe group practising experimental techniques can legitimately constitute a responsible body despite being contrary to the norm.⁷⁶⁵

What the court in *DeFreitas* should have done was ask: The treatment you undertook was not done routinely by the vast majority of your colleagues. The innovative treatment was risky. Can you justify its use? Unfortunately, the court simply utilised the normal rules for assessing negligence and once a responsible body of opinion endorsing the treatment was found the court appeared to have no further part to play. In essence, *DeFreitas* licenses the taking of risks.⁷⁶⁶

It appears to be only in extreme cases that the courts are prepared to protect the patient from reckless experimentation and require justification of the technique attempted. In the case of *Hepworth v. Kerr* an anaesthetist was found negligent for reducing a patient's blood pressure to a level lower than what was accepted as normal.⁷⁶⁷ Despite the defendant's claim that he had utilised the technique in 1500 patients, the court did not accept that the technique had been properly validated. He had failed to follow up any of these patients, there was no expert support or endorsement of his work, it was not known how many of the previous patients had suffered similarly to the claimant and there was no safety margin for error.

The defendant, as he accepted, was to begin with ... plainly experimenting. ...

I simply cannot, and do not, accept that the defendant was justified in doing what he did without proper scientific validation of his technique.⁷⁶⁸

Indeed, since *Bolam* would have provided protection if there was external expert support⁷⁶⁹ for the technique, the case was only lost by the defendant because this was not forthcoming. As occurred in *DeFreitas*⁷⁷⁰, if a small fringe group practising the same experimental technique had come forward, the case may very well have been lost by the plaintiff. The question that the

⁷⁶⁵ Khan M, Robson M, Swift K. *Clinical Negligence*. 2nd ed. London: Cavendish Publishing, 2002, p 166

⁷⁶⁶ Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.31.

⁷⁶⁷ *Hepworth v. Kerr* [1995] 6 Med LR 139.

⁷⁶⁸ *Hepworth v. Kerr* [1995] 6 Med LR 139, 164.

⁷⁶⁹ Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.30.

⁷⁷⁰ *DeFreitas v. O'Brien and Connelly* [1993] 4 Med LR 281, [1995] 6 Med LR 108, CA.

court should therefore address is whether the defendant could justify the technique in the light of possible risks. Clearly the court would need expert opinion on the acceptability of the technique in light of its benefits and risks. The court's problem is that it would then be constrained by *Bolam* or *Hunter* and cases such as *Maynard v. W.Midlands RHA*⁷⁷¹ into having to accept the view of a responsible body of opinion if this thought the technique was acceptable. In other words, the court would appear to have no discretion to refuse this opinion if it felt the risks were too great. The profession is thus held to be the sole source of competence to assess the acceptability of a particular treatment, whether standard or experimental. The position in innovative practice seems to be excessively favourable to the medical profession. *Bolam*, *Hunter* and *Maynard* permit medical experts to establish the standard of care in innovative treatment and not the courts.

... the law imposes the duty of care: but the standard of care is a matter of medical judgment.⁷⁷²

Although cases such as *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital*⁷⁷³, *Bolitho v. Hackney HA*⁷⁷⁴ and *Pearce v. United Bristol Healthcare NHS Trust*⁷⁷⁵, all appear to qualify this to a certain degree (and will be reviewed in the next chapter), they concern issues of information disclosure. With respect to the acceptability of a particular medical treatment, the fundamental principle still remains that this is to be judged against the standards of the medical profession.

While it is clear that the courts are extremely reluctant to interfere with the standards of medical practice this should only, if at all, occur in the normal therapeutic setting. If the courts accept that innovation is a separate entity, as has been argued throughout this thesis, this should allow them some discretion to scrutinise a particular innovative practice to see whether it is reasonable.

***Karp v. Cooley*⁷⁷⁶:**

Arguably one of the more reckless experiments undertaken was the implantation of an innovative device, a mechanical heart, into a patient. The patient died and his widow subsequently sued the surgeon. In an earlier chapter it was stated that the mechanical heart was stolen from a colleague and little animal experimentation had been undertaken to assess its suitability for implantation into humans. The operation was planned in advance as Cooley was desperate for recognition.⁷⁷⁷ This is one of the major problems with innovation.

⁷⁷¹ *Maynard v. W.Midlands RHA* [1985] 1 All ER 635

⁷⁷² *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 at 881.

⁷⁷³ *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1984] 1 All ER 1018, [1985] AC 871, [1985] 1 All ER 643, HL.

⁷⁷⁴ *Bolitho v. Hackney HA* [1993] 4 MLR 381

⁷⁷⁵ *Pearce v. United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, CA.

⁷⁷⁶ *Karp v. Cooley* 493 F 2d 408 (1974) (United States Court of Appeals, Fifth Circuit)

⁷⁷⁷ Fox RC, Swazey JP. *The Courage to fail: a social view of organ transplants and dialysis*. Chicago: University of

When it becomes technically possible to perform a “ground breaking” surgical procedure, an important moral problem arises. In view of the strong incentive for surgeons to be the first to perform a novel operation, their judgments about whether such an intervention is justified may well be clouded.⁷⁷⁸

It has been argued in the previous section that it is this justification that needs to be examined by the courts.

Mrs Karp claimed that her husband had been the unfortunate victim of experimentation. The defendant had failed to inform him (or her) about the experimental nature of the device and had fraudulently obtained his consent. The device had only been approved for animal experimentation and furthermore had not been tested adequately in animals.

The case revolved around this latter point, that is, whether the prosthesis had been adequately tested in animals before its use in Karp. Many members of the medical profession had been surprised at the news that Cooley had implanted the artificial heart as he was not associated with work in this area. They also believed the first clinical use of such a device was years away and that it was too soon to be used on man.⁷⁷⁹

Despite this, few appeared for the plaintiff. The only evidence available regarding its prior trial in animals was a paper published by deBakey and colleagues reporting its use in seven calves, only one of which lived for any significant time.⁷⁸⁰ In it deBakey had claimed:

Human experimentation must await unequivocal evidence of the safety and effectiveness of such a device in humans.⁷⁸¹

His evidence was therefore crucial to the case. Surprisingly the judge confined the interrogation of Dr deBakey to his chambers. Records of the investigation by Baylor College of Medicine into the affair were also ordered sealed during the trial.

Questions about the quality of consent obtained were also raised. The court held that physicians and surgeons had a duty to make reasonable disclosure to a patient of risks that were relevant to medical diagnosis and treatment. At the time the standard in Texan law against which the doctor’s disclosure was

Chicago Press, 1984. *The Case of the Artificial Heart*, 135-197.

778 Benatar D, Hudson DA. A tale of two novel transplants not done: the ethics of limb allografts. *BMJ* 2002;324:971-3.

779 Fox RC, Swazey JP. *The Courage to fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984. *The Case of the Artificial Heart*, 135-197 at 139.

780 DeBakey M, Hall CW, et al. Orthotopic cardiac prosthesis: Preliminary experiments in animals with biventricular artificial heart. *Cardiovasc Res Cent Bull* 1969;7:127-42.

781 DeBakey M, Hall CW, et al. Orthotopic cardiac prosthesis: Preliminary experiments in animals with biventricular artificial heart. *Cardiovasc Res Cent Bull* 1969;7:127-42 at 142.

to be tested was a medical one, based on expert medical evidence of what a reasonable practitioner would have advised the patient under similar circumstances, i.e. the professional standard previously described. The court gave great import to the fact that Karp had signed a consent form in which each step of the three-stage operation had been set out. Furthermore, because the court decided that the use of the innovation was therapeutic, the action had to be measured by traditional malpractice evidentiary standards. In other words, innovation was to be tested under negligence rules in the same way as medical diagnosis and treatment. As has previously been argued, the rules created to assess negligence should not be used to assess the acceptability of an innovative technique. The law needs to be more sensitive and be able to distinguish between the two.

The defendant in this case was found not to have been negligent. Despite the court's findings, the case raises serious questions about the appropriateness and adequacy of the regulatory mechanisms to ensure ethical practice in undertaking new procedures. Formal peer group review was bypassed, no sanctions were taken against the surgeons concerned and the law clearly did not protect the patient.⁷⁸² This is especially so regarding the information that needed to be disclosed as the experimental operation was held to be therapeutic and thus the standard of care was assessed by medical opinion utilising standards established for normal therapy.

The main importance of this case, although occurring many years ago, is that it shows that the medical and legal professions, and the larger society to which they belong, have not satisfactorily dealt with the social, moral, and legal issues involved in therapeutic experimentation with human subjects.⁷⁸³ As mentioned, the law used was inappropriate in that, despite the treatment clearly being experimental, the law of negligence applicable to standard treatment was used. The law failed to make a distinction. If the law had used the recognised risk avoidance concept and asked the surgeon to justify the use of a technology that was previously untried in humans, the court's conclusion may have been different.

It is interesting to note that a very similar scenario is currently unfolding in the US.⁷⁸⁴ A patient who received an artificial heart in November 2001 lived to regret his decision to undergo the experimental therapy and died a few months later following a stroke. His wife has started legal proceedings against the maker of the implantable device, the hospital and a patient advocate alleging fraud, negligence and intentional assault and battery. Interestingly, the company had tried to ensure that patients gave fully informed consent by appointing a panel of independent patient advocates. The claim is that the patient and his wife were not aware just how experimental the artificial heart was. They were led to believe that the heart was a therapeutic device. Indeed,

782 Fox RC, Swazey JP. *The Courage to fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984. *The Case of the Artificial Heart*, 135-197.

783 Fox RC, Swazey JP. *The Courage to fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984. *The Case of the Artificial Heart*, 135-197.

784 Anon. Widow sues artificial heart-maker. *Bull Med Eth* 2002;181:24.

their lawyer claims that they should have been told that the goal of the experiment was not to make the first recipients well but to test a new technology for future patients. In other words, the lawyer claims that the operation was actually research as the aim was the generation of information and knowledge to benefit future patients.

This claim is similar to one made many years ago by Annas. He alleged that many early transplantation procedures were in reality purely non-therapeutic and intended only for the benefit of society.⁷⁸⁵

Despite this, it has already been argued that all these cases represent innovative treatment rather than research because there was a possibility of benefit for the individual patient, as well as the generation of knowledge for the benefit of society. It may well be that the innovators can justify the use of such experimental treatment. However, the question of what information was disclosed to the patients also needs to be assessed, a point returned to in the next chapter.

THE LAW REGARDING GUIDELINES:

The above discussion regarding experimental therapy highlights a further problem. It has been suggested that to protect patients further from unwittingly being given experimental therapy it may be necessary to set up a formal accreditation process.⁷⁸⁶ For example, in some hospitals adoption of new procedures may be formalised through ethics or practice committees. Indeed, the use of ethics committees to review and sanction any new interventional procedures, whether of the 'experimental' or of the 'personal innovation' type, was advocated by the Bristol Inquiry report.⁷⁸⁷

Similarly, Government schemes regulating the use of public funding for drugs provide an avenue for formal acceptance of drug therapies.⁷⁸⁸ Concerns over the introduction and use of laparoscopic procedures led the Academy of Medical Royal Colleges to set up SERNIP, the Safety And Efficacy Register of New Interventional Procedures.⁷⁸⁹ This register has now been taken over by the National Institute of Clinical Excellence, as previously discussed.

The price of formalising accreditation of new procedures, however, may be to reduce the flexibility of medical and therapeutic innovation.⁷⁹⁰ The creation of NICE, with its dual role of supplying special warranty to clinical guidelines and activating an extensive programme of implementation, is likely to result in

785 Annas G. Death and the Magic Machine. *Western New England Law Review* 1987;9:89 at 98.

786 Gaze E, Dawson K. Distinguishing medical practice and research: the special case of IVT. *Bioethics* 1989;3:301-319

787 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, p36, rec 101.

788 Rawlins M. In pursuit of quality: the National Institute for Clinical Effectiveness. *Lancet* 1999;353:1079-82

789 Bower H. A safety net cast over new surgery. *Hospital Doctor*, 16th May, 1996, p5.

790 Gaze E, Dawson K. Distinguishing medical practice and research: the special case of IVT. *Bioethics* 1989;3:301-319

NICE-approved guidelines being credited with greater prominence from a legal point of view. These guidelines, as argued in the previous chapter, may become mandatory. Failure to implement them or heed their advice, such as the recommendation not to use laparoscopic herniorrhaphy for economic reasons, could be deemed negligent and ultimately lead to a stifling of innovative practice.

In the previous chapter it was stated that guidelines can be used to regulate experimental treatment. The question of their legal status was also raised and it is appropriate at this point to assess this further. Early in the lifetime of guidelines, the government published its approach to their development, appraisal and application.⁷⁹¹ The authors advised against the term 'protocol' and reinforced the status of guidelines as guidance rather than instructions or commands. They were seen as aids to, not substitutes for, clinical judgement. The NHS Executive stated that when endorsed by prestigious professional bodies,

clinical guidelines can still only assist the practitioner; they cannot be used to mandate, authorise or outlaw treatment options. Regardless of the strength of the evidence, it will remain the responsibility of the practising clinicians to interpret their application . . . It would be wholly inappropriate for clinical guidelines to be used as a means of coercion of the individual clinician.⁷⁹²

The Department of Health's view was similar⁷⁹³:

Guidance for clinicians does not override their professional responsibility to make the appropriate decision in the circumstances of the individual patient, in consultation with the patient or guardian/carer and in the light of any locally agreed policies.

Furthermore, at the time the NHS Executive believed that the task of developing national guidelines was specifically the responsibility of the professional Royal Colleges.⁷⁹⁴

There were still many concerns, however, regarding their use. In particular, they were believed to erode clinical abilities, diminish clinical judgement and reduce medical practice to cookbook medicine.⁷⁹⁵ These concerns were enhanced when NICE was created. Professor Sir Michael Rawlins, its chairman, wrote that NICE would provide a single, authoritative source of advice to health professionals and their managers. While this advice would not be mandatory, there was an expectation that its recommendations on

⁷⁹¹ Mann T. Clinical guidelines: using clinical guidelines to improve patient care within the NHS. Leeds: NHS Executive, 1996.

⁷⁹² NHS Executive. Clinical guidelines. NHS Executive, Leeds: 1996 at p10

⁷⁹³ Department of Health. Memorandum of understanding on appraisal of health interventions. Department of Health, London, 13 August 1999, p4

⁷⁹⁴ West E, Newton J. Clinical guidelines. BMJ 1997;315:324.

⁷⁹⁵ Ellwood PM. Outcomes management, a technology of patient experience. N Engl J Med 1988;318:1549-56.

technologies would be universally accepted, and he warned that health professionals would be wise to record their reasons for non-compliance with NICE guidelines in patients' medical records.⁷⁹⁶

Later the Government, in its response to the Bristol Inquiry stated that where NICE guidance existed it provided the standard. Indeed, if conflicts existed with other advice, such as from professional bodies, NICE guidance would be paramount.⁷⁹⁷

It therefore appears that such guidelines now present the doctor with an explicit threshold for treatment, whereas previously he or she relied upon professional discretion drawn from accumulated experience.⁷⁹⁸ Thus, as guidelines receive increasing acceptance, health service lawyers have argued that acting in accordance with them could come to be viewed as acceptable medical practice *per se* and conversely, failure to apply a guideline could be seen as *prima facie* evidence of a case to answer.⁷⁹⁹

Codes of practice applicable to a given professional activity are in substance no more than formalised accepted practice and it is therefore not surprising that conduct which departs from the code may lead to liability.⁸⁰⁰

Thus, the way guidelines are beginning to be regarded is causing even greater concern.⁸⁰¹ They have always been a *basis* for action. The problem is that they are tending to become *prescriptions* for action. Indeed, the Clinical Standards Board for Scotland, now known as NHS Quality Improvement Scotland, has referred to the guidelines produced by SIGN as 'standards'.⁸⁰² It may therefore be appropriate, at this point, to define the terms guidelines, protocols and standards because, although they are sometimes used interchangeably, they do have different meanings and thus implications.

Guidelines are systematically developed statements, which assist in decision-making about appropriate healthcare for specific clinical conditions.⁸⁰³ The World Health Organisation believes that

guidelines should not be seen as rigid constraints on a practising doctor's decisions. Guidelines should provide extensive, critical, and well balanced information on benefits and limitations of the various

796 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. The Lancet 1999;353:1079-82.

797 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London: HMSO, 2002, p58 at 4.11.

798 Haycox A, Bagust A, Walley T. Clinical guidelines- the hidden costs. BMJ 1999;318:391-3.

799 Harpwood V. NHS reform, audit, protocols and standards of care. Med Law Int 1994;1:241-59.

800 Dugdale AM, Stanton KM. Professional Negligence. Butterworths, 3rd ed, 1998, at 15.23.

801 Haycox A, Bagust A, Walley T. Clinical guidelines- the hidden costs. BMJ 1999;318:391-3.

802 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh: CSBS: 2001 at p10.

803 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh: CSBS: 2001 at p40

diagnostic and therapeutic interventions so that the physician may exert the most careful judgement in individual cases.⁸⁰⁴

A protocol, on the other hand, is a policy or strategy that defines appropriate action. It also covers the adoption, by all staff, of national or local guidelines to meet local requirements in a specified way.⁸⁰⁵

Standards, in turn, have been defined as an overall statement of desired performance⁸⁰⁶ or as an accepted or approved example of something against which others are judged or measured.⁸⁰⁷ It is unclear, however, who has accepted or approved these standards. There is also an element of subjectivity when judging. Ideally a suitable unit of measurement and a robust measuring tool will enable objective assessment. Certain standards are quite clear and explicit. The Recommended Minimum Standards for Obstetric Anaesthetic Services, published by the Obstetrics Association of Anaesthetists⁸⁰⁸ (a respected body within anaesthetic circles) clearly sets out minimum standards in terms of staffing levels and care that should be available in all units. This is the accepted level of care and failure to comply and thus fall below the minimum standard implies negligence.

These definitions imply that standards and protocols allow little scope for deviation whereas guidelines allow a far greater degree of freedom. On the other hand guidelines are 'recommendations that can be accepted, rejected or modified to fit the circumstances of the case at issue'.⁸⁰⁹ There is therefore a clear distinction between guidelines and standards (or protocols).

Despite this, clinical guidelines now appear to form the basis of protocols and, as previously mentioned, the CSBS considered the SIGN guidelines to be recognised standards. This offers an indication of the standard-setting potential or the regulatory role now accorded to clinical guidelines. Similarly, at first Rawlins wrote that NICE's output would not be mandatory, suggesting he was describing guidelines. However he also wrote that 'health professionals would be wise to record their reasons for non-compliance in patients' medical records',⁸¹⁰ which strongly suggests standards. An article by Radford and Rawlins had a diagram showing NICE producing 'standards' of clear service, with CHI (among others) monitoring these standards.⁸¹¹ The

804 Subcommittee of WHO/ISH Mild Hypertension Liaison Committee. Summary of 1993 World Health Organisation-International Society of Hypertension guidelines for the management of mild hypertension. *BMJ* 1993;307:1541-6 at 1541.

805 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh; CSBS: 2001 at p42

806 Clinical Standards: Generic. Clinical Standards Board for Scotland. Edinburgh; CSBS: 2001 at p43

807 Harmer M. Editorial. *Anaesthesia* 2001;56:611-2.

808 Obstetrics Anaesthetists' Association. Recommended Minimum Standards for Obstetric Anaesthetic Services. London: Obstetric Anaesthetists' Association, 1995.

809 Shomaker TS. Practice policies in anesthesia: a foretaste of practice in the 21st century. *Anesthesia and Analgesia* 1995;80:388-403 at 390.

810 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. *The Lancet* 1999;353:1079-82 at 1079

811 Radford G, Rawlins M. The National Institute for Clinical Excellence: the government's agenda and the College's

Department of Health has also stated that NICE is the pre-eminent authority in setting clinical standards.⁸¹²

The proliferation of clinical guidelines therefore appears to have increased the risk that patients and their lawyers will use them to show that a doctor's practice has fallen below acceptable levels. This may tempt doctors to abandon their own clinical judgement if this is not in keeping with a particular guideline.

Indeed, in the case of *R v. North Derbyshire Health Authority, ex p Fisher*⁸¹³, which concerned the failure of the health authority to fund the drug beta interferon, the judge held that it had failed to take a reasoned decision after consideration of all the relevant factors, especially ignoring a circular from the Department of Health advising that serious consideration be given to providing the drug to certain categories of patients with multiple sclerosis.

As mentioned, in discussions on medical technical matters the law has always relied on medical expertise to guide it. However, guidelines, which are essentially standards of care created by experts, could remove the need for the courts to rely on expert testimony. All the court would need is access to the relevant guideline. Since the guideline has been written by experts it could be argued that it would have the expertise to guide the court.

The problem is that guidelines, as discussed, are not applicable to each and every medical situation. Doctors are expected to use appropriate clinical discretion. In the meantime the courts continue to place the testimony of witnesses about what constitutes reasonable practice above the recommendations of prestigious works of reference⁸¹⁴ in contrast to the hierarchy used for generating guidelines, where systemic reviews and meta-analyses are deemed the most important and expert opinion the least.⁸¹⁵

The courts therefore believe that doctors must be prepared to deal with each patient on an individual basis. Clinical judgements often go beyond explicit input information, adding considerations of feeling, attitude, and value to the output. Differences in patients' choices and expectations may also underpin such variation.⁸¹⁶ Applying guidelines to individual care is always likely to require judgement, even when recommendations are properly linked to irrefutable evidence.⁸¹⁷

role. J R Coll Phys Lond 1999;33:303-4.

812 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London: HMSO, 2002, p58 at 4.11.

813 *R v. North Derbyshire Health Authority, ex p Fisher* [1997] 8 Med LR 327

814 Hurwitz B. Legal and political considerations of clinical practice guidelines. BMJ 1999;318:661-4

815 Harbour R, Miller J et al. A new system for grading recommendations in evidence based guidelines. BMJ 2001;323:334-6.

816 McPherson K. Why do variations occur? In: Anderson TF and Mooney G. eds. The challenge of medical practice variations. London: Macmillan, 1990:17.

817 Black D. The limitations of evidence. J R Coll Phys London 1998;32:23-5.

It is thus unlikely that the 'Bolam test' will be superseded by a legal standard entirely determined without reference to a responsible body of medical practitioners.⁸¹⁸ This is because clinical guidelines currently have a subservient role to that of the expert witness in court proceedings.

Although doctors fear that the proliferation and influence of guidelines will increase their legal exposure⁸¹⁹, in practice this does not appear to be so. For example, in the US where the guideline movement is more advanced, they only played a relevant or pivotal role in the proof of negligence in less than 7% of malpractice actions.⁸²⁰

Thus, appropriate interpretation and application of a clinical guideline is likely to generate better clinical care and a safer medico-legal strategy than either uncritical disregard or unthinking compliance.⁸²¹ Doctors cannot claim that merely following a guideline is an acceptable defence to negligence.⁸²² Clinical judgement should not be corrupted by guidelines. Divergence from national guidelines may come to be commonplace as good clinicians seek to tailor care to individual patients, as for example the advice given by the Association of Endoscopic Surgeons urging its members to ignore NICE guidelines discouraging the use of laparoscopic surgery for hernia repair.⁸²³

So far, UK legal cases have not tended to credit guidelines with a special 'self-evident' status as regards their legal value, and have not adopted standards of care advocated by guidelines, without first evaluating their authority, applicability and the extent to which they represent customary practice. In the case of *Loveday v. Renton and Wellcome Foundation Ltd*, a case that concerned the possibility of brain damage caused by the pertussis vaccine, the judge stated that:

Medical and expert opinion is deeply divided on the issue. The question has to be determined on all the evidence in the case, which is primarily the oral evidence of the witnesses tested in cross examination. The court cannot simply accept the opinion or belief of a witness, however eminent, that such is or is not the case. The basis for the opinion must be examined, tested against other evidence, for consistency and logic and the validity of the reasoning.⁸²⁴

818 Stern K. Clinical guidelines and negligence liability. In: Deighan M, Hitch S, eds. *Clinical effectiveness: from guidelines to cost effective practice*. Brentwood: Earlybrave, 1995:127-35.

819 Newton J, Knight D, Woolhead G. General practitioners and clinical guidelines: a survey of knowledge, use and beliefs. *Br J Gen Pract* 1996;46:513-7.

820 Hyams AL, Brandenburg JA, Lipsitz SR, Shapiro DW, Brennan TA. Practice guidelines and malpractice litigation: a two way street. *Ann Int Med* 1995;122:450-5.

821 Dworkin R. *Limits. The role of law in bioethical decision making*. Bloomington: Indiana University Press, 1997:3.

822 *Wickline v California* (1986) 228 Cal Rptr 661 (Cal CA).

823 Bratby L. Doctors warn NICE is losing its credibility. *Hospital Doctor* 24th May 2001, 1-2.

824 *Loveday v Renton and Wellcome Foundation Ltd* [1990] 1 Med LR 117 at 182.

Similarly, in *Vernon v. Bloomsbury HA* the court found the defendant not guilty of negligence despite administering a drug in excess of the manufacturer's guidelines.⁸²⁵ The court applied a risk/benefit approach in that the claimant was suffering from a serious disease and experts confirmed that doses higher than recommended by the manufacturer had been given on other occasions. In other words, the court did not rely solely on guidelines. Whether the defendant was in breach would be a question of fact.

This case implies that the court accepted the use of experimental treatment because there was a responsible body of opinion to support its use. In other words, whether experimental treatment was acceptable was a professional judgement. As previously argued, what the court should have asked was whether the treatment could be justified.

PERSONAL INNOVATION:

The other type of innovation described in this thesis is personal innovation. This is where a doctor personally attempts an already established standard technique for the first time. The issue of learning curves is inextricably linked to this form of innovation.

Dickens believes that when a procedure is applied to train personnel rather than to test the procedure itself, its use may be described as educational rather than experimental.⁸²⁶ It is usual, of course, for such training to be combined with a therapeutic purpose, the trainee acting under the direction of an experienced supervisor who is at hand in case of emergency. However, this is essentially an identical concept to personal innovation and thus merely a difference in terminology. In keeping with the distinction entertained in this thesis, Dickens has separated innovation into its two components, experimentation on the one hand and personal innovation, his so called educational model, on the other.

How would the law behave if it were faced with a problem arising when a doctor is trying to learn a new technique?

Under the laws of negligence already discussed, the standard a doctor has to achieve is that of the ordinary skilled doctor. By holding himself out as possessing the special skills of his profession, the doctor is under a duty to conform to the ordinary standards of that profession.⁸²⁷ He should have a reasonably sound grasp of medical techniques and be as informed of new medical developments as the average competent doctor would expect to be.⁸²⁸ The custom test, i.e. the test whereby a defendant's conduct is tested against the normal usage of his profession, is one that is applied in all areas of negligence law.⁸²⁹ This was endorsed by *Hunter*.⁸³⁰

825 *Vernon v Bloomsbury HA* [1995] 6 Med LR 297.

826 Dickens BM. What is a medical experiment? *Can Med Assoc J.* 1975;113:635-9

827 Stauch M, Wheat K, Tingle J. *Sourcebook on Medical Law.* 2nd ed. London: Cavendish, 2002, p310.

828 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics.* Butterworths 2002, 6th ed, 9.22.

829 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics.* Butterworths 2002, 6th ed, 9.25.

830 *Hunter v. Hanley* [1955] SC200, at 206.

Nettleship v. Weston:

This means that the law in the UK appears to make no allowance for personal innovation. Indeed, it is well established that inexperience is no defence to a claim of negligence. In the case of *Nettleship v. Weston* the same standard of care was expected of a learner driver as of an experienced one.⁸³¹ In the original case (unreported) the judge had dismissed the claim against the learner-driver, saying that the only duty owed by Mrs Weston (the driver) to Mr Nettleship (a friend helping her learn) was that she should do her best, and that she did not fail in that duty. This was appealed. In the Appeal Court Lord Denning stated:

In the criminal law it is no defence for a driver to say: 'I was a learner-driver under instruction. I was doing my best and could not help it.' Such a plea may go to mitigation of sentence, but it does not go to exculpation of guilt. The criminal law insists that every person driving a car must attain an objective standard measured by the standard of a skilled, experienced and careful driver.⁸³²

Similarly, when considering civil law he stated:

It is no answer for him to say: 'I was a learner-driver under instruction. I was doing my best and could not help it.' The civil law permits no such excuse. It requires of him the same standard of care as any other driver.⁸³³

One of the other judges stated:

... if this doctrine of varying standards were to be accepted as part of the law on these facts, it could not logically be confined to the duty of care owed by learner-drivers. There is no reason, in logic, why it should not operate in a much wider sphere. The disadvantages of the resulting unpredictability, uncertainty and, indeed, impossibility of arriving at fair and consistent decisions outweigh the advantages. The certainty of a general standard is preferable to the vagaries of a fluctuating standard.⁸³⁴

I for my part ... do not think that our legal process could successfully or satisfactorily cope with the task of fairly assessing, or applying to the facts of a particular case, such varying standards, depending on such complex and elusive factors, including the assessment by the court, not merely of a particular person's actual skill or experience, but also of another person's knowledge or assessment of that skill or experience at a particular moment in time.⁸³⁵

⁸³¹ *Nettleship v Weston* [1971] 3 All ER 581.

⁸³² *Nettleship v. Weston* [1971] 3 All ER 581, 585d.

⁸³³ *Nettleship v. Weston* [1971] 3 All ER 581, 586a.

⁸³⁴ *Nettleship v. Weston* [1971] 3 All ER 581, 592h/j.

⁸³⁵ *Nettleship v. Weston* [1971] 3 All ER 581, 593h.

Thus the learner driver could not use her inexperience as a defence because the law requires the same standard of care to be demonstrated as with any other driver. Her incompetent best was not enough. This is an understandably pragmatic approach as the courts do not want to apply a sliding scale of standards of care depending on the subjective attributes of the particular defendant.⁸³⁶

The implications of this decision can be summarised thus:

The Court of Appeal is saying, in essence, that as a matter of public policy the law must set a standard for the benefit of all below which everyone engaging in risk-creating behaviour may not fall. Thus, a junior doctor would be held to that minimum level of competence necessary for the safety and proper treatment of a patient regardless of his actual level of competence or experience.⁸³⁷

In medical negligence in the UK, the leading authority is the previously mentioned case of *Wilsher v. Essex Area Health Authority*.⁸³⁸ In this case the plaintiff had been born prematurely and been admitted to a specialist neonatal intensive care unit. It was alleged the plaintiff suffered blindness from too much oxygen being administered due to incorrect placement of a measuring catheter by a junior doctor. The catheter had been placed into a vein when it should have been placed in the adjacent artery. The incorrect placement was not in itself negligent. Negligence was alleged upon failure to spot the error when the catheter's position was checked on the x-ray.

In court the defendants argued that the standard of care expected of the junior doctor was not the same as that of an experienced colleague. A junior doctor had to learn on the job, otherwise it would be impossible for medicine to develop and function and ultimately patients would suffer. Therefore unavoidable mistakes would be made. One of the judges accepted this argument. Sir Nicholas Browne-Wilkinson QC stated:

... a doctor ... should only be held liable for acts and omissions which a careful doctor with his qualifications and experience would have done or omitted.⁸³⁹

The majority view, however, dismissed this argument. Glidewell LJ held:

... the law requires the trainee or learner to be judged by the same standard as his more experienced colleagues. If it did not, inexperience would frequently be urged as a defence to an action for professional negligence.⁸⁴⁰

⁸³⁶ Stauch M, Wheat K, Tingle J. Sourcebook on Medical Law. 2nd ed. London: Cavendish, 2002, p311.

⁸³⁷ Kennedy I, Grubb A. Medical Law, 3rd ed. Butterworths 2000, p420.

⁸³⁸ *Wilsher v. Essex AHA* [1987] QB 730, [1986] 3 All ER 801, CA; revsd [1988] AC 1074, [1988] 1 All ER 871, HL.

⁸³⁹ *Wilsher v Essex AHA* [1986] 3 All ER 801, 834.

⁸⁴⁰ *Wilsher v Essex AHA* [1986] 3 All ER 801, 831.

while Lord Mustill stated:

... this notion of a duty tailored to the actor, rather than to the act which he elects to perform has no place in the law of tort.⁸⁴¹

He further commented:

Doctors are not the only people who gain their experience, not only from lectures or from watching others perform, but from tackling live clients or customers, and no case was cited to us which suggested that any such variable duty of care was imposed on others in a similar position. To my mind, it would be a false step to subordinate the legitimate expectation of the patient that he will receive from each person concerned with his care a degree of skill appropriate to the task which he undertakes, to an understandable wish to minimise the psychological and financial pressures on hard-pressed young doctors.⁸⁴²

These statements reaffirm findings in earlier cases that inexperience was no excuse.⁸⁴³ This eliminates the personal equation and is independent of the idiosyncrasies of the particular person whose conduct is in question.⁸⁴⁴

Furthermore, in *Wilsher* the court found that a member of a specialist unit would be expected to display greater skill than an equivalent person on a general ward.⁸⁴⁵ Junior staff may meet the standards required by acknowledging their inexperience. Clearly doctors should not undertake procedures that are beyond their capacity⁸⁴⁶ and if they attempt to do something they were not qualified to do, the failure to refer to someone properly skilled may well itself be negligent.⁸⁴⁷ Thus, if the health carer either unwittingly or knowingly attempted something beyond his experience then that would constitute a breach of the standard of care.⁸⁴⁸ Whether a doctor was sufficiently competent and experienced to carry out an operation unsupervised would be a question of fact based on the evidence. For example, in *Burgess v. Newcastle HA* it was held that the unsupervised defendant was competent to undertake the operation on his own.⁸⁴⁹ There was evidence of the defendant's great experience and impressive list of research projects.

841 *Wilsher v Essex AHA* [1986] 3 All ER 801, 813.

842 *Wilsher v Essex AHA* [1986] 3 All ER 801, 813.

843 *Jones v Manchester Corporation* [1952] 2 QB 852, [1952] 2 All ER 125, CA.

844 *Glasgow Corpn. v. Muir* [1943] AC 448, 457 per Lord Macmillan.

845 *Wilsher v. Essex AHA*. [1986] 3 All ER 801, 813.

846 Mason JK, McCall Smith. *Law and Medical Ethics*. Butterworths 1994, 4th ed, p202

847 *Wilsher v. Essex AHA*. [1986] 3 All ER 801, 833.

848 Khan M, Robson M, Swift K. *Clinical Negligence*. 2nd ed. London: Cavendish Publishing, 2002, at 159

849 *Burgess v Newcastle HA* [1992] 3 Med LR 224.

From the legal perspective, reasonable conduct, therefore, does not vary according to a defendant's level of experience and once a health carer performs a task the patient can assume he has the competence to perform it with skill and care.⁸⁵⁰ Furthermore, once a doctor holds himself out as being more experienced than he actually is, he must reach that standard.⁸⁵¹ On the other hand, the more skilled a person is, the more care that is expected of him.⁸⁵² The standard of care will be met, however, if a junior doctor seeks advice from more experienced colleagues when appropriate.

The problem with this is that it may be difficult for a doctor to know when to refer to a more senior or experienced colleague.⁸⁵³ Often the doctor does not realise that the task at hand is beyond his capabilities and therefore does not seek help. In the Canadian case of *Fraser v. Vancouver General Hospital* the court held that an intern must have an appreciation of his own limitations.⁸⁵⁴ The junior doctors were found negligent for failing to consult a specialist. However, this in itself is problematic.

It is all very well saying that a doctor must appreciate his own capabilities, but in most situations the junior doctor is already acting under the firm belief that this is in fact what he is already doing.⁸⁵⁵

The problem, therefore, with these decisions is how to reconcile two entirely different requirements. On the one hand doctors need to learn on the job and obtain the necessary experience. This is unavoidable and in the interests of society as it benefits future patients. On the other hand, the patient under the doctor's care, who is being practised on, needs to be protected from potential harm or, at least, to have the risk of harm minimised.

It must be appreciated that it is difficult for the law to accommodate both approaches. However, rather than trying to find a solution to enable it to do so, the law focuses all its attention on the protection of the particular patient while making no allowance for the unavoidable requirement for doctors to learn.

Once again, the law appears unable, or perhaps unwilling, to appreciate the subtleties of the medical act. Because of this, the standard it uses is inappropriate. Strict application of the *Bolam* principle would lead the courts to expect that a doctor should show the degree of skill of the reasonably competent doctor, irrespective of his own level of experience. No allowance is made for inexperience.

However, in the previously mentioned Scottish case of *McHardy v. Dundee General Hospitals' Board of Management*, Lord Cameron stated:

⁸⁵⁰ Khan M, Robson M, Swift K. *Clinical Negligence*. 2nd ed. London: Cavendish Publishing, 2002, at p159.

⁸⁵¹ R v. Bateman (1925) 94 LJKB 791 (CCA)

⁸⁵² Ashcroft v. Mersey RHA [1983] 2 All ER 245.

⁸⁵³ Wilsher v. Essex AHA. [1986] 3 All ER 801, 833.

⁸⁵⁴ Fraser v. Vancouver General Hospital (1951) 3 WWR 337

⁸⁵⁵ Khan M, Robson M, Swift K. *Clinical Negligence*. 2nd ed. London: Cavendish Publishing, 2002, at p159.

I think it is well that the search for further knowledge *and experience* (my italics) should not be inhibited by undue apprehension of charges of negligence for the consequences to a patient of treatment or diagnosis where such may diverge from the normal.⁸⁵⁶

This implies that, unless the law offers some understanding of the need for doctors to gain experience, then the threat of legal action may very well inhibit the search for experience, which would be contrary to the interests of future patients. The law of negligence, as currently applied to personal innovation, appears to be too harsh because it takes no account of reality. How can it be that a junior doctor will be judged as if he were a consultant, as *Nettleship* implies.

Reconciling different requirements:

How therefore can the law take account of the unavoidable fact that doctors need to learn while at the same time ensuring patients are protected and have recourse to the courts?

One option is for the law to change and show some understanding of the subtleties of the medical act. This is not a homogenous entity but rather can be extremely variable. As has been argued, this variability arises because of its various components and their presence to a greater or lesser degree. The medical act therefore can range from a simple therapeutic intervention to non-therapeutic research. Indeed, in the case of doctors acting as an impartial medical examiner on behalf of, for example, an insurance company, the doctor's duty of care is towards the company and not the patient. Any tests are carried out are not done primarily for the purposes of the health care of the patient but for the insurance company. This specific issue was not examined in this thesis but is merely mentioned here to further highlight the extreme variability of the medical act. Adding to this variability is the problem of inexperience of the operator. In many instances, and indeed, it is how the National Health Service functions, treatment of patients is undertaken by junior medical staff striving to gain more experience.

Change the law:

Can the law change? It may be appropriate briefly to examine how the problem has been considered by other jurisdictions. Given the same facts, it is well recognised that different jurisdictions may reach different conclusions. For example, let us first review, once again, the English case of *Nettleship v. Weston*.⁸⁵⁷ As previously mentioned, it was held that inexperience was no excuse and the same standard of care was expected of a learner driver as of an experienced one.

The High Court of Australia, however, refused to follow this decision.⁸⁵⁸

⁸⁵⁶ McHardy v Dundee General Hospitals' Board of Management. (1960) SLT (Notes) 19

⁸⁵⁷ *Nettleship v. Weston* [1971] 3 All ER 581.

⁸⁵⁸ *Cook v Cook* [1987] 61 ALJR 25.

It would be contrary to common sense and the concept of what is reasonable in the circumstances (considerations which are basic to the common law of negligence)...⁸⁵⁹

The Court held that, although the standard of care was objective, it could be adjusted to fit the special relationship under which it arises.

In *Donoghue v. Stevenson* it was held that the neighbour to whom a duty to take reasonable care is owed is the person to whom injury might foreseeably be caused by the careless doing of the act, the test of reasonable foreseeability depending on the closeness and directness of the effect of the act on the person or persons affected by it.⁸⁶⁰

Reasonable care is, thus, not susceptible of abstract definition; it must be related to particular circumstances.⁸⁶¹ The known incompetence and inexperience of the driver controlled the relationship of proximity between the parties and took it out of the ordinary relationship, such that the standard of the duty of care arising was that of an unqualified and inexperienced driver. Such an argument had been accepted in the case of *The Insurance Commissioner v. Joyce*.⁸⁶²

It is because that relation may vary that the standard of duty or of care is not necessarily the same in every case.⁸⁶³

In *Cook* it was held that

(It) is not ... to say that ...the relationship between a driver and a passenger is, for the purposes of the law of negligence, a completely standardised one or that the content of the duty of care where that general relationship exists is necessarily immutable. ...

... special and exceptional facts may so transform the relationship between driver and passenger that it would be unreal to regard the relevant relationship as being simply the ordinary one of driver and passenger and unreasonable to measure the standard of skill and care required of the driver by reference to the skill and care that are reasonably to be expected of an experienced and competent driver...⁸⁶⁴

It was the very absence of skill that lay at the heart of the special relationship.

... the standard of care which arises from the relationship of pupil and instructor is that which is reasonably to be expected of an unqualified

⁸⁵⁹ *Cook v Cook* [1987] 61 ALJR 25, 28.

⁸⁶⁰ *Donoghue v. Stevenson* [1932] AC 562.

⁸⁶¹ *Cook v Cook* [1987] 61 ALJR 25, 31.

⁸⁶² *Insur Comm v. Joyce* (1948) 77 CLR 39.

⁸⁶³ *Insur Comm v. Joyce* (1948) 77 CLR 39, 56 per Dixon J.

⁸⁶⁴ *Cook v Cook* [1987] 61 ALJR 25, 27.

and inexperienced driver in the circumstances in which the pupil is placed. The standard of care remains an objective one. It is, however, adjusted to fit the special relationship under which it arises.⁸⁶⁵

Actions resulting from inexperience, rather than carelessness, did not of themselves constitute a breach of duty. However, the court held that, when the driver accelerated just before the accident, this act was deliberate and careless and therefore actionable. Thus, the court held that what resulted out of inexperience was not actionable but the additional element of carelessness was.

... (there was) an element of carelessness over and above what could be attributed merely to inexperience.⁸⁶⁶

Fundamentally, however, *Cook* held that:

As a duty of care is owed to individuals, the circumstances to which regard must be had in deciding what is required to discharge the duty in a particular case are the circumstances out of which the duty to the injured plaintiff arises.

To follow the *Nettleship* approach is to deny the relevance of the circumstances which gave rise to the relationship out of which the duty of care arose

It would be artificial to exclude those circumstances from consideration in determining what is reasonable care.⁸⁶⁷

Different views have also arisen when considering whether a passenger is owed a duty of care when accepting a lift from a drunk driver.

If he knowingly accepts the voluntary services of a driver affected by drink, he cannot complain of improper driving caused by his condition, because it involves no breach of duty.⁸⁶⁸

This view was accepted in Australia⁸⁶⁹ but not in Canada.⁸⁷⁰ In the UK, Lord Denning, when considering *Nettleship*, felt that confusion would arise if this view was upheld.

If the driver were to be excused according to the knowledge of the passenger, it would result in endless confusion and injustice.⁸⁷¹

865 *Cook v Cook* [1987] 61 ALJR 25, 28.

866 *Cook v Cook* [1987] 61 ALJR 25, 30.

867 *Cook v Cook* [1987] 61 ALJR 25, 32.

868 *Insurance Comr v. Joyce* (1948) 77 CLR 39 at 56,57.

869 *Walker v. Turton-Sainsbury* [1952] SASR 159

870 *Carr and General Insurance Corp'n Ltd v. Seymour and Maloney* [1956] 2 DLR 369 at 375.

871 *Nettleship v. Weston* [1971] 3 All ER 581, 587a.

This was especially so, he felt, if there were a number of passengers in the care. Megaw similarly believed there would be difficulties arising from 'this doctrine of varying standards.'⁸⁷²

However, these problem of multiple passengers would not arise in medicine because each act would be specific to one patient. There would not therefore be the conflict envisaged by Lord Denning as there is only one patient in each doctor patient relationship.

Furthermore, as argued in *Cook*

...it seems to us that ...fears of practical disadvantages – “resulting unpredictability, uncertainty and, indeed, impossibility of arriving at fair and consistent decisions” – resulted from (a) mistaken impression that Dixon J. in *Joyce* was advocating some wholesale abandonment of the ordinary objective duty of care to be expected of a driver. (It) involved no abandonment of the objective nature of the standard provided by the reasonable person of the law of negligence. It merely involved the recognition that exceptional circumstances could take the relationship of proximity between a driver and a passenger into a special category in which what could reasonably be expected of the hypothetical reasonable person must necessarily be governed by the nature of the relationships constituting that category.⁸⁷³

This was also agreed by Salmon LJ in *Nettleship*.

The duty of care springs from relationship. The special relationship which the passenger has created by accepting a lift in the circumstances postulated surely cannot entitle him to expect the driver to discharge a duty of care or skill which *ex hypothesi* the passenger knows the driver is incapable of discharging.⁸⁷⁴

Indeed, UK law, at times, does recognise that the circumstances in which a doctor treats his patient will be taken into account. Thus a doctor working in an emergency will not be expected to achieve the same results as a doctor working in ideal conditions. Errors of judgment are more excusable in such an emergency.⁸⁷⁵ Allowance should be made for 'battle conditions'.⁸⁷⁶

The findings in *Wilsher* are also not entirely clear cut. Sir Nicholas Browne-Wilkinson V-C dissented as he could not accept that an individual doctor holding a post in a hospital was an objective standard to be determined irrespective of his experience or the reason why he was occupying the post in question.

⁸⁷² *Nettleship v. Weston* [1971] 3 All ER 581, 597.

⁸⁷³ *Cook v Cook* [1987] 61 ALJR 25, 29.

⁸⁷⁴ *Nettleship v. Weston* [1971] 2 QB 691, 704.

⁸⁷⁵ *The Metagama* (1927) 138 LT 369 at 370.

⁸⁷⁶ *Wilsher v. Essex AHA*. [1986] 3 All ER 801, 812.

In my judgment, so long as English law rests liability on personal fault, a doctor who has properly accepted a post in a hospital in order to gain necessary experience should only be held liable for acts or omissions which a careful doctor with his qualifications and experience would not have done or omitted.⁸⁷⁷

Also, while Mustill LJ rejected the notion of a duty tailored to the actor, he arguably muddled the waters by proposing that one could ascertain the standard of care by reference to the 'post' that the doctor held:

For my part, I prefer ... the proposition ... which relates the duty of care, not to the individual, but to the post which he occupies. I would differentiate 'post' from 'rank' or 'status'. In a case such as the present, the standard is not just that of the averagely competent and well-informed junior houseman (or whatever the position of the doctor) but of such a person who fills a post in a unit offering a highly specialised service. But even so, it must be recognised that different posts make different demands. If it is borne in mind that the structure of hospital medicine envisages that the lower ranks will be occupied by those of whom it would be wrong to expect too much, the risk of abuse by litigious patients can be mitigated, if not entirely eliminated.⁸⁷⁸

It is contended that there does not appear to be any significant difference between this proposition and a requirement for the inexperience of a junior doctor to be taken into consideration, which, as we have seen, the UK courts have refused to do.

The answer may therefore seem to lie in describing a minimum standard to be applicable to each post below which a doctor in the post cannot fall. If a doctor acts in a careless way then this would be actionable. This at least goes some way to recognising the inevitability of doctors gaining experience 'on the job'.

Thus in *Djermal v. Bexley Health Authority*, the standard of care to be applied was that of a reasonably competent senior houseman acting as a casualty officer without reference to the length of experience.⁸⁷⁹

Even in *Nettleship* there appears to be a dissenting argument, as per Salmon LJ:

...there might be special facts creating a special relationship which displaces this standard or even negatives any duty, although the onus would certainly be on the driver to establish such facts.⁸⁸⁰

Indeed, he agreed with the reasoning and conclusions of Sir Owen Dixon in *Insurance Comr v. Joyce*.⁸⁸¹

⁸⁷⁷ *Wilsher v. Essex AHA*. [1986] 3 All ER 801, 833.

⁸⁷⁸ *Wilsher v. Essex AHA*. [1986] 3 All ER 801, 813.

⁸⁷⁹ *Djermal v. Bexley Health Authority* [1995] Med LR 269, 271.

⁸⁸⁰ *Nettleship v. Weston* [1971] 3 All ER 581, 589f.

Quite apart from being negligent, a passenger who accepts a lift (from a driver known to be drink) ... clearly cannot expect the driver to drive other than dangerously.⁸⁸²

He argued that in most cases involving a learner-driver and instructor, the instructor knew that the driver had practically no driving experience or skill and that he would therefore almost certainly make mistakes which could well cause the instructor injury; accordingly, in Salmon's eyes,

The relationship is ... such that the beginner does not owe the instructor a duty to drive with the skill and competence of an experienced driver.⁸⁸³

Could it really be said that in order to give this contract (between learner-driver and instructor) ordinary business efficacy, it is necessary to imply a term that the learner owed the instructor a duty to drive with the degree of skill and competence which both parties know that he does not possess? If the law were to imply such a term ... it would ... only make both itself and the contract look absurd.⁸⁸⁴

He believed this would apply even if there were no contract.

I do not think that the learner is usually liable to his instructor if an accident occurs as a result of some mistake which any prudent beginner doing his best can be expected to make. I recognise that, on this view, cases in which a driving instructor is injured whilst his pupil is driving may raise difficult questions of fact and degree. Equally difficult questions of fact and degree are, however, being assessed and decided in our courts every day. The law lays down principles but not a rule of thumb for deciding issues arising out of any special relationship between the parties. A rule of thumb, if it existed, might no doubt remove difficulties, but could hardly produce justice either in practice or in theory.⁸⁸⁵

Salmon accepted that the instructor, Mr Nettleship, deserved compensation because he had specifically asked about the insurance coverage in the event of an accident and was assured of compensation. Mrs Weston therefore had accepted responsibility for any injury which Mr Nettleship might suffer as a result of any failure on her part to exercise the ordinary driver's standards of reasonable care and skill. In other words, this assurance altered the nature of the relationship between the two parties.

881 *Insur Comm v. Joyce* (1948) 77 CLR 39.

882 *Nettleship v. Weston* [1971] 3 All ER 581, 589h.

883 *Nettleship v. Weston* [1971] 3 All ER 581, 590e/f.

884 *Nettleship v. Weston* [1971] 3 All ER 581, 590g/h.

885 *Nettleship v. Weston* [1971] 3 All ER 581, 591b/c.

Thus, in both *Nettleship* and *Wilsher* there were reasonable dissenting arguments. Furthermore, one of the fundamental principles established by *Donoghue* was that no case law rule or principle is ever settled for all time.⁸⁸⁶

In summary, it is unavoidable that doctors need to learn on the job. UK law appears not to take this into consideration and merely applies standard laws of negligence in which the standard of care expected is that of an experienced doctor. Other jurisdictions, however, have accepted that special circumstances could adjust the standard of care. Furthermore, in both *Nettleship* and *Wilsher* there were persuasive dissenting arguments. Even UK law does, on occasion, accept that the circumstances of treatment would be taken into account, as in the emergency situation. It was even argued in *Wilsher* that allowance should be made for the post held by the doctor when considering whether there was a breach of the duty of care.

Supervision:

At the same time it is important also to accept that it would not be appropriate, whenever a patient suffers harm when treated by an inexperienced doctor, for the defence merely to be the inexperience of that doctor. The answer may therefore lie in closer supervision by more senior colleagues, as considered in chapter 3.

Professionals generally are responsible only for their own mistakes and not for those of other members of the team.⁸⁸⁷ However, a more senior doctor may be negligent in failing adequately to supervise a more junior doctor⁸⁸⁸ while a consultant would be negligent for delegating to a junior in the knowledge that the junior was not capable of performing his duties properly.⁸⁸⁹

Even being supervised, however, does not necessarily absolve the trainee of responsibility. In *Bouchta v. Swindon HA*⁸⁹⁰ the junior operating surgeon was under the direct supervision of a senior surgeon. The judge was impressed with the supervising surgeon, Mr Bond, who:

'was faced with the particular difficulty of recalling an operation where his main role was a supervisory one. Had he been carrying out the operation himself rather than supervising as far as he could ... I would have had great difficulty in making the findings I do. But there came a time when, despite that supervision, and it may be something that Mr Bond could not have prevented, Dr Habiba, a normally careful surgeon, failed to exercise the high standards of his profession.'⁸⁹¹

The court held that the junior failed to exercise reasonable care when the patient's ureter was damaged. Despite being under supervision the junior was

886 Farrar JH, Dugdale AM. Eds. *Introduction to Legal Method*, 2nd ed. London: Sweet & Maxwell, 1984. p84.

887 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p178

888 *Wilsher v. Essex AHA* [1997] QB 730 at 774.

889 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.54.

890 *Bouchta v. Swindon HA* [1996] 7 Med LR 62.

891 *Bouchta v. Swindon HA* [1996] 7 Med LR 62, 69.

still liable. Interestingly, Puxon M, QC, commented that a feature of the case, which might have been further explored, was the relationship between the supervisory status of the senior surgeon and the responsibility of the junior, operating surgeon.⁸⁹²

If we accept the argument that gaining experience in unavoidable and supervision by more senior colleagues may diminish the risk to patients, how do we resolve the problem of the Bristol doctors? Being consultants and thus practising without supervision, they could simply state that their results were unavoidable as they were merely learning a new technique. Indeed, one of the surgeons excused the level of mortality and morbidity in his practice as being due to his learning curve⁸⁹³, blaming 'beginner's bad luck' for some of the deaths.

The answer to this might lie in firstly, stating that culpability arose when the doctors concerned ignored their own poor results. Secondly, it is well recognised that the system of regulation, which included immediate colleagues, the employer, the Royal College of Surgeons and the Department of Health, also failed. This was discussed earlier in chapter 3.

Hospital liability?

Another option may be for patients to sue the hospitals who employ inexperienced staff.

In *Nettleship* Lord Denning stated:

We are beginning to apply the test: 'On whom should the risk fall?' morally the learner-driver is not at fault; but legally she is liable to be because she is insured and the risk should fall on her.⁸⁹⁴

In other words, he recognised that morally the learner-driver was not at fault but, in order that an injured person was not left to bear the loss on his own, he should be compensated out of the driver's insurance fund. As the injured person would only be able to recover if the driver was liable in law, then legally she, the learner-driver, was liable.⁸⁹⁵

Clearly, this appears to imply that the reason she was held to be liable was because she carried insurance and thus the injured party could be compensated.

Denning's other alternative was to hold neither the driver nor instructor to be at fault.

The only alternative is to hold that the accident is the fault of neither, so that the injured person gets no compensation from anyone. To my

⁸⁹² *Bouchta v. Swindon HA* [1996] 7 Med LR 62, 70.

⁸⁹³ Dyer C. Surgeon blamed beginner's bad luck for cardiac deaths. *BMJ* 1998;316:1114

⁸⁹⁴ *Nettleship v. Weston* [1971] 3 All ER 581, 586d/e.

⁸⁹⁵ *Nettleship v. Weston* [1971] 3 All ER 581, 586c/d.

mind, that is not an acceptable solution, at any rate in these days of compulsory insurance.⁸⁹⁶

Yet again, it appears that the case was argued in such a way that the end result would leave the injured party in a position to receive compensation. If, for example, there was a central fund set up by Government to compensate any road accident victim, then the case may have never needed to come before the courts but even if it did, it may very well have been reasoned differently.

Therefore, an avenue to explore if wishing to give some allowance for inexperience while still allowing patients recourse to the law if harmed, is to find another way of compensating victims. There was no other way in *Nettleship* to do so but there are other possibilities in medicine.

For example, the patient may sue the hospital and obtain compensation that way. This is because employers are liable for any negligent acts committed by their employees under the doctrine of vicarious liability.⁸⁹⁷ However, this does not absolve the employee of liability. There may also be a direct liability of provider units for failures in their services. Thus a hospital may owe a duty of care towards its patients. In *Wilsher* Lord Browne-Wilkinson said:

...a health authority which so conducts its hospital that it fails to provide doctors of sufficient skill and experience to give the treatment on offer ... may be directly liable in negligence to the patient ... I can see no reason why, in principle, the health authority should not be [directly] liable if its organisation is at fault.⁸⁹⁸

In the same case, Glidewell LJ stated:

There seems to be no reason in principle why, in a suitable case ... a hospital management committee should not be held directly liable ... for failing to provide sufficient qualified and competent staff.⁸⁹⁹

In *Jones v. Manchester Corporation*⁹⁰⁰ a junior doctor had been left with little supervision, in accordance with common practice. This was no defence. Lord Denning stated:

It would be in the highest degree unjust that the hospital board, by getting inexperienced doctors to perform their duties for them, without adequate supervision, should be able to throw all the responsibility on to those doctors as if they were fully experienced practitioners.⁹⁰¹

⁸⁹⁶ *Nettleship v. Weston* [1971] 3 All ER 581, 589b.

⁸⁹⁷ Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p178

⁸⁹⁸ *Wilsher v. Essex AHA*. [1986] 3 All ER 801 at 833, as per Browne Wilkinson.

⁸⁹⁹ *Wilsher v. Essex AHA*. [1986] 3 All ER 801 at 831, per Glidewell LJ.

⁹⁰⁰ *Jones v Manchester Corporation* [1952] 2 QB 852, [1952] 2 All ER 125, CA.

⁹⁰¹ *Jones v Manchester Corporation* [1952] 2 QB 852 at 871, [1952] 2 All ER 125 at 133, CA.

In this case the Court of Appeal found that the cause of an anaesthetic accident was primarily the inadequacy of the support and supervision provided for a junior doctor. Thus the hospital was held to be responsible for 80 per cent of the damages payable, and the doctor for only 20 per cent.

Similarly in *Bull v. Devon AHA*⁹⁰² the Court of Appeal examined a hospital's system for providing obstetric support for women in labour and found their system of cover had produced a real risk of danger to their patients. The Court accepted that the Health Authority owed the plaintiffs a duty of care directly. The health authority had been negligent in implementing a system that was 'unreliable and essentially unsatisfactory'.⁹⁰³ While it was accepted that the overall staffing levels were in line with current professional practice, the administrative systems were judged against judicial conceptions of what was acceptable.⁹⁰⁴

Thus, a solution may lie in a hospital accepting direct legal responsibility on behalf of its inexperienced doctors. In such a case, the courts, knowing that the patient has a source of reimbursement for the injury caused, may either hold the inexperience of the doctor as only partially responsible, as in *Jones v. Manchester Corporation*⁹⁰⁵, or hold that no negligence was proven because the doctor's unavoidable inexperience could be used as a defence. Legal liability would then fall entirely on the employing hospital.

Another option is to consider aspects of information disclosure and patient consent. Thus, the patient could accept a lower standard of care if told that that care is to be provided by a more junior doctor. For example, in *Nettleship* it was held that the special factor in the case was that the plaintiff was not a mere passenger in the car but the instructor. Thus

He may, of course, be guilty of contributory negligence ... but, apart (from this), he is not excluded (from claiming damages) unless it be that he had voluntarily agreed to incur the risk.⁹⁰⁶

Even in *Cook* it was stated that

...a basic ingredient of the relationship between the particular driver and the particular passenger is their mutual knowledge that the driver is unqualified and lacks ... skill.⁹⁰⁷

In medicine the patient would not know the doctor treating her was less experienced unless this was specifically disclosed. This point of patients being informed that they were being treated by inexperienced doctors and thereby accepting a greater risk will be returned to in the next chapter.

⁹⁰² *Bull and Another v. Devon AHA* [1993] 4 Med LR 117 (CA).

⁹⁰³ *Bull and Another v. Devon AHA* [1993] 4 Med LR 117, 138 (CA).

⁹⁰⁴ Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p183.

⁹⁰⁵ *Jones v Manchester Corporation* [1952] 2 QB 852, [1952] 2 All ER 125, CA.

⁹⁰⁶ *Nettleship v. Weston* [1971] 3 All ER 581, 587f/g.

⁹⁰⁷ *Cook v Cook* [1987] 61 ALJR 25, 26.

CONCLUSION:

The problem is thus that the law uses principles established in the context of a normal therapeutic doctor patient relationship when determining negligence in cases of innovation. In experimental practice, mainly because medicine is seen as needing to progress and thus benefiting society, the law treats experimentation as if it were normal therapy and makes no distinction. The law is thus too benevolent towards innovators. As the Lord President Clyde stated:

... a deviation (from ordinary professional practice) is not necessarily evidence of negligence. Indeed it would be disastrous if this were so, for all inducement to progress in medical science would then be destroyed.⁹⁰⁸

Similar sentiments were uttered by Lord Diplock in *Sidaway* as otherwise it would encourage 'defensive medicine' with a vengeance.⁹⁰⁹

Thus the courts currently accept the use of experimental treatment merely on the grounds that a responsible body of medical opinion supported its use. As previously mentioned

Bolam provides some protection for the innovative or minority opinion. If this protection is removed, then the opinion which the cautious practitioner will wish to follow will be that which involves least risk. This may have an inhibiting effect on medical progress: after all, many advances in medicine have been made by those who have pursued an unconventional line of therapy. Such doctors may quite easily be regarded as negligent by a judge given to favouring conventional medical opinion.⁹¹⁰

Indeed, not even *Bolam* may be needed according to Butler Sloss in her judgement in *Simms*. At trial the judge stated:

The 'Bolam test' ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the 'Bolam test' to be complied with to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted.⁹¹¹

However, it is argued that the law should change to require the experimenters to justify their actions (or potential actions as occurred in *Simms*). Annas has alleged that many early transplantation procedures were in reality purely non-therapeutic and intended only for the benefit of society.⁹¹² It may be that the

908 *Hunter v. Hanley* 1955, SC200 at 206

909 *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1984] 1 All ER 1018, [1985] AC 871, [1985] 1 All ER 643, HL.

910 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.30.

911 *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669, 680-1.

912 Annas G. *Death and the Magic Machine*. *Western New England Law Review* 1987;9:89 at 98.

innovators can justify the use of such experimental treatment on these grounds but a further question then needs to be asked. Was this information disclosed to the patients? This point will be returned to in the next chapter.

On the other hand, with respect to personal innovation and learning new techniques, the law of negligence is too harsh, taking no account of the need for doctors to learn and develop their skills, in the interests of future patients. Some arguments have been proposed to counteract this.

In summary, two important issues have been raised. Firstly, the context in which the innovative treatment, whether of the experimental or personal innovation variety, was administered needs to be taken into consideration by the courts. Standard laws of negligence, based on principles created in the normal doctor-patient relationship, do not take this into account. Secondly, the question of what information is disclosed to the patient regarding this innovation also needs to be considered. Thus, the doctor could inform the patient, either that the treatment proposed was experimental, or that he or she was inexperienced in the particular technique proposed. This issue will be analysed next.

THE REGULATION OF INNOVATION:

CHAPTER 6:	
 CONSENT	169
Informed consent and autonomy	170
The elements of consent	173
Competence	174
Disclosure	174
Understanding	178
Voluntariness	180
The Law	181
Battery	182
Negligence	188
Professional standard test	188
Patient centred standard	189
Causation	189
Beyond Bolam	192
<i>Sidaway v. Bethlem Royal</i>	
<i>Hospital Governors</i>	192
<i>Bolitho v. City and Hackney HA</i>	196
<i>Pearce v. United Bristol</i>	
<i>Healthcare NHS Trust</i>	201
Deference	202
Consent and innovation in the UK	205
Heart transplants revisited	206
Bristol revisited	210
Two meanings of consent	212
Disclosure in the research setting	215
Foreign law - in brief	218
UK law- revisited	220
Evidence of change?	229
An ethical foundation	230

CHAPTER 6: CONSENT

All medical and research codes of ethics hold that physicians and research investigators must obtain the informed consent of patients and subjects before undertaking any procedure. A feature of our present society is the emphasis placed on the value and dignity of the individual. Respect for patients and their rights lies at the heart of the issue of consent. The introduction of the European Convention on Human Rights into United Kingdom law⁹¹³ is likely to touch virtually every aspect of the law. Consent is a human rights issue, in that respect for bodily integrity and privacy are values that are central to any theory of consent and are central values in the Convention.⁹¹⁴ Each person who is competent should decide what happens to his or her body.⁹¹⁵

Although it may appear self-evident that the obligations or duties of physicians and the rights or claims of patients are interdependent, many issues have been little considered before the present century. For example, although in the Hippocratic corpus (especially in the Oath) one finds descriptions of both physician and patient 'rights', there is little which concerns the concept of consent, or even truth telling. Here the main concerns for physicians relate firstly to the profession, not the patient, in requiring loyalty and respect for their teachers (and their offspring). There are also duties to teach, though only to a chosen few; a duty to sick patients in terms of benefit is implied and, at most, an effort to avoid treatment which might be deleterious is required. Indeed, it is expected that 'the patient must co-operate with the physician in combating the disease'.⁹¹⁶ This paternalistic emphasis persisted well into the nineteenth century and in many areas persists today.

Even in modern times there are still disagreements regarding when consent should be obtained. For example, a recent debate in the British Medical Journal on whether consent was needed to undertake research on stored body samples drew different and diametrically opposite responses. One reviewer claimed that self determination was not an overriding principle in the case of material that would otherwise be thrown away⁹¹⁷ while, on the contrary, Savulescu believed consent should be obtained because it was important to respect autonomy.⁹¹⁸

It is therefore important to examine the question of what consent is and the ethical reasons why it is an essential requirement prior to commencing treatment, innovative therapy or undertaking research.

913 Human Rights Act 1998. London: Stationery Office, 1998.

914 McCall Smith RA. Obtaining consent for examination and treatment. *BMJ* 2001;322:810-1.

915 British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMJ Publishing Group. 2004, 71.

916 Beck P. Informed consent. In 'Why should we care?' Evans D (ed). London: MacMillan Press, 1990: 107.

917 Van Diest PJ. No consent should be needed for using leftover body material for scientific purposes. *BMJ* 2002;325:648-9.

918 Savulescu J. No consent should be needed for using leftover body material for scientific purposes: against. *BMJ* 2002;325:649-51.

INFORMED CONSENT and AUTONOMY:

Commentators such as Katz⁹¹⁹ have reduced the concept of informed consent to shared decision making between doctor and patient, so that informed consent and mutual decision making are identical ideas. Similarly, the British Medical Association states that the relationship between doctor and patient is based on the concept of partnership and collaborative effort. It claims that, ideally, decisions are made through frank discussion, in which the doctor's clinical expertise and the patient's individual needs and preferences are shared, to select the best treatment option. The patient's consent to be examined and to receive treatment is the trigger that allows the interchange to take place. The basic premise is that treatment is undertaken as a result of patients being actively involved in deciding what is to be done to them.⁹²⁰

However, informed consent is not restricted to clinical medicine and is used no less frequently in research contexts, where a model of shared decision-making may be inappropriate. Even in the clinical setting the information exchange through which patients elect to undergo medical interventions should be distinguished from their act of permitting or approving the intervention.⁹²¹

Physicians and other health-care professionals and researchers do not have a right to do anything to patients or subjects without their consent because the right to consent or refuse is grounded in the ethical principle of respect for autonomy. It is, however, doubtful whether autonomy can be viewed as a single concept and is so imprecise in its ordinary meaning that further examination is required before it can be used in moral theory.⁹²²

Some writers maintain that autonomy is a matter of having the capacity to reflectively control and identify with one's basic ... desires or preferences through higher-level ... desires or preferences. ... [S]erious problems confront this theory. Acceptance or repudiation of a desire can be motivated by an overriding desire that is simply *stronger*, not more *rational* or *autonomous*. [There must be] a way for ordinary persons to qualify as deserving respect for their autonomy, even when they have not reflected on their preferences at a higher level. Few choosers, and also few choices, would be autonomous if held to the standards of higher-order reflection in this theory, which in effect presents an aspirational ideal of autonomy. No theory of autonomy is acceptable if it presents an ideal beyond the reach of normal choosers.⁹²³

919 Katz J. The silent world of doctor and patient. New York: Free Press, 1984:86-7.

920 British Medical Association. Medical Ethics Today. 2nd ed. London: BMJ Publishing Group. 2004, 71.

921 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:78.

922 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:57-8.

923 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:58-9.

An ideal theory of this sort therefore reaches beyond the criteria needed for a theory of autonomous actions.

An agent's autonomous actions can be analysed in terms of acting intentionally, with understanding, and without controlling influences that determine the action taken. The first condition, that of intention, requires planning on the agent's part and is not a matter of degree: an act is either intentional, therefore potentially autonomous, or non-intentional, and therefore not autonomous. In contrast, the other two conditions, of understanding and absence of controlling influences, can both be satisfied to a greater or lesser extent. Actions can therefore be autonomous by degrees, depending on to what degree the latter two conditions are satisfied. Thus, the conditions of understanding and non-control are analysed in terms of a broad continuum, from being fully present to wholly absent.⁹²⁴

For an action to be autonomous ... it needs only a substantial degree of understanding and freedom from constraint, not a full understanding or a complete absence of influence. To restrict adequate decision-making by patients and research subjects to the ideal of fully or completely autonomous decision-making strips their acts of any meaningful place in the practical world, where people's actions are rarely, if ever, fully autonomous.⁹²⁵

The problem then lies in defining substantial because the line between what is substantial and what is not substantial seems arbitrary. However, thresholds marking substantially autonomous decisions can be reasoned in light of specific goals and objectives.

Patients and research subjects can achieve substantial autonomy in their decisions, just as substantially autonomous choice occurs in other areas of life ...⁹²⁶

Therefore, the criteria of substantiality and substantial autonomy must be related to a particular context and situation, rather than being viewed through a general theory of what is a substantial amount. The more serious the harm done to the person, as when bodily privacy is invaded, the greater the degree of information and absence of controlling influences required.

The viability of autonomy in the medical context can be questioned because of the dependent condition of the patient and the authoritative position of the medical professional. It is sometimes doubtful whether authority and autonomy are compatible. This doubt does not arise because the two concepts are intrinsically incompatible but because in the context under consideration authority has not been properly delegated or accepted.⁹²⁷ In turn, it is possible for individuals to exercise their autonomy by choosing to

924 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:59.

925 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:59.

926 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:60.

927 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:60.

submit to the authoritative demands of an institution or tradition.⁹²⁸ When a patient accepts a doctor's advice, it does not mean a rejection of autonomy. Autonomy is a concept that is properly linked to reflective individual choice but should not be thought to require a rejection of authority, tradition, or social morality.⁹²⁹ The autonomous person thus acts in accordance with a freely self-chosen and informed plan. A person of diminished autonomy, by contrast, is to some extent either controlled by others or incapable of deliberating or acting on the basis of his or her desires or plans.⁹³⁰ Personal autonomy, at the very least, allows self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice.⁹³¹

However, being autonomous and choosing autonomously is not the same as being respected as an autonomous agent. To respect an autonomous agent means recognising that person's capabilities and perspective, including his or her right to hold views, to make choices, and to take actions based on personal values and beliefs. Furthermore, it involves treating agents so as to *enable* them to act autonomously. That is, true respect includes acting to respect, not the mere adoption of a certain attitude. Kant has argued that respect for autonomy flows from the recognition that all persons have unconditional worth, each having the capacity to determine his or her own destiny.⁹³² To violate a person's autonomy is to treat that person merely as a means, to treat that person in accordance with one's own goals and without regard to that person's goals. To reject that person's goals and considered judgements or to restrict his or her freedom to act on those goals and judgements is to fail to respect their autonomy.⁹³³

The principle can be stated in its negative form as follows: autonomous actions are not to be subjected to controlling constraints by others. This principle provides the justification for the right to make autonomous decisions, which in turn takes the form of specific autonomy-related rights, such as liberty and privacy. However, the principle should only be treated as a broad abstract principle because like all moral principles, it has only *prima facie* standing and can sometimes be overridden by competing moral considerations.

If our choices endanger the public health, potentially harm others, or require a scarce resource for which no funds are available, others can justifiably restrict our exercises of autonomy.⁹³⁴

928 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:60.

929 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:60-1.

930 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:58.

931 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: oxford University Press, 2001:58

932 Kant I. Groundwork of the Metaphysics of Morals. Trans Paton HJ. New York: Harper and Row, 1964.

933 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:64.

934 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:65.

If restriction is justified, the justification must rest on some competing moral principle such as beneficence or justice. The principle of respect for autonomy, however, has clear positive implications when applied to certain relationships. For example, in medicine, either in research, innovative therapy or routine health care, it engenders a positive or affirmative obligation of respectful treatment in disclosing information and fostering autonomous decision making.⁹³⁵

Paternalism, on the other hand, is interference with a person's liberty of action or freedom of information, where the alleged justification for that interference is that it is good for the person whose liberty has been restricted.⁹³⁶ This justification is based on the principles of beneficence and non-maleficence. However, autonomy deserves protection even if a person's choice would not maximise individual or social welfare.⁹³⁷ A criticism of evidence based medicine was that it robbed patients of their personal choices in reaching a decision about their care.^{938 939} Evidence does not make decisions, people do.⁹⁴⁰ Patients are entitled to make irrational choices. Indeed, doctors should not assume that decisions are made on a rational basis.⁹⁴¹ Patients may behave in ways that are at odds with prevailing medical opinion, an increasingly recognised consequence of patient centred care.⁹⁴²

The elements of consent:

From the patient's perspective, for consent to be a valid authorisation for the professional to proceed, it must be based on understanding and must be voluntary. Informed consent thus can be further defined by specifying the elements that make up the concept, in particular the elements of the information component and the consent component.

Because of the unequal distribution of knowledge between professionals on the one hand and patients or subjects on the other, the principle of respect for autonomy entails that professionals have a prima facie obligation to disclose information, to ensure understanding and voluntariness, and to foster adequate decision making. Thus, the information component can be said to consist of adequate disclosure of information followed by the understanding and comprehension of what is disclosed. The consent component, in turn, refers to a voluntary decision making process which is followed by authorisation.

935 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:64.

936 Buchanan A. Medical Paternalism. *Philosophy and Public Affairs* 1978;7(4): 370-390 at 371-2.

937 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:57-112.

938 DaCruz D. You have a choice, dear patient. *BMJ* 2002;324:674.

939 Kerridge I, Lowe M, Henry D. Ethics and evidence based medicine. *BMJ* 1998;316:1151-3.

940 Haynes RB, Devereaux PJ. Physicians' and patients' choices in evidence based practice. *BMJ* 2002;324:1350.

941 Dowding K, Hindmoor A. The usual suspects: rational choice, socialism and political theory. *New Political Economy* 1997;2:451-63.

942 Smith R. The discomfort of patient power. *BMJ* 2002;324:497-8.

In other words, the function of the whole process is to facilitate decision making, offering plausible options to allow a choice to be made. This is conceptually different from consent *per se*.

In a previous edition, Beauchamp and Childress analysed informed consent in terms of the following elements⁹⁴³:

- 1: Threshold Element
 - a: Competence
- 2: Information Elements
 - b: Disclosure of Information
 - c: Understanding of Information
- 3: Consent Elements
 - d: Voluntariness
 - e: Authorisation

This five element definition is vastly superior to the one element definition in terms of disclosure that medical convention and malpractice law have proposed.⁹⁴⁴ A more recent edition of their textbook has added a further two elements to the above five,⁹⁴⁵ firstly that of recommendation (of the planned action) by the doctor and secondly, the decision in favour of, or refusal of, the recommended plan.

If a recommendation [to enter a research project] is made, it may be quite different from recommendations in clinical medicine.⁹⁴⁶

However, in essence, neither of these two elements makes a substantial difference to the following discussion and will therefore be ignored.

Competence:

Competence is a precondition of being able to authorise autonomously. It is closely tied to autonomy. A person is generally competent to authorise or refuse to authorise an intervention if that person is autonomous.⁹⁴⁷ Whereas in a normal discussion of consent it is of primary importance, from the point of view of this thesis it will be assumed that competence has been established when discussing the regulation of innovation.

Disclosure:

The requirement to inform the patient regarding the material risks of a procedure or other intervention and of obtaining consent from that patient derive from the principle of autonomy.⁹⁴⁸ Information disclosure is the only

943 Beauchamp TL, Childress JF. Principles of biomedical ethics. 4th ed. Oxford: Oxford University Press, 1994:78-9.

944 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:79.

945 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:80.

946 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:80.

947 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:70-77.

948 Cotler M, Katz R. Consent. In Ethical Issues in Anaesthesia, ed Scott WE, Vickers MD, Draper H. Butterworth-Heinemann, Oxford, 1994, p34

mechanism available to redress the imbalance of power between the patient and the doctor.⁹⁴⁹ The patient is not confined to accept or refuse treatment that is offered; he or she should be allowed to choose the type and scope of treatment and to base this choice on adequate information as to success rates, risks, and the like.⁹⁵⁰ Patients cannot express informed preferences unless they are given sufficient and appropriate information. Unfortunately, many patients report considerable difficulties in obtaining relevant information.⁹⁵¹

There are many reasons for these problems, including health professionals underestimating the patients' desire and ability to cope with information, limited consultation times and lack of information regarding treatment options and their effects by the health professionals themselves.⁹⁵² Mishler has argued that doctors and patients talk to each other with different voices.⁹⁵³

It is increasingly recognised that decisions may vary from circumstance to circumstance, and from patient to patient in the same circumstances.⁹⁵⁴ Studies have shown that doctors often fail to understand patients' preferences⁹⁵⁵ but improving the quality of this communication is related to positive health outcomes.⁹⁵⁶ Being well informed about treatment options, especially regarding potential benefits and risks, leads to patients being more likely to adhere to treatment and result in a better outcome.⁹⁵⁷ They are also less likely to accept risky procedures.⁹⁵⁸ A recent editorial on laparoscopic cholecystectomy ended by stating:

Surgeons are responsible for informing their patients as completely as possible about the risks and benefits of a procedure, and that must include the new scientific data now available. The patient may then make the choice between a larger scar or a slightly increased risk of bile duct surgery.⁹⁵⁹

949 McLean SAM. A patient's right to know. Dartmouth: Medico-Legal Series, 1989.

950 Mason JK. Consent to Treatment and Research in the ICU. in Ethics and the Law in intensive care. Pace N, McLean SAM (eds). Oxford: Oxford University Press, 1996, 29-46 at p38.

951 Audit Commission. What seems to be the matter: communication between hospitals and patients. London:HMSO, 1993.

952 Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? BMJ 1999;318:318-22.

953 Mishler EG. The discourse of medicine, dialects of medical interviews. Norwood, New Jersey: Ablex Publishing Corporation, 1984.

954 Haynes RB, Devereaux PJ. Physicians' and patients' choices in evidence based practice. BMJ 2002;324:1350.

955 Cocburn J, Pit S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations. BMJ 1997;315:520-3.

956 Di Blasi Z, Harkness E, Ernst E, Georgiou A, Kleijnen J. Influence of context effects on health outcomes: a systematic review. Lancet 2001;357:757-62.

957 Mullen PD. Compliance becomes concordance. BMJ 1997;314:691.

958 Volk RJ, Cass AR, Spann SJ. A randomized controlled trial of shared decision making for prostate cancer screening. Arch Fam Med 1999;8:333-40.

959 Terpstra OT. Laparoscopic cholecystectomy: the other side of the coin. Br Med J 1996;312:1375-6 at 1376.

It is necessary to examine further what type of information is needed in order to obtain valid consent. It is clearly impossible for a health professional to convey to the patient a summary of all available information. It is not the doctor's role just to provide a list of alternatives from which patients select options, according to their need and desires. In general, patients look for the doctor's advice about which procedure is likely to be the most effective or appropriate for them from a clinical perspective. Failing to give this advice can be as unhelpful as failing to offer any information about possible alternatives to the proposed treatment.⁹⁶⁰ It is therefore important that the doctor attempts to recognise what the patient wants.

In such a case, the doctor should inform the patient about any risks inherent in the treatment, which might be particularly important to that patient, as well as explaining the risks and benefits of alternatives and of non-treatment.⁹⁶¹ Without an adequate transfer of information from doctor to patient there will be insufficient information for decision making. Frequently, the professional's own perspective, opinions, and recommendations may be more important than disclosure of information and may be essential for the patient's or subject's deliberation.⁹⁶²

However, if this leads to the doctor making calculations about the materiality of risk, it is unsatisfactory for the vindication of patient autonomy.⁹⁶³

...the doctor may decide that his or her knowledge of the patient is sufficient for a decision to be made that only certain risks matter. This is open to objection on the very obvious ground that the doctor can never know the full facts of the patient's life, nor what values the patient places on certain aspects of that life. This kind of assessment, therefore, amounts to little more than guesswork, and is unacceptable to those who have knowledgeable decision making as a goal.⁹⁶⁴

Evidence suggests that in medical practice a risk of death of one per million is neglected by doctors and the public. Risks of the order of 10 per million, however, whether of death or of severe non-fatal consequences, are not in general ignored by non-medical people, although they may be neglected by doctors. It appears that the borderline of negligibility for doctors probably lies at about 50 per million, although larger risks are effectively ignored when the patient's condition already puts him at high risk of death.⁹⁶⁵ Although there are objective measures for risk, subjective perception is also important. Individuals evaluate risk not merely on statistical numbers but also on subjective qualitative aspects. Furthermore, psychologists have found that, in general, people are more afraid of risks of very low probability and great

960 British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMJ Publishing Group. 2004, 77.

961 British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMJ Publishing Group. 2004, 77-8.

962 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:79-80.

963 McLean SAM. *A patient's right to know*. Dartmouth: Medico-Legal Series, 1989.

964 McLean SAM. *A patient's right to know*. Dartmouth: Medico-Legal Series, 1989 at 10.

965 Nicholson RH. *Medical research with Children: Ethics, Law, and Practice*. Oxford University Press, 1986, p89.

severity than they are of risks that are more likely but less severe.⁹⁶⁶ There is also a natural tendency to overestimate rare risks and underestimate common ones.⁹⁶⁷ However, the most important aspect of risk assessment, which is *essential* in the health care setting, is that *it is performed by the person exposed to it*.⁹⁶⁸

Because of the problems inherent in risk assessment, it is difficult to exclude value judgements entirely. Although it is the perception of risk by the patient that is of overriding importance, these perceptions will, in practice, depend on the information given by the doctor. There is therefore a considerable onus on the doctor to be able to distinguish what is known objectively about a risk from his own perception of it.

Risk communication is thus an open two-way exchange of information and opinion about risk, leading to better understanding and better decisions about clinical management.⁹⁶⁹ Partnership models should replace models of traditional soft paternalism with strong autonomy models of informed request and contract and participatory forms of risk and benefit sharing.⁹⁷⁰

The more actively patients are involved in risk recognition and allowed and encouraged to establish their own risk-reward balances, the better. It is thus not acceptable for information, including risk, merely to be passed from doctor to patient and in return the patient signals his or her acceptance of that risk. There must be a two way exchange of information and opinion which is important if decisions about treatment are to reflect the attitudes to risk of the people who will live with the outcomes.⁹⁷¹

If information disclosure is undertaken to protect patient autonomy, then all relevant information needs to be disclosed.⁹⁷² Thus, risks that may be relevant, but rarely if ever discussed, are those inherent to the doctor. Dollery believes that concerns such as unwise enthusiasts, poorly trained staff and inadequate facilities may also need to be considered⁹⁷³ and although he listed these when discussing the risks involved in research, they also are relevant to treatment and the undertaking of innovative procedures. To these must be added the problem of learning curves. Thus, from the patient's perspective, there is not only a requirement to have risks disclosed that are relevant to

966 Broadbent DE. Psychology of risk. In: Cooper MG ed. Risk. Man-made Hazards to Man. Oxford: Clarendon Press, 1985.

967 Lichtenstein S, Slovic P, Fischhoff B, Layman M, Combs B. Judged frequency of lethal events. J Exp Psychol 1978;4:551-78.

968 Council for Science and Society. The acceptability of risks. Barry Rose, London, 1978

969 Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. BMJ 2002;324:827-30.

970 Sass HM. Moral Aspects of Risk and Innovation. Artif Organs 1997; 21(11): 1217-1221.

971 Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. BMJ 2002;324:827-30.

972 McLean SAM. A patient's right to know. Dartmouth: Medico-Legal Series, 1989.

973 Dollery CT. Clinical pharmacology. In Ethical committees for clinical research: report of a symposium.. Medico-pharmaceutical forum, London. 1982, p127.

themselves but also to be told of risks and other information that are particular to the doctor. This point will be returned to later.

Understanding:

Physicians rarely assess the patient's understanding of the information disclosed.⁹⁷⁴ Increasingly, however, the ethical focus has changed from the physician's or researcher's obligation to disclose information to the quality of a patient's or subject's understanding and consent.⁹⁷⁵

It has become progressively clear that the focus of statutory law, case law and regulatory guidelines has been on disclosure and that this focus is misguided. Problems about the quality and adequacy of consent probably cannot be resolved unless conventional disclosure requirements are abandoned and a shift occurs towards quality of understanding in the subject, patient and representative.⁹⁷⁶

Finding a way to evaluate and ensure patient understanding is difficult, although the duty to disclose, based on the patient's right to be informed, can be analysed independently of patient understanding.⁹⁷⁷ The doctor fulfils his or her obligation by making the disclosure in a reasonable way that will allow the average person to understand what is being discussed. Furthermore, what needs to be understood are human rather than technical matters. Ordinarily, the doctor has only limited insight into the distinct values, fears, hopes, and informational needs of the patient. Asking questions, eliciting the concerns and interests of the patient, and establishing a climate that encourages the patient to ask questions is thus more important to the person's understanding than a vast amount of disclosed information. The key to effective communication, understanding and decision making is therefore participation by patients or subjects in an exchange of information.

However, it is not essential that patients have a precise understanding of prognosis or what a particular choice will entail. In cancer care it is quite possible both to maintain patient hope and to provide sufficient prognostic information so that patients would be able to make treatment decisions consistent with their underlying values.⁹⁷⁸ It is possible that the same personality traits or coping strategies that lead certain individuals to cling to overly optimistic views of their prognoses may also lead those patients to opt for life-extending therapies⁹⁷⁹ against the recommendations of their doctors. The most important aspect of this is that it is the patient's choice.

974 Braddock CH, Finn SD, Levenson W, Jonsen AR, Pearlman RA. How doctors and patients discuss routine clinical decisions: informed decision-making in the outpatient setting. *J Gen Intern Med* 1997;12:339-45.

975 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:77.

976 Beauchamp T. Informed Consent. In R Veatch (ed), *Medical Ethics*, Jones and Bartlett, Boston, 1989, 175 at 176.

977 McLean SAM. *A Patient's Right to Know*. Dartmouth: Aldershot. 1989, at 74.

978 Miyaji NT. Informed consent, cancer and truth in prognosis. *N Engl J Med* 1994;331:810.

979 Weeks JC, Cook EF, O'Day SJ, et al. Relationship between cancer patients' predictions of prognosis and their treatment preferences. *JAMA* 1998;279:1709-14.

The importance of patient choice is illustrated by two recent developments. Firstly, a large multicentre trial in hormone replacement therapy in postmenopausal women was stopped early because women taking continuous combined oestrogen-progestogen had an increased risk of developing breast cancer.⁹⁸⁰ The results projected that for every 10000 women taking the treatment there will be in each year (compared with women on no treatment) eight extra cases of invasive breast cancer, seven heart attacks, eight strokes and eight pulmonary embolisms. There will also be six fewer bowel cancers and five fewer hip fractures. Overall mortality is not affected. An editorial on the problem stated:

Researchers can try to unravel the consequences of different treatment regimens. Doctors can offer advice. But ultimately only the woman herself can decide.⁹⁸¹

On a similar note the Food and Drug Administration (FDA) in the United States has recently decided to reinstate the drug alosetron, used for irritable bowel syndrome, onto the market after it was voluntarily withdrawn by its sponsor, GlaxoSmithKline.⁹⁸² The reasons given included lobbying from both patient action groups and the pharmaceutical company itself. However,

a third reason may be a shift in the FDA - from being traditional and paternalistic to holding a more republican view of health. The agency would now rather provide the best information for patients and doctors to make their own decisions than to make the decisions in their name.⁹⁸³

Despite significant risks associated with the drug, patients testified to an FDA advisory committee that they were prepared to take those risks.⁹⁸⁴ However, if a misconception occurs regarding a particular risk, which is material to decision making, it implies that adequate understanding was not achieved and thus an autonomous authorisation was not given. There are similar problems with the amount of information that can meaningfully be processed. Information overload may be as likely to lead to uninformed decisions as failure to disclose. For such reasons, in the research setting, research ethics committees request research information sheets to be as short as possible and written in layman's terms.

The difficulty is that the standard of full disclosure and full understanding cannot possibly be attained. Furthermore the doctor does not and cannot have a duty to make sure that those to whom he conveys it understand all the information disclosed. His duty is to make a reasonable effort to be

980 Writing group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. JAMA 2002;288:321-33.

981 Anon. Big trials and human stories. BMJ 2002;325:111.

982 Moynihan R. FDA advisers warn of more deaths if drug is relaunched. BMJ 2002;325:561.

983 Lievre M. Alosetron for irritable bowel syndrome. BMJ 2002;325:555-6 at 556.

984 Moynihan R. Alosetron: a case study in regulatory capture, or a victory for patients' rights? BMJ 2002;325:592-5.

understood.⁹⁸⁵ As previously discussed, just because actions are never fully informed, voluntary or autonomous, it does not follow that these actions are never adequately informed, free, or autonomous.⁹⁸⁶ It is clear that understanding does not need to be full or complete, because a substantial grasp of central facts and other descriptions will often be sufficient.⁹⁸⁷

Voluntariness:

Voluntary decision making means that the patient is independent of manipulative and coercive influences exerted by others in order to control that person. However, there are degrees of influence and three primary categories have been described: coercion, manipulation, and persuasion.⁹⁸⁸

Coercion occurs when one person intentionally uses a credible and severe threat of harm or force to control another. This entirely compromises autonomy. At the other end of the spectrum lie weak forms of influence such as rational persuasion. Here a person is convinced to agree to something by the merit of reasons advanced by another person. Such situations probably arise frequently in the doctor-patient relationship. Manipulation, in turn, means getting people to do what the manipulator wants by means other than coercion or persuasion. For the purposes of decision-making in health care, the most important form of manipulation is informational manipulation. This is the deliberate act of managing information to successfully influence a person, thus altering the person's understanding of a situation and thereby motivating the person to do what the agent of influence intends. Some forms of informational manipulation are incompatible with informed consent. For example, deception that involves lying, withholding information, true assertions that omit a vital qualification, and misleading exaggerations in order to lead patients to believe what is false, are all inconsistent with autonomous choice.⁹⁸⁹ There is also a possibility that clinicians will utilise the therapeutic privilege to withhold information, not because of the principle of non-maleficence, but to manipulate patients into agreeing to their recommendations.

It is, however, easy to inflate the threat of control by influence beyond its proper significance. Virtually all decisions in life are made in the context of competing influences, such as wants, needs, familial interests, legal obligations and persuasive arguments. Patients may be influenced by their family and friends, memories, the media, and hospital staff, who all make up a complex jigsaw of knowledge.⁹⁹⁰ Although significant, these influences may not be controlling to any substantial degree.

985 Buchanan A. Medical Paternalism. *Philosophy and Public Affairs* 1978;7(4): 370-390.

986 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:89.

987 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:88.

988 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:94-5.

989 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:95.

990 Alderson P, Goodey C. Theories of consent. *BMJ* 1998;317:1313-5.

From the perspective of decision-making by patients and subjects, we need only establish general criteria for the point at which autonomous choice is imperilled, while recognizing that in many cases no sharp boundary separates controlling and noncontrolling influences.⁹⁹¹

Beauchamp and Childress, however, believe that, from a clinician's point of view, while it may be claimed that there is an obligation to abstain from controlling influences, there can be occasions when doctors will be blameworthy if they don't attempt to persuade resistant patients to pursue treatments that are medically essential. Thus, reasoned argument may be vital to ensuring understanding and should never be considered an unjustified form of influence.⁹⁹²

In summary, respect for patient autonomy is generally regarded as one of the central ethical principles in medical practice.⁹⁹³ Many would claim a moral imperative of respecting human autonomy in almost all circumstances and to fail to respect the autonomy of competent people is to inflict harm on them that is just as morally unacceptable as direct physical or mental harm.⁹⁹⁴ Doctors who fail to provide full and balanced information about risks and the uncertainties of treatment can create unrealistic expectations.⁹⁹⁵ Patients are often given a biased and highly optimistic picture of the benefits of medical care.⁹⁹⁶ This 'misplaced paternalism', trying to protect patients from bad news, merely fuels false hope.⁹⁹⁷

On the contrary, patient autonomy is only protected when there is a possibility of meaningful choice being made by the patient.⁹⁹⁸ This choice is made on the basis of adequate information regarding risks and benefits, including the operator specific risks, and alternatives of treatment. Such disclosure protects not only the patient but the doctor as well. It is clear that patients undergoing the first heart transplants or who were operated on in Bristol would have been better protected if doctors had followed the ethical principles described here. Whether the law follows such ethical principles, however, needs to be discussed.

THE LAW:

The previous chapter discussed how an act of medical malpractice may give rise to two common law actions in court; those of trespass to the person (assault) and of negligence. Malpractice litigation also applies when dealing

991 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:95.

992 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:95.

993 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: oxford University Press, 2001:57-112.

994 Len Doyal. Informed consent- a response to recent correspondence. BMJ 1998;316:1000-1.

995 Coulter A. After Bristol: putting patients at the centre. BMJ 2002;324:648-51.

996 Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? BMJ 1999;318:318-22.

997 Coulter A. After Bristol: putting patients at the centre. BMJ 2002;324:648-51 at 649.

998 McLean SAM. A patient's right to know. Dartmouth: Medico-Legal Series, 1989.

with issues of consent. It is the consent of the patient that legalises the whole of medical examination and treatment and that is why it is such an important issue.⁹⁹⁹ Significant case law has arisen due to doctors failing to communicate adequately with their patients, either because there had been no proper consultation prior to treatment or because the medical practitioner failed to disclose the risks inherent in the proposed treatment.

The patient-physician relationship is founded on trust and confidence and the physician is necessarily a trustee for the patient's medical welfare.¹⁰⁰⁰ Any professional person such as a physician, lawyer, priest or other who enters into a relationship of trust and confidence with another has a positive obligation to disclose all relevant facts. Since the essence of a professional relationship is that the professional knows more about his subject than the person who seeks his help there is an affirmative duty of disclosure.¹⁰⁰¹

As argued earlier in this chapter, patients thus need to be given a clear explanation of any treatment proposed, including any risks and alternatives, before they decide whether they will agree to the treatment. Consent, expressed or implied, must be given in most cases before treatment is lawful. Without such consent health professionals would commit the crime of battery (assault in Scotland) and a tort (trespass to the person) when they touch their patient.

Battery:

The tort of battery has already briefly been mentioned in the previous chapter. It is committed where any non-consensual contact takes place.¹⁰⁰² Furthermore, an intention to injure is not essential. It is the act that violates the bodily integrity, i.e. it is the contact that must be intentional.¹⁰⁰³

Respect for bodily integrity and privacy are values that are central to any theory of consent and are central values in the European Convention of Human Rights, now incorporated into UK law by the Human Rights Act 1998.¹⁰⁰⁴

These rights, however, are not new. In the 1914 case of *Schloendorf v. Society of New York Hospital* Cardozo J stated:

Every human being of adult years and sound mind has a right to determine what shall be done with his body.¹⁰⁰⁵

⁹⁹⁹ Mason JK. Consent to treatment and research in the ICU. Pace NA, McLean SAM eds. Ethics and the law in intensive care. Oxford: Oxford University Press, 1996, p30.

¹⁰⁰⁰ Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001, 312.

¹⁰⁰¹ Holder AR. Medical Malpractice Law. New York: John Wiley, 1975, p225

¹⁰⁰² Brazier M. Medicine, Patients and the Law. 3rd ed. London: Penguin, 2003, 91.

¹⁰⁰³ Lewis CJ. Medical Negligence: a Practical Guide. 4th ed. London: Butterworths, 1998, 282.

¹⁰⁰⁴ Human Rights Act 1998. London: Stationery Office, 1998.

¹⁰⁰⁵ *Schloendorf v. Society of New York Hospital* [1914] 211 NY 125, 126

The common law has thus long recognised the principle that every person has the right to have his bodily integrity protected against invasion by others. The seriousness with which the law views any invasion of physical integrity is based on the strong moral conviction that everyone has the right to self-determination with regard to his body.¹⁰⁰⁶

The existence of the patient's right to make his own decisions.... may be seen as a basic human right protected by the common law.¹⁰⁰⁷

Indeed, the rules regarding consent are designed to perform this function; that is, to permit the patient the continued exercise of self-determination.¹⁰⁰⁸

Furthermore,

There is nothing especially 'medical' about the requirement that a doctor must obtain a patient's consent ... These requirements are imposed not in the interests of the patient's health, but in the interests of individual liberty.¹⁰⁰⁹

The question of what constitutes consent has thus been inextricably connected with the tort of battery. Lawyers acting on behalf of patients have previously argued that, if the patient's consent for an operation or a mode of treatment was given on the basis of inadequate information, either of the risks of the treatment or of the extent of the treatment, then the case should be heard in battery and the patient should have a right to compensation under the laws of battery.

However, it should be pointed out that there is no actual law of consent *per se*. Consent is merely a defence to the tort of battery.¹⁰¹⁰ The principle importance of battery lies in its role in emphasising that patients are entitled to veto the care provided by health professionals: in other words, a right to refuse treatment.

Thus recently in England it was stated that:

it is in general terms a criminal and tortious assault to perform physical invasive treatment without a patient's consent.¹⁰¹¹

Similarly, in the case of an adult who was 34 weeks pregnant:

1006 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. 6th ed. London:Butterworths, 2002, at 10.4.

1007 Sidaway v Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital and others. [1985] 1 BMLR 132 per Lord Scarman, p140.

1008 McLean SAM. A Patient's Right to Know. Dartmouth: Aldershot, 1989, at 80.

1009 Skegg PDG. Law, Ethics and Medicine. Oxford: Clarendon Press, 1984, at 85.

1010 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134.

1011 Re JT (Adult: Refusal of Medical Treatment) [1998] 1 FLR 48, 51

An adult patient ... has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered.¹⁰¹²

This absolute right applies even if the patient were to die if the proposed treatment was refused. In the above case, in the Appeal Court, Lord Donaldson MR stated:

The patient's interest consists of his right to self-determination – his right to live his own life how he wishes ... society's interest is in upholding the concept that all human life is sacred and that it should be preserved if at all possible. It is well established that in the ultimate the right of the individual is paramount.¹⁰¹³

Thus, failure to obtain *any* consent could lead to a doctor being charged with battery, as in the previously mentioned case of *Devi v West Midlands RHA*.¹⁰¹⁴ Recently a gynaecologist who sterilised patients against their wishes was struck off the medical register by the General Medical Council.¹⁰¹⁵ There are, however, relatively few cases in English law where the patient has successfully sued his or her doctor for battery on the ground that *no* consent was given. This does not mean that the tort of battery is unimportant. Its significance lies in the fact that it represents a statement by the law that a patient is entitled to decide what is to be done to his or her own body.

As previously discussed, the distinction between an action based on battery and one based on negligence is important for a number of reasons. Battery, which is a non-consensual touching, is itself a legal wrong, whether or not any specific damage can be shown to result. Thus a patient may bring a successful action for battery even when the procedure carried out without consent was clearly for his or her benefit. In negligence, however, in addition to showing that the professional fell below the required standard, the patient must prove that some damage resulted. This means that a patient will lose their case where the procedure benefited them or where the carelessness or negligence of the professional did not cause the damage. The most common example of the latter situation in the consent context would be where, even if the patient had been told of the risks which were not mentioned, she or he would have been prepared to take them. The professional may have withheld information that should have been disclosed but it would have made no difference had he or she acted properly.¹⁰¹⁶

It has however been argued in cases such as *Chatterton v Gerson*¹⁰¹⁷ that if a patient gave consent but did not know all the facts necessary to take an autonomous decision, then, by implication, that consent was invalid. Thus, the

1012 Re T (Adult: Refusal of Medical Treatment) [1992] 4 All ER 649,652-3.

1013 Re T (Adult: Refusal of Medical Treatment) [1992] 4 All ER 649,661.

1014 *Devi v West Midlands RHA* [1981] (CA Transcript 491)

1015 Dyer O. Gynaecologist is struck off for sterilising women without their consent. *BMJ* 2002;325:1260.

1016 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p228

1017 *Chatterton v Gerson* [1981] QB 432, [1981] 1 All ER 257 (QBD)

failure of a doctor to disclose either risks inherent in a procedure or other alternatives available (which the patient might have preferred) can invalidate the consent given and could lead to a charge of battery being brought against the doctor. In this case the patient had been treated by a pain specialist for chronic pain around a hernia scar. Unfortunately the treatment rendered her right leg completely numb and hence impaired her mobility. The plaintiff alleged that her consent was vitiated because she had not been informed of the risk of numbness and thus the defendant was liable in battery. The trial judge dismissed the claim.

I think justice requires that in order to vitiate the reality of consent there must be a greater failure of communication between doctor and patient than that involved in a breach of duty if the claim is based on negligence. ... In my judgement once a patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of action on which to base a claim for failure to go into risks and implications is negligence, not trespass. Of course, if information is withheld in bad faith, the consent will be vitiated by fraud. ... in my judgement it would be very much against the interests of justice if actions which are really based on a failure by the doctor to perform his duty adequately to inform were pleaded in trespass.¹⁰¹⁸

This state of affairs was reiterated when the case of *Sidaway v. Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital and others* reached the Court of Appeal. Sir John Donaldson stated that it was only if the consent was obtained by fraud or misrepresentation of the nature of what was to be done that it could be said the apparent consent was not a true consent. Dunn LJ agreed.

The ... argument was that unless the patient's consent to the operation was a fully informed consent the performance of the operation would constitute a battery on the patient by the surgeon. This is not the law of England. If there is consent to the nature of the act, then there is no trespass to the person.¹⁰¹⁹

In the same case heard later in the House of Lords, Lord Scarman held that 'it would be deplorable to base the law in medical cases of this kind on the torts of assault and battery.'¹⁰²⁰

Similarly in *Freeman v Home Office* it was held that:

if there was real consent to the treatment, it mattered not whether the doctor was in breach of his duty to give the patient the appropriate information before that consent was given. Real consent provides a complete defence to a claim based on the tort of trespass to the

¹⁰¹⁸ Chatterton v Gerson [1981] QB 432, at 443

¹⁰¹⁹ Sidaway v. Bethlem Royal Hospital Governors [1984] QB 493 at 513, [1984] 1 All ER 1018, CA

¹⁰²⁰ Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643, at 650

person. Consent would not be real if procured by fraud or misrepresentation but, subject to this and subject to the patient having been informed in broad terms of the nature of the treatment, consent in fact amounts to consent in law.¹⁰²¹

Thus the argument that battery may also lie where consent is given in ignorance of relevant material facts seems to have no place in English law.¹⁰²² The law considers what the duty of the doctor to his patient is, rather than the validity of consent. However, the notion that it would be wrong to find a doctor liable in battery because of the implication that he intended to harm his patient is misplaced.¹⁰²³ Motive is not a defence and furthermore, as previously mentioned, although battery is an intentional tort, the intention relates to the act and not to the harm suffered. An intention to cause harm is therefore not necessary.¹⁰²⁴

There may also be other valid arguments why the proper course of action should lie in battery. One issue in a battery case is whether the patient understood the nature and purpose of the procedure. Furthermore, the courts can manipulate the content of this 'nature and purpose' test in order to expand or contract the scope of battery.¹⁰²⁵ For example, the Bristol Inquiry recommended that patients are *always* entitled to be know the extent to which a procedure which they are about to undergo is innovative or experimental. Recommendation 102 also stated that they are entitled to be informed about the experience of the clinician who is to carry out the procedure.¹⁰²⁶

Thus if a patient is not told that the procedure they are about to undergo is innovative, especially if it concerns a case similar to those of implanting artificial hearts described in previous chapters, it is not unreasonable for them to claim that the consent they gave was obtained by deception, as per the Master of the Rolls in *Sidaway*.

... if the consent is obtained by a fraud or by a misrepresentation of the nature of what is to be done ... it can be said that an apparent consent is not a true consent.¹⁰²⁷

This was confirmed in the case of *Appleton v. Garrett*.¹⁰²⁸ In this case a dentist deceived patients as to their need for treatment over a number of years. The consent given was vitiated by the fraudulent misrepresentation of

1021 *Freeman v Home Office* (no 2) [1984] 1 All ER 1036

1022 Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p652

1023 Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134 at 106.

1024 *Wilson v. Pringle* [1986] 2 All ER 440, 445.

1025 Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p672

1026 Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001

1027 *Sidaway v Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital and others*. [1984] 2 WLR at 790a/b

1028 *Appleton v. Garrett* [1996] PIQR P1

the dentist. The defendant had acted in bad faith throughout and this made an action in battery appropriate.

Similarly, it is proposed that fraudulent representation were made in respect of certain innovative treatments. The purpose of such treatments, as in *Karp v Cooley*¹⁰²⁹ or the pending US case of a patient who received an artificial heart in November 2001¹⁰³⁰, was not to make the first recipients well from a health perspective but rather to test a new technology for future patients. These procedures were non-therapeutic and of no benefit to the patient and thus only for the benefit of society.¹⁰³¹ The consent the patients gave therefore appears not to be valid. It has also been claimed that some risks are so significant that they may well change the nature of the proposed procedure if they are not disclosed, thereby vitiating consent and leading to a claim and liability in battery.¹⁰³²

The UK courts, however, have been intolerant of any attempt to have these cases heard under the laws of battery. Any such attempt has been seen as a device to side step difficulties in sustaining an action for negligence based on failures to communicate proper information,¹⁰³³ and the courts have been consistent in holding that actions for battery should play a very limited role in health care law.

As mentioned, in *Chatterton v. Gerson* consent was judged to be real so long as the patient was informed 'in broad terms' of the nature of the intended procedure and no action for trespass to the person would lie.¹⁰³⁴ Similarly in *Hills v. Potter*¹⁰³⁵ the plaintiff sued in negligence and in battery following the failure of an operation to relieve symptoms caused by a deformity of her neck known as spasmodic torticollis. The operation, although performed with skill and competence, resulted in a severe deterioration so that the plaintiff became paralysed from the neck downwards. The plaintiff alleged that she had not been properly informed about the risks inherent in the surgery and that her consent was therefore vitiated by the lack of information that paralysis could result. Hirst J found in relation to the action in battery:

As to the claim for assault and battery the plaintiff's undoubted consent to the operation which was in fact performed negatives any possibility of liability under this head, see *Chatterton v. Gerson*. I should add that I respectfully agree with Bristow J in deploring reliance on these torts in medical cases of this kind; the proper course of action, if any, is negligence.¹⁰³⁶

¹⁰²⁹ *Karp v. Cooley* 493 F 2d 408 (1974) (United States Court of Appeals, Fifth Circuit)

¹⁰³⁰ Anon. Widow sues artificial heart-maker. *Bull Med Eth* 2002;181:24.

¹⁰³¹ Annas G. Death and the Magic Machine. *Western New England Law Review* 1987;9:89 at 98.

¹⁰³² Tan Keng Feng. 'Failure of Medical Advice: Trespass or Negligence?' (1987) 7 LS 149-68

¹⁰³³ Nelson-Jones R, Burton F. *Medical Negligence Case Law*. Fourmat Publishing, London, 1990, p3-4

¹⁰³⁴ *Chatterton v. Gerson* [1980] 3WLR 1003.

¹⁰³⁵ *Hills v. Potter* [1983] 3 All ER 716, [1984] 1 WLR 641

¹⁰³⁶ *Hills v. Potter* [1983] 3 All ER 716, [1984] 1 WLR 641 at 653 d/e

The Master of the Rolls in *Sidaway v. Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital and others* adopted a similar position when he expressed the view:

I am wholly satisfied that as a matter of English law a consent is not vitiated by a failure on the part of a doctor to give a patient sufficient information before the consent is given.¹⁰³⁷

Although this position has been criticised^{1038 1039} it seems highly likely that it will not be altered in the foreseeable future. As a result, battery can normally be successfully alleged only when there was no consent to the procedure actually carried out. This usually occurs when there has been a blatant error by health care staff, such as when the wrong leg is amputated, or when no consent was obtained at all. Liability in such cases is virtually always admitted and usually settled out of court. The crime of battery does not reflect reality in the medical context where in the main there is absence of fraud or malice.

Negligence:

On the other hand, it is clear that if professionals fail to counsel patients in a way recognised by their peers as appropriate they may be negligent. Thus patients who allege that they have been given insufficient information must argue that the professionals have been negligent in carrying out their duty to advise them about the decision. Much of the debate regarding consent has focussed on the appropriate standard of disclosure.¹⁰⁴⁰ When considering the extent and quality of information that should be provided, this depends on whether the standard is based on what the profession believes should have been disclosed, the professional standard, or on the patient's own expectations, that is a patient-based standard.

The professional standard test:

The professional standard test has already been described in the previous chapter. With respect to consent and information disclosure, the test is based on what the *profession* believes the patient should be told. In keeping with the arguments and cases described in the previous chapter, a doctor would not be guilty of negligence if he acted in accordance with a practice accepted as proper by a responsible body of medical opinion skilled in that particular art.¹⁰⁴¹ Thus, a doctor would not be found guilty of negligence if a responsible body of medical opinion would not have disclosed what the defendant did not disclose. Thus, even a significant minority of doctors in agreement with the defendant may leave the plaintiff in difficulties. In *DeFreitas v. O'Brien and Connolly* the Court of Appeal ruled that a small number of medical practitioners could constitute a 'responsible body of medical opinion against

1037 *Sidaway v. Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital and others*. [1984] 2 WLR at 790a/b

1038 Tan Keng Feng. 'Failure of Medical Advice: Trespass or Negligence?' (1987) 7 LS 149-68

1039 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134

1040 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134 at 104.

1041 *Bolam v Friern HMC* [1957] 2 All ER 118, 121.

which the practices of a doctor could be measured.¹⁰⁴² The standard is therefore professionally based, in that the profession decides what is acceptable. Consent is thus governed by the same rules and principles that apply to ordinary malpractice cases¹⁰⁴³, as described in the previous chapter.

The main problem therefore is that the *Bolam* test has been allowed to encroach into information disclosure. It has been used to abdicate the courts' responsibility for defining and enforcing patients' rights.¹⁰⁴⁴ Most disturbingly, it has been allowed to become the litmus test, not just of clinical practice, but also of medical ethics.¹⁰⁴⁵ As will be seen, however, other more recent cases may appear to have qualified the professional standard test.

The patient centred standard:

The patient centred standard can be subdivided into two, a particular patient standard and a prudent patient standard, corresponding to subjective or objective tests.

The particular patient (subjective) test, in terms of duty of care and breach of that duty, defines what information the actual plaintiff would have wanted disclosed to them. This test suffers from the use of hindsight and since the relevant facts only exist in the mind of the individual an accusation of incomplete disclosure is very hard to refute. It is, however, a desirable standard in so far as it embodies personal factors, including many that are non-medical, which might affect a particular person's decision. It is also the standard that most forcefully establishes the right to self-determination, discussed earlier in this chapter.

The prudent patient test requires the plaintiff to establish what a reasonable person would have wanted to know. This suffers from the impossibility of defining what a reasonable person is, specific to each case. However, some believe it to be fair to both sides in that a reasonable doctor and a reasonable patient are meeting on comparable terms.¹⁰⁴⁶

Causation:

When a claim for non-disclosure is brought in negligence and the claimant has overcome the *Bolam* test with respect to the breach of that duty of disclosure of information, the plaintiff must further prove causation. This means that the breach of duty caused the damage concerned. In the context of consent and information disclosure, the plaintiff must show that, had the appropriate information been disclosed, he or she would not have consented to the relevant treatment and thus the risk which materialised would have been avoided. In other words, if he had been warned about the inherent risk in the procedure he would not have accepted the treatment. In many ways this

1042 DeFreitas v. O'Brien and Connolly [1995] 6 MLR 108, 115, CA.

1043 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p227

1044 Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? Med L Rev 2000;8:85 at 85.

1045 Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? Med L Rev 2000;8:85, 90.

1046 Mason JK. Consent to treatment and research in the ICU. Chapter in: Pace NA, McLean SAM eds. Ethics and the law in intensive care. Oxford University Press, 1996, p38.

makes much of the preceding argument pertaining to the duty to disclose less important because the plaintiff still has to prove that he would have refused treatment if all the facts regarding risks and alternatives had been available to him.

In law, the question is whether the test of causation is objective and based on the 'prudent' or 'reasonable' patient or whether the test is subjective and considers what the 'particular' patient would have wished.

In the English case of *Chatterton v Gerson* a subjective test appears to have been utilised.

When the claim is based on negligence the plaintiff must prove not only the breach of duty to inform but had the duty been broken she would not have chosen to have the operation.¹⁰⁴⁷

The plaintiff lost the case because the judge determined she would still have consented because she was desperate for pain relief.

In *Smith v Barking, Havering and Brentwood HA*,¹⁰⁴⁸ the patient suffered permanent quadriplegia following a second operation due to a brain cyst. It was accepted that the neurosurgeon had not fully disclosed the risks inherent in the operation. Thus the main issue was whether the plaintiff, had she been given proper advice, would have refused the operation. The judge stated that, as a matter of principle, the decision should be subjectively based:

If this plaintiff had been given the advice that she should have been given, would she have decided to undergo the operation or not.¹⁰⁴⁹

However, the judge pointed out the problems with this approach. How could the plaintiff, already knowing what the adverse outcome will be, give reliable answers to what she would have done? One's reaction had to be influenced by what had transpired and in his view an objective assessment also had to be made. But the less confidently the trial judge could ascertain what the reasonable person would have done, the more important subjective elements would become.¹⁰⁵⁰ Thus, there was a blending of the objective and subjective approaches. One consequence of this decision is that, had the operation not been urgent and possibly not needed, then the plaintiff would have been more believable and the subjective approach utilised.¹⁰⁵¹ Therefore, English courts appear to apply a subjective test with an element of objectivity regarding reasonableness.

Similarly in South Africa, the Supreme Court employed the reasonable patient test to set an initial standard which was then modified by a subjective

¹⁰⁴⁷ *Chatterton v Gerson* [1981] QB 432 at REF

¹⁰⁴⁸ *Smith v Barking, Havering and Brentwood HA* [1994] 5 Med LR 285 (QBD)

¹⁰⁴⁹ *Smith v Barking, Havering and Brentwood HA* [1994] 5 Med LR 285 (QBD) at 288.

¹⁰⁵⁰ *Smith v Barking, Havering and Brentwood HA* [1994] 5 Med LR 285 (QBD) at 289.

¹⁰⁵¹ Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p732

standard; that is, what additional informational needs of the patient were or should reasonably have been known by the doctor?¹⁰⁵²

In other jurisdictions such as Canada, however, an objective test is applied.¹⁰⁵³ Here the question is whether a reasonable person, in the claimant's situation and knowing the risks involved, would have declined the proposed treatment. In most cases where an objective test is applied, causation becomes even more burdensome to the claimant and tends to obscure what the real issue is; namely, what would the claimant have done had he possessed all of the relevant information?¹⁰⁵⁴

Indeed one commentator has stated that

This is not, strictly, a test of causation but a filter for excluding plaintiffs who do not conform to the 'norm' in their willingness to accept certain types of risk. Of course, it also functions as a crude catch-all device for denying recovery to plaintiffs who are deemed essentially to be untruthful because they are viewing the situation with hindsight. English law at least permits the plaintiff to attempt to persuade the court that she would have refused treatment if the risks had been disclosed.¹⁰⁵⁵

Furthermore, it has been established that, following *Reibl v Hughes*, a case utilising an objective test, 56% of plaintiffs in Canada failed to meet the test for causation despite having shown a breach of duty of disclosure by the doctor.¹⁰⁵⁶ So, in this respect, and possibly offering some hope for the future with respect to the standard of care to be achieved, the greater utilisation of the subjective test in the English Courts appears to be granting greater respect to personal autonomy and self-determination.

However, although there is a difference between the two tests, in practice the claimant must still convince the court that he would not have had the treatment had the risks been disclosed. The court will therefore examine the claimant's evidence and its credibility by reference to the reasonable man.

An assessment, thus, still needs to be made in terms of reasonableness. In the Canadian case of *Reibl v. Hughes* Laskin CJC stated:

In saying that the test is based on the decision of the reasonable person in the patient's position would have made, I should make it clear that the patient's particular concerns must also be reasonably based otherwise there would be more subjectivity than would be warranted under an objective test ... In short, although account must be taken of a patient's particular position, a position which will vary with

¹⁰⁵² *Castell v De Greef* (1994) (4) SA 408

¹⁰⁵³ *Arndt v Smith* [1997] 2 SCR 539 (Can SC)

¹⁰⁵⁴ Khan M, Robson M, Swift K. *Clinical Negligence*. Cavendish Publishing: London, 2nd ed. 2002, p211

¹⁰⁵⁵ Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134, at 119-120.

¹⁰⁵⁶ Robertson G. Informed Consent 10 Years Later: The Impact of *Reibl v Hughes*. (1991) 70 *Canadian Bar Review* 423 at 428.

the patient, it must be objectively assessed in terms of reasonableness.¹⁰⁵⁷

However, Giesen argues that a standard determined by reference to objective criteria alone will not in all cases suffice to vindicate the patient's right to self determination which should be the starting point and indeed shape the boundaries of the duty of disclosure.¹⁰⁵⁸ Furthermore, he argues that to use an objective test to measure an individual's informational needs is blunt paternalism that is no less excusable when exercised by the courts than by the medical profession.¹⁰⁵⁹ He does concede however that the 'reasonable patient' test is an acceptable starting point to assess the average patient's minimum informational needs.¹⁰⁶⁰

Beyond Bolam:

If the *Bolam* test, illustrating the professional standard test, is assumed for the moment to be representative of the current law, the doctor would have to warn of all risks of which a responsible body of medical opinion considers the patient should be warned, as opposed to every possible risk. The British Medical Association (BMA), in an earlier edition of its book *Medical Ethics Today*, claims that how much or how little information regarding risks is considered to be adequate will vary with each patient.

It must also be a matter of clinical judgement and the standards set by other doctors. From an ethical viewpoint, the criteria should be as much information as the patient needs or desires. It is interesting to note that in the *Bolam* case, the law set the level at the standard adopted by the medical profession and a doctor who gives as much detail as a recognised body of medical opinion considers appropriate would be unlikely to be held liable in law.¹⁰⁶¹

It must be pointed out that the BMA considered it *unlikely* that doctors would be held liable in law if they did what other professionals would have done. The reason for this is that *Bolam* appears to have been softened by various statements made in cases such as *Sidaway v Bethlem Royal Hospital Governors*¹⁰⁶² and more recently *Bolitho v. City and Hackney HA*.¹⁰⁶³ Indeed, in the latest edition of the above book, the *Sidaway* case has been given greater prominence.¹⁰⁶⁴

Sidaway v. Bethlem Royal Hospital Governors:

The attitude of deference to the medical professional's view, via the professional standard test, appears to have been qualified by the case of

¹⁰⁵⁷ Reibl v. Hughes (1980) 114 DLR (3d) 1

¹⁰⁵⁸ Giesen D. International Medical Malpractice Law. J CB Mohr: Tubigen, 1988, at par 576

¹⁰⁵⁹ Giesen D. International Medical Malpractice Law. J CB Mohr: Tubigen, 1988, at par 580

¹⁰⁶⁰ Giesen D. International Medical Malpractice Law. J CB Mohr: Tubigen, 1988, at par 590

¹⁰⁶¹ BMA, Medical ethics today: Its practice and philosophy, p10

¹⁰⁶² Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643.

¹⁰⁶³ Bolitho v. City and Hackney HA [1993] 4 Med LR 381, [1997] 4 All ER 771.

¹⁰⁶⁴ British Medical Association. Medical Ethics Today. 2nd ed. London: BMJ Publishing Group. 2004, 78-9.

Sidaway v. Bethlem Royal Hospital Governors, where the court reserved the right to decide that even standard practice may be negligent.¹⁰⁶⁵ The claimant underwent an operation on her spine to relieve pressure on one of the nerve roots in her neck. Unfortunately during the operation her spinal cord was damaged, leaving her severely disabled. The neurosurgeon had told her about the risk of damage to the nerve root, estimated at 2%, but had not told her about the risk to the spinal cord, a risk of less than 1%. There was no evidence that the operation had been carried out negligently. The claimant, however, argued that the defendant had been negligent in not informing her of the risk to the spinal cord. Other neurosurgeons testified that it was not their practice to inform patients of the risk of damage to the spinal cord. The trial judge therefore dismissed the claim.

The Court of Appeal affirmed the trial judge's view that the law in relation to failures in diagnosis and treatment also applied to failures in the realm of advice. Lord Donaldson, the Master of the Rolls, reviewed the leading transatlantic cases giving rise to the prudent patient test in the doctrine of informed consent, but declined to incorporate those principles:

...what information should be disclosed and how and when it should be disclosed is very much a matter for medical judgement, to be exercised in the context of the doctor's relationship with a particular patient in particular circumstances. It is for this reason that I would reject the American formulation of the duty by reference to a 'prudent patient test'.¹⁰⁶⁶

He also did not view the adoption of the medical standard implicit in *Bolam* as abdicating responsibility to the medical profession. The practice held by the body of responsible practitioners had to be one that was *rightly and properly held*, and the court would not:

stand idly by if the profession by an excess of paternalism denies their patients real choice. In a word, the law will not permit the medical profession to play God. ... I think that, in an appropriate case, a judge would be entitled to reject a unanimous medical view if he were satisfied that it was manifestly wrong and that the doctors must have been misdirecting themselves as to their duty in law.¹⁰⁶⁷

However, Lord Browne-Wilkinson formulated a proposition that a doctor was under a duty to disclose to the patient information relevant to the decision the patient would have to take. This would include the benefits and risks but would be subject to the emotional state of the patient as well as the degree of risk concerned. He further stated:

...I have been very conscious of the need to ensure that the duty of care imposed by the law is not such as to inhibit the proper function of

¹⁰⁶⁵ *Sidaway v Bethlem Royal Hospital Governors* [1984] 1 All ER 1018

¹⁰⁶⁶ *Sidaway v. Bethlem Royal Hospital Governors* [1984] 2 WLR at 790-91

¹⁰⁶⁷ *Sidaway v. Bethlem Royal Hospital Governors* [1984] QB 493 at 513, [1984] 1 All ER 1018 at 1028, CA

the medical profession in caring for the sick in exposing doctors to the threat of legal proceedings in which their actions will be judged by hindsight, not by reference to the standards of those skilled in the art, but by judge and jury. It is for this reason that I am not prepared to adopt the much stricter rules as to disclosure laid down in the transatlantic cases which involve an objective judgement both as to the materiality of the risk and the adequacy of disclosure.¹⁰⁶⁸

The House of Lords affirmed the Court of Appeal's reasoning that the Bolam test was applicable in deciding whether a practitioner was negligent in failing to disclose inherent risks in treatment.¹⁰⁶⁹ However one of the Lords, Lord Scarman, believed this was not acceptable. The standard for the amount of information to be given was not what the medical profession thought appropriate but ideally what the individual patient required, and failing that, what the average "prudent patient" would want to know.

If one considers the scope of the doctor's duty by beginning with the right of the patient to make his own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risk and the doctor's corresponding duty are easy to understand: for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment.

Ideally, the court should ask itself whether in the particular circumstances the risk was such that this particular patient would think it significant if he was told it existed. I would think that, as a matter of ethics, this is the test of the doctor's duty. The law, however, operates not in Utopia but in the world as it is: and as such an inquiry would prove in practice to be frustrated by the subjectivity of its aim and purpose. The law can, however, do the next best thing, and require the court to answer the question, what would a reasonably prudent patient think significant if in the situation of this patient. The "prudent patient" cannot, however, always provide the answer for the obvious reason that he is a norm, not a real person: and certainly not the patient himself.¹⁰⁷⁰

Elsewhere Lord Scarman has stated that, although he would permit medical experts to establish the standard of care in relation to diagnosis and treatment¹⁰⁷¹, he found it unacceptable in relation to informed consent. He has attacked the law's reliance on medical expertise in matters of consent and risk disclosure. It is a totally medical proposition erected into a working rule of law.¹⁰⁷²

¹⁰⁶⁸ Sidaway v. Bethlem Royal Hospital Governors [1984] 2WLR at 801

¹⁰⁶⁹ Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643

¹⁰⁷⁰ Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643, at 654-5.

¹⁰⁷¹ Maynard v. W. Midlands RHA [1985] 1 All ER 643, 649

¹⁰⁷² L. Scarman. Law and Medical Practice. in: P. Byrne (ed.), *Medicine in Contemporary Society*. London: King Edward's Hospital Fund for London, 1987, 131-139 at 134.

His view in *Sidaway*, however, was in the minority and as such if a doctor can show that his advice reached a standard of care which was accepted by a respectable and responsible body of medical opinion as adequate he cannot be liable in damages if anything goes wrong.

Similarly, in the Scottish case of *Moyes v Lothian Health Board*, Lord Caplan stated:

In my view...the appropriate tests to apply in medical negligence cases are to be found in *Hunter v Hanley* and *Bolam*...As I see it, the law in both Scotland and England has come down firmly against the view that the doctor's duty to the patient involves at all costs obtaining the informed consent of the patient to specific medical treatments...I can read nothing in the majority view in *Sidaway* which suggests that the extent and quality of warning to be given by a doctor to his patient should not in the last resort be governed by medical criteria.¹⁰⁷³

It is therefore clear that the courts and medical literature in the United Kingdom allow medical authority and physician responsibility to take precedence over patient autonomy when the patient gives consent. Many believe this is to be an acceptable position.

In other jurisdictions, including Australia, a different and possibly higher standard has been adopted. ... I believe our courts achieve a more balanced approach by leaving it to medical men themselves to set the standards. I regard this as the preferable approach even though it involves transferring to the expert doctors who are called before the courts the task of providing the often hotly disputed evidence of what the profession would or would not accept.¹⁰⁷⁴

Similarly, McCall Smith has argued that:

the medical profession should be left some areas where it can safely rely on its own collective judgment and wisdom.¹⁰⁷⁵

However, comments in *Sidaway* do imply a slight shifting in the deferential attitude of the courts towards medical practitioners. In the House of Lords, the previously mentioned minority view of Lord Scarman was that the standard for the amount of information to be given was not simply what the medical profession thought appropriate.¹⁰⁷⁶

Also, Lord Bridge stated that the courts might depart from the standards set by the profession where

¹⁰⁷³ *Moyes v. Lothian Health Board* [1990] SLT 444 at 449.

¹⁰⁷⁴ Lord Woolf. Self regulation – dentists, discipline and defence. *BDentJ* 1997;182(12):473-477 at 475.

¹⁰⁷⁵ McCall Smith A. Obtaining consent for examination and treatment. *BMJ* 2001;322:810-811 at 811.

¹⁰⁷⁶ *Sidaway v. Bethlem Royal Hospital Governors* [1985] 1 All ER 643, at 654-5.

disclosure of a risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it¹⁰⁷⁷

while Lord Templeman declared that

... the court must decide whether the information afforded to the patient was sufficient to alert the patient to the possibility of serious harm of the kind in fact suffered.¹⁰⁷⁸

This case, therefore, appears to set the precedent for the consideration of a 'prudent professional test', where the professional view would be scrutinised for acceptability by the courts. Thus, even standard practice may be negligent.¹⁰⁷⁹

Similarly in *Hills v. Potter*¹⁰⁸⁰ Hirst J stated:

In every case the court must be satisfied that the standard contended for on their behalf accords with that upheld by a substantial body of medical opinion, and that this body of medical opinion is both respectable and responsible, and experienced in this particular field of medicine.

Bolitho v. City and Hackney HA:

The more recent case of *Bolitho v. City and Hackney HA*¹⁰⁸¹ also indicated that judges are becoming less reluctant to set standards for doctors. In this case the defendant's employee failed to attend to a child who had been admitted to hospital with breathing difficulties. The court, however, could not say whether such an omission had caused the claimant's injuries because it was not apparent what the doctor would have done had she responded. The defendant argued that, even if she had attended, she would not have intubated the child. The court accepted this but went on to consider whether a failure to intubate would have been negligent as 'contrary to accepted practice in the profession'.¹⁰⁸² The claimant's solicitors contended that the child should have been intubated while the defendant argued that she should not. Both sides were supported by experts. As the claimant could, therefore, not prove that the failure to intubate was contrary to medical practice (i.e. utilising the Bolam test) the claim failed. This was endorsed when the case reached the House of Lords.¹⁰⁸³ The burden was on the claimant to demonstrate that by not acting the defendant had fallen below the standard of acceptable medical practice.

1077 *Sidaway v. Bethlem Royal Hospital Governors* [1985] 1 All ER 643, 663

1078 *Sidaway v. Bethlem Royal Hospital Governors* [1985] 1 All ER 643, 665

1079 *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 AC 871, [1985] 2 WLR 840, [1985] 1 All ER 643.

1080 *Hills v Potter* [1984] 1 WLR 641, 653

1081 *Bolitho v. City and Hackney HA* [1993] 4 Med LR 381, [1997] 4 All ER 771.

1082 *Bolitho v. City and Hackney HA* [1998] AC 232, at 237, HL.

1083 *Bolitho v. City and Hackney HA* [1998] AC 232, HL.

Earlier, in the court of appeal, Farquaharson LJ had noted the possibility of an accepted medical practice being held to be negligent because it put the patient unnecessarily at risk.

It is not enough for a defendant to call a number of doctors to say that what he had done or not was in accord with accepted clinical practice. It is necessary for the judge to consider that evidence and decide whether that clinical practice puts the patient unnecessarily at risk.¹⁰⁸⁴

He did not, however, regard this as being an issue in *Bolitho* and gave no examples of when it might arise.

This view was qualified by Dillon who warned:

In my judgement, the court could only ... reject medical opinion on the ground that the reasons of one group of doctors do not really stand up to analysis, if the court, fully conscious of its own lack of medical knowledge and clinical experience, was nonetheless clearly satisfied that the views of that group of doctors were ... such as no reasonable body of doctors could have held.¹⁰⁸⁵

Later, when the case reached the House of Lords it was said by Lord Browne-Wilkinson that:

The use of these adjectives – responsible, reasonable and respectable – all show that the court has to be satisfied that the exponents of the body of opinion relied on can demonstrate that such opinion has logical basis. In particular, in cases involving ... the weighing of risks against benefits, the judge before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risk and benefits and have reached a defensible conclusion on the matter.¹⁰⁸⁶

This essentially appears to give the courts the jurisdiction to declare accepted medical practice as lacking a logical foundation. His Lordship's argument retains the court's right to analyse critically expert witness evidence to ensure it is reasonable. Although some commentators have suggested that *Bolitho* has 'reinterpreted *Bolam*'¹⁰⁸⁷ and handed back to the courts the ultimate power of deciding whether a particular medical practice is acceptable or not¹⁰⁸⁸, even if medical experts found it acceptable, it is respectfully submitted

1084 *Bolitho v. City and Hackney HA* [1993] 13 BMLR 111 (CA) at 119

1085 *Bolitho v. City and Hackney HA* [1993] 13 BMLR 111 (CA) at 132

1086 *Bolitho v. City and Hackney HA* [1997] 4 All ER 771, 778

1087 Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p441.

1088 Khan M, Robson M, Swift K. *Clinical Negligence*. 2nd ed. London: Cavendish Publishing, 2002.

that this case merely reaffirms statements made in *Sidaway*¹⁰⁸⁹ that accepted medical practice may no longer always find favour with the courts.

Some academics have claimed that *Bolitho* restores *Bolam* to its proper and original limits.¹⁰⁹⁰ Thus,

Bolitho has set in train a process whereby judges scrutinise medical evidence, using the same mixture of common sense and logical analysis that they use to scrutinise other expert evidence in negligence claims against professionals such as architects and accountants.¹⁰⁹¹

More controversially,

information disclosure and the supremacy of the 'reasonable doctor test' may be the first *Bolitho* casualty.¹⁰⁹²

However, a recent analysis of appropriate post-*Bolitho* cases showed a significant number still relied on *Bolam*.¹⁰⁹³ Furthermore, *Bolitho* appears to have been used most commonly as a test of credibility rather than as a standard *per se*. The author concluded:

The judiciary appears to be more prepared to assess expert evidence, but only in relation to credibility rather than undertaking an assessment of the proffered standard which would be necessary if the test is to have an appropriate normative force.¹⁰⁹⁴

Thus, although *Bolitho* may be a step in the right direction, it does not travel far enough down the road of judicial scrutiny.¹⁰⁹⁵ The plaintiff still faces a steep uphill climb to overcome the barrier of accepted professional practice.¹⁰⁹⁶

In keeping with this, it is not clear how far the courts are prepared to refuse to accept medical evidence. This is illustrated by their Lordships' differing opinion on how to proceed if the patient made a specific enquiry. While in *Sidaway*, Lord Scarman rejected the *Bolam* test, with respect to consent, because it left the determination of the legal duty to doctors,¹⁰⁹⁷ Lord Bridge did not accept that applying *Bolam* handed the whole question of the scope of duty of care to the medical profession. According to him,

¹⁰⁸⁹ *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 AC 871, [1985] 2 WLR 840, [1985] 1 All ER 643.

¹⁰⁹⁰ Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? MLR 2000;8:85.

¹⁰⁹¹ Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? MLR 2000;8:85 at 103.

¹⁰⁹² Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? MLR 2000;8:85, at 108-9.

¹⁰⁹³ Maclean A. Beyond Bolam and Bolitho. M L Int 2002;5:205-30.

¹⁰⁹⁴ Maclean A. Beyond Bolam and Bolitho. M L Int 2002;5:205-30, 224.

¹⁰⁹⁵ Keown J. Reining in the Bolam test. CLJ 1998;57:248, 249.

¹⁰⁹⁶ Maclean A. Beyond Bolam and Bolitho. M L Int 2002;5:205-30, 222.

¹⁰⁹⁷ *Sidaway v. Bethlem Royal Hospital Governors* [1985] 1 All ER 643, at 654-5.

When questioned specifically by a patient of apparently sound mind about risks involved in a particular treatment proposed, the doctor's duty must ... be to answer both truthfully and as fully as the questioner requires.¹⁰⁹⁸

However, the example he gave of judicial intervention was one of failure to disclose a 10 per cent risk of stroke, which in any event is unlikely to be withheld by any reasonably prudent medical man. Furthermore, even such a risk could be withheld if there was a clinical reason for doing so. Thus, during the therapeutic process the physician should have the discretion to withhold certain information from his patient if he believes disclosure of it would prove harmful. He may need to protect his patient from more serious adverse reaction if the patient were to learn the details of his condition or the full risks of its proposed treatment.¹⁰⁹⁹ This right to withhold certain information is commonly described as the physician's therapeutic privilege. Indeed, the decision not to invoke it may itself constitute malpractice.¹¹⁰⁰

Some believe that even the most dedicated advocates for patient autonomy will allow the doctor the 'therapeutic privilege' to withhold information which would merely serve to distress or confuse the patient.¹¹⁰¹ Thus Lord Scarman in *Sidaway* stated:

It is plainly right that a doctor may avoid liability for failure to warn of a material risk if he can show that he reasonably believed that communication to the patient of the existence of the risk would be detrimental to the health (including, of course, the mental health) of his patient.¹¹⁰²

The issue of 'therapeutic privilege' will be considered further later but for the moment it appears to justify less than full disclosure of information.

This was reiterated in the case of *Blyth v. Bloomsbury AHA* where the Appeal Court appeared to take the view that the doctor need only adhere to the *Bolam* standard.¹¹⁰³ In this case Mrs Blyth alleged that her doctor was negligent in not informing her of the potential side effects of the contraceptive drug Depo-Provera. She had repeatedly and specifically questioned the doctor about the risk associated with the drug. The court ruled that the defendant had complied with accepted practice; there was no obligation to pass on to the patient all the information available to the hospital. Kerr LJ held:

1098 *Sidaway v. Bethlehem Royal Hospital Governors* [1985] 1 AC 871, 898

1099 Dickens BM. What is a medical experiment? *Can Med Assoc J.* 1975;113:635-9

1100 *Male v. Hopmans*, 2 OR 457, 465 (Ont CA) 1967

1101 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. 6th Ed. Butterworths: London 2002, at 10.105.

1102 *Sidaway v. Bethlehem Royal Hospital Governors* [1985] 1 All ER 643, at 654

1103 *Blyth v. Bloomsbury AHA* [1993] 4 MLR 151.

The question of what a plaintiff should be told in answer to a general enquiry cannot be divorced from the Bolam test, any more than when no such enquiry is made. In both cases, the answer must depend upon the circumstances, the nature of the enquiry, the nature of the information which is available, its reliability, relevance, the condition of the patient and so forth.¹¹⁰⁴

From these arguments it would appear that a distinction could be made between a general enquiry, where the *Bolam* test will apply, and a specific enquiry, where the question must be answered truthfully. However, even a specific enquiry need not lead to a full disclosure. In the same case of *Blyth v Bloomsbury HA*, Balcombe LJ believed there was no rule of law that, if a patient has doubts or asks questions, the doctor must disclose all the information he possesses on the subject.

I do not understand that [in] the decision of the House of Lords in *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871 ... either Lord Diplock or Lord Bridge were laying down any rule of law to the effect that where questions are asked of a patient, or doubts are expressed, a doctor is under an obligation to put the patient in possession of all information on the subject ... The amount of information to be given must depend on the circumstances, and as a general proposition it is governed by what is called the Bolam test.¹¹⁰⁵

Furthermore, Kerr LJ was not convinced that

the Bolam test is irrelevant even in relation to what answers are properly to be given to specific enquiries ...¹¹⁰⁶

and

there will always be grey areas, with differences of opinion, as to what are the proper answers to be given to any enquiry, even a specific one.¹¹⁰⁷

Even in *Bolitho* Lord Browne-Wilkinson stated that:

These decisions ... demonstrate that in cases of diagnosis and treatment there are cases where, despite a body of professional opinion sanctioning the defendant's conduct, the defendant can properly be held liable in negligence (I am not here considering questions of risk). In my judgment that is because, in some cases, it cannot be demonstrated to the judge's satisfaction that the body of opinion relied on is reasonable or responsible. In the vast majority of cases the fact that distinguished experts ... are of a particular opinion

¹¹⁰⁴ *Blyth v. Bloomsbury HA* [1993] 4 Med LR 151, 157.

¹¹⁰⁵ *Blyth v. Bloomsbury HA* [1993] 4 Med LR 151, 160.

¹¹⁰⁶ *Blyth v. Bloomsbury HA* [1993] 4 Med LR 151, 157.

¹¹⁰⁷ *Blyth v. Bloomsbury HA* [1993] 4 Med LR 151, 157.

will demonstrate the reasonableness of that opinion ... But if in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible. I emphasise that ... it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable.¹¹⁰⁸

Thus, as clearly explained by Lord Browne-Wilkinson, in the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. This implies that the status of the witness will go a long way to satisfying any test of reasonableness.¹¹⁰⁹ In particular, where there are questions of assessment of relative risk and benefits of adopting a particular practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. Nonetheless, the case made it clear that medical decisions will be subject to review, reaffirming the courts' role.

Pearce v. United Bristol Healthcare NHS Trust:

The recent case of *Pearce v. United Bristol Healthcare NHS Trust*¹¹¹⁰ has also indicated that the courts will depart from the medical professional approach if they see fit, the ultimate test being what the court itself thinks was a reasonable amount of information to give the patient.¹¹¹¹ The court held that a doctor had a duty to disclose significant risks.

... if there is a significant risk which would affect the judgement of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.¹¹¹²

This is very similar to the meaning of 'material risks' that needed to be disclosed per the Australian High Court case of *Rogers v Whittaker*¹¹¹³ Although the UK Court of Appeal located the standard in the 'reasonable professional' test, in essence it is advocating a more patient friendly test, similar to the Australian High Court. In asking the question 'what would a reasonable doctor disclose' both courts answer 'what a reasonable patient would consider significant.'¹¹¹⁴ The Australian High Court did go further and required disclosure of risks which the doctor ought reasonably to know would be significant to the 'particular patient.'

1108 Bolitho v. City and Hackney HA [1993] 4 Med LR 381, [1997] 4 All ER 771, 779.

1109 Maclean A. Beyond Bolam and Bolitho. MLInt 2002;5:205-30, 208.

1110 Pearce v. United Bristol Healthcare NHS Trust (1998) 48 BMLR 118, CA.

1111 McCall Smith A. Obtaining consent for examination and treatment. BMJ 2001;322:810-1.

1112 Pearce v. United Bristol Healthcare NHS Trust (1998) 48 BMLR 118, 124. CA.

1113 Rogers v Whittaker [1993] 4 Med LR 79; [1992] 3 Med LR 331; (1992) 109 ALR 625.

1114 Kennedy I, Grubb A. Medical Law. Butterworths: London, 3rd ed (2000), p709

However, although the court in *Pearce* appeared supportive of the individual patient approach, it concluded that in this case it would not be proper for the courts to interfere with the clinical opinion of the expert medical men responsible.¹¹¹⁵

Thus it seems clear that judges are prepared to accept that it would, in the vast majority of cases, be acceptable to them, and hence lawful, for doctors to withhold information from a patient who asked questions if a responsible body of professional opinion supported such an action.¹¹¹⁶

The evidence of medical experts should be examined carefully to ensure that it is honest and objective. Medical expertise is to be overridden, it will appear, when the medical experts hold views that the judges believe no reasonable doctor could hold. This, however, is tantamount to suggesting that the doctors must be either dishonest or lacking in the necessary objectivity. It would appear therefore that once their credibility is established, their evidence will in fact be accepted without further questioning.¹¹¹⁷

Similarly, the previously mentioned Scottish case of *Moyes v. Lothian Health Board*¹¹¹⁸ considered that the extent and quality of warning to be given by a doctor to his patient should in the last resort be governed by medical criteria.

Deference:

Why do the UK courts give such weight to the opinion of medical experts, even in cases concerning non-disclosure of risk? The problem is that the courts are presented with facts and views of technical complexity outwith their area of expertise, - hence their reliance on 'experts'. Because there is frequently conflicting evidence, they try to untangle all the evidence and determine the quality of what was done. However what they should be doing is determining what *ought* to have been done.

Finding it difficult to determine what is done and hearing evidence of what *is* done tends to depend on particular facts of each case, the court has tended to elide the distinct issue of what *ought* to be done with its decision of what *is* done.¹¹¹⁹

Determining what ought to have been done is a value judgement and not a technical medical issue at all. Thus there appears to be an unreasonable reliance on medical experts when considering issues of disclosure of information.

¹¹¹⁵ *Pearce v. United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, CA.

¹¹¹⁶ The Court of Appeal in *Blyth* decided that the claimant had not in fact asked any questions and thus the comments on the duty to answer questions are not technically binding on subsequent courts.

¹¹¹⁷ Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p175

¹¹¹⁸ *Moyes v Lothian Health Board* [1990] 1 Med LR 463,469

¹¹¹⁹ Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p430

Another reason for showing deference was the desire to avoid the ‘American disease of defensive medicine.’ In the Court of Appeal in *Whitehouse v Jordan* Lord Denning stated:

Take heed of what has happened in the United States. ‘Medical malpractice’ cases there are very worrying, especially as they are tried by juries who have sympathy for the patient and none for the doctor, who is insured. The damages are colossal. The doctors insure but the premiums are very high: and these have to be passed on in fees to the patients. Experienced practitioners are known to have refused to treat patients for fear of being accused of negligence. Young men are even deterred from entering the profession because of the risks involved. In the interests of all, we must avoid such consequences in England.¹¹²⁰

However, if the law requires doctors to do what other doctors deem reasonable, where is the need for defensive medicine?¹¹²¹ Further, there is a distinction to be made between pure factual matters, such as in diagnosis and treatment (as for example, is this the correct drug for this disease) and matters of judgement, as in risk disclosure, especially as this is fundamental to the principle of respect for autonomy.

Montgomery asks whether the unusual deference shown to medical expertise is a matter of law or practice.¹¹²² Earlier cases such as *Maynard v. W.Midlands RHA*¹¹²³ implied that there could be no judicial intervention to declare standard accepted medical practice to be negligent. However, more recent cases such as *Sidaway* and *Bolitho* suggest that the reality is that judges are entitled to intervene but have chosen not to. Thus, it is not a question of law but merely of practice, judges choosing to defer to the advice of fellow professionals. However, no profession is above the law¹¹²⁴ and medical professionals fall into no special category¹¹²⁵ which singles them out for privileged treatment.¹¹²⁶ Other professionals are not treated with the same ‘hands off’ attitude. The *Bolam* principle was not applied to negligence cases concerning employee claims^{1127 1128} or, more importantly, other professional negligence actions such as those brought against lawyers.¹¹²⁹ Even if, in these cases, the *Bolam* test was consulted, it was not determinative. In the latter case¹¹³⁰, although the body of professional opinion was almost universally held, the court decided it was not a reasonable or responsible opinion.

¹¹²⁰ *Whitehouse v Jordan* [1980] 1 All ER 650 at 658, CA

¹¹²¹ Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p 430

¹¹²² Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p170

¹¹²³ *Maynard v. W.Midlands RHA* [1985] 1 All ER 635

¹¹²⁴ *Hajgato v. London Health Assn* (1982) 36 OR2d 669, 693a

¹¹²⁵ *Whitehouse v Jordan* [1981] 1 All ER 267, HL at 276

¹¹²⁶ Giesen D. *International Medical Malpractice Law*. JCB Mohr: Tubingen, 1988, at para 129.

¹¹²⁷ *Cavanagh v Ulster Weaving Co Ltd* [1960] AC 145

¹¹²⁸ *Thompson v Smiths Shiprepairers (North Shields) Ltd* [1984] QB 405

¹¹²⁹ *Edward Wong Finance Co Ltd v Johnson Stokes & Masters* [1984] AC 296, [1984] 2 WLR 1.

¹¹³⁰ *Edward Wong Finance Co Ltd v Johnson Stokes & Masters* [1984] AC 296, [1984] 2 WLR 1.

By thus deferring to a standard set by the medical profession itself in place of its own usual standard of reasonable care, the law in effect confers a special privilege on the medical profession which it denies to accountants, lawyers and others practising special skills. Its rationale is the layman's ignorance of medical science, coupled with an apprehension of exposing physicians to the vagaries of jury sympathy for victims. The deferential standard is applied in England not only to matters of diagnosis and treatment, but also to information and counselling ...¹¹³¹

The practice adopted with respect to the medical profession could therefore be easily changed. The crux of the matter is whether negligence is a normative doctrine, setting standards for the profession, or a descriptive doctrine, merely reflecting reality.¹¹³²

The standard for establishing negligence in all aspects of law relates to 'the reasonable man' or the 'prudent and reasonable man'.¹¹³³ This does not mean, however, that if one does what an ordinary person would have done, one is exonerated. Thus Montrose criticises McNair in *Bolam* for failing to recognise that the ordinary man in the street does not always act and show the care of the reasonably prudent man required in the circumstances.¹¹³⁴ The question of establishing negligence is 'what ought to be done' in the circumstances. Thus,

in so far as negligence is concerned with what ought to be done, it may be called an ethical concept: in so far as it is concerned with what is done, with practice, it may be said to be a sociological concept.¹¹³⁵

The ethical interpretation is to apply the normative requirement of 'reasonableness' to the practice accepted as proper by a respectable body of practitioners; the sociological interpretation is to argue that, once the body of professionals is accepted as a 'responsible body' then any act that body approves cannot incur negligence liability. If *Bolam* is applied as a sociological test then the profession effectively sets the standard.¹¹³⁶

In turn, Jones has described a number of weaknesses with respect to the law of consent.¹¹³⁷ Primarily, he believes the notion that it would be wrong to find a doctor liable in battery because the implication would be that he intended to harm his patient is misplaced. Motive is not a defence and the intention relates to the act and not the harm suffered. An intention to cause harm is not

¹¹³¹ Fleming. *The Law of Torts* (9th ed, 1998). The Law Book Co Ltd, at 121.

¹¹³² Montrose JL. Is negligence an Ethical or a Sociological Concept? 1958; 21 MLR 259-64

¹¹³³ *Blyth v Birmingham Waterworks* (1856) 11 Exch 781

¹¹³⁴ Montrose JL. Is negligence an Ethical or a Sociological Concept? 1958; 21 MLR 259-64.

¹¹³⁵ Montrose JL. Is negligence an Ethical or a Sociological Concept? 1958; 21 MLR 259-64 at 259.

¹¹³⁶ Maclean A. Beyond Bolam and Bolitho. *MLInt* 2002;5:205-30.

¹¹³⁷ Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134 at 105-8.

necessary.¹¹³⁸ Furthermore, case law cannot ever be a comprehensive framework and cannot cover all eventualities. Because the law is not widely known and is poorly understood by doctors, it would be better to have guidance provided by doctors which can be more specific and more likely to be read and acted upon by doctors.¹¹³⁹ Therefore, Jones believes the law does not serve as a template for what ought to happen, does not have a positive effect and does not influence doctors' behaviour.¹¹⁴⁰

From the courts' perspective the standard of disclosure is tied to the doctor's duty rather than the patient's need for information to allow a choice to be made. Thus it appears to require doctors to fulfil their obligations rather than enabling patients to participate in a therapeutic alliance of good medical practice.¹¹⁴¹

Jones also believes that the law does not work in terms of being a remedy for breach of the duty of information disclosure because it fails to protect patients' rights. It gives doctors significant discretion to determine the boundaries of acceptable behaviour regarding what needs to be disclosed, contrary to the ethical principle of respect for autonomy. Furthermore, the need to prove causation, that is that the disclosure of the risk that was not mentioned would have led to a refusal of consent, makes it even more difficult. On the other hand, legal liability is not an objective in itself. 'The law is meant to be purposive, to achieve a specific social goal.'¹¹⁴² That goal should be the achieving of respect for patient autonomy and not merely a legal requirement.

The law's paternalistic treatment of the doctrine of informed consent undoubtedly provides a foundation for the medical profession's perception of it. There seems to be a failure on the part of doctors to take a step back in order to try to understand the meaning of informed consent. Instead the tendency is to perceive informed consent mainly as a medico-legal concept centred on the requirement to get a signature on a form.¹¹⁴³

CONSENT and INNOVATION in the UK:

Following from this discussion, it is unclear how UK law will deal with a case of innovation, either of experimental treatment or at the personal level of learning on the job. The following clinical example will highlight some of the problems a court could face.

Fibreoptic intubation is a technique used in anaesthesia, sometimes in an emergency, to put a tube into the patient's trachea. This is undertaken while the patient is still awake. This can sometimes be lifesaving and, fortunately, is rarely required. However to be able to undertake it in an emergency doctors

1138 *Wilson v. Pringle* [1986] 2 All ER 440, 445.

1139 Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134 at 106.

1140 Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134, 105-109.

1141 Teff H. Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance? (1985) 101 *LQR* 432.

1142 Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134 at 108.

1143 Kessel AS. On failing to understand informed consent. *Br J Hosp Med* 1994;52:235 at 237.

need to practice it fairly regularly. In other words the skill needs to be both learned and more importantly maintained. There are not enough patients requiring fiberoptic intubation 'in extremis' to allow the technique to be learned and the skill maintained. So doctors tend to justify its use in other situations. Thus the clinical scenarios in which such intubations are deemed acceptable to the operator vary according to that operator. One doctor may only use this form of intubation in extreme conditions but because he rarely practices it may not be very good at it, to the detriment of a subsequent patient who requires the use of the technique. Another doctor, using less stringent criteria, uses it in such conditions as a loose tooth or slightly enlarged tongue (where many colleagues believe it is not warranted). However he does become proficient at it and, more importantly, is much more likely to save the life of the patient who really needs it because he has practised it more often.

The patients of this second doctor do actually consent and authorise the use of the technique. There are no risks, apart from the fact that it is quite uncomfortable and takes longer than the normal method of intubating the trachea. Furthermore in very rare and unexpected cases it may actually be safer. What they are not told is that most other doctors would not undertake a fiberoptic intubation on them in their condition. From a legal viewpoint there may well be a responsible body of opinion from like-minded doctors that would support the use of the technique in these situations. Ethically, however, it appears unacceptable that the patient is undergoing a procedure that many would deem unnecessary and mainly in the interests of maintaining the skills of a practitioner, which may benefit other patients.

Since no legal cases have been heard in this regard, no definite conclusions can be reached. However it may be deduced how a court would resolve such a problem. It would start by defining what the standard of care was and whether it was breached. Medical opinion would be sought and the opinion from a responsible body of medical men who tend to be experts in the field of fiberoptic intubation would have a heavy bearing on the court, despite the fact that the majority of medical professionals may not find its use in the circumstances acceptable. Any argument for its use to allow skills to be maintained would be overshadowed by discussions about whether the technique was clinically indicated. It would only be at the limits of these indications where few, if any, colleagues would be supportive that the courts may find the doctor negligent. Thus while its use in, for example, a stiff neck might find favour, its use in a patient with a loose tooth may very well not. The final decision, of course, would rest with the courts. However, credible experts, as per *Bolitho*, may well sway the court into accepting the technique and the circumstances in which it is used.

Similar difficulties arise when examining how issues of consent in UK law would apply to the early heart transplants and the situation which arose in Bristol.

Heart transplants revisited:

There can be little doubt that in many instances during the early heart transplant operations patients were given little and sometimes misleading

information. For example, Barnard misled the first heart recipient's wife regarding the chance of success. It is also clear that he did not believe in patient autonomy but rather that the doctor's duty was to provide all available treatment.¹¹⁴⁴ Cooley similarly believed that consent in these patients did not appear to be an issue. There was no real problem in convincing a patient who was at the end of his tether.¹¹⁴⁵

However, consent in this experimental form of innovation suffers from limitations. Firstly desperate patients were seeking untried therapy. An intrinsic feature of consent lies in the presentation of sound alternatives to the patient.¹¹⁴⁶ Explaining alternatives in these cases was not an option because there were none. Experimental treatment by way of a heart transplant was the patient's only hope. Even when others had died, new potential recipients still wanted to go ahead. It is also not clear whether, if there were alternatives and these were not disclosed to the patient, the doctors concerned would have been negligent. There are currently no UK legal cases specifically addressing the issue of disclosure of alternative treatment. Such a case may well turn on whether other doctors, in a similar situation would disclose those alternatives. If the judge considered their opinion condoning the failure to disclose, for whatever reason, as one that was rightly and properly held, and that they were credible in terms of their status, any claim would fail.

Secondly, the very fact that the procedure had not previously been carried out meant that the doctors themselves lacked the critical information to disclose to patients to allow them to make a fully informed choice. There appears to have been little information to impart.

But while the first limitation regarding alternatives is probably true in most instances (apart, as shall be seen, from the use of the first artificial heart) the second is not necessarily so. Indeed, there can be little doubt that, in some cases, doctors could have been found negligent (under UK law). For example, the first South American heart transplant recipient was not informed of *any* of the risks involved in his operation. He did not understand its nature or seriousness.¹¹⁴⁷ Indeed, it could also be argued that, since the patient was not informed in broad terms of the nature of the procedure¹¹⁴⁸, an action in battery could have been appropriate.

Regarding the other early recipients, disclosure of information was still critical to allow an informed choice to be made. It is unclear, however, whether many of the early recipients knew of the relatively poor success rate, especially in

1144 Barnard C. In Experience with human heart transplantation. Proceedings of the Cape Town Heart Transplantation Symposium, 1968. Ed Shapiro HA. New York: Appleton-Century-Crofts 1969, p266-7.

1145 Cooley D. in Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p297.

1146 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p366

1147 Anon. News in brief: Transplant patient 'didn't know what he was in for'. World Medicine 1968;3(21):1.

1148 Chatterton v Gerson [1980] 3 WLR 1003

those countries where it was felt that a transplant had to be attempted.¹¹⁴⁹ In these cases it is unclear whether patients were told they would be the first 'to be experimented on' and that their surgeons had never attempted the operation before. The option of patients going to other centres (with more experienced surgeons and better facilities) was almost certainly not offered because the surgeons concerned would have wanted to try the operation themselves.

Such a scenario existed in the UK when the first heart transplant was undertaken in May 1968. The surgeons were congratulated in a leading article in the *British Medical Journal* for undertaking the 'successful' operation.¹¹⁵⁰ Furthermore, as previously described, the world wanted to believe that such operations were possible. The early era of transplantation was described as being a time of 'tremendous euphoria.'¹¹⁵¹ Public opinion in countries around the world virtually forced doctors into attempting heart transplants. All over the world, in various 'advanced' countries, it was felt that a transplant had to be attempted. There was 'a very nationalistic dimension to it.'¹¹⁵² It is therefore very unlikely that a claim in negligence would have been upheld.

Of greater concern, however, was the use of the first artificial heart. There is little doubt that the recipient of this technology, Haskell Karp, did not give informed consent. He and his wife were unaware of many of the problems with the pump, as discussed previously. He also had the option of delaying the original operation and avoiding the use of the pump as an emergency stopgap, but this was not disclosed.

Even if he had consented to this innovative treatment, it is not certain that this would have absolved the doctor of responsibility. In the non medical case of *R v. Brown*¹¹⁵³ it was accepted that even if a real consent was given, public policy issues may prevent the consent from decriminalising certain behaviour. So for example, statutes, such as the Prohibition of Female Circumcision Act 1985, limit the impact of consent. There is thus a remote possibility that a court may find an innovation so unacceptable that consent does not absolve the doctor from responsibility. Once again, the evidence of credible experts would be determinative.

For many of the surgeons, professional and public recognition was a stimulus to trying out the new operations.¹¹⁵⁴ For many involved in the transplant endeavour, there was the desire to achieve more than ordinary professional status and recognition.¹¹⁵⁵ Thus, the presentation of alternatives was coloured

1149 Fox R. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: *Early Heart Transplant Surgery in the UK*. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p50.

1150 Anon. First British heart transplant. *BMJ* 1968; ii:315.

1151 Rochelle D. Thompson T. *Hearts*. New York: McCall, 1971 at p167.

1152 Fox R. in *Wellcome Witnesses to Twentieth Century Medicine* vol 3: *Early Heart Transplant Surgery in the UK*. Tansey EM, Reynolds LA (Eds). Wellcome Trust 1999 at p50.

1153 *R v. Brown* [1993] 2 All ER 75 (HL)

1154 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at xvii

1155 Fox RC, Swazey JP. *The Courage to Fail*. Chicago: University of Chicago Press, 2nd ed. 1978 at p102.

by subjective factors on the part of the doctors.¹¹⁵⁶ This was especially so regarding the treatment of Haskell Karp.¹¹⁵⁷ Operations were undertaken without obtaining fully informed consent. Many of the patients had little understanding of what the operations entailed, little knowledge of risk and personal mortality figures were undoubtedly not disclosed.

However, whether the doctors would have been found guilty of malpractice is a different matter and it could be argued that it would have been highly unlikely. At the time these operations were undertaken the law unreservedly accepted medical opinion regarding what was acceptable medical practice. *Hunter v. Hanley* was heard in 1955 and *Bolam* was heard in 1957 (although only fully accepted and applied by the House of Lords in *Whitehouse v. Jordan* in 1981). Neither case broke new ground but rather stated and reaffirmed the law as it had long been accepted.¹¹⁵⁸ Thus a responsible body of opinion would have supported the operations that surgeons such as Barnard, Cooley and Ross were undertaking. Although the patients did not give informed consent, medical experts would have testified that what was disclosed was sufficient and acceptable.

The question then is whether today's laws, especially following *Sidaway* and *Bolitho*, would have resulted in a different outcome. Medical opinion now needs to have a logical basis and be rightly accepted. Because the operations were extreme measures and the patients had little other hope, arguably the courts would have accepted the desperate attempt to save lives. Although courts today could find fault with the extent of disclosure of risk, there were few alternatives to offer apart from the option of travelling to another more experienced centre. Thus, it is highly unlikely that the doctors concerned would have been found negligent, under present UK law, especially given the public opinion, enthusiasm and euphoria present at the time. Furthermore, it has already been argued that cases such as *Bolitho* merely appear to assess the credibility of the experts. It is extremely unlikely that if Barnard or Cooley appeared as expert witnesses, their testimony would not have been accepted in full.

There has not yet been a case in the UK where failure to disclose personal results has led to a finding of negligence. That, of course, may change following Bristol, which is re-examined next.

Bristol revisited:

Bristol was different from the scenario described for the early heart transplants because patients (or parents) did have other options. They were also not fully informed and therefore did not make an informed choice.

1156 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p366.

1157 Thompson T. *Hearts*. New York: McCall, 1971 at p211.

1158 Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed. 2000, at 416.

One of the surgeons was well aware of the concern of professional colleagues about the level of mortality and morbidity in paediatric cardiac surgery at the hospital.¹¹⁵⁹ Despite this, he operated on further patients who subsequently died. He did not pay sufficient regard to the safety and best interests of the patients concerned when deciding to continue operating. In addition, he misled two sets of parents when he had said that the risks of mortality were 20-25%, a figure that did not accurately reflect his own experience as a surgeon. He therefore denied the parents the facts they needed in order to make informed decisions about their child's treatment.

The other surgeon continued to operate despite also knowing his results were poor and having been made aware of concerns about his work. This was a serious departure from safe and proper practice. Again, accurate information was not provided to parents.¹¹⁶⁰

The public inquiry that followed made 198 recommendations, many urging doctors to include patients as active participants.¹¹⁶¹ However, they remain recommendations. They are not enshrined in law, despite the Government accepting many of them.¹¹⁶² Clearly if the surgeons had followed them Bristol would not have occurred. Patients (or parents) would have known of the surgeons' and unit's poor results and would have had the option of taking their child elsewhere. With the information provided they would have been able to make an informed choice. This is what *ought* to have happened. The law does not necessarily follow ethical principles. The question is therefore whether the failure of disclosure or the continuation of treatment would have led to a charge of negligence being found proven.

From a legal viewpoint expert testimony will be crucial. Surprisingly, not all testimony would be damaging. Many consider the Bristol doctors to have been scapegoated for the failures of a whole system.¹¹⁶³ Some have even disputed the mortality figures provided.¹¹⁶⁴ A consultant paediatrician who was invited to be a member of the panel on the Bristol Inquiry but was later withdrawn after he mentioned at an initial meeting that perhaps a surgeon should be included on the panel felt the media coverage was simplistic and condemnatory.¹¹⁶⁵ He believed all doctors must have shared the deep sympathy he felt for the Bristol doctors. He described the Health Secretary's response to the GMC findings ('if the GMC struck off two of the doctors they should have struck off all three')¹¹⁶⁶ as 'a Pavlovian political response to any

1159 Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

1160 Dyer C. Bristol trust admits liability in baby heart surgery case. *BMJ* 1999;319:213

1161 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

1162 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002

1163 Smith R. One Bristol, but there could have been many. *BMJ* 2001;323:179-80.

1164 Gibbs JL, Cunningham D. Volunteered mortality data may be unreliable. *BMJ* 2002;324:1096.

1165 Barnes N. (Very) short service on the Bristol inquiry. *BMJ* 1998;317:1577-9.

1166 Warden J. Dobson criticises GMC. *BMJ*1998;316:1925.

situation in which there is serious public anger.’¹¹⁶⁷ Many senior doctors raised serious questions about the GMC findings and believed the doctors had been tried by the media.¹¹⁶⁸

Furthermore, as previously mentioned, personal performance figures are not (and at the time of Bristol certainly were not) currently divulged when obtaining consent. Indeed, there are no legal cases in the UK where this has been an issue. Thus, this failure to disclose personal mortality figures does not necessarily mean that the doctors concerned would have been found guilty of negligence on the basis of a failure to inform.

On the other hand, despite being aware of their poor results, they persisted in performing these operations, hoping their results would improve, thereby disregarding their immediate patients’ interests. Also, most experts would have been concerned by the poor mortality rate. Once a health carer performs a task, the patient can assume that he has the competence to perform that task with skill and care. If the health carer, either knowingly or not, attempts something beyond his experience then that will constitute a breach of the standard of care.¹¹⁶⁹ Furthermore, in the converse situation where the doctor holds himself out to be more experienced than he actually is and claims to possess the degree of skill and knowledge required, then he must reach that standard.¹¹⁷⁰ A similar argument can be made if the doctor holds himself out as achieving more successful results than he actually does. It is therefore probable that a successful negligence claim could be made. It would be highly unlikely for experts to support the continuation of surgery when the results had been so poor. Even if some experts could be found in support of the defendants’ actions, it would still be up to the court to decide if the experts were credible and their views were logical and right.

The problem of learning new techniques also needs to be discussed in the light of what happened in Bristol. One of the surgeons blamed ‘beginner’s bad luck’ for some of the deaths. Two deaths were explained as part of his learning curve.¹¹⁷¹

As mentioned in the previous chapter, the courts have held that inexperience is no defence to a charge of negligence. In *Nettleship v. Weston* it was held that the same standard of care was expected of a learner driver as of an experienced driver.¹¹⁷² In medicine, the case of *Wilsher v Essex AHA*¹¹⁷³ also established this principle otherwise ‘inexperience would frequently be urged as a defence to an action for professional negligence.’¹¹⁷⁴

1167 Barnes N. (Very) short service on the Bristol inquiry. *BMJ* 1998;317:1577-9 at 1577.

1168 Dunn PM. The Wisheart affair: paediatric cardiological services in Bristol, 1990-5. *BMJ* 1998;317:1144-5.

1169 Khan M, Robson M, Swift K. *Clinical Negligence*. Cavendish Publishing: London, 2nd ed. 2002, p159

1170 *R v Bateman* (1925) LKJB 791.

1171 Dyer C. Surgeon blamed beginner's bad luck for cardiac deaths. *BMJ* 1998;316:1114.

1172 *Nettleship v Weston* [1971] 2 QB 691.

1173 *Wilsher v Essex AHA* [1986] 3 All ER 801.

1174 *Wilsher v Essex AHA* [1986] 3 All ER 801 at 831.

It therefore appears clear that, disclosure apart, the doctors at the centre of the Bristol controversy could have been found guilty of negligence for their conduct. As argued in the previous chapter, however, it is not the inexperience *per se* that should lead to a finding of negligence but the lack of supervision.

The failure to disclose their own experience and that they were still learning the technique, on the other hand, may not have been negligent if other doctors in a similar position would not have disclosed such facts. This is an issue that therefore needs to be considered. Because of this, the Bristol Inquiry recommended that consent was a process (recommendation 24) and as part of that process sufficient information was to be given about the risks, uncertainties, alternatives and likely outcome to enable an informed choice to be made (recommendation 26).¹¹⁷⁵ Patients were also entitled to be informed about the experience of the clinician undertaking the procedure (recommendation 102) and the performance of the consultant (recommendation 27). The Government accepted all of these recommendations.¹¹⁷⁶

The existence of the patient's right to make his own decisions.... may be seen as a basic human right protected by the common law.¹¹⁷⁷

If the law truly believes this, then it needs to change. A decision cannot be made on less than adequate information. It is not in keeping with the meaning of informed consent, which, as discussed, is better analysed in terms of autonomous authorisation.¹¹⁷⁸

TWO MEANINGS OF CONSENT:

As previously mentioned, there are different meanings to 'informed consent' with at least two entrenched views, based on different concepts.¹¹⁷⁹ In the first sense, informed consent can be analysed in terms of autonomous choice by patients: an informed consent is an autonomous authorisation of a medical intervention by individual persons. This first sense of informed consent requires that a patient does more than express agreement with, yield to, or comply with an arrangement or proposal. He or she must actively authorise the proposal in the act of consent. A person does not authorise in this sense if he or she merely assents to a treatment plan by submission to a doctor's authoritative order; nor is there autonomous authorisation if the treatment plan is not specific about what is authorised. An informed consent thus occurs if a

1175 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

1176 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002

1177 Sidaway v Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital and others. 1 BMLR 132 per Lord Scarman, p140.

1178 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:p78

1179 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:78.

patient with substantial understanding and in substantial absence of control by others intentionally authorises the doctor to do something.

In the second sense, informed consent is analysable in terms of the social rules of informed consent in those institutional contexts in which it is necessary to obtain legally valid consent from potential patients before proceeding. Reduction of risk and avoidance of unfairness and exploitation still function as the primary justifications for many professional, regulatory, and institutional controls.¹¹⁸⁰ Such requirements appear to be at the heart of the signing of the consent form prior to an operation. It is an institutional requirement, although it has been claimed that the so-called authority is so ambiguous as to be almost completely worthless.¹¹⁸¹ Furthermore it frequently involves a hasty discussion between a patient and junior doctor, whose sole aim is to get a signature on a form. Options and alternatives are rarely discussed.¹¹⁸²

Apart from the dubious usual practice of allowing the most inexperienced member of the surgical team to explain the operation to the patient and 'get consent', in one study up to 44% of post-operative patients who signed consent forms were unaware of the exact nature of the procedure they had undergone.¹¹⁸³ Similarly, 'consenting' the patient suggests that consent is something that is done to the patient, usually for the purposes of avoiding legal liability, rather than a process that the patient participates in or controls.¹¹⁸⁴

Informed consent is clearly not always an autonomous act in these settings and is not necessarily even a meaningful authorisation. This second sense of consent may be understood in terms of institutional rules of consent, because informed consent here refers to an institutionally or legally effective authorisation from a patient or subject. Such an authorisation is effective if obtained through procedures that satisfy the rules that govern specific institutional practices of consent. Any consent is therefore claimed to be 'informed' if it satisfies the operative rules governing the practice.

The law courts, as has been discussed, appear to have adopted this second sense of consent. Institutional rules of informed consent will not, however, result in autonomous authorisations. It is clear, therefore, that a physician who obtains consent under institutional criteria may fail to meet the rigorous standards of the autonomy-based model.

In turn, Lord Donaldson has stated that consent plays two quite different functions in the doctor patient relationship.¹¹⁸⁵ One, which he called the legal,

1180 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:77.

1181 *Rogers v. Lumbers Mutual Cas Co* 119 So 2d 649 (La, 1960).

1182 Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. *BMJ* 1993;306:885-90.

1183 Byrne DJ, Napier A, Cuschieri A. How informed is signed consent? *BMJ* 1988; 296:839.

1184 Jones MA. Informed Consent and Other Fairy Stories. *MLR* 1999;7:103-134 at 125.

1185 *Re W* [1992] 4 All ER 627,633

is to provide a legal justification for care. Without such consent health professionals would commit a crime (battery) and a tort (trespass to the person) when they touch their patient. The other function, termed 'clinical' by Lord Donaldson, is to secure the patient's trust and co-operation. This aspect of consent may involve far more extensive counselling on the implications, risks and side effects of treatment than the laws of trespass and battery require.

This latter function is more in keeping with the true meaning of informed consent, when analysed as an autonomous authorisation.¹¹⁸⁶ Trust and co-operation should be at the centre of the doctor patient relationship. The basic proposition is that most good relationships, whether professional or personal, are built upon truth and integrity, and the trust that this creates.¹¹⁸⁷ However, one of the most important reasons that leads to a legal action being brought against doctors and hospitals is a quest for an explanation, either to patients or relatives, of what went wrong. A survey of 227 litigants who sued healthcare providers found that the overwhelming majority were doing so because they were dissatisfied with the nature and clarity of the explanations they were given and the lack of sympathy displayed by staff after the incident.¹¹⁸⁸

Similarly, the Wilson Report, a review of NHS complaints procedures, found that complainants usually want information, an explanation of what happened and why, and that failure to provide these often leads to the making of a complaint.¹¹⁸⁹ One study showed that where explanations were given, less than 15 per cent were considered satisfactory.¹¹⁹⁰ Furthermore there is evidence that a patient who feels inadequately informed is more likely to sue if there is an adverse event during surgery.¹¹⁹¹

While the failure to tell the truth undermines the very foundation of the legal process, in the context of the doctor-patient relationship it is often presented as an essential part of therapy.¹¹⁹² This is especially so when considering the doctor's therapeutic privilege, where the doctor is allowed to exercise judgement in deciding what to disclose. As discussed, the information to be disclosed, whether volunteered by the doctor or in response to queries from the patient, appears to be determined by standards set by the medical profession. This undermines the patient's right and ability to make a choice.

1186 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:p78

1187 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134 at 104.

1188 Vincent C, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. Lancet 1994;343:1609-13.

1189 Being Heard- Report of the Review Committee on NHS Complaints Procedures. NHSE 1994.

1190 Vincent C, Young M, Phillips A. Why Do People Sue Doctors? Lancet 1994;343:1609.

1191 Morrison AW. Silence in court: Twenty-one years of otolaryngology litigation. J Laryngol. Otol 1990;104:162.

1192 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134.

While it is clear that the two functions of consent described by Lord Donaldson¹¹⁹³, a clinical function and a legal function, correspond to the preceding description of the two meanings of informed consent, it must be recognised that the rules of consent need not conform to only one of the two classes of definitions discussed. They should conform to both. Many rules of informed consent in policy contexts reflect a strong and definite reliance on informed consent in the first sense, i.e. based on autonomous decision-making. This first definition ought to serve as the benchmark for the evaluation of the moral adequacy of rules framed for institutional purposes. This follows from the understanding that the primary goal of informed consent in the medical care setting is to enable potential patients and subjects to make autonomous decisions about whether to authorise an intervention.¹¹⁹⁴

Despite this, as has been argued earlier, the law in England and Scotland does not accept this when dealing with the information that needs to be disclosed to patients presenting for treatment. The law still relies heavily on professional opinion, thereby failing to respect patient autonomy. Even when a judge described a particular operation as *unusual* there still did not appear to be a duty for the surgeon to disclose this¹¹⁹⁵ because the technique used had not been professionally rejected as wrong.¹¹⁹⁶

DISCLOSURE IN THE RESEARCH SETTING:

The obligation of full disclosure, however, has been accepted in law when considering the consent process for research projects, thereby preventing exploitation of vulnerable patients. Although a doctor has the discretion to withhold certain information from his patient if he believes it would prove harmful if given, the so-called therapeutic privilege, this option is not acceptable in the research setting. Thus in the case of *Halushka v University of Saskatchewan*, the judge stated

there can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice.¹¹⁹⁷

The court here was insistent that the research subject was spared no detail of his relevant condition or of his exposure to risk. The case concerned issues of consent when recruiting research subjects. The research project involved the testing of a new drug to be used for anaesthesia and the subject had been reassured that the test was safe. All he was told was that a catheter was to be inserted into his vein. There was no mention made of this catheter being advanced into his heart nor that the defendants had not yet used the research drug in question. The research subject suffered a cardiac arrest during the procedure. One of the appeal judges stated:

¹¹⁹³ Re W [1992] 4 All ER 627,633.

¹¹⁹⁴ Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:- 78-9.

¹¹⁹⁵ Newbury v Bath DHA [1998] 47 BMLR 138, 150.

¹¹⁹⁶ Newbury v Bath DHA [1998] 47 BMLR 138, 162.

¹¹⁹⁷ Halushka v University of Saskatchewan (1965) 53 DLR (2d) 436

The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself. The example of risks properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The subject of medical [research] is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.¹¹⁹⁸

The point of raising the subjective element and higher standards of disclosure used by the law when dealing with issues of research is that it highlights that the law, when it so wishes, is fully prepared to accept and respect patient autonomy. Furthermore, it also illustrates that the law does accept that the doctor patient relationship is not uniform and circumstances may be present which require different rules to be followed. The requirements to satisfy the legal obligations for information disclosure are thus much greater in the research setting than in the normal therapeutic doctor patient relationship.

It must be pointed out, however, that *Halushka* is a Canadian case and is only being reviewed because there is a paucity of UK case law in this respect.

Though the ethics of many [research trials] have been challenged by professional and lay critics, in many of these there has been no detectable damage. ... A further reason for the paucity of lawsuits is the fact that the subject is normally not aware nor in possession of the evidence to demonstrate his interests have not been properly protected.¹¹⁹⁹

Until recently, research on human subjects in the United Kingdom remained virtually untouched by specific laws, although a significant amount of quasi-law existed on which the practice of those involved was based.¹²⁰⁰ Thus, medical research in humans in the UK was regulated through guidelines and advice from various professional and governmental authorities.¹²⁰¹

More recently, the European Trials Directive 2001/20/EC was developed with the intention of simplifying and harmonising regulation of clinical trials across the European Community. The provisions of this directive have been translated into United Kingdom regulations through the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), which came into force on the 1st May 2004. This should lead to tighter control than occurred previously, with new responsibilities placed on those managing and conducting clinical trials.

1198 *Halushka v. University of Saskatchewan*, 52 WWR 608 (Sask CA), 1966 at 616

1199 Jaffe LL. Law as a System of Control. In *Experimentation with human subjects*. Ed Freund PA. New York: George Braziller. 1970, 197-217 at p199.

1200 Montgomery J. *Health Care Law*. 2nd ed. Oxford:Oxford University Press, 2003, p16.

1201 Evans D, Evans M. *A decent proposal: ethical review of clinical research*. Wiley and sons, Chichester, 1996, p1

The law, however, cannot be more than a fallback position in the control of medical research, control lying in the first place in the hands of the medical profession through self regulation. In the absence of formal statutory regulation, the responsibility for regulating medical research is entrusted largely to research ethics committees.¹²⁰²

Furthermore,

Should the public, and patients in particular, come to believe that there is a real likelihood of being involved in a trial unknowingly, or, having agreed to participate, discovering that they have been given inadequate or inaccurate information, the supply of volunteers for research will dry up and patients' confidence in general health care will be seriously undermined.¹²⁰³

To reiterate, the importance of the *Halushka* case lies in the court's endorsement of a philosophy of full disclosure in the research setting. This is as close as possible to recognising the ethical principle of respect for autonomy. Free and full consent is thus central to the propriety and legality of clinical research.¹²⁰⁴

However, while the law appears to accept a different doctor patient relationship, and hence different rules, depending on whether one is undertaking a normal therapeutic intervention or research, the courts have made no allowance for innovation and consider it to be part of treatment. As has been argued throughout this thesis, innovation, whether of the experimental or personal type, is distinct from both normal therapy and research and different rules may need to be applied.

Furthermore, it is ethically desirable for patients to be as informed as possible and while 'it would not be correct to say that every moral obligation involves a legal duty, every legal duty is founded on a moral obligation.'¹²⁰⁵ If society and the courts do believe in the ethical principle of autonomy and self-determination, then a different legal duty of disclosure, one that does not merely pay lip service to the ethical principle, must be imposed. As previously mentioned,

The patient's interest consists of his right to self-determination ... It is well established that in the ultimate the right of the individual is paramount.¹²⁰⁶

¹²⁰² Brazier M. *Medicine, Patients and the Law*. 3rd ed. London: Penguin, 2003, p398.

¹²⁰³ Brazier M. *Medicine, Patients and the Law*. 3rd ed. London: Penguin, 2003, p405

¹²⁰⁴ Doyal L, Tobias JS. *Informed Consent in Medical Research*. London: BMJ Publishing, 2000.

¹²⁰⁵ *R v. Instan* [1893] 1 QB at 453.

¹²⁰⁶ *Re T (Adult: Refusal of Medical Treatment)* [1992] 4 All ER 649,661.

Good practice is not interchangeable with the legal minimum. Lord Scarman's comments in *Sidaway*¹²⁰⁷, mentioned earlier, while not necessarily indicative of all legal opinion, encapsulate this ethical position.

Autonomy is associated with individual choice and self-determination. It reflects mutual respect. From an institutional point of view, informed consent is often understood primarily in terms of the obligation to inform patients. Disclosure has traditionally been portrayed as a necessary condition of valid informed consent, especially in the courts, which have spoken of disclosure of facts as the staple ingredient in informed consent. The legal doctrine of consent has been primarily a law of disclosure based on a general obligation to exercise reasonable care by giving information. Litigation has erupted over the absence of informed consent because of an alleged civil injury to one's person or property that is intentionally or negligently inflicted by a physician's failure to disclose – an injury that is measured in terms of, and compensated by, monetary damages. This focus results from the legal system's need for a functional mechanism to assess injury and responsibility. However, although disclosure requirements are vitally important in legal and regulatory contexts, from the moral point of view, informed consent has less to do with the liability of professionals as agents of disclosure and more to do with the autonomous choices of patients and subjects.¹²⁰⁸

Although UK law pays little respect to patient autonomy, other common law jurisdictions have long accepted the right to autonomous decision-making and this has had an impact on their laws regarding information disclosure.

FOREIGN LAW- IN BRIEF:

In Australia, the judge in the case of *Ellis v. Wallsend District Hospital*¹²⁰⁹ relied on Lord Scarman's dissenting opinion in *Sidaway* and the judgement of King CJ in *F v. R*¹²¹⁰ (reviewed below) to find that a doctor was in breach of his duty in failing to warn of the risk of paralysis and of failure to relieve pain, despite medical evidence to the contrary in support of non-disclosure. The case however failed on causation.

The seminal case of *Rogers v Whittaker* also rejected the *Bolam* test.¹²¹¹ The claimant, who was almost blind in one eye, consulted an eye surgeon about an operation and the possible risks associated with such an operation. The defendant made no reference to the slight risks to the good eye. Mason CJ stated:

... That standard [of care] is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion ... in the field of non-disclosure of risk and provision of advice and information, the *Bolam* principle has been discarded and

¹²⁰⁷ *Sidaway v. Bethlem Royal Hospital Governors* [1985] 1 All ER 643, at 654-5.

¹²⁰⁸ Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 5th ed. Oxford: Oxford University Press, 2001:81.

¹²⁰⁹ *Ellis v. Wallsend District Hospital* [1990] 2 Med LR 103; (1989) 70 NSWLR 553.

¹²¹⁰ *F v R* (1983) 33 SASR 189

¹²¹¹ *Rogers v Whittaker* [1993] 4 Med LR 79; [1992] 3 Med LR 331; (1992) 109 ALR 625.

instead, the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to the paramount consideration that a person is entitled to make his own decisions about his own life.¹²¹²

What was important was whether the risk was material. If so then it had to be disclosed.

A risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.¹²¹³

Further, the court held there was a distinction to be made between cases concerning diagnosis and treatment, when professional standards would play a large part in determining negligence, and risk disclosure, which was not about accepted practice, except possibly when therapeutic privilege was involved. What was important was whether the doctor had communicated relevant and sufficient information to allow the patient to make an informed decision. The patient had expressed concern about the possible danger to her good eye and therefore the risk was material.

Similarly, the Supreme Court of South Australia, in *F v. R*¹²¹⁴, held that all material risks must be disclosed. In this case, which concerned the failure to discuss other options of contraception and a failure to warn of a failure rate of less than 1%, the judge stated:

Mr Perry's [counsel for the doctor] answer was that the responsible body of medical opinion should prevail over the view of the Court. That would mean that there was no room for the opinion of the Court on vital issues. The Court's function would be limited to ascertaining that there was a responsible body of medical opinion and deciding whether the surgeon had followed it. But in the end it is the Court which must say whether there was a duty owed and a breach of it. The Court will have been guided and assisted by the expert evidence. ... But the Court does not merely follow expert evidence slavishly to a decision. The Court considers and weighs up all admissible evidence which it has received. If the Court did merely follow the path apparently pointed by expert evidence with no critical consideration of it and other evidence, it would abdicate its duty to decide, on the evidence, whether in law a duty existed and has not been discharged. ... I can find nothing in *Bolam v Friern Hospital Management Committee* which justifies any suggestion that evidence of the practice obtaining in the medical profession is automatically decisive of any issue in an action against a

¹²¹² *Rogers v Whittaker* [1993] 4 Med LR 79, 83

¹²¹³ *Rogers v Whittaker* (1992) 175 CLR 479 at 490.

¹²¹⁴ *F v R* (1983) 33 SASR 189.

surgeon for damages in negligence. Sometimes that evidence will be decisive, sometimes not. It is least likely to be decisive when the allegation is of a failure to warn or heed complaints of pain, ie where no information about the method of procedure or basis of diagnosis is required.

... I respectfully think that some of the cases in England have concentrated rather too heavily on the practice of the medical profession. The ultimate question ... is not whether the defendant's conduct accords with the practice of his profession ... but whether it conforms to the standard of reasonable care demanded by law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.¹²¹⁵

Thus, all material risks should be disclosed to a patient prior to obtaining the patient's consent, a material risk being defined as

when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk ... in determining whether or not to forego the proposed therapy.¹²¹⁶

Similarly, in the Canadian case of *Reibl v. Hughes* it was held that:

[the] scope of the duty of disclosure ... is not a question that is to be concluded on the basis of medical evidence alone ... What is under consideration here is the patient's right to know what risks are involved in undergoing or forgoing certain surgery or other treatment.¹²¹⁷

UK LAW - REVISITED:

It is clear, therefore, that the UK, when considering standards of information disclosure, differs from other jurisdictions, such as Australia, Canada and parts of the United States. Indeed, the position is at odds with that in most other common law countries and is notably isolated within the context of the European Community. Patients in these other jurisdictions will be better informed than their UK counterparts where the decision on what information to disclose appears, in the main, to be decided by health carers. This goes against everything that has been argued regarding patient autonomy. From an autonomy based perspective there is a requirement to disclose any information which a patient needs to know to allow full participation in the decision making process.

The discussion regarding the duty to disclose so far has revolved around the disclosure of potential risks arising out of a particular treatment. Earlier, risks relevant to the particular doctor were mentioned and concerns raised about

¹²¹⁵ *F v R* (1983) 33 SASR 189, 194.

¹²¹⁶ *Canterbury v. Spence* (1972) 464 F (2d) 772, 787

¹²¹⁷ *Reibl v Hughes* (1980) 114 DLR (3d) 1, 13.

unwise enthusiasts, poorly trained staff and inadequate facilities.¹²¹⁸ The question that needs to be asked is whether these risks need to be disclosed.

Kennedy and Grubb, commenting on the American case of *Faya and Rossi v Almaraz*¹²¹⁹, suggest that courts in the UK would take the view that non-disclosure by a doctor of his or her HIV or hepatitis status breached the doctor's duty of care.¹²²⁰ This risk is one not inherent in the procedure but rather related to the doctor concerned. Legally however there is no difference. The patient has been exposed to a risk and the question is whether it was negligent not to disclose it. The court held that it was negligent.

Similarly, in *Behringer Estate v Princeton Medical Center*¹²²¹ the court ruled that a hospital had the right and the duty to inform patients that the plaintiff plastic surgeon was infected with HIV, even though the surgeon contested that the risk of transmission was negligible. This implies that the court believed the patient had a right to know about this risk.

UK courts have not considered the question of the doctor's duty to disclose alternative forms of treatment. However, this has been considered in Canada where a failure to disclose that a more conservative form of treatment was available to the patient was held to be a breach of the doctor's duty to the patient.¹²²² Thus the failure of a doctor to disclose essential information, such as alternative treatment options, did not allow the patient to make a choice.

Using similar reasoning, Kennedy and Grubb pose a question of particular pertinence to this thesis: is a doctor required to disclose his inexperience and thus the greater likelihood of something going wrong? When league tables are available would the doctor's position in that table or that of his hospital need to be disclosed?

The Bristol Inquiry report recommended that patients are entitled to be informed about the experience of the clinician undertaking the procedure.¹²²³ Reasonable conduct does not vary according to a defendant's level of experience and once a health carer performs a task the patient can assume he has the competence to perform it with skill and care.¹²²⁴ Once a doctor holds himself out as being more experienced than he actually is, he must reach that standard.¹²²⁵ A doctor would be negligent if he undertook treatment for which he knew he lacked the necessary experience and skill.

1218 Dollery CT. Clinical pharmacology. In Ethical committees for clinical research: report of a symposium,. Medico-pharmaceutical forum, London. 1982, p127.

1219 *Faya and Rossi v Almaraz* (1993) 620 A. 2d:327 (Maryland CA).

1220 Kennedy I, Grubb A. Medical Law. 3rd ed. London: Butterworths, 2000, at 712-3.

1221 *Behringer Estate v Princeton Medical Center* (1992) 592 A. 2d:1251 (New Jersey Supreme Court)

1222 *Haughia v Paine* (1987) 37 DLR (4th) 624 (Sask CA)

1223 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001: Recommendation 102.

1224 Khan M, Robson M, Swift K. Clinical Negligence. 2nd ed. London: Cavendish Publishing, 2002, at p159.

1225 *R v. Bateman* (1925) 94 LJKB 791 (CCA)

However, the law in the UK allows medical authority to set the standards, taking precedence over patient autonomy. It is therefore likely that, provided a responsible body of medical opinion would not have disclosed this information, any claim for non-disclosure of inexperience would fail. Current medical practice in the UK is not to discuss personal results, thereby denying patients material information that is needed to make an autonomous choice.

There are currently no UK legal cases specifically addressing the issue of disclosure of either alternative treatment or the operator's experience. However, the question of whether the operator was sufficiently experienced has recently been considered in the case of *Ryan v East London and City, HA and ORS*.¹²²⁶ In this case one of the allegations was that the defendants were too inexperienced to perform the operation. The expert witnesses were split on this and the judge declined to find the defendants liable.

While I am satisfied that ... [the operation] did indeed stretch Mr Hamlyn in particular to the limit I am not prepared to find that on the totality of the evidence I have heard that he, and/or Mr Sabin fell below the appropriate standard.¹²²⁷

The question of disclosure of the operator's experience and track record is a major issue regarding the consent process. A patient describing her ordeal during treatment for cancer complained that she was not told that four doctors furthering their education would be actively involved in her care and her agreement was not sought.¹²²⁸ Similarly, an editorial on carotid endarterectomy stated that it was imperative for all vascular surgeons to use their own personal and unit data, as opposed to citing the results of international studies, in discussions with patients on the risk associated with the procedure.¹²²⁹

This was endorsed by the GMC in the Bristol case. The GMC insisted that surgeons must quote their own mortality figures. In this case the estimates of the risk of death given were substantially less than the true risk of surgery in that unit. There was no justification for the rosy glow where the operations were elective, could be performed elsewhere and the difference between success and failure was potentially many years of life. It appears to be self-evident that parents had a right to know the truth from both referring cardiologists and the surgeon.

Similarly, an article on the use of laparoscopic herniorrhaphy stated that for the patient to be able to give informed consent surgeons untrained in the technique but capable of performing 'open' surgery would need to say that:

¹²²⁶ *Ryan v East London and City, HA and Ors* (2001) Transcript No HQ0004817.

¹²²⁷ *Ryan v East London and City, HA and Ors* (2001) Transcript No HQ0004817, at 24.

¹²²⁸ Blennerhassett M. Deadly charades. *BMJ* 1998;316:1890-3.

¹²²⁹ Naylor AR, London NJM, Bell PRF. Carotid endarterectomy versus carotid angioplasty. *Lancet* 1997;349:203-4.

the results of laparoscopic repair (“keyhole surgery”) are similar to those of open operation with regard to recurrence and adverse events but that the procedure costs more and hurts less. If return to full activity was an issue, as it is for many patients, then they would have to tell the patient that return to work is likely to be slower after open repair, but that a government agency and they themselves prefer this method.¹²³⁰

Clearly, if the patient then chooses laparoscopic repair, referral to a suitable colleague who undertakes such operations is required. In a previous chapter it was stated that NICE was reluctant to recommend laparoscopic hernia repair. The implication here is that to obtain consent not only is knowledge of the relevant guideline required but also disclosure that the recommendations are not being followed.

The question of disclosure of experience was central to the Australian case of *Chappel v Hart*.¹²³¹ The case concerned the failure to advise of risks inherent in a medical procedure. The plaintiff successfully argued that she had not been warned of the risk of injury and would not have consented had she known of the risks. Furthermore she claimed that she would have deferred treatment until someone more experienced was available to undertake the procedure and therefore the injury she suffered, damage to her vocal cords, was due to the failure of that disclosure. This was accepted by the court. There was, however, no evidence that Dr Chappel had performed the operation negligently.

Australian courts had already accepted that, following *Rogers v Whittaker*,¹²³² doctors should disclose material risks.¹²³³ *Chappel v Hart* was an unusual case in that the patient had made her concerns very clear. If those concerns had been met, as required by law, the likelihood is that she would not have been injured. One of the judges speaking for the majority said:

Although no statistical or other evidence was called to demonstrate that recourse to a more experienced surgeon would necessarily have reduced the risk of the kind of injury that occurred (and while some risk was unavoidable), intuition and commonsense suggest that the higher the skill of the surgeon, the less is the risk of any perforation of the oesophagus into the mediastinum. ... intuition and commonsense suggest that the greater the skill and more frequent the performance, the less the risk of perforation.¹²³⁴

Thus, although the nature of the risk would have been the same had she been operated on by someone more experienced, the degree of risk would have been diminished.

1230 Motson RW. Why does NICE not recommend laparoscopic herniorrhaphy? *BMJ* 2002;324:1092-4 at 1093.

1231 *Chappel v Hart* [1998] HCA 55.

1232 *Rogers v Whittaker* (1992) 175 CLR 479

1233 *Rogers v Whittaker* (1992) 175 CLR 479 at 490.

1234 *Chappel v Hart* [1998] 72 ALJR 1344 (HCA) at para 97.

If the foreseeable risk to Mrs Hart was the loss of an opportunity to undergo surgery at the hands of a more experienced surgeon, the duty would have been a duty to inform her that there were more experienced surgeons practising in the field. Because the risk was a risk of physical injury, the duty was to inform her of that risk.¹²³⁵

There are problems with this line of argument. Firstly it is impossible for every patient to demand referral to the most experienced surgeon. The most experienced surgeon can only operate on a few of the total number of cases requiring treatment. The vast majority of patients will therefore have to be treated by less experienced doctors. Also, the only way to get to become the most experienced surgeon in a particular field is to undertake the most cases.

One of the judges in *Chappel* addressed the first point.

To the complaint that [the experienced surgeon] could not possibly undertake every Dohlman's operation (any more than the most skilful barrister can appear for every client) the answer comes back. This was not an ordinary patient. It was an inquisitive, persistent and anxious one who was found to have asked a particular question to which she received no proper answer. Had a proper answer been given, as the law required, it was found that she would not have undergone the operation at the hands of Dr Chappel when she did.¹²³⁶

This implies that, in Australia, if a case is brought against a surgeon for failure to disclose his experience or what his results were (as recommended by the Bristol Inquiry report¹²³⁷), when asked, and injury befalls the patient, a claim in negligence could succeed. It also implies different standards of care depending on the experience of the operator because no evidence was presented that the performance of the operation was undertaken negligently by Dr Chappel. Indeed in the UK the judge in the case of *Ashcroft v Mersey RHA* stated that

the more skilled a person is, the more care that is expected of him.¹²³⁸

The court expected a higher degree of care from someone professing to be a specialist.

However, what also needs to be born in mind in *Chappel* is that there was an element of subjectivity in the standard of care required because the patient had been so persistent and had made her concerns very clear. This was no ordinary patient. This is, as argued, much more in keeping with the principle of

¹²³⁵ *Chappel v Hart* [1998] 72 ALJR 1344 (HCA) at para 10

¹²³⁶ *Chappel v Hart* [1998] 72 ALJR 1344 (HCA) at para 99.

¹²³⁷ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001: Recommendation 102.

¹²³⁸ *Ashcroft v Mersey RHA* [1983] 2 All ER 245 at 247.

respect for autonomy. It is for the individual patient to decide what he or she ought to know, if true individual decision-making is to be allowed.

Would a lower standard of care be acceptable if a junior identified himself as such to the patient? An analysis of a similar situation was undertaken in the previously discussed case of *Nettleship v Weston*.¹²³⁹

This brings me to the defence of *volenti non fit injuria*. Does it apply to the instructor? In former times this defence was used almost as an alternative defence to contributory negligence. Either defence defeated the action. Now that contributory negligence is not a complete defence, but only ground for reducing the damages, the defence of *volenti non fit injuria* has been closely considered, and, in consequence, it has been severely limited. Nothing will suffice short of an agreement to waive any claim for negligence. The plaintiff must agree, expressly or implied, to waive any claim for the injury that may befall him due to lack of reasonable care by the defendant; or more accurately, due to the failure of the defendant to measure up to the standard of care that the law requires of him.¹²⁴⁰

However, it is unlikely that a court would accept that any such agreement by a patient was truly *voluntary* rather than reached under the duress of the circumstances. Within a state organised National Health Service, the courts are unlikely to entertain arguments that the standard of care may be lowered by agreement. 'Dumbing down' of the duty is contrary to public policy.¹²⁴¹ Furthermore, it is not entirely clear what significance a patient may place on being treated by a Senior House Officer rather than a Specialist Registrar. Unless the patient knew what either was capable of, disclosure of this information would not lead to a real choice being made. In other words, the patient would need to understand the implications of any disclosure that is made.

The problem is how to reconcile two different requirements. On the one hand doctors need to learn on the job and obtain the necessary experience. This is in the interests of society and benefits future patients. On the other hand, the patient under the doctor's care needs to be protected from potential harm or at least to have the risk of harm minimised.

One answer to this dilemma, discussed in the previous chapter, lies in adequate supervision. If a doctor lacks the competence to undertake a particular procedure, whatever he does to the patient must be under supervision by a more experienced colleague, as recommended by the Bristol Inquiry.¹²⁴² Recommendation 99 proposed that doctors undertaking procedures for the first time need to be properly trained and directly

¹²³⁹ *Nettleship v Weston* [1971] 3 All ER 581.

¹²⁴⁰ *Nettleship v Weston* [1971] 3 All ER 581, 587 g/h/j.

¹²⁴¹ Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p423-4.

¹²⁴² Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001

supervised. The Government accepted this recommendation.¹²⁴³ The appropriate course of action, therefore, appears to be for the junior doctor to disclose their inexperience to the patient but also to state that they will be directly supervised by a more senior and experienced colleague. However, while in the main inexperienced trainee doctors are supervised by consultants, the same cannot be said of consultants attempting new procedures.

However, there is some evidence that this recommendation regarding supervision is starting to be put into practice.¹²⁴⁴ Consultant surgeons hoping to limit their learning curve when starting to undertake the 'Ross procedure' all undertook a course in aortic root surgery, refined their surgical technique through cadaveric dissection, undertook the first operation with an expert, and later assisted each other with the operation. The authors felt that these strategies had paid dividends, not only in limiting mortality but also in minimising the morbidity that would have been associated with such an operation.

If it is accepted that doctors should disclose their experience to the patient, should they also disclose that the procedure they are undertaking is experimental or innovative at a personal level?

Failure to obtain any consent could lead to a charge of battery, as discussed earlier. However it is more likely that the patient would claim that, although consent was given, all the relevant issues had not been discussed. The case would then be heard in negligence. The Bristol Inquiry recommended that patients are always entitled to know the extent to which a procedure which they are about to undergo is innovative or experimental.¹²⁴⁵ There have been very few cases in the UK in which this issue was raised. In the case of child B, discussed in an earlier chapter, the experimental nature of the proposed treatment was specifically referred to. However, the case turned on whether the health authority was justified in refusing to fund the treatment.¹²⁴⁶

A more recent case concerned a patient who had been referred to an orthopaedic surgeon because of pain in her spine.¹²⁴⁷ After a number of operations, including a lumbar spinal decompression and fusion, the patient was left with bladder, bowel and sexual dysfunction. One of the issues before the court was whether the plaintiff's consent to the operation had been negligently obtained and, if so, whether she would have undergone the operation had consent been properly sought.

1243 Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. CM 5363. London:HMSO, 2002.

1244 Hasan A, Pozzi M, Hamilton JRL. New surgical procedures: can we minimise the learning curve? *BMJ* 2000;320:171-3

1245 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

1246 *R v Cambridge Health Authority, ex parte B (a minor)* (1995) 23 BMLR 1 (CA).

1247 *Newbury v Bath DHA* 1998, 47BMLR 138

The plaintiff argued that the method used, the insertion of Harrington rods, was so exceptional that the surgeon was expected to explain that to the plaintiff. The judge stated:

the issue here is whether the plaintiff was entitled to more information than she was given. I accept that there may well be circumstances where a patient is entitled to be told that a proposed operation is not in the mainstream of treatment. That would ... be so if it involved a method which was entirely new or even relatively untried. ... My personal view is that it would have been desirable to tell [the patient] that the use of Harrington rods for this kind of surgery was *unusual* and to set out the alternatives ... [The surgeon] was, however, under no duty to do so.¹²⁴⁸

Thus, the judge appeared to distinguish between an unusual procedure and an experimental one. The implication was that an experimental procedure would need to be disclosed.

However, in Canada it was held that a distinction was to be made between the information needing to be disclosed if the case was one of research as compared to whether it was a case of innovative therapy. It was not accepted that every new development in medical methodology was research as this would discourage advances in the field of medicine.¹²⁴⁹

Canadian law therefore appears to hold that innovation is to be distinguished from research. A similar decision was made in the American case of *Karp v Cooley*¹²⁵⁰.

At this point it might be pertinent to return to the issue of therapeutic privilege discussed earlier. The acceptance that certain facts may be omitted only applies to certain specific items that the doctor must show would distress the patient if disclosed. As a general rule jurisdictions with an objective patient-based standard of disclosure are less inclined to entertain notions of therapeutic privilege than those utilising professional based standards.¹²⁵¹

For example, although early North Carolina law stated that 'any conflict between [the physician's primary duty to do what is best for the patient] and that of a frightening disclosure ordinarily should be resolved in favor of the primary duty'¹²⁵², the Appellate Court later ruled that these earlier cases no longer reflected the law of informed consent.¹²⁵³

In Australia, the Supreme Court of South Australia held that

¹²⁴⁸ *Newbury v Bath* DHA 1998, 47BMLR 138, 150.

¹²⁴⁹ *Zimmer v. Ringrose* (1981) 124 DLR (3d) 215 (Alberta Court of Appeal)

¹²⁵⁰ *Karp v. Cooley* 493 F 2d 408 (1974) (United States Court of Appeals, Fifth Circuit)

¹²⁵¹ Giesen D. *International Medical Malpractice Law*. JCB Mohr: Tubigen, 1988, at para 377

¹²⁵² *Watson v. Clutts*, 136 SE2d 617,621 (NC 1964)

¹²⁵³ *Nelson v. Patrick*, 326 SE2d 45 (NC App 1985)

The extent of the duty of disclosure must depend greatly on the patient's expressed or apparent desire for information ... An express and apparently seriously intended request for information necessary to make an informed decision will ordinarily place the doctor under an obligation to give a truthful and careful answer. I say "ordinarily" because there may be circumstances in which reasonable care for the patient may justify or even require an evasive or less than fully candid answer even to a direct request; and a doctor may in the exercise of his skill and judgement reasonably judge that a request is made, not out of a desire for a frank answer but out of a desire for reassurance. A doctor should hesitate long, however, before withholding the full truth as to real risk of harm or failure when asked to explain them. ... The governing consideration is the right of every human being to make the decisions which affect his own life and welfare and to determine the risks which he is willing to undertake. The presumption is clearly in favour of disclosure of the information which is relevant to the making of the decision.¹²⁵⁴

And although the leading American case of *Canterbury v. Spence* admitted that

the second exception [to the general rule of disclosure] obtains when risk-disclosure poses such a threat of detriment to the patient as to become unfeasible or contra-indicated from a medical point of view ...

the court continued

[but] to withhold information for therapeutic reasons must be carefully circumscribed ..., for otherwise it might devour the disclosure rule itself.¹²⁵⁵

This was reiterated in the US President's Commission in 'Making Health Care Decisions':

The obvious danger with such an exception is the ease with which it can swallow the rule, thereby legitimating wholesale noncompliance with the general obligation of disclosure. Accordingly, some courts and commentators hold that the scope of therapeutic privilege should be severely circumscribed, and that, at the least, the privilege should not apply in situations when the potential harm to the patient from full disclosure would result not from the disclosure itself but from a treatment decision the practitioner fears the patient might make as a result of the information disclosed.¹²⁵⁶

This implies that it would not be acceptable to utilise therapeutic privilege when discussing innovative practice, whether of the experimental type or

¹²⁵⁴ F v. R (1983) 33 SASR 189, 192

¹²⁵⁵ *Canterbury v. Spence* 464 F2d 772,789 (DC Cir 1972)

¹²⁵⁶ President's Commission: Making Health Care Choices. US Government Printing Office: 1983, at 95-6.

when learning due to inexperience (i.e. personal innovation). In terms of prioritising what any patient would want to know, the fact that the treatment was innovative would be high on any patient's list, as would knowledge of the experience of the operator. Disclosure of both would lead to the patient being treated in an autonomous manner and thus make an informed choice. Without that knowledge it is submitted that an informed choice cannot possibly be made. Thus, therapeutic privilege cannot be used to justify not telling the patient about the innovator's inexperience in case it unduly worries them.

Evidence of change?:

There is some evidence that the deferential respect shown to the medical profession in the UK is diminishing¹²⁵⁷, although earlier in this chapter it was argued that this is not quite to the extent that some commentators believe. However, there have been a few recent cases where the judge has assessed, and rejected, the reasonableness of medical practice. In *McAllister v. Lewisham and North Southwark HA* Rougier J held a senior consultant neurosurgeon liable in negligence for failing to disclose adequate information regarding the risks associated with a particular operation.

I have come to the conclusion that those who say that the warnings given ... were inadequate were right ... It is in this sphere that I am compelled to hold that Mr Strong [consultant neurosurgeon] fell below the standard which could have been expected of him.¹²⁵⁸

In *Lybert v. Warrington HA*¹²⁵⁹ the court held that a warning given by the defendant was inadequate. Most importantly, in *Smith v. Tunbridge Wells HA*¹²⁶⁰ the judge directly rejected expert opinion. In this case Morland J held a consultant negligent for not giving a patient a warning of a particular risk, even though it was accepted that, in failing to do so, the defendant was doing what other experienced, competent surgeons would have done. He held that omission to be neither reasonable nor responsible.

In my judgement ... general surgeons in 1988 ... would have regarded it as the proper and accepted practice to warn such a patient of the risk of impotence.¹²⁶¹

The previously mentioned case of *Pearce v. United Bristol Healthcare NHS Trust*¹²⁶² has also indicated that the courts will depart from the medical professional approach if they see fit, the ultimate test being what the court itself thinks was a reasonable amount of information to give the patient.¹²⁶³ However, although the court here appeared supportive of the individual patient approach, it concluded that in this case it would not be proper for the

¹²⁵⁷ *Marriot v W Midlands RHA and Others* [1999] Lloyd's Rep Med 23.

¹²⁵⁸ *McAllister v. Lewisham and North Southwark HA* [1994] 5 Med LR 343,352.

¹²⁵⁹ *Lybert v. Warrington HA* [1996] 7 Med LR 71

¹²⁶⁰ *Smith v. Tunbridge Wells HA* [1994] 5 Med LR 334

¹²⁶¹ *Smith v. Tunbridge Wells HA* [1994] 5 Med LR 334, 388.

¹²⁶² *Pearce v. United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, CA.

¹²⁶³ *McCall Smith A. Obtaining consent for examination and treatment. BMJ* 2001;322:810-1.

courts to interfere with the clinical opinion of the expert medical men responsible.¹²⁶⁴

In *Penney, Palmer and Cannon v. East Kent HA*¹²⁶⁵ the judges did not blindly follow expert evidence. The opinion of the defendants' experts, that it was appropriate to classify a slide as 'negative' (for tumour), was held to be illogical given the factual finding of what the slide disclosed. In this regard, the judge did not apply the Bolam test because he was required to make findings of fact, i.e. what was on the slide. Both sets of experts agreed that the screeners were wrong. What was further debated, however, was whether their conduct was excusable. This is a question of standards and thus does fall within the *Bolam* principle. The judge had to decide what ought to have been done. This is a normative question. It implies, once again, that judges are prepared to set standards for the profession, rather than merely accepting professional practice. We thus seem to be moving away from a descriptive doctrine towards a normative one and setting standards for doctors based, in the words of Montrose, on an ethical foundation.¹²⁶⁶

An ethical foundation:

As has been argued, this is a far better foundation on which to base these standards, not only from the 'patient's autonomy' perspective but also from that of the medical profession itself. The General Medical Council, for example, states that doctors are expected to be aware of the legal principles set by relevant case law regarding consent, this case law giving a guide to what should be considered the minimum requirements of good practice.¹²⁶⁷ However, what needs to be disclosed in law is that which no reasonably prudent doctor would fail to disclose. There is little way of doctors knowing exactly what they need to disclose until after the event.¹²⁶⁸

There is even great difficulty in identifying a common practice amongst doctors with regard to information disclosure.

It is precisely because a lack of knowledge of what other doctors tell their patients that a signed form that merely states that the patient has consented to, for example, 'radiotherapy to the chest wall and adjacent lymph node areas' is totally inadequate from both the doctor's and the patient's point of view ... no oncologist knows what the professional standard is in this situation. The signing of a consent form is an obligatory ritual which has little value in terms of meaningful consent.¹²⁶⁹

Thus the law fails on both counts. It fails to provide guidance for doctors and also fails to provide a remedy for patients who claim they have not been

¹²⁶⁴ Pearce v. United Bristol Healthcare NHS Trust (1998) 48 BMLR 118, CA.

¹²⁶⁵ Penney, Palmer and Cannon v. East Kent HA [2000] 1 Lloyd's Rep Med 41 (CA)

¹²⁶⁶ Montrose JL. Is negligence an Ethical or a Sociological Concept? 1958; 21 MLR 259-64

¹²⁶⁷ General Medical Council. Seeking Patients' Consent: The Ethical Considerations. February 1999.

¹²⁶⁸ Brazier M. Patient Autonomy and Consent to Treatment: the Role of the Law? (1987) 7LS 169.

¹²⁶⁹ Paterson IC. Consent to Treatment: Somebody's Moved the Goalposts. Clin Oncology 1994;6:179 at 181

properly informed. The law is simply too blunt an instrument, applied *post hoc*, and too far removed from the practical realities of the consulting room or hospital ward.¹²⁷⁰ The medical and legal professions, and the larger society to which they belong, thus have not dealt satisfactorily with the social, moral, and legal issues involved in therapeutic innovation with human subjects as exemplified by the Karp case.¹²⁷¹ UK law has not considered many of the aspects of innovation, especially with regard to disclosure of information appropriate to making an autonomous choice, where there has been a consistent failure to disclose all relevant facts.

While the UK courts have not gone as far as foreign jurisdictions in demanding a patient-centred approach to information disclosure, other institutions in the UK have made the first moves towards an 'individual patient' approach based on the ethical principle of respect for autonomy. The traditional guardians of clinical standards, the Royal Colleges of Medicine, have become more and more proactive, issuing guidelines about good practice with reference to treatment and procedures.¹²⁷² In turn, the General Medical Council, in its recent guidelines, has emphasised the need to provide information in an intelligible way. Further, 'when providing information [the doctor] must do [his] best to find out about patients' individual needs and priorities.'¹²⁷³

The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation may include... advice about whether a proposed treatment is experimental;... whether doctors in training will be involved, ...¹²⁷⁴

Additionally, at paragraph 13 the GMC states:

Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between [the doctor and the patient]... Whenever possible, [the doctor] should discuss treatment options at a time when the patient is best able to understand and retain the information. ... In particular the doctor should ...
 -explain the probabilities of success, or the risk of failure of, or harm associated with options for treatment, using accurate data;...
 -allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of the risks is great. Where patients have difficult understanding information, or there is a lot of information to absorb, it may be appropriate to provide it in manageable amounts, with appropriate

¹²⁷⁰ Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134 at 133.

¹²⁷¹ Fox RC, Swazey JP. The Courage to fail: a social view of organ transplants and dialysis. Chicago: University of Chicago Press, 1984. The Case of the Artificial Heart, 135-197.

¹²⁷² Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? Med L Rev 2000;8:85, 99.

¹²⁷³ General Medical Council. Seeking Patients' Consent: The Ethical Considerations. November 1998.

¹²⁷⁴ General Medical Council. Seeking Patients' Consent: The Ethical Considerations. February 1999, para 5.

written or other back-up material, over a period of time, or to repeat it.¹²⁷⁵

Similarly, the British Medical Association Ethics Department has recently stated¹²⁷⁶ that:

Patients involved in innovative therapies need to know:

- Why the therapy is proposed in their case
- The evidence to support its use and the areas of uncertainty about it
- Whether it has had any form of ethical review
- The clinician's experience with it
- The alternatives, if any
- How it differs from standard treatment
- The likely risks and benefits for themselves
- The measures for safety monitoring and support that will be provided if things go wrong
- The likely future use of the therapy, if successful.

Indeed, Jones believes that

It is difficult to envisage any court, whether applying *Bolam* or any other standard, coming up with such a detailed set of rules by way of guidance.¹²⁷⁷

The public outcry that has followed recent medical disasters such as Shipman¹²⁷⁸, Alder Hey¹²⁷⁹ and Bristol¹²⁸⁰ suggests that society will not be as accepting of deficiencies in the medical profession as it once was. Doctors need to be sensitive to the changing views of society. Over time, opinions change about what constitutes acceptable behaviour. It is contended that following the GMC guidelines described above would have led to better protection for the patients concerned in the two areas of innovation under consideration, namely the early heart transplants and the occurrences at Bristol. In these cases the patients concerned would have received information, namely the experimental nature of the procedure or the experience (and performance) of the operator, that would have been pivotal in making the decision about whether to proceed with the proposed treatment, thereby enhancing their autonomy. Furthermore, such actions would have protected not only the patient but the doctor as well.

1275 General Medical Council. Seeking Patients' Consent: The Ethical Considerations. February 1999, para 13.

1276 British Medical Association. Medical Ethics Today. 2nd ed. London: BMJ Publishing Group. 2004, 499.

1277 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134 at 133.

1278 Dyer C. Shipman inquiry to investigate 466 deaths. BMJ 2001;322:1201.

1279 Hunter M. Alder Hey report condemns doctors, management and coroner. BMJ 2001;322:255

1280 Dyer C. Bristol doctors found guilty of serious professional misconduct. BMJ 1998;316:1924.

THE REGULATION OF INNOVATION:

Chapter 7:

SUMMARY and CONCLUSIONS	234
A new model of contact- innovation	234
A continuum	235
Examples of innovation	235
Self-regulation	236
Government regulation	237
Legal regulation	238
Failure of legal regulation of experimentation	240
Failure of legal regulation of personal	
Innovation	243
Solutions?	244
Consent	247
Consent and Innovation	250
An ethical foundation	255
Practicalities	256
Conclusion	260

CHAPTER 7: SUMMARY and CONCLUSIONS:

Patients are asking for greater involvement in what happens to them, reflected by a gradual evolution in the legal control of medical practice.¹²⁸¹ This control may vary depending on the form that the doctor patient relationship takes.

Traditionally it has been held that a doctor may come in contact with a patient in one of three ways: as part of the normal therapeutic doctor/patient relationship, when involved in clinical research and when acting as an impartial medical examiner. The fundamental difference is the objective of the contact between patient and doctor. This is of major importance when considering the difference between therapy and research. In the therapeutic setting the physician is expected to act in the patient's interest, with the intent being the treatment and resulting benefit of that patient. However, when involved in research, the primary objective changes and becomes the accumulation of medical knowledge, although there may also be benefit to the research subject. Thus, the distinction between therapy and research derives from intent.¹²⁸² Because there are different intentions and objectives, ethical and legal rules of consent, confidentiality and negligence may vary according to the model of contact.

A NEW MODEL OF CONTACT- INNOVATION:

This thesis is proposing a fourth model of contact. Some procedures or treatments lie in the grey area between medical treatment and research. Thus, Brazier uses the case of *Simms v Simms and another*¹²⁸³ to illustrate this point.

... if a doctor caring for patients with new variant CJD attempts a novel treatment as a last resort, knowing that there is no conventional treatment that will prolong the patient's life, has he crossed that line and made his patient a research subject?¹²⁸⁴

This fourth model of contact is that of *innovative* practice. This, in turn, has been defined as taking two forms: *experimental* and *personal*. In experimental innovation a completely new intervention is being attempted. As an example of this, this thesis has utilised the first heart transplants as an illustration. In personal innovation the proposed technique has already been established but the practitioner concerned has either never attempted it before or is still learning how to perform it. The concept of learning curves is inextricably linked to this latter form of innovation, best illustrated by the occurrences in Bristol.^{1285 1286}

1281 British Medical Association. Rights and responsibilities of doctors. BMA, 1992, 2nd ed, p xxi.

1282 Royal College of Physicians. Research Involving Patients. Royal College of Physicians, London, 1990 at 5

1283 *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669.

1284 Brazier M. Medicine, Patients and the Law. 3rd ed. London: Penguin, 2003, p405.

1285 Ramsay, S. Evidence against "Bristol-case" doctors found proven. Lancet 1998;351:1707

1286 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

This concept of experimentation and personal innovation as being separate from both therapy and research has been largely unrecognised but it is important because it allows re-evaluation of the ethical and legal requirements for each. If these distinctions are not made, ethical and legal norms, guidelines, and regulations may be developed that do not fit the class of activities to which they are applied.¹²⁸⁷

A CONTINUUM:

However, the distinction does not necessarily lead to clear, circumscribed entities, as there appears to be a continuum ranging from normal medical treatment, through innovation (encompassing both experimental and personal innovation), to research, depending on the balance of therapy and generation of knowledge intended. In addition, considerations such as mortality rates, patient selection criteria, media coverage and the number of surgeons and centres undertaking a particular procedure help to define where along the continuum it lies.

Although there will be ambiguities in deciding at what stage along this continuum a particular patient contact lies, it has been argued that it is nonetheless important to recognise that innovative practice needs to be assessed separately from research or treatment.

However, attitudes towards the introduction of innovative practice remain archaic. Whereas strict licensing laws exist for the introduction of new drugs, new surgical and other invasive procedures are assimilated relatively unchecked¹²⁸⁸, with no assessment of their efficacy and usually no guidance on their use.¹²⁸⁹ Chalmers and Silverman have argued that these double standards are inexcusable and those who suggest that 'the interests of patients involved in poorly controlled, casual experiments are less in need of formal protection [than those involved in research] must be called to account.'¹²⁹⁰

EXAMPLES OF INNOVATION:

The introduction of heart transplantation was used to illustrate the need for a separate assessment of experimental practice. These first patients were subjected to an experimental procedure designed to obtain knowledge and for the personal benefit (in terms of personal fame) of the surgeons. This was especially so after the implantation of the first artificial heart.¹²⁹¹ The medical community was deeply divided over its merits. Some believed it was a brilliant scientific breakthrough while others felt it was a severe breach of ethics, a reckless attempt undertaken solely in the interests of ambition.¹²⁹² For

1287 Levine RJ. In: Legal and ethical issues in human research and treatment. Ed Gallant DM, Force R. Halsted Press, New York, 1978, p86

1288 Ridgway PF, Darzi AW. Placebos and standardising new surgical techniques. *BMJ* 2002;325:560.

1289 Dent T, Wortley S, Campbell B. New interventional procedures. *BMJ* 2004;329:3-4.

1290 Chalmers I, Silverman WA. Professional and public double standards on clinical experimentation. *Control Clin Trials* 1987;8:388-91 at 391.

1291 Thorwald J. *The Patients*. New York: Harcourt Brace Jovanovich, 1971.

1292 Thorwald J. *The Patients*. New York: Harcourt Brace Jovanovich, 1971 at p411.

example, Annas alleges that many of these early procedures were purely non-therapeutic and intended only to benefit society.¹²⁹³

With respect to personal innovation, the General Medical Council found three Bristol doctors guilty of serious professional misconduct because they continued to undertake paediatric cardiac procedures despite colleagues' concerns about excess mortality.¹²⁹⁴ One of the doctors argued that every surgeon experienced a learning curve when he or she started undertaking a new procedure.¹²⁹⁵

Patients, whether experimented upon or suffering at the hands of personal innovators, deserve protection. As illustrated by the introduction of the early heart transplants and artificial pump or the events in Bristol, some patients did not receive this. This is the consequence of a failure to regulate innovation adequately.

The interests of such patients need to be safeguarded. The law plays a vital role in regulating the practice of medicine. Three types of law have been described.¹²⁹⁶ In its strictest sense the courts or Parliament make 'the law'. Professional 'law' on the other hand is made and policed by regulatory bodies. The third type of 'law' describes sets of rules made only to offer guidance.

SELF-REGULATION:

With respect to 'professional law', it has been argued that professionals are more concerned with doing what is right than avoiding punishment.¹²⁹⁷ Self-regulation is essential to the concept of being a profession. It is clear, however, that self-regulation failed to protect patients during the early heart transplant years and the events in Bristol.

When the early heart transplants were undertaken, the ambitions of the surgeons involved led to the interests of the patients being overridden. Rejection problems had not been resolved at that time¹²⁹⁸ and yet, despite this, the surgeons still undertook the operations. The failure of self-regulation can be shown to an even greater degree when the first artificial heart pump was implanted. Its design had been stolen from a colleague. Such operations were undertaken solely in the interests of ambition.¹²⁹⁹ Patient interests were of secondary importance.

Similarly, self-regulation failed to protect the patients in Bristol. The whole episode could have been avoided if local 'informal' self-regulation through peer pressure had materialised and expressed concerns been acted upon. Immediate colleagues, their employer, and professional bodies outside Bristol,

1293 Annas G. Death and the Magic Machine. *Western New England Law Review* 1987;9:89 at 98.

1294 Ramsay, S. Evidence against "Bristol-case" doctors found proven. *Lancet* 1998;351:1707

1295 Dyer C. Compensation claims expected to follow GMC's findings. *BMJ* 1998;316:1691

1296 Montgomery J. *Health Care Law*. Oxford University Press, 1997, p5.

1297 Montgomery J. *Health Care Law*. Oxford University Press, 1997, p5.

1298 Ross D. in: Thorwald J. *The Patients*. New York: Harcourt Brace Jovanovich, 1971 at p291.

1299 Thorwald J. *The Patients*. New York: Harcourt Brace Jovanovich, 1971 at p411.

such as the Royal College of Surgeons and the Department of Health, were aware of the poor success rate but either failed to act or did not use their position of authority to force a change in practice.¹³⁰⁰

The subsequent public inquiry was clearly critical of the system of self-regulation.¹³⁰¹ While recognising the problem of 'learning curves' and that competence is acquired gradually with an upward gradient of success, it was critical of the assumption that failure was initially inevitable and for that reason justifiable.¹³⁰² It suggested three guiding principles; supervision, a system within hospitals for managing innovation, and openness and honesty with the patient.¹³⁰³

Therefore it is clear that, in the past, self-regulation did not succeed in regulating innovation and protecting patients, with deep-seated flaws in the culture of the medical profession. There is therefore a need to change the basis of professional regulation so that the profession performs as the public and individual patients expect.

GOVERNMENT REGULATION:

The Government and National Health Service management have introduced their own plans for strengthening institutional responsibility for the standard of patient services through external review and clinical governance.^{1304 1305} The National Institute for Clinical Excellence (NICE) and the Commission for Health Improvement (CHI)¹³⁰⁶, more recently replaced by the Commission for Healthcare Audit and Inspection (CHAI) and then by the Healthcare Commission, were created to influence the clinical practice of doctors and manage the introduction of new technologies.¹³⁰⁷

Many of their recommendations are based on evidence-based medicine (EBM), creating guidelines for treatment or new technology. However, the value of EBM is limited. Searching for precise answers in the form of numbers and probabilities can only have a limited role in medicine.¹³⁰⁸ One of the fundamental flaws of EBM is that it fails to cater for the individual.¹³⁰⁹ The

1300 Anon. First lessons from the "Bristol case." *Lancet* 1998;351:1669

1301 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001

1302 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, chapter 25: 1-4.

1303 Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations. CM 5207(ii). London: HMSO, 2001, chapter 25: 1-4.

1304 Secretary of State for Health. The new NHS: modern, dependable (Cmnd 3807). London: HMSO, 1997.

1305 Secretary of State for Health. A first class service: quality in the new NHS. London: Department of Health, 1998.

1306 Secretary of State for Health. A first class service: quality in the NHS. London: Stationery Office, 1998.

1307 Smith R. NICE: a panacea for the NHS? *BMJ* 1999;318:823-4.

1308 Kleinert S. Rationing of healthcare- how should it be done? *Lancet* 1998;352:1244.

1309 Ellis SJ. Some unanswered questions about NICE. *J R Soc Med* 1999;92:538-9

technique of meta-analysis is also flawed because it depends on the statistical averaging of different trials performed in different places by different people for different purposes. An evidence-based decision will need to vary from one patient to another according to individual circumstances.¹³¹⁰

A further problem is that matters of cost are also considered¹³¹¹, implying a shift of emphasis to cost-effectiveness. This requires the making of value judgements on what should be accepted or rejected. There are serious flaws in the use of cost-effectiveness as a basis of rationing. While cost-effectiveness comparisons can inform debate, they cannot direct it.¹³¹²

Furthermore, although NICE has taken over the functions of SERNIP and be responsible for evaluating new technology, it is unclear how it will achieve this since most new interventional procedures are surgical in nature and thus difficult to be assessed through placebo-controlled trials.

With regard to clinical guidelines, the main problems are that they are not very good at recommending treatment for an individual patient, they are frequently founded on limited evidence and they can be subjective.

Thus, external governmental control through NICE and the creation of guidelines is unlikely to be successful on its own and unlikely to lead to patient protection from the effects of innovation.

LEGAL REGULATION:

This leaves the third form of law, namely that made by the courts or Parliament, to be examined to see whether it is better able to protect patients.

Medical malpractice may give rise to two common law actions in court. The first is that of trespass to the person, or battery. The second is that of negligence. The latter forms the basis of most malpractice claims and is by far the more important of the two when considering the regulation of innovation.

In most cases of medical negligence the key question is whether the professional has reached the standard of care required of them by the law. That standard was established by the cases of *Hunter v. Hanley*¹³¹³ and *Bolam v. Friern Hospital Management Committee*.¹³¹⁴

In essence, both cases state that professionals are to be judged against the standards of their peers. Experts appearing before the court merely have to regard the defendants' actions as being within the range of acceptable practice. This, in turn, means a minimal level of acceptable practice, not what the expert would have liked to see happen.¹³¹⁵ Furthermore, the House of

¹³¹⁰ Haynes RB, Devereaux PJ. Physicians' and patients' choices in evidence based practice. *BMJ* 2002;324:1350.

¹³¹¹ Anon. NICE to sort clinical 'wheat from chaff'. *BMJ* 1999;318:416.

¹³¹² Ellis SJ. Some unanswered questions about NICE. *J R Soc Med* 1999;92:538-9

¹³¹³ *Hunter v. Hanley* [1955] SC 200, SLT 213.

¹³¹⁴ *Bolam v Friern HMC* [1957] 2 All ER 118, [1957] 1 WLR 582

¹³¹⁵ Montgomery J. *Health Care Law*. 2nd ed. Oxford: Oxford University Press, 2003, p170

Lords has stated that it will not choose between different bodies of medical opinion¹³¹⁶, (provided they are both regarded as responsible and suitable qualified), implying that there could be no judicial intervention to declare standard medical practice to be negligent. The law imposes the duty of care but the standard of care is a matter of medical judgment.¹³¹⁷

This appears to run against the normal principles of negligence, in which there is an expectation that the judiciary will scrutinise a particular practice and assess whether it is reasonable. Thus, the professional, or *Bolam*, test appears to have been softened by various statements made in cases such as *Sidaway v Bethlem Royal Hospital Governors*¹³¹⁸ and more recently *Bolitho v. City and Hackney HA*¹³¹⁹ and *Pearce v. United Bristol Healthcare NHS Trust*¹³²⁰.

In *Sidaway v. Bethlem Royal Hospital Governors*, for example, the court reserved the right to decide that even standard practice may be negligent.¹³²¹ The practice held by the body of responsible practitioners had to be one that was rightly and properly held. A judge could reject a unanimous medical view if he were satisfied that it was manifestly wrong.¹³²²

The more recent case of *Bolitho v. City and Hackney HA*¹³²³ also indicated that judges are becoming less reluctant to set standards for doctors. In the Court of Appeal, it was held that the judge should consider the evidence and decide whether a clinical practice put the patient unnecessarily at risk.¹³²⁴ In the House of Lords, it was held that the court had to be satisfied that the exponents of the body of opinion relied on could demonstrate that such opinion had a logical basis.¹³²⁵

Such statements have lead some commentators to suggest that *Bolitho* has 'reinterpreted Bolam'¹³²⁶ and has handed the ultimate power of deciding whether a particular medical practice is acceptable or not back to the courts.¹³²⁷ Others have claimed that *Bolitho* restores *Bolam* to its proper and original limits¹³²⁸ and that the first casualty may be the supremacy of the 'reasonable doctor test'.¹³²⁹

1316 Maynard v. W.Midlands RHA [1985] 1 All ER 635, 1 WLR 634, 639.

1317 Sidaway v. Board of Governors of the Bethlem Royal Hospital [1985] AC 871 at 881.

1318 Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643.

1319 Bolitho v. City and Hackney HA [1993] 4 Med LR 381, [1997] 4 All ER 771.

1320 Pearce v. United Bristol Healthcare NHS Trust (1998) 48 BMLR 118, CA.

1321 Sidaway v Bethlem Royal Hospital Governors [1984] 1 All ER 1018

1322 Sidaway v. Bethlem Royal Hospital Governors [1984] QB 493 at 513, [1984] 1 All ER 1018 at 1028, CA

1323 Bolitho v. City and Hackney HA [1993] 4 Med LR 381, [1997] 4 All ER 771.

1324 Bolitho v. City and Hackney HA [1993] 13 BMLR 111 (CA) at 119

1325 Bolitho v. City and Hackney HA [1997] 4 All ER 771, 778

1326 Kennedy I, Grubb A. Medical Law. Butterworths: London, 3rd ed (2000), p441.

1327 Khan M, Robson M, Swift K. Clinical Negligence. 2nd ed. London: Cavendish Publishing, 2002.

1328 Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? MLR 2000;8:85.

1329 Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? MLR 2000;8:85, at 108-9.

However, a recent analysis of appropriate post-*Bolitho* cases showed a significant number still relied on *Bolam*.¹³³⁰ Furthermore, *Bolitho* appears to have been used most commonly as a test of credibility rather than as a standard *per se*. Thus, although *Bolitho* may be a step in the right direction, it does not travel far enough down the road of judicial scrutiny.¹³³¹ The plaintiff still faces significant problems in trying to overcome the barrier of the judiciary allowing the expert professionals to determine what is acceptable practice.¹³³² Although the courts will examine medical experts' evidence, it appears that this expertise will only be overridden when the medical experts hold views that the judges believe no reasonable doctor could hold.

Failure of legal regulation of experimentation:

Historically the law has regarded failed experimentation as a species of negligence.¹³³³ However, it is important for experimentation to occur so that medical knowledge improves and society benefits. In certain cases resort to an experimental technique may be appropriate but it must be made with caution.¹³³⁴ Indeed, the courts do allow some discretion to develop medical practice¹³³⁵, as shown by the recent granting of permission by the English High Court for the injection of an unlicensed experimental treatment into the brains of two teenagers suffering from variant Creutzfeldt Jacob disease (vCJD).^{1336 1337} These were two separate cases heard together.

The judge concluded that:

... there was a responsible body of relevant professional opinion which supports this innovative treatment.¹³³⁸

Since then two other cases requesting the use of experimental innovative treatment have been heard by the courts. Both were heard in the High Court of Justice (Family Division). The first was heard on the 10th of October 2003.¹³³⁹ Here the Trust applied under the court's inherent jurisdiction for an order that the treatment was lawful and in the best interests of the patient. In the second¹³⁴⁰ the patient sought a declaration that it was lawful for him to receive the experimental treatment. In both it was held that, although innovative, the treatment was proper since a responsible body of medical opinion supported its use. It is interesting to note that in all these cases involving the intracerebral infusion of pentosan polysulphate, the treatment

1330 Maclean A. Beyond Bolam and Bolitho. MLInt 2002;5:205-30.

1331 Keown J. Reining in the Bolam test. CLJ 1998;57:248, 249.

1332 Maclean A. Beyond Bolam and Bolitho. MLInt 2002;5:205-30, 222.

1333 Dickens BM. What is a medical experiment? Can Med Assoc J. 1975;113:635-9 at 636

1334 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 9.38.

1335 McHardy v Dundee General Hospitals' Board of Management. (1960) SLT (Notes) 19

1336 Simms v Simms and another, A v A and another. [2003] 1 All ER 669

1337 Dyer O. Family finds hospital willing to give experimental CJD treatment. BMJ 2003;326:8.

1338 Simms v Simms and another, A v A and another. [2003] 1 All ER 669, 681.

1339 An NHS Trust v HM [2004] Lloyd's Rep Med 207.

1340 EP v Trusts A, B and C. [2004] Lloyd's Rep Med 211.

only had potential to be beneficial. Although results had been encouraging (in the case of Simms), there was no proven scientific benefit.

It is clear, therefore, that the courts do sanction experimental therapy, provided it is supported by a responsible body of medical opinion. This implies that the rules for assessing the acceptability of experimental treatment are the same as for normal therapy. However, it could be argued that this is not adequate. As previously mentioned, clinical fervour leads doctors to overestimate how successful and routine a particular experimental innovation has become. Also, when experimental treatment is attempted, it stands to reason that the patient is exposed to a greater risk, simply because the doctor is attempting something unknown. The courts must, in some way, take this extra risk to the patient into consideration. This could be achieved by requiring the doctor to justify his use of the experimental treatment, either on the basis that there was no extra risk or that the potential benefit was so great that any extra risk was justified. The important point here is that the courts could require the doctor to justify what he has done or intends to do.

In the case of *Clark v. McLennan*¹³⁴¹ the judge held that the defendant was negligent in failing to take a precaution that resulted in damage. The defendant had tried something innovative.

... the burden lies on the defendant to show that he was not in breach of duty as well as to show that the damage did not result from his breach of duty.¹³⁴²

This 'recognised risk avoidance' concept¹³⁴³ could be very useful in negligence cases concerning experimental innovation. The plaintiff could thus argue that although there was a standard way of performing an operation, the defendant departed from it and attempted an experimental treatment. The defendant, therefore, had to justify its use, as opposed to the current *Hunter v Hanley* test.

This concept is very similar to the doctrine of *res ipsa loquitur*, which gives rise to an inference of negligence on the defendant's part.¹³⁴⁴ However, it appears that, attractive as it may be for the plaintiff to utilise this doctrine, the courts have shown general antipathy towards it.^{1345 1346} Thus, in the case of *Wilsher v. Essex Area Health Authority* in the House of Lords¹³⁴⁷ their Lordships held that the burden of causation still rested on the claimant alone and did not move to the defendants, even though negligence had been proved or admitted.¹³⁴⁸

1341 *Clark v. McLennan* [1983] 1 All ER 416.

1342 *Clark v. McLennan* [1983] 1 All ER 416, 427.

1343 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.70

1344 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.61.

1345 *Ratcliffe v. Plymouth and Torbay Health Authority* (1998) 42 BMLR 64, [1998] Lloyd's Rep Med 162, CA.

1346 *Gray v. Southampton and South West Hampshire Health Authority* (2000) 57 BMLR 148.

1347 *Wilsher v. Essex AHA* [1987] QB 730, [1986] 3 All ER 801, CA; revsd [1988] AC 1074, [1988] 1 All ER 871, HL.

1348 *Wilsher v. Essex Area Health Authority* [1988] 1 All ER 871, 882-3, HL.

Legal commentators appear to support the risk avoidance concept although they also believe that it is not acceptable to the courts.^{1349 1350} The belief that the courts refuse to accept the risk avoidance concept, however, follows the determination in *Wilsher*, which did not concern innovative treatment. Furthermore, the recognised risk avoidance concept concerns the *standard of care* while the House of Lords in *Wilsher* refused to accept the shifting of the burden of proof with respect to *causation*. In other words, the risk avoidance concept could still be used for assessing innovative treatment and this would still be compatible with the judgement in *Wilsher*.

The problem with the Law's approach is that rules created for assessing negligence in the normal therapeutic setting are being used for assessing the acceptability of experimental practice. Thus, in the case of *Karp v. Cooley*¹³⁵¹, which concerned the first use of an artificial heart, the court utilised traditional malpractice evidentiary standards, that is, those employed for medical diagnosis and treatment. This was inappropriate in that, despite the treatment clearly being experimental, the standard law of negligence applicable to normal treatment was used. The law failed to make a distinction.

The medical act is not homogenous. It does not always slot conveniently into either therapy or research and furthermore, there is a failure to recognise experimental innovation. As previously mentioned, there is a continuum ranging from therapy through innovation to research that depends on the intended objective of the contact. The law fails to recognise this and is thus unable to examine the subtleties of each individual medical act. It is not acceptable for the rules created to assess negligence in a normal therapeutic doctor / patient relationship to be used to assess the acceptability of an experimental technique. The law needs to be more sensitive and distinguish between therapy and experimental innovation. Thus, in *Karp v. Cooley*¹³⁵², if the recognised risk avoidance concept was acceptable in law and the court allowed to ask the surgeon to justify the use of a technology that was previously untried in humans, its conclusion may have been different.

The case of *DeFreitas v. O'Brien and Connelly*¹³⁵³ further illustrates the problem of utilising normal rules of negligence to assess experimental treatment. Here the Court of Appeal held that a small number of medical practitioners could constitute a 'responsible body of medical opinion' against which the practices of a doctor could be measured.¹³⁵⁴ This had led some commentators to comment that

1349 Mason JK, McCall Smith RA, Laurie GT. Law and Medical Ethics. Butterworths 2002, 6th ed, 9.38.

1350 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p170

1351 Karp v. Cooley 493 F 2d 408 (1974) (United States Court of Appeals, Fifth Circuit)

1352 Karp v. Cooley 493 F 2d 408 (1974) (United States Court of Appeals, Fifth Circuit)

1353 DeFreitas v. O'Brien and Connelly [1993] 4 Med LR 281, [1995] 6 Med LR 108, CA.

1354 DeFreitas v. O'Brien and Connelly [1995] 6 Med LR 108, 115, CA.

DeFreitas sets a worrying precedent in that perhaps now a small fringe group practising experimental techniques can legitimately constitute a responsible body despite being contrary to the norm.¹³⁵⁵

The proper solution would therefore have been for the court in *DeFreitas* to recognise that the experimental treatment undertaken was not done routinely by the vast majority of colleagues and furthermore was risky. Could the defendants therefore justify its use? Unfortunately, the court simply utilised the established rules for assessing negligence. Medical experts established the standard of care and not the courts, even though it was experimental treatment, a situation analogous to normal therapy. The position in experimental practice thus seems to be excessively favourable to the medical profession because the law utilises the same standards to judge therapy and experimentation. However, if the courts accept that experimentation is a separate entity this should allow them some discretion to scrutinise a particular experimental practice to see whether it is reasonable and the potential increased risk acceptable. On a separate note, it also emphasises the need for adequately informed consent.

Failure of legal regulation of Personal Innovation:

The problem of the law failing to take account of the subtleties of the medical act is equally applicable to personal innovation, where a doctor is trying to learn a new technique.

The law in the UK expects the standard of care to be achieved is that of the ordinary skilled doctor. It is well established that inexperience is no defence to a claim of negligence. In the case of *Nettleship v. Weston* the same standard of care was expected whether one was a learner driver or an experienced one.¹³⁵⁶ As a matter of public policy, the courts do not want to apply a sliding scale of standards of care depending on the subjective attributes of the particular defendant.¹³⁵⁷

This means that the law in the UK makes no allowance for personal innovation. In medicine the leading authority regarding inexperience is *Wilsher v. Essex Area Health Authority*.¹³⁵⁸ In court the defendants argued that a junior doctor could not be expected to achieve the same standard of care as that of an experienced colleague. A junior doctor had to learn on the job. This was necessary for medicine to develop and function. If this was not allowed ultimately patients would suffer. Therefore unavoidable mistakes would be made. Although one of the judges accepted this argument, the majority dismissed it and required the trainee or learner to be judged by the same standard as his more experienced colleagues.^{1359 1360}

¹³⁵⁵ Khan M, Robson M, Swift K. *Clinical Negligence*. 2nd ed. London: Cavendish Publishing, 2002, p 166

¹³⁵⁶ *Nettleship v Weston* [1971] 3 All ER 581.

¹³⁵⁷ Stauch M, Wheat K, Tingle J. *Sourcebook on Medical Law*. 2nd ed. London: Cavendish, 2002, p311.

¹³⁵⁸ *Wilsher v. Essex AHA* [1987] QB 730, [1986] 3 All ER 801, CA; revsd [1988] AC 1074, [1988] 1 All ER 871, HL.

¹³⁵⁹ *Wilsher v Essex AHA* [1986] 3 All ER 801, 831.

¹³⁶⁰ *Wilsher v Essex AHA* [1986] 3 All ER 801, 813.

Thus the law makes no allowance for the unavoidable requirement for doctors to learn. As previously discussed under experimentation, it once again appears unwilling to appreciate the subtleties of the medical act. Consequently, the standard it uses is inappropriate. By strictly applying the *Bolam* principle the courts expects a junior doctor to show the same degree of skill as a reasonably competent doctor, irrespective of his own level of experience. No allowance is made for any inexperience on behalf of the junior doctor, although issues of supervision may become relevant.

SOLUTIONS?

The law needs to understand the need for doctors to gain experience. Otherwise, the threat of legal action may very well inhibit the search for experience, and this clearly would not be in the interests of future patients. Current application of the law of negligence to personal innovation appears to be too harsh because it takes no account of reality, which is that a junior doctor cannot have the same experience as a consultant and therefore cannot provide the same standard of care. It is not appropriate for the junior doctor to be judged as if he were a consultant, as *Nettleship* and *Wilsher* imply.

It is unavoidable that doctors need to learn. The law needs to take account of this while at the same time ensuring patients are protected. A number of options are available.

The first option is for the law to recognise the subtleties of the medical act. As previously mentioned, this is not a homogenous entity, ranging from a simple therapeutic intervention to non-therapeutic research. In addition, the problem of inexperience of the operator also needs to be understood by the law. Treatment of National Health Service patients is necessarily undertaken by junior medical staff striving to gain more experience.

This problem has been considered quite differently by other jurisdictions and reached different conclusions. For example, the High Court of Australia refused to follow the judgement in *Nettleship v. Weston*¹³⁶¹ and held it would be contrary to common sense.¹³⁶² Although the standard of care was objective, it could be adjusted to fit the special relationship under which it arose. Reasonable care had to be related to particular circumstances.¹³⁶³ Thus, the standard of the duty of care arising was that of an unqualified and inexperienced driver.

[it would be] unreasonable to measure the standard of skill and care required of the driver by reference to the skill and care that are reasonably to be expected of an experienced and competent driver...¹³⁶⁴

¹³⁶¹ *Nettleship v. Weston* [1971] 3 All ER 581.

¹³⁶² *Cook v Cook* [1987] 61 ALJR 25, 28.

¹³⁶³ *Cook v Cook* [1987] 61 ALJR 25, 31.

¹³⁶⁴ *Cook v Cook* [1987] 61 ALJR 25, 27.

It was the very absence of skill that lay at the heart of the special relationship. Fundamentally Cook held that

As a duty of care is owed to individuals, the circumstances to which regard must be had in deciding what is required to discharge the duty in a particular case are the circumstances out of which the duty to the injured plaintiff arises.

To follow the *Nettleship* approach is to deny the relevance of the circumstances which gave rise to the relationship out of which the duty of care arose

It would be artificial to exclude those circumstances from consideration in determining what is reasonable care.¹³⁶⁵

Indeed, even UK law recognises that the circumstances in which a doctor treats his patient may be taken into account. In an emergency situation, a doctor will not be expected to achieve the same results as a doctor working in ideal conditions. In an emergency, errors of judgment are more excusable¹³⁶⁶ and an allowance made for 'battle conditions'.¹³⁶⁷

The findings in *Wilsher* are also not entirely clear cut. Firstly there is the dissenting opinion of Sir Nicholas Browne-Wilkinson V-C. He was not able to accept an objective standard determined without consideration of the doctor's experience.

... a doctor ... should only be held liable for acts or omissions which a careful doctor with his qualifications and experience would not have done or omitted.¹³⁶⁸

Also, despite rejecting the notion of a duty tailored to the actor, Mustill LJ proposed that one could ascertain the standard of care by reference to the 'post' that the doctor held:

... I prefer ... the proposition ... which relates the duty of care, not to the individual, but to the post which he occupies. ... it must be recognised that different posts make different demands. ... the lower ranks will be occupied by those of whom it would be wrong to expect too much¹³⁶⁹

There appears to be no *significant* difference between this proposition and a provision to take into account the inexperience of a junior doctor, circumstances the UK courts have refused to do. In other words, since junior jobs are undertaken by junior members of staff, and Lord Musill was prepared to ascertain the standard of care by reference to the post held by that junior

¹³⁶⁵ Cook v Cook [1987] 61 ALJR 25, 32.

¹³⁶⁶ The Metagama (1927) 138 LT 369 at 370.

¹³⁶⁷ Wilsher v. Essex AHA. [1986] 3 All ER 801, 812.

¹³⁶⁸ Wilsher v. Essex AHA. [1986] 3 All ER 801, 833.

¹³⁶⁹ Wilsher v. Essex AHA. [1986] 3 All ER 801, 813.

member of staff, he appears to be accepting that a different standard of care could apply.

A solution therefore lies in the courts accepting a minimum standard applicable to each post below which a doctor in that post cannot fall. This recognises the inevitability of doctors gaining experience 'on the job'. Although this requires a fundamental change in the law, one of the fundamental principles established by *Donoghue v Stevenson*¹³⁷⁰ was that no case law rule or principle is ever settled for all time.¹³⁷¹

However, it would not be appropriate for the defence merely to be inexperience whenever a patient suffers harm when treated by a doctor learning a new technique. Closer supervision by more senior colleagues is therefore essential.

Indeed, a more senior doctor may be found negligent if a more junior doctor is not adequately supervised.¹³⁷² A consultant would also be negligent for inappropriate delegation to a junior if it was known that the junior was not capable of performing his duties properly.¹³⁷³ Even being supervised, however, does not necessarily absolve the trainee of responsibility.¹³⁷⁴

One problem is that the Bristol doctors, being consultants and thus practising without supervision, could simply state that their results were unavoidable. They were learning a new technique and thus the level of mortality and morbidity was part of that learning curve.¹³⁷⁵ However, culpability arose precisely because the doctors concerned ignored their own poor results. Furthermore, the system of regulation, which included immediate colleagues, the employer, the Royal College of Surgeons and the Department of Health, also failed. The poor results were therefore not unavoidable.

A further legal option is available. In *Nettleship* Lord Denning recognised that morally the learner-driver was not at fault. The injured person, nevertheless, needed to be compensated and the only available resource was the driver's insurance fund. Damages, however, were only recoverable if the driver was liable in law. As such, legally she, the learner-driver, was liable.¹³⁷⁶

Clearly, therefore, the reason she was found liable was to allow the injured party to be compensated through the driver's insurance. If, however, another source of compensation was found, then the case may have never needed to come before the courts or, if it did, the decision might have been different.

1370 *Donoghue v Stevenson* [1932] AC 562.

1371 Farrar JH, Dugdale AM. Eds. *Introduction to Legal Method*, 2nd ed. London: Sweet & Maxwell, 1984, p84.

1372 *Wilsher v. Essex AHA* [1997] QB 730 at 774.

1373 Mason JK, McCall Smith RA, Laurie GT. *Law and Medical Ethics*. Butterworths 2002, 6th ed, 9.54.

1374 *Bouchta v. Swindon HA* [1996] 7 Med LR 62.

1375 Dyer C. Surgeon blamed beginner's bad luck for cardiac deaths. *BMJ* 1998;316:1114

1376 *Nettleship v. Weston* [1971] 3 All ER 581, 586c/d.

Therefore, if the law wishes to take into consideration inexperience while still allowing patients recourse to the law if harmed, it needs to find another way of compensating victims. In medicine this may be achieved by the patient suing the hospital to obtain compensation for injuries suffered since employers are vicariously liable for any negligent acts committed by their employees.¹³⁷⁷ Although this does not absolve the employee of liability, there may also be *direct* liability for failures in services provided. Thus a hospital may owe a direct duty of care towards its patients. In *Wilsher* Lord Browne-Wilkinson said:

...a health authority which so conducts its hospital that it fails to provide doctors of sufficient skill and experience to give the treatment on offer ... may be directly liable in negligence to the patient ... I can see no reason why, in principle, the health authority should not be [directly] liable if its organisation is at fault.¹³⁷⁸

Thus, a solution may be found if a hospital accepts direct legal responsibility on behalf of its inexperienced doctors. The courts, knowing that the patient has a source of reimbursement for the injury caused, may therefore only need to hold the inexperienced doctor as partially responsible, as in *Jones v. Manchester Corporation*.¹³⁷⁹ It may even hold that there was no negligence on the doctor's behalf because his inexperience was unavoidable. In such case, legal liability would fall entirely on the employing hospital.

Another option is to consider aspects of information disclosure and patient consent. Can a patient accept a greater risk by agreeing to be treated by an inexperienced doctor? This leads to the issue of information disclosure and consent.

CONSENT:

It is well established that, based on the principle of autonomy, every competent person should decide what happens to his or her body. An autonomous person acts in accordance with a freely self-chosen and informed plan. Such actions can be analysed in terms of acting intentionally, with understanding, and without controlling influences that determine the action taken. To respect an autonomous person involves treating that person so as to *enable* him or her to act autonomously. Thus, in medicine, there is a positive obligation of respectful treatment in disclosing information and fostering autonomous decision-making.¹³⁸⁰ The patient should be allowed to choose the treatment based on adequate information such as success rates and risks.¹³⁸¹ Patients cannot express informed preferences unless they are given sufficient and appropriate information.

¹³⁷⁷ Montgomery J. Health Care Law. 2nd ed. Oxford: Oxford University Press, 2003, p178

¹³⁷⁸ *Wilsher v. Essex AHA*. [1986] 3 All ER 801 at 833, as per Browne Wilkinson.

¹³⁷⁹ *Jones v Manchester Corporation* [1952] 2 QB 852, [1952] 2 All ER 125, CA.

¹³⁸⁰ Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001 64

¹³⁸¹ Mason JK. Consent to Treatment and Research in the ICU. in Ethics and the Law in intensive care. Pace N.

McLean SAM (eds). Oxford: Oxford University Press, 1996, 29-46 at p38.

Furthermore, because risk is evaluated not merely by looking at statistical numbers but also on subjective qualitative aspects, the most important aspect of risk assessment, which is *essential* in the health care setting, is that the person exposed to it makes that assessment.¹³⁸²

All relevant information therefore needs to be disclosed if the aim of this disclosure is to protect patient autonomy.¹³⁸³ There is therefore not only a requirement for doctors to disclose risks that are relevant to the patient but also to disclose risks and other information that are particular to the doctor.

Two different meanings of 'informed consent' have been established.¹³⁸⁴ Firstly, it can be analysed in terms of autonomous choice. This requires the patient, with substantial understanding and in the absence of control by others, to actively authorise the proposal.

Secondly, informed consent can be analysed in terms of providing a legal justification for proceeding with treatment.¹³⁸⁵ In such a setting, informed consent is not always an autonomous act. The function of this second sense of consent is to legalise the whole of medical examination and treatment.¹³⁸⁶ There is a duty of disclosure because the essence of a professional relationship is that the professional knows more about his subject than the person who seeks his help does.¹³⁸⁷

Patients thus need to be given a clear explanation of any treatment proposed, including any risks and alternatives, before they decide whether they will agree to the treatment. If doctors fail to provide this information, they may be negligent. Much of the debate regarding the law surrounding consent has focussed on the appropriate standard of disclosure.¹³⁸⁸ This depends on whether it is based on what the profession believes should have been disclosed, known as the professional standard, or on the patient's own expectations; that is a patient-based standard.

The professional standard test holds that a doctor is judged according to what other doctors would have done. In other words, if he failed to disclose an aspect of information, he would not be found guilty of negligence if a responsible body of medical opinion would also not have disclosed what the defendant failed to disclose. Even a significant minority of doctors in agreement with the defendant may be persuasive and leave the plaintiff in

1382 Council for Science and Society. The acceptability of risks. Barry Rose, London, 1978

1383 McLean SAM. A patient's right to know. Dartmouth: Medico-Legal Series, 1989.

1384 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:78.

1385 Re W [1992] 4 All ER 627,633

1386 Mason JK. Consent to treatment and research in the ICU. Pace NA, McLean SAM eds. Ethics and the law in intensive care. Oxford: Oxford University Press, 1996, p30.

1387 Holder AR. Medical Malpractice Law. New York: John Wiley, 1975, p225

1388 Jones MA. Informed Consent and Other Fairy Stories. MLR 1999;7:103-134 at 104.

difficulties.¹³⁸⁹ If such a test is used, consent would be governed by the same rules and principles that apply to ordinary malpractice cases.¹³⁹⁰

The patient centred standard, in turn, can be subdivided into two; a particular patient standard and a prudent patient standard, corresponding to subjective or objective tests.

The particular patient (subjective) test defines what information the actual plaintiff would have wanted disclosed to them. Although suffering from the possibility of hindsight, it is the only desirable standard that forcefully establishes the right to self-determination.

The prudent patient (objective) test requires the establishment of what a reasonable person would have wanted to know. One of the problems with this test is that it is impossible to define what a reasonable person is. Furthermore, a standard determined by reference to objective criteria alone will not in all cases suffice to vindicate the patient's right to self-determination, which should be the starting point and indeed shape the boundaries of the duty of disclosure.¹³⁹¹

The professional, or *Bolam*, test is representative of the current law, although as discussed earlier, it has been softened by the approach taken in cases such as *Sidaway*¹³⁹² and *Bolitho*¹³⁹³. For example, in the House of Lords, it was held that the court had to be satisfied that the exponents of the body of opinion relied on could demonstrate that such opinion had a logical basis.¹³⁹⁴

Essentially, therefore, medical expertise is to be overridden when the medical experts hold views that the judges believe no reasonable doctor could logically hold. From the courts' perspective, the standard of disclosure is tied to the doctor's duty rather than the patient's need for information in order to allow a choice to be made. This gives doctors significant discretion to determine the boundaries of acceptable behaviour regarding what needs to be disclosed, contrary to the ethical principle of respect for autonomy.

The law's paternalistic treatment of the doctrine of informed consent undoubtedly provides a foundation for the medical profession's perception of it. There seems to be a failure on the part of doctors to take a step back in order to try to understand the meaning of informed consent. Instead the tendency is to perceive informed consent mainly as a medico-legal concept centred on the requirement to get a signature on a form.¹³⁹⁵

1389 DeFreitas v. O'Brien and Connolly [1995] 6 MLR 108, 115, CA.

1390 Montgomery J. Health Care Law. 2nd ed. Oxford:Oxford University Press, 2003, p227

1391 Giesen D. International Medical Malpractice Law. J CB Mohr: Tubigen, 1988, at par 576

1392 Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643.

1393 Bolitho v. City and Hackney HA [1993] 4 Med LR 381, [1997] 4 All ER 771.

1394 Bolitho v. City and Hackney HA [1997] 4 All ER 771, 778

1395 Kessel AS. On failing to understand informed consent. Br J Hosp Med 1994;52:235 at 237.

CONSENT AND INNOVATION:

It is not entirely clear how UK law would deal with a case of innovation because it does not recognise the concept, whether of the experimental or personal variety.

It would be expected that a court would proceed by firstly defining what the standard of care was and then try to ascertain whether it was breached. To enable it to do this, medical opinion would be sought. The opinion of a responsible body of medical professionals expert in the particular field would have a heavy bearing on the court. So for example, with respect to the early heart transplants, although patients were given little and sometimes misleading information, it is highly unlikely any of the pioneering surgeons, such as Barnard or Cooley, would have been found guilty of negligence. They did not believe consent or the information that needed to be disclosed was an issue^{1396 1397} while the presentation of alternatives was coloured by subjective factors.¹³⁹⁸ Referral to another better-equipped centre was not an option. Furthermore, it took some time for the poor success rates during the early years to become known. Although the final decision would rest with the courts, such credible experts would likely have swayed the court into accepting heart transplantation and the circumstances in which it was used.

Despite the fact that many of the patients had little understanding of what the operations entailed and potential risks and personal mortality figures were not disclosed, the professional standard test would have left the patients with little chance of success. A responsible body of opinion would have supported the operations that eminent surgeons such as Barnard, Cooley and Ross were undertaking. Although the patients did not give informed consent, medical experts would have testified that what was disclosed was sufficient and acceptable. The law with respect to experimentation therefore appears to be too soft because it utilises standards created for normal therapy, despite the fact that experimental procedures would carry more risk, and still rely heavily on professional opinion, thereby failing to respect patient autonomy.

On the other hand, it has already been established that the law, when considering personal innovation, appears to be too harsh. As previously discussed, the cases of *Nettleship v. Weston*¹³⁹⁹ and *Wilsher v Essex AHA*¹⁴⁰⁰ have shown the courts to be unwilling to accept that inexperience is a defence to a charge of negligence. No allowance has been made for personal innovation and the courts merely consider it to be part of routine therapy. However, arguments have been made that personal innovation is distinct from normal therapy and different rules need to be applied. To do otherwise may

1396 Barnard C. In Experience with human heart transplantation. Proceedings of the Cape Town Heart Transplantation Symposium, 1968. Ed Shapiro HA. New York: Appleton-Century-Crofts 1969, p266-7.

1397 Cooley D. in Thorwald J. The Patients. New York: Hardcourt Brace Jovanovich, 1971 at p297.

1398 Moore FD. Therapeutic innovation: Ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In Experimentation with human subjects. Ed Freund PA. New York: George Braziller. 1970, 358-78 at p366.

1399 *Nettleship v Weston* [1971] 2 QB 691.

1400 *Wilsher v Essex AHA* [1986] 3 All ER 801.

have an inhibitory effect on doctors gaining experience. It is clearly essential that doctors are allowed to continue to learn while practising. This is in the interests of all present and future patients.

The primary goal of consent in the medical care setting is to enable patients to make autonomous decisions about whether to authorise an intervention.¹⁴⁰¹ A requirement of full disclosure has already been enshrined in law when considering the consent process for research projects, thereby preventing exploitation of vulnerable patients. Thus in the Canadian case of *Halushka v University of Saskatchewan*¹⁴⁰² the court was insistent that the research subject was spared no detail of his relevant condition or of his exposure to risk. The requirements to satisfy the legal obligations for information disclosure are thus much greater in the research setting than in the normal therapeutic doctor patient relationship.

The subjective element and higher standards of disclosure required by the law when dealing with issues of research highlights two important issues. Firstly, the law, when it so wishes, is fully prepared to accept and respect patient autonomy. Secondly, the law does accept the variability of the doctor patient relationship, thereby recognising that circumstances may be present requiring different rules and standards to be adopted.

Clearly, patients should be as informed as possible. Accepting the ethical principle of autonomy and self-determination means that society and the courts need to adopt a different legal duty of disclosure. Although disclosure requirements are vitally important in legal and regulatory contexts, from the ethical point of view, consent has less to do with the legal liability of professionals and more to do with patients being able to make an autonomous choice.¹⁴⁰³

It has already been shown that UK law, by adopting the professional standard test, pays little respect to patient autonomy. However, other common law jurisdictions have long accepted the right to autonomous decision-making with subsequent repercussions on their laws regarding information disclosure.

In Australia the case of *Rogers v Whittaker*¹⁴⁰⁴ held that what was important was whether the risk was material and if so then that risk had to be disclosed. Similarly, the Canadian case of *Reibl v. Hughes* held that what was under consideration was the patient's right to know what risks were involved in undergoing or forgoing certain surgery or other treatment.¹⁴⁰⁵

Thus, the UK differs from other jurisdictions when considering standards of information disclosure. This includes most other common law countries and

1401 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001: 78-9.

1402 *Halushka v University of Saskatchewan* (1965) 53 DLR (2d) 436

1403 Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press, 2001:81.

1404 *Rogers v Whittaker* [1993] 4 Med LR 79, 83

1405 *Reibl v Hughes* (1980) 114 DLR (3d) 1, 13.

the European Community.¹⁴⁰⁶ In these jurisdictions the law expects patients to be better informed than their UK counterparts, where the disclosure requirements are decided by the medical profession. This is not in keeping with the principle of autonomy in which there would be a requirement to disclose any information which a patient needed to know to allow full participation in the decision making process.

To allow such participation, it would be expected that information relating to the particular doctor would also need to be disclosed. For example, it would be appropriate for a doctor to disclose his or her HIV or hepatitis status and failure to do so would imply a breach of the doctor's duty of care.¹⁴⁰⁷ Although the risk is not inherent in the procedure, it applies to the doctor concerned. From a legal perspective, however, there is no difference. The patient has been exposed to a risk and the question is whether it was negligent not to disclose it.

Thus, it has been held that a hospital had the right and the duty to inform patients that a plastic surgeon was infected with HIV.¹⁴⁰⁸ This clearly implies that the court in this case believed the patient had a right to be told about this risk.

UK courts as yet have not considered whether the doctor has a duty to disclose alternative forms of treatment. In Canada, however, a doctor was held liable for failing to disclose the availability of a more conservative form of treatment.¹⁴⁰⁹

From the perspective of personal innovation, the question therefore that needs to be posed is whether a doctor is required to disclose his inexperience, the implication being that there is a greater likelihood of something going wrong. Clearly, a patient would consider such information very important and pivotal to the decision-making process. Indeed, the Bristol Inquiry report concluded that patients are entitled to be informed about the experience of the clinician undertaking the procedure.¹⁴¹⁰ However, as the law currently stands, the medical profession sets the standards and current medical practice is not to discuss personal results. It is therefore unlikely a case would succeed if a patient sues because a doctor has failed to disclose his inexperience. However, this denies patients material information that is essential if an autonomous choice is to be made.

This very point was made by a patient who complained that she was not told that four doctors who were still learning would be actively involved in her care

1406 Giesen D. *International Medical Malpractice Law*. J CB Mohr: Tubigen, 1988.

1407 Kennedy I, Grubb A. *Medical Law*. 3rd ed. London: Butterworths, 2000, at 712-3.

1408 *Behringer Estate v Princeton Medical Center* (1992) 592 A. 2d:1251 (New Jersey Supreme Court)

1409 *Haughia v Paine* (1987) 37 DLR (4th) 624 (Sask CA)

1410 Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001: Recommendation 102.

and her agreement not sought.¹⁴¹¹ Similarly, an editorial claimed it was essential that vascular surgeons should quote their own personal and unit data when discussing the risks of carotid endarterectomy with patients, rather than quoting the results of international studies.¹⁴¹²

The GMC have endorsed this view, insisting that surgeons must quote their own mortality figures.¹⁴¹³ In the Bristol case, parents were given estimates of the risk of death that were substantially less than those being achieved in that unit. Such a disclosure could not be justified for elective cases or cases that could be performed elsewhere. It appears undeniable that parents had a right to know the truth.

The question of disclosure of experience has also been considered in the Australian case of *Chappel v Hart*.¹⁴¹⁴ The plaintiff successfully argued that, not only had she not been warned of the risk of injury, but that she would also have deferred treatment until someone more experienced was available to undertake the procedure. The injury she suffered was therefore consequent on the failure to make that disclosure, even though there was no evidence that the operation had been performed negligently.

The patient in *Chappel v Hart* had made her concerns very clear and the law required those concerns to be addressed. Had they been, she would not have undertaken the operation and she would not have been injured. One of the judges affirmed that there would be less risk to the patient the higher the skill of the surgeon and the more frequently the operation was performed.¹⁴¹⁵

Thus, if someone with more experience had undertaken the operation, the degree of risk would have been less, even though the nature of that risk was the same. There therefore was a duty to inform her that there were more experienced surgeons practising in that field.¹⁴¹⁶

There are clearly practical problems with this line of argument. Not every patient can be operated on by the most experienced surgeons. Indeed, the vast majority of patients will have to be treated by less experienced doctors. However, even if experienced surgeons are only allowed to operate, how does one gain experience? The only way to gain experience is to undertake cases and this in turn requires a learning curve.

Despite these problems, *Chappel* implies that a claim in negligence could succeed if a surgeon fails to disclose his experience or his results despite being asked and the patient suffers an injury. The patient had made her concerns very clear. Those concerns were not addressed and thus a claim in negligence succeeded. This is in keeping with the principle of respect for

1411 Blennerhassett M. Deadly charades. BMJ 1998;316:1890-3.

1412 Naylor AR, London NJM, Bell PRF. Carotid endarterectomy versus carotid angioplasty. Lancet 1997;349:203-4.

1413 Dyer C. Compensation claims expected to follow GMC's findings. BMJ 1998;316:1691.

1414 *Chappel v. Hart* [1998] HCA 55.

1415 *Chappel v Hart* [1998] 72 ALJR 1344 (HCA) at para 97.

1416 *Chappel v Hart* [1998] 72 ALJR 1344 (HCA) at para 10

autonomy. The individual patient should decide what information he or she ought to be given if true individual decision-making is to be allowed.

On the other hand, it is highly unlikely that the courts would accept the standard of care to be lowered because a doctor identified himself as a junior. Although in *Nettleship v Weston* the court held that an agreement to waive any claim for negligence due to inexperience would have sufficed¹⁴¹⁷, this is unlikely to happen within the conditions of medical treatment. Firstly, there would be doubts about the voluntary nature of such an agreement and secondly, any such agreement would be contrary to public policy within the context of the National Health Service.¹⁴¹⁸

Thus, while doctors need to learn on the job and obtain the necessary experience, any current patients also need to be protected from potential harm. There are a number of ways in which these two different requirements can be reconciled.

Firstly, inexperienced doctors should be directly supervised by a more experienced colleague.¹⁴¹⁹ Junior doctors should disclose their inexperience to the patient and also state that they will be directly supervised by a more senior and experienced colleague. This is even applicable to consultants, as exemplified by consultant surgeons who undertook a number of supervised strategies to limit a new procedure's morbidity and mortality.¹⁴²⁰

A similar problem concerns whether the attempt of an experimental procedure should be disclosed to the patient. The Bristol Inquiry recommended that patients are always entitled to know the extent to which a procedure which they are about to undergo is innovative or experimental.¹⁴²¹ However, very few legal cases in the UK have addressed this issue.

In one such case, a plaintiff argued that the surgical method used to cure a pain in her spine was so exceptional that it should have been explained to her.¹⁴²² The judge, however, stated that the surgeon was under no duty to tell the patient that the surgery was unusual. He, however, did appear to distinguish between an unusual procedure and an experimental one¹⁴²³, the implication being that an experimental procedure would have needed to be disclosed.

1417 *Nettleship v Weston* [1971] 3 All ER 581, 587 g/h/j.

1418 Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p423-4.

1419 Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001

1420 Hasan A, Pozzi M, Hamilton JRL. New surgical procedures: can we minimise the learning curve? *BMJ* 2000;320:171-3

1421 Department of Health. *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Summary and Recommendations*. CM 5207(ii). London: HMSO, 2001

1422 *Newbury v Bath DHA* 1998, 47BMLR 138

1423 *Newbury v Bath DHA* 1998, 47BMLR 138, 150.

Despite all this discussion, there is some evidence to show that the UK law's deferential respect to the medical profession is diminishing.¹⁴²⁴ A few recent cases have rejected a proposed reasonable and professionally accepted particular practice.^{1425 1426 1427} In particular, the case of *Pearce v. United Bristol Healthcare NHS Trust*¹⁴²⁸ has indicated a departure from the professional standard test, the ultimate test being what information the court itself thought ought to have been disclosed.¹⁴²⁹ In this case the court held that a doctor had a duty to disclose significant risks, in essence advocating a more patient friendly test. This implies that doctors ought to disclose what a reasonable patient would consider significant.¹⁴³⁰

Thus, judges have recently appeared prepared to set standards for the profession, such standards being based on an ethical foundation.¹⁴³¹

AN ETHICAL FOUNDATION:

The General Medical Council has stated that doctors should be familiar with the law regarding consent and this should be considered the minimum requirements of good practice.¹⁴³² However, as has been shown throughout this thesis, the law fails to provide guidance for doctors and also fails to provide protection for patients who claim they have not been properly informed. The law is simply too blunt an instrument, applied *post hoc*, and too far removed from the practical realities of medicine.¹⁴³³ The social, moral, and legal issues involved in therapeutic innovation, as exemplified by the Karp case,¹⁴³⁴ have not been satisfactorily addressed. Indeed, UK law has not even recognised that innovation is a separate entity from research and therapy. With respect to information that needs to be disclosed in order to allow an autonomous choice to be made, the medical profession has consistently failed to disclose all relevant facts.

However, other institutions in the UK have made the first moves towards a patient-centred approach based on the ethical principle of respect for autonomy. This is a far better foundation on which to base standards of disclosure, not only from the 'patient's autonomy' perspective but also from that of the medical profession itself. Thus, the Royal Colleges of Medicine have issued guidelines about good practice with reference to treatment and procedures¹⁴³⁵ while the General Medical Council (GMC) has emphasised the

1424 *Marriot v W Midlands RHA and Others* [1999] Lloyd's Rep Med 23.

1425 *McAllister v. Lewisham and North Southwark HA* [1994] 5 Med LR 343.

1426 *Lybert v. Warrington HA* [1996] 7 Med LR 71

1427 *Smith v. Tunbridge Wells HA* [1994] 5 Med LR 334

1428 *Pearce v. United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, CA.

1429 McCall Smith A. Obtaining consent for examination and treatment. *BMJ* 2001;322:810-1.

1430 Kennedy I, Grubb A. *Medical Law*. Butterworths: London, 3rd ed (2000), p709

1431 Montrose JL. Is negligence an Ethical or a Sociological Concept? 1958; 21 MLR 259-64

1432 General Medical Council. *Seeking Patients' Consent: The Ethical Considerations*. February 1999.

1433 Jones MA. *Informed Consent and Other Fairy Stories*. MLR 1999;7:103-134 at 133.

1434 Fox RC, Swazey JP. *The Courage to fail: a social view of organ transplants and dialysis*. Chicago: University of Chicago Press, 1984. *The Case of the Artificial Heart*, 135-197.

1435 Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? *Med L Rev* 2000;8:85, 99.

need to provide information in an intelligible way and for the doctor to do his best to find out what the patients' individual needs and priorities are.¹⁴³⁶

Such information includes whether a proposed treatment is experimental and whether doctors in training will be involved.¹⁴³⁷ The GMC further stated that consent involved a continuing dialogue between the doctor and the patient. Information to be discussed included the probabilities of success or harm and the options for treatment.¹⁴³⁸ Such detailed guidelines surpass any that may be produced by any court.¹⁴³⁹

Echoing the GMC guidelines, the British Medical Association Ethics Department has recently stated¹⁴⁴⁰ that:

Patients involved in innovative therapies need to know:
 Why the therapy is proposed in their case
 The evidence to support its use and the areas of uncertainty about it
 Whether it has had any form of ethical review
 The clinician's experience with it
 The alternatives, if any
 How it differs from standard treatment
 The likely risks and benefits for themselves
 The measures for safety monitoring and support that will be provided if things go wrong
 The likely future use of the therapy, if successful.

It is clear that following such guidelines would have led to better protection for the patients concerned in the two areas of innovation under consideration, namely the early heart transplants (experimentation) and the occurrences at Bristol (personal innovation). The experimental nature of the procedure or the experience (and performance) of the operator, pivotal in the decision-making process, would have had to be disclosed. Such actions would have protected not only the patient but the doctor as well.

PRACTICALITIES:

While the courts understand that patients subjected to experimentation or personal innovation need to be protected, the problem has been their failure to appreciate that both forms of innovation can be shown to be distinct from therapy and have therefore utilised inappropriate rules. This thesis has shown that rules for establishing negligence in the normal therapeutic doctor-patient relationship have failed to protect patients subjected to experimentation while being too harsh when considering personal innovators who, unavoidably, need to learn new skills and techniques.

¹⁴³⁶ General Medical Council. *Seeking Patients' Consent: The Ethical Considerations*. November 1998.

¹⁴³⁷ General Medical Council. *Seeking Patients' Consent: The Ethical Considerations*. February 1999, para 5.

¹⁴³⁸ General Medical Council. *Seeking Patients' Consent: The Ethical Considerations*. February 1999, para 13.

¹⁴³⁹ Jones MA. *Informed Consent and Other Fairy Stories*. *MLR* 1999;7:103-134 at 133.

¹⁴⁴⁰ British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMJ Publishing Group. 2004. 499.

From a practical point of view, therefore, the courts, firstly, need to appreciate the subtleties of the medical act and be sensitive to the concept of innovation. This should not be difficult as many cases have already addressed issues raised by experimentation, such as *Hunter v. Hanley*¹⁴⁴¹ and *Hepworth v Kerr*¹⁴⁴², or personal innovation, such as *Wilsher v Essex*¹⁴⁴³ and *Djermal v Bexley Health Authority*¹⁴⁴⁴.

Having recognised the concept of innovation, the courts then need to appreciate that a particular medical intervention may lie anywhere on the described continuum from routine therapy, through experimentation, to therapeutic and non-therapeutic research. While it is recognised that there is a complex multivariate nature to the development of therapeutic innovation, the courts should be able, in individual cases, to ascertain the nature of a particular intervention by considering what the intention of that intervention was. The courts should also be able to decide at what stage the intervention was by considering issues such as mortality rates, how patients had been selected, the extent of media coverage and the evidence of experts in the field regarding whether the technique was accepted and established or not. Such evidence could also be taken from NICE, since its Interventional Procedures Programme assesses the safety and efficacy of new interventional procedures, gauges the extent of uncertainties and makes recommendations on their implications.

With respect to personal innovation, the courts should be able to ascertain whether a particular intervention was being undertaken as part of the doctor's learning process and also the level of supervision on offer.

Having established where along the continuum a particular innovative intervention lay, the courts then need to establish whether it was carried out negligently, both in terms of its actual undertaking and also in respect of what was disclosed to enable an informed choice to be made.

With respect to the actual undertaking, the plaintiff would still need to prove a duty of care existed, that the standard of care required was not achieved, and that this breach caused the injuries suffered. However, while it has been shown that doctors themselves set the standard of care required and the courts in turn appear extremely reluctant to interfere with these standards, this should only apply to normal therapeutic situations. Normal principles of negligence require the judiciary to scrutinise a particular practice to see whether it is reasonable, irrespective of whether their professional colleagues believe they acted appropriately. The reasonableness test, for example, was utilised in the application for the use of experimental treatment in patients

1441 *Hunter v. Hanley* [1955] SC 200, SLT 213.

1442 *Hepworth v Kerr* [1995] 6 Med LR 139.

1443 *Wilsher v Essex Area Health Authority* [1986] 3 All ER 801, [1988] AC 1074, [1988] 1 All ER 871. HL.

1444 *Djermal v Bexley Health Authority* [1995] Med LR 269.

suffering from variant Creutzfeld Jacob disease.¹⁴⁴⁵ Furthermore, reasonable care must be related to particular circumstances.¹⁴⁴⁶

In other words, the courts, having established that a particular practice was innovative, would be able to scrutinise it for reasonableness in relation to those particular circumstances and not to those pertaining to normal therapy. The experimenting doctor would need to justify the experimental treatment to the court and show there was a rational basis for undertaking it. The involvement of NICE and any guidance offered would be particularly helpful to the experimenting doctor's case. Thus, although medical evidence would still be required, the appropriate standard of care would no longer be purely a matter of medical judgement. The judge would have greater leeway in finding that the standard of care required was not achieved if, for example, there had been no discussion with NICE's Interventional Procedures Programme or the risks involved not fully appreciated. If so, it could be held that it was not conducted in a responsible manner. Even then, the plaintiff would still need to prove causation, as per *Wilsher v Essex*¹⁴⁴⁷, as there has not been a reversal of burden of proof.

A consequence of these changes in the law's perception is that, in the future, if an experimental procedure is to be attempted, it would be expected that the surgeon concerned would notify the hospital in which the procedure would be undertaken, which in turn would need to establish a clinical governance committee. This committee would review the evidence for the proposed procedure and also enquire from NICE as to its acceptability and risks. NICE in turn would be able to collect and analyse data pertaining to the innovation, arrange systematic reviews, may recommend further training and provide advice on the safety and efficacy of the new procedure. This would allow patients to be reassured that such new procedures are being monitored and reviewed to ensure safety. It would also allow them access to information about such procedures.

When considering a case of personal innovation, the court should be able to take into account the inexperience of the practitioner because other avenues are available to it to ensure the plaintiff receives proper compensation if warranted. Firstly, the court would consider whether the defendant's conduct was reasonable in the particular circumstances, including the post held, and appropriate for his or her level of experience. The standard to be applied would therefore be of the reasonably competent doctor in that particular post.¹⁴⁴⁸ The level of supervision by more senior colleagues would also be scrutinised. If either is found to be deficient, the court has the option of finding the employing hospital liable, both vicariously and directly, or the consultant liable for failing to provide proper supervision.

¹⁴⁴⁵ *Simms v Simms and another, A v A and another*. [2003] 1 All ER 669.

¹⁴⁴⁶ *Cook v Cook* [1987] 61 ALJR 25, 31.

¹⁴⁴⁷ *Wilsher v Essex Area Health Authority* [1988] 1 All ER 871, HL.

¹⁴⁴⁸ *Djemal v Bexley Health Authority* [1995] Med LR 269

From a professional point of view, although operative experience lies at the heart of any surgical training programme, consultants in the future would be required to provide much greater supervision and monitoring. This should lead to a consultant based service rather than the current consultant lead one. It may lead to having a consultant immediately available at all hours to deal with any potential problems and being able to directly supervise more junior colleagues at all times. Although this is likely to lead to longer training programs, it should ensure patients are being treated by experienced and properly doctors at all times. A consequence of this, however, is that consultants may not be available for work the following day if they have been supervising more junior colleagues undertaking emergency work. Proper organisation of on-call rotas should minimise disruption.

Furthermore, while the surgical community would expect to learn new techniques, there will be increasing recognition of learning curves. The obligation not to harm patients, central to the ethical practice of medicine, will mean that it would no longer be acceptable for consultants to learn new techniques by attempting them on their patients. Thus, new skills will need to be acquired under supervision, as exemplified by Hasan and colleagues.¹⁴⁴⁹

The courts also need to establish whether the information disclosed to patients has enabled a proper informed choice to be made. With a few exceptions, the *Bolam* test has been utilised when assessing the acceptability of what has been disclosed when considering the normal therapeutic doctor-patient relationship. This is because the law in relation to failures in diagnosis and treatment also applies to failures in the realm of advice. The same does not apply to research, however. In this situation a full and frank disclosure of all significant risks would be expected to be disclosed, thereby preventing exploitation of vulnerable subjects. Such a disclosure would also need to be in language that a lay person could understand. This implies that the law, when considering research, is prepared to accept and respect patient autonomy and thus the requirements to satisfy the legal obligations for disclosure are much greater.

Accepting the concept of innovation and its place on the continuum between therapy and research will lead to significantly more information requiring to be disclosed than is currently the case. This is because it would no longer be considered part of normal therapy, where the influence of medial opinion is significant, but rather closer to the requirements of disclosure for research, where all information needs to be disclosed.

Thus, once the court establishes that a particular intervention was innovative, it would expect the doctor to have disclosed much more information than had the case been one of normal therapy, where even therapeutic privilege is still acceptable in certain situations. By allowing consent to be considered from an autonomy based perspective, the court would also require disclosure of any information which a patient needs to know to allow full participation in the

1449 Hasan A, Pozzi M, Hamilton JRL. New surgical procedures: can we minimise the learning curve? BMJ 2000;320:171-3.

decision making process. Because risk assessment should be performed by the person exposed to it¹⁴⁵⁰, the patient would also need to be told of risks and other information particular to the doctor. This could include disclosure of personal results or experience. The implication of such a disclosure is that a patient may refuse to undertake the intervention and choose to go elsewhere. The important fact is that the patient now is able to make a proper informed choice based on information disclosed.

While it is accepted that patients subjected to innovation need to be protected, the courts cannot undertake this in isolation. A functioning internal morality is still required.¹⁴⁵¹ The GMC, as the governing body of the medical profession, should set standards of care, competency and conduct that are beyond reproach. In particular, guidelines on the expected conduct of doctors faced with innovative treatment should be widely disseminated and taught at medical schools. Doctors also need to be able to communicate anxieties about unethical behaviour. Self regulation should make individual practitioners more accountable to their peers. In turn, professional bodies such as the Royal Colleges should act when it is apparent that patients are being harmed. Standards should be monitored at a local and national level. Doctors should also be encouraged to be increasingly openness and honest with their patients about uncertainty.

There is much evidence that the professional bodies are already taking such action. The Royal Colleges of Medicine have issued guidelines about good practice with reference to treatment and procedures¹⁴⁵², while the GMC has emphasised the need to provide information in an intelligible way.¹⁴⁵³ Most importantly, the British Medical Association Ethics Department has recently issued guidelines with respect to what patients involved in innovative therapies should be told.¹⁴⁵⁴ All have issued more detailed guidance to protect patients involved in innovative therapies than the law ever could.

CONCLUSION:

This thesis has proposed a fourth model of contact between patient and doctor, that of innovation. The law fails to recognise this and therefore uses principles established in the context of a normal therapeutic doctor patient relationship to determine negligence in cases of innovation. Innovation in turn can take two forms, experimental or personal.

The law treats experimentation as if it were normal therapy and is thus too benevolent towards experimenters. The courts currently accept the use of experimental treatment merely on the grounds that a responsible body of medical opinion supports its use. However, it has been argued that the law should change to require the experimenters to justify their actions.

1450 Council for Science and Society. *The acceptability of risks*. Barry Rose, London, 1978

1451 Paul C. Internal and external morality of medicine: lessons from New Zealand. *BMJ* 2000;320:499-503.

1452 Brazier M, Miola J. Bye-Bye Bolam: A Medical Revolution? *Med L Rev* 2000;8:85, 99.

1453 General Medical Council. *Seeking Patients' Consent: The Ethical Considerations*. November 1998.

1454 British Medical Association. *Medical Ethics Today*. 2nd ed. London: BMJ Publishing Group. 2004, 499.

On the other hand, with respect to personal innovation and learning new techniques, the law of negligence is too harsh, taking no account of the need for doctors to learn and develop their skills, which is in the interests of future patients. Some suggestions have been proposed to overcome this.

In summary, the benefit of recognising that innovation is a separate model of contact between doctor and patient is that it will be fairer to both parties. Two important issues have been raised. Firstly, the context in which the innovative treatment of either variety is administered needs to be taken into consideration by the courts. Standard laws of negligence, based on principles established when considering the normal doctor-patient relationship, do not take this into account. Secondly, the question of what information is disclosed to the patient regarding this innovation also needs to be considered. The doctor should inform the patient, either that the treatment proposed was experimental, or that he or she was inexperienced in the particular technique proposed. Primarily this should lead to better protection from risk for patients and allow them the choice of whether to proceed. However, it is also fairer to the doctor and provides better protection, as the patient cannot then claim that he or she was not fully informed and the realities of medical practice are respected.

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